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The development of an online intervention for post-treatment cancer survivors with cancer-related fatigue.

Volume I of thesis submitted for the Degree of Doctor of Philosophy

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Submitted August 2016

Declaration

I declare that this thesis has not been submitted as an exercise at this or any other university.

I declare that this thesis is entirely my own work.

Signed: ____________________________________

Teresa Corbett
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Statement of contribution

The candidate was responsible for the design, data collection, analysis, and write-up of each of the three studies conducted in this research. The supervisory team, Graduate Research Committee, and local experts advised and provided support in conducting the research.

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Abstract

Background

The number of post-treatment cancer survivors in Ireland is set to increase in coming years, due to advances in screening and treatment. This group will require ongoing supportive care as many will experience persistent negative side-effects that can impair quality of life. Cancer-related fatigue (CrF) is the most common and disruptive symptom experienced by cancer survivors. Fatigue is extremely complex, and likely to involve the interaction of several physiologic and psychological mechanisms. Current evidence supports the use of nonpharmacological treatment strategies for reducing CrF. In order to develop evidence-based psychological interventions there is a need to understand the biological, psychological, and social contributors to positive adjustment in post-treatment cancer survivors. Online interventions have been shown to be an effective mode of delivery and can facilitate self-management of long-term conditions.

Aim

This thesis will outline the rationale, decision-making processes, methods, and findings which led to the development of an online intervention that was tested in a feasibility trial. This theory-based intervention aimed to facilitate self-management and enhance coping with fatigue following cancer treatment.

Methods

The studies conducted in this research were based on the development phase of the UK Medical Research Council Framework for developing complex interventions. In the first study a systematic review and meta-analysis was conducted to identify the evidence base
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related psychological interventions for cancer-related fatigue in post-treatment cancer survivors. A qualitative study involving fatigued cancer survivors was then conducted to establish a theoretical basis for the intervention. The findings of the preparatory deductive and inductive research were collated to create a draft content manual and plan for the structure of the website. An iterative review process then took place to assess and improve usability of the website. Finally, a feasibility study was conducted to test the processes and potential of carrying out a larger trial.

Findings

The findings of the systematic review suggested there is some tentative support for psychological interventions for fatigue after cancer treatment. However, the RCTs were very heterogeneous in nature and the number of high quality studies was limited. The majority of the interventions were based on the principles of cognitive-behavioural therapy (CBT). Current guidelines recommend the use CBT for the treatment of fatigue. Qualitative research indicated that using the Self-regulation Model to describe fatigue after cancer may provide an integrated theoretical model for developing interventions for fatigue based on cognitive–behavioural principles. An online intervention was developed based on this theoretical framework, as well as current guidelines and input from stakeholders. The feasibility study found that the website considered acceptable to users and findings suggested that the trial was feasible. The study led to recommendations for final refinements to the intervention before its effectiveness is tested in a fully powered RCT.

Conclusion

Despite being a complex and multifaceted intervention, transparency was sought by detailing the components of the intervention, the proposed mechanisms of change. This is the first
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intervention of its kind based on SRM theory, with the primary aim of targeting the representations of fatigue and enhancing self-management of CrF specifically. The results from this trial indicated that the website was considered feasible. However, improvements can be made to enhance the website for participants. Further research is needed in order to establish if the intervention could have an impact on clinical, psychological, and behavioural outcomes.
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Chapter 1. Introduction

1.1 Chapter overview
In this chapter the background to this research will be described. An introduction to important aspects of the study will be presented, including information related to cancer survivorship, cancer-related fatigue and its implications during the transition from patient to post-treatment cancer survivor, and the relevance of using an online programme to facilitate coping with chronic symptoms. Finally, the potential to apply what is known about cancer-related fatigue in the development of an online intervention for this group will be addressed. The rationale and proposed structure for the current research will then be outlined.

1.2 Cancer and Cancer Survival rates
The prevalence of cancer is increasing in developed countries (Siegel, Miller, & Jemal, 2015). This is largely due to ageing populations and enhanced detection. It is anticipated that the number of cancer incidences is set to rise (Stewart & Wild, 2015). The number of cancer survivors will also continue to increase over time as a consequence of earlier diagnoses and advances in treatment (Maddams, 2009). Screening for certain cancers has been more widely adopted. For example, BreastCheck – The National Breast Screening Programme in Ireland provides free mammograms to women aged 50-64 every two years. In 2014 the uptake rate of this programme was 76.5%. This was a significant increase from the previous year (70.2%) (BreastCheck, 2015). Early diagnoses have been facilitated by advances in diagnostic imaging, genetic profiling, and treatments, with a proliferation of targeted drugs, multidisciplinary care, and an increased concentration of treatment in specialist centres (Munro, 2014).
The most recent National Cancer Registry in Ireland (NCRI) report summarises cancer incidence in Ireland for the period 1994 to 2013 (NCR, 2015). The report found that the total number of cancers continues to rise, primarily due to the ageing population. At the end of 2013 it was estimated that 124,000 people were still alive whose cancer had been diagnosed over the previous 20 years (1994-2013) (NCR, 2015). The majority of these cancer survivors had been diagnosed with breast cancer (29,828), prostate cancer (28,432), bowel cancer (16,754) or melanoma of the skin (8,510).

Long-term survival for those diagnosed with cancer has doubled and there is now a life expectancy of 10 years or more for some common cancers (although exceptions such as lung and pancreatic cancers have poorer survival rates) (Richards, Corner, & Maher, 2011). In Ireland, 42% of men and 50% of women diagnosed with cancer currently survive for five years and longer. Survival rates improved from 57% to 61% for bowel cancer patients, from 80% to 82% for breast cancer and from 56% to 62% for cervical cancer, for those diagnosed in 2008-2012 compared to those diagnosed in 2003-2007 (NCR, 2015). Improvements in cancer survival rates for Irish citizens are similar to those across European countries and internationally for cancers of the colon, rectum, breast, and prostate, as well as some of the less common cancers. The EUROCARE 5 report published in 2014 (De Angelis et al., 2014) reported increased cancer survival in Europe. In the UK, survival for cancer has been improving gradually over the last 30 years, with average survival at 10 years being 46.2% (Richards et al., 2011). A report by the American Cancer Society recently estimated that there are up to 14.5 million cancer survivors alive in the United States. The figure is expected to grow to almost 19 million by 2024 (El-Shami et al., 2015).

With nearly two thirds of newly diagnosed patients expected to survive their cancer for more than 5 years, they will require continued active treatment and/or ongoing care (Shulman et
The “Cansurvivor” Project (Ivers, Dooley, & Bates, 2009) concluded that many Irish cancer survivors have a variety of needs, some of which only emerge after treatment ends. The findings highlighted needs for specific information about life after cancer, stress management and anxiety reduction, and lifestyle changes (Ivers et al., 2009).

1.3 Cancer survivorship and side effects of treatment: Lost in Transition

Hewitt, Greenfield, and Stovall (2006) recognise survivorship as a distinct phase of the cancer trajectory. Cancer treatment can be intensive, resulting in persistent negative side-effects and a reduction in quality of life (Servaes, Gielissen, Verhagen, & Bleijenberg, 2007). Prolonged symptoms lead to ongoing challenges for post-treatment cancer survivors and delay the patients’ return to normal life (El-Shami et al., 2015). Cancer survivors have reported ongoing health problems, poor general health, poor physical well-being, and pain (Elliott et al., 2011). Cancer survivors use health services more than those who do not have a cancer diagnosis or chronic condition. Social and economic disparities are also reported in relation to occupational and financial difficulties (Elliott et al., 2011).

Persistent long-term effects caused by cancer or its treatment may be physical or psychosocial in nature (El-Shami et al., 2015). Psychosocial factors such as social isolation, conflict, a low sense of control, expectations of negative outcomes and avoidance of cancer-related thoughts and feelings have been found to predict poor adjustment and functional limitations (Stanton, 2006). Conversely, protective factors such as coping strategies that enable enhanced emotional expression and communication skills may lead to improved outcomes. These include increasing knowledge, challenging unhelpful thoughts, and engaging in problem solving and positive reappraisal (Stanton, 2006).

Sinding and Gray (2005) have described a discourse of survivorship in society that often presupposes a “return to health”. However, cancer survivors have specific emotional and
physical needs (Khan, Mant, Carpenter, Forman, & Rose, 2011). The experience of cancer, the fear of its recurrence and the consequences of the disease can be very difficult to manage for many individuals (Sinding & Gray, 2005). Up to 75% of post-treatment cancer survivors experience negative health-related consequences (Aziz & Rowland, 2003; Downing et al., 2015; Richards et al., 2011). Individuals often feel underprepared for late effects of cancer, and can feel pressured by a societal expectation for cancer to be “over” when treatment ends. Healthcare professionals and family members can be perceived as dismissive of the cancer survivor’s ongoing concerns. The expectation (of the survivor or those around them) to return to pre-diagnosis levels of functioning may lead to feelings of shame, guilt, disappointment, and isolation (Sinding & Gray, 2005).

Given the long-term implications for quality of life following cancer, there has been an increasing focus on cancer survivorship (Aziz & Rowland, 2003; Ganz, 2005, 2006; Knobf et al., 2015; Richards et al., 2011). The period following primary treatment is a critical time in the cancer trajectory and the exploration of late effects of treatment, ongoing symptoms, survivorship care and self-management is now considered a priority (Knobf et al., 2015). This period is characterised by transitions in care and the need to manage late effects of cancer and its treatment (Wronski, 2015). The need for long-term care has led to the concept of a more holistic style of “survivorship care” that extends beyond the detection (or exclusion) of cancer recurrence and includes the psychological health of survivors (Brennan & Houssami, 2011).

Recent research has advocated reconceptualising cancer survivorship as a long-term condition that requires ongoing management and adjustment (Brennan, 2001; A. Johnson, 2015). Adjustment refers to psychological processes that occur as the individual, and those around them, learn to manage and adapt to the changes that have occurred due to illness and
its treatment (Brennan, 2001). The changes due to treatment may be visible in some instances due to scarring or hair loss. However, often the less visible consequences of treatment may be the most difficult to cope with. These might include pain, diminished sexual functioning, low mood and increased anxiety (Stanton, 2006). Factors such as financial burden and a reduced ability to perform emotional and physical roles can also be difficult to cope with (Stanton, 2006). Fatigue is frequently reported as a debilitating symptom of cancer and its treatment (Finnegan-John, Molassiotis, Richardson, & Ream, 2013a).

1.4 Fatigue in Cancer Survivors

Cancer-related fatigue (CrF) is the most common and disruptive symptom experienced by cancer survivors (Horneber, Fischer, Dimeo, Rüffer, & Weis, 2012; Weis & Horneber, 2015a). It is a distressing, persistent, subjective feeling of physical, emotional and/or cognitive tiredness associated with cancer or cancer treatment (Berger, Mooney, et al., 2015). CrF is not proportional to recent activity and interferes with usual functioning (Mock et al., 2000). CrF is described as being of a different quality and severity compared to ‘usual’ fatigue and is often unrelieved by rest or sleep (Cella, Lai, Chang, Peterman, & Slavin, 2002).

Consequences of fatigue often include diminished concentration, lethargy, emotional reactivity, an increased need for rest, limb heaviness, and feeling unwell after exertion (Mitchell, 2010). Some individuals have described their fatigue in terms of mental fogginess, a loss of efficiency, or feeling listless. Qualitative research has indicated that distress associated with CrF is exacerbated by the unpredictability of the symptom and difficulties in self-management of fatigue (Andrykowski, Schmidt, Salsman, Beacham, & Jacobsen, 2005; Wu & McSweeney, 2007).

Fatigue is a subjective symptom and is therefore experienced and reported differently by each individual. Screening and evaluation of fatigue in patients with cancer is currently suboptimal
Patients are often dissatisfied with the support received from healthcare professionals, and the provision of health information regarding their symptoms (Morrison et al., 2012; Nekhlyudov et al., 2013; Vogelzang et al., 1997). Fatigue is often undertreated, and health-care professionals do not always understand the extent of distress and functional impairment associated with symptoms (Mitchell, 2010; Nekhlyudov et al., 2013; Vogelzang et al., 1997). CrF is often thought of as an inevitable consequence of illness and therefore, clinicians and patients may not recognise the need to manage fatigue (Mitchell, 2010). Barriers to communication about fatigue often include patients’ own lack of knowledge about the symptom or effective treatments, and patients wanting to avoid being considered a “complainer” (Curt et al., 2000; Passik et al., 2002).

### 1.4. 1 Prevalence of CrF

Prevalence of CrF in those with active cancer ranges from 50-100% (Weis & Horneber, 2015b). Fatigue during treatment is a risk factor for developing chronic CrF following treatment (Weis & Horneber, 2015c). Prevalence of fatigue symptoms may vary depending on the cancer type, treatment type, and the scale used to measure fatigue as an outcome (Prue, Rankin, Allen, Gracey, & Cramp, 2006).

Fatigue persists beyond the end of treatment in approximately a quarter of those treated for cancer (Wang et al., 2014), with some studies reporting CrF in up to 35% of long-term survivors (Weis & Horneber, 2015b). CrF can last for many years after treatment has ended and can cause ongoing functional impairment (Weis & Horneber, 2015c). It is an often untreated symptom that contributes to diminished functioning, reduced quality of life, and socioeconomic consequences (Hjollund, Andersen, & Bech, 2007; Ollie Minton et al., 2013). CrF has a profound impact on peoples’ lives. Those with persistent fatigue may have difficulties resuming their work or daily life to a level similar to that before the cancer
diagnosis (Fong et al., 2012). Fatigue can thus be an economic burden on both patients and their families (Stone & Minton, 2008). Fatigue that persists for 3 months or longer after cancer treatment completion is unlikely to decrease of its own accord (Servaes et al., 2007).

1.4. 2 Causes of fatigue after cancer

The cause of persistent significant fatigue is difficult to identify but is likely to be a consequence of multifactorial complex interactions between biological, physical, psychological, and contextual factors (Berger, Mooney, et al., 2015; Bower, 2005; Neefjes, van der Vorst, Blauwhoff-Buskermolen, & Verheul, 2013; Piper et al., 1998).

Many physical factors may be involved in the initiation and persistence of fatigue during and after cancer. Cancer and its treatment can often result in anaemia, pain, elevated body mass index, malnutrition, deconditioning or sleep disturbance that may be linked to CrF (Mitchell, 2010). Likewise, adverse effects of medications may cause or contribute to fatigue.

Significant CrF has also been found to frequently co-occur with other physical symptoms and comorbidities such as cardiopulmonary, hepatic, or renal dysfunction, hypothyroidism, myeloid suppression, electrolyte disturbances, hypogonadism, adrenal insufficiency or infections (Servaes et al., 2007; Wagner & Cella, 2004; Yavuzsen et al., 2009).

Some researchers have also implicated factors including gene polymorphisms, altered circadian rhythm, immune dysregulation, abnormal cortisol secretion, and pro-inflammatory cytokine activity (Minton, Foster, & Maher, 2015; Mitchell, 2010).

Research has also linked psychological factors to fatigue. For example, mood disturbance has been identified as an important correlate of significant CrF (Jacobsen, Donovan, & Weitzner, 2003; Jones et al., 2016; Servaes et al., 2007). Symptom burden and psychological distress have been shown to have significant associations with CrF (Oh & Seo, 2011), while other
researchers have linked personality and coping style to how individuals experience CrF (Andrykowski et al., 2005; Hulbert-Williams, Neal, Morrison, Hood, & Wilkinson, 2012; Nail, 2004).

CrF is therefore extremely complex, and likely to involve the interaction of several physiologic and psychological mechanisms (Bower, 2005). For this reason, a multimodal treatment approach may be required. This would incorporate psychoeducational interventions, efforts to manage concurrent symptoms and interventions to improve sleep quality and activity levels, together with relaxation. This multi-faceted approach is recommended by the evidence-based guidelines from the National Comprehensive Cancer Network (Mock et al., 2000) and the Oncology Nursing Society (Mitchell, Beck, Hood, Moore, & Tanner, 2007).

1.5. Interventions to target fatigue in cancer survivorship

The National Cancer Survivorship Initiative for England Vision has called for a greater focus on recovery and well-being after cancer treatment (Richards et al., 2011). This includes promoting supported self-management, based on individual needs and preferences and empowering individuals to enable early recognition of the consequences of treatment (Morrison et al., 2012). Long-term fatigue can often be influenced by adjustment to symptoms, for example, maladaptive emotions or cognitions can exacerbate and prolong symptoms (Weis & Horneber, 2015d, 2015e).

There is currently no gold standard treatment for CrF (Minton et al., 2013). There is little evidence to support the use of pharmacologic treatment for CRF in cancer survivorship - pharmacological interventions are only recommended in instances of high levels of ongoing fatigue that is not responsive to other approaches (Horneber et al., 2012; Weis & Horneber, 2015d). Evidence supports the use of nonpharmacological treatment strategies for reducing
These include a variety of interventions such as psychosocial support, stress management, energy conservation, nutritional therapy, sleep therapy, and exercise (Campos, Hassan, Riechelmann, & Del Giglio, 2011; Jacobsen et al., 2003; Kangas, Bovbjerg, & Montgomery, 2008; Minton, Foster, et al., 2015).

Patient education may also be a potentially useful approach for reducing CRF. Such strategies can encourage effective self-management and often incorporates the setting of reasonable and achievable goals (Du et al., 2015a). Psychoeducational interventions also include information about patterns of fatigue; recommendations for augmenting exercise activity levels and sleep/rest patterns; and motivation training (Jacobsen, Donovan, Vadaparampil, & Small, 2007). These interventions primarily focus on active coping and efforts to increase self-efficacy and enhance feelings of control (Goedendorp, Gielissen, Verhagen, & Gijs Bleijenberg, 2009; Mitchell, 2010).

The National Comprehensive Cancer Network (NCCN) recommend psychosocial interventions such as cognitive behavioural therapy (CBT) to support the individual's management of fatigue (Berger, Mooney, et al., 2015; Goedendorp et al., 2009; Mock et al., 2000; Weis & Horneber, 2015a). CBT includes cognitive restructuring to support positive coping and target catastrophizing thought patterns. Such thought patterns can negatively impact mood, goal-setting attempts, self-efficacy, and goal achievement (Berger, Mooney, et al., 2015; Mitchell, 2010). Maladaptive cognitions or representations of fatigue can lead to the development of unhelpful coping strategies. For example, patients may attempt to manage fatigue by resting, however, this is likely to actually worsen fatigue (Weis & Horneber, 2015c). CBT approaches also often include relaxation training, stimulus control therapy, and approaches to decrease cognitive-emotional arousal. Energy conservation and activity management encourage participants to regulate energy use and alternate periods of rest and
activity - participants are discouraged from engaging in “all-or-nothing” behaviour and physical inactivity (Goedendorp, Gielissen, Verhagen, & Bleijenberg, 2013; Weis & Horneber, 2015d).

In order to develop evidence-based psychosocial interventions there is a need to understand the biological, psychological, and social contributors to positive adjustment in people living with and beyond cancer (Stanton & Bower, 2015). The primary aim of any treatment programme is to alleviate any factors that may be worsening CrF and enhance the individual’s capacity to cope with the symptoms and limitations associated with CrF. This can be achieved by appreciating the individual’s perspective and resources. Post-treatment cancer survivors should be informed about CRF and develop a biopsychosocial understanding of the different factors that are contributing to their fatigue symptoms. Many individuals are not familiar with the concept of CrF, and can be left feeling confused and frustrated when they are faced with unexplained and persistent exhaustion after the completion of treatment (Horneber et al., 2012).

1.6: Incorporating Psychological theory: Fatigue-related perceptions in Cancer Survivors

Theoretical models that aim to explain contributory factors that initiate and sustain fatigue symptoms, or that influence the efficacy of interventions for CrF, require testing (Bower, 2005; Weis & Horneber, 2015c). Cognitions and behaviours related to fatigue and the illness can play a role in the maintenance of fatigue (Skerrett & Moss-Morris, 2006). CBT is aimed at altering unhelpful cognitions and behaviours (Mock et al., 2000). Changing negative beliefs about fatigue into more positive beliefs has been found to play an important role in reducing fatigue (Knoop, Van Kessel, & Moss-Morris, 2012). For example, the PACE trial demonstrated that, when added to specialist medical care, CBT and GET improved fatigue
and physical functioning in people with CFS (White et al., 2011; Sharpe et al., 2015). A change in cognitions has been found to mediate the positive effect of CBT and graded exercise therapy in patients with Chronic Fatigue Syndrome (CFS) (Moss-Morris, Sharon, Tobin, & Baldi, 2005; Wiborg, Knoop, Stulemeijer, Prins, & Bleijenberg, 2010). CBT has also been shown to effectively reduce fatigue in cancer survivors (Gielissen, Verhagen, & Bleijenberg, 2007; Gielissen, Verhagen, Witjes, & Bleijenberg, 2006; Price, Mitchell, Tidy, & Hunot, 2008).

CBT models focus on similar cognitive, emotional, and coping/behavioural factors as those outlined by Leventhal’s self-regulation model of health and illness (SRM). CBT may be considered as a practical application of many of the theoretical constructs addressed in the SRM (E. Leventhal, 2003; Moss-Morris, 2013). Leventhal’s SRM is a useful framework for conceptualising a symptom such as fatigue (Moss-Morris, Petrie, & Weinman, 1996). The model proposes a hierarchically organized adaptive system that consists of three main constructs including (i) ‘representation’ of the illness experience leading to (ii) ‘coping’ responses and performance of these, which is followed by (iii) ‘appraisal’ of the success or failure of any coping attempts (Hagger & Orbell, 2003; Hale, Treharne, & Kitas, 2007; H. Leventhal, Leventhal, & Contrada, 1998). The theory suggests that the representation of a symptom such as fatigue involves a cognitive pathway (i.e. the creation of a knowledge-based conceptualisation of CrF) and an emotional pathway (i.e. emotional response to CrF) (Hagger & Orbell, 2003).

One of the key propositions of the model is that individuals make sense of their symptoms and guide any coping actions based on their illness representations or ‘lay’ beliefs about illness (Leventhal et al., 1998). These are generally constructed based on normative beliefs, knowledge and experiences (Hagger & Orbell, 2003; Hale et al., 2007). The model describes
five dimensions of cognitive representations of illness: identity (label for the symptom), consequences (beliefs about the consequences of symptom), timeline (beliefs about the duration of symptom), cure/control (beliefs about whether the symptom can be treated or kept under personal control) and cause (beliefs about the cause of the symptom).

Coping behaviours, procedures, and action plans are then guided by the cognitive representations of the symptom. People engage in a process of actively testing these common-sense theories or representations by engaging in various emotion- and problem-focused coping efforts (Hale et al., 2007). As the individual acquires new information about their symptoms, they begin to appraise their attempts to cope. As a result of these appraisals new representations may be formed, with information being adopted, discarded or modified as required (Hagger & Orbell, 2003; Hale et al., 2007). This is an iterative feedback process of developing and analysing coping efforts and representations of the problem, leading to further coping attempts (McAndrew et al., 2008; Moss-Morris et al., 1996).

The illness representations model has previously been employed in CBT intervention studies focused on fatigue (Hale et al., 2007; Moss-Morris et al., 2012). This model may, therefore, be useful in identifying and specifying the hypothesised mechanisms of change in an effective intervention for cancer-related fatigue, leading to the development of more effective and efficient interventions that are specifically aimed at the perceptions of fatigue (McAndrew et al., 2008; Moss-Morris et al., 1996).

1.7 The potential for the use of an online interventions to facilitate coping with fatigue

As CrF is a multidimensional and complex symptom (Stone & Minton, 2008), an intervention mode that can incorporate multiple and complex behaviour change techniques is required (Bradbury, Watts, Arden-Close, Yardley, & Lewith, 2014). Online interventions have been shown to be an effective mode of delivery and can facilitate self-management of long-term
conditions (van Genugten, Dusseldorp, Webb, & van Empelen, 2016; Webb, Joseph, Yardley, & Michie, 2010). Using the Internet may serve survivors’ needs as it is increasingly being used as a resource by cancer survivors (Foster, Calman, Grimmett, Breckons, Cotterell, & Yardley, 2015). Internet delivery overcomes the obstacles of time, mobility, and geography (Griffiths, Lindenmeyer, Powell, Lowe, & Thorogood, 2006) that are sometimes cited as barriers to seeking support for CrF (Wagner-Johnston, 2013). Online interventions allow participants to engage with the content an infinite number of times, at their own pace and in the comfort of their chosen environment (Bradbury et al., 2014). Such interventions may, therefore, increase access for users by providing 24-hour access to healthcare interventions and having the potential to reach huge numbers of people (Griffiths et al., 2006). While online interventions can reduce the costs of face-to-face care, they are primarily designed to supplement traditional healthcare practice. Incorporating the use of behaviour change strategies into habitual daily life may be facilitated by online home-based programmes (Bradbury et al., 2014) and the use of such tools may enhance empowerment and effective self-management of fatigue (Foster, Calman, Grimmett, Breckons, Cotterell, & Yardley, 2015; Yun et al., 2012).

1.7.1 LifeGuide open-source software

One of the main barriers to the development of online interventions has been the cost and difficulties associated with designing the programmes which require expertise in programming (Bradbury et al., 2014). ‘LifeGuide’ is a set of open-source software that enables researchers to collaboratively create and evaluate interventions (Yardley et al., 2009). This software allows non-programmers to create and easily modify web-based interventions (Bradbury et al., 2014). The pages of these websites can include text, pictures, or videos and a series of pages can be shown one after another to produce a session (Bradbury et al., 2014).
LifeGuide can send email prompts to users and can allow healthcare professionals to monitor user progress (Yardley et al., 2009). The software collects both research data (from questionnaire responses) and usage data, which allows for a more in-depth insight into how participants are using the website. This tool has been used by researchers to create websites which provide tailored long-term support for behaviour change (Michie et al., 2012). Researchers can rapidly test the effects of intervention components and facilitates easily modification and improvement of components at any stage of the intervention (Michie et al., 2012). The framework for developing the website is outlined in Figure 1.1.

1.8 Developing theory-based online interventions to target fatigue in cancer survivorship

This thesis describes the development of a theory-based, interactive web-based intervention designed to facilitate self-management and enhance coping with cancer-related fatigue (CrF) following cancer treatment. LifeGuide software was used to develop the programme (www.lifeguideonline.org) in line with existing interventions of this nature (Grimmett, Armes, Breckons, Calman, Corner, Fenlon, Hulme, May, May, Ream, et al., 2013; Michie et al., 2012) The development of the intervention was informed by the Medical Research Council’s (MRC) guidelines on developing complex interventions (Craig et al., 2013). Complex interventions are those that comprise multiple interacting components (Craig et al., 2013). Michie et al. (2012) argued that there is a need for the publication of more detailed descriptions of foundations that underpin complex interventions, promoting methodological rigour and transparency in the design process (Chalmers et al., 2014; Craig et al., 2013). The aim of this thesis is to outline the rationale, decision-making processes, methods, and findings which led to the development of an online intervention to be tested in a feasibility trial (Hoddinott, 2015).
The Behaviour Change Model for Internet Interventions (Ritterband, Thorndike, Cox, Kovatchev, & Gonder-Frederick, 2009) proposes that effective internet interventions produce behaviour change and symptom improvement through various mechanisms of change. The primary factors to consider are the characteristics of the intended user and the problem being targeted. Change mechanisms function as the catalysts for symptom improvement and behaviour change, according to Ritterband et al. (2009). Bradbury et al. (2014) note that deductive approaches (including reviews of the existing literature) are useful to ascertain what is already known about changing a behaviour and to inform intervention design. This thesis addresses both the design of the psychological content of the intervention and the design of the website used to deliver the intervention.

This project sought to integrate psychological theory, existing evidence of effective interventions, empirically derived principles of web design, and the views of potential users into the systematic planning and design of an intervention that is easy to use website for cancer survivors (Bradbury et al., 2014; Craig et al., 2013; Grimmett, Armes, Breckons, Calman, Corner, Fenlon, Hulme, May, May, Ream, et al., 2013; Webb et al., 2010). The research was based on previously established evidence and guidelines. The author aims to provide a thorough description of the content and principles used in the development process, while also clarifying hypothesised causal mechanisms (Moore et al., 2015).

1.9 Overall aim

The overall aim of this research was to develop and test a theory-based online intervention for post-treatment cancer survivors with cancer-related fatigue. This thesis will include a rationale for the chosen theory of behavioural change, the quality of the evidence on which the intervention is based and guiding principles established with targeted groups (Marion A Maar et al., 2016). The final feasibility trial will assess if there is a strong rationale for further
testing of the intervention for any subsequent further trial while also testing the operational procedures of the trial (Hoddinott, 2015).

1.9.1 Research questions and thesis outline

The methodology used to conduct this research is outlined in detail in the chapters that follow. A general discussion of the findings of the studies, the limitations of the studies, and implications for future research and practice is presented in the final chapter of this thesis.
Chapter 1. Introduction

Figure 1.1. The framework for developing the REFRESH website

- Systematic review of Psychological Interventions for fatigue
- Theoretical basis and principles underpinning of intervention content established
- Literature review and in-depth study of similar interventions
- Content Manual developed
- Design scheme, logo and graphics
- Overall flow-chart of website structure
- Preferences of potential users sought in design
- Application of Psychological theory in design process
- Draft versions of all pages in LifeGuide’s Virtual Research Environment (VRE)
- Iterative process of drafting sections of the website
  - Comments from team members and expert advisers
  - Revising sections based on feedback
- Testing content with panel of adults (including psychologists, cancer support staff, nurses, cancer survivor and spouse of cancer survivor).
- Linking sections together and applying the changes to larger sections until full website developed.

*Figure 1.1. The framework for developing the REFRESH website*
Chapter 2. Systematic Review: The Effectiveness of Psychological Interventions for Fatigue in Cancer Survivors: Systematic Review and Meta-analysis

2.1 Background

There is little understanding of the underlying aetiology of CrF (Berger, Mitchell, Jacobsen, & Pirl, 2015) but it is considered a multidimensional symptom that is comprised of physical, mental, and emotional aspects (Du et al., 2015). There is limited evidence of the effectiveness of pharmacological interventions for the management of CrF (Finnegan-John, Molassiotis, Richardson, & Ream, 2013). However, some reviews of non-pharmacological interventions have indicated that psychological and activity-based interventions may be effective (Berger, Mitchell, et al., 2015). Interventions that incorporate restorative approaches, supportive-expressive techniques, and cognitive-behavioural psychosocial interventions may reduce levels of CrF (Jacobsen, Donovan, Vadaparampil, & Small, 2008). In this review, we have focused on psychological therapies designed to improve functioning and/or reduce the physical and psychological impact of CrF.

Psychological interventions such as cognitive-behavioural therapy (CBT) aim to influence or change cognitions, emotions, behaviours, or a combination of these (Goedendorp et al., 2009). Interventions which target these processes may improve symptom management in cancer-related fatigue (Adam, Bond, & Murchie, 2015). Patients and healthcare professionals have been reported to have high expectations of, and relatively positive attitudes towards, these types of therapies (Newell, Sanson-Fisher, & Savolainen, 2002). The possible benefits of these therapies may be related to increased knowledge, improved emotional adjustment, and enhanced quality of life. These therapies have also been associated with improved coping skills, physical health and functional adjustment; and improvements in immune system indicators (Newell et al., 2002; White et al., 2011).
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There is some evidence that psychosocial interventions are effective in reducing fatigue in patients undergoing active treatment for cancer (Goedendorp et al., 2009). While biological insults such as cancer or cancer treatment may lead to fatigue symptoms during the treatment phase of those with cancer, behavioural and cognitive variables may prolong fatigue during survivorship (Bower et al., 2015). However, it is still unclear whether psychological interventions are helpful for managing fatigue in post-treatment cancer survivors beyond the early diagnostic and treatment phase (Minton et al., 2013). Consequently, there is a need to conduct a critical review of the literature pertaining to psychological interventions in post-treatment cancer survivorship.

2.1.1. Objectives

This review aimed to systematically review and synthesize the evidence from randomized controlled trials (RCTs) investigating the effectiveness of psychological interventions for persistent fatigue in people after the completion of cancer treatment.

This systematic review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) database (registration number: CRD42014015219) and the protocol has been published (Corbett, Devane, Walsh, Groarke, & McGuire, 2015). The review is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher, Liberati, Tetzlaff, & Altman, 2009).
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2.2 Methods

2.2.1. Criteria for considering studies for this review

**Types of studies**

This review included randomised controlled trials (RCTs) that compared psychological treatments with no intervention (i.e. usual care or wait list controls), attention controls, or another intervention for cancer-related fatigue (S. Bennett et al., 2009). Studies were included regardless of treatment intensity or duration, mode of treatment delivery (e.g. individual, group) or medium of treatment (e.g. in-person, online). We did not impose date restrictions. Studies found in the grey literature were included if a full-text paper in English was made available, either through databases or through contact with the study authors.

**Types of participants**

Participants in included studies were adults 18 years and older who had completed treatment for cancer regardless of gender, tumour type, and type of medical treatment received.

**Types of interventions**

We included studies that evaluated the effect of psychological therapies in the management of CrF. Studies that reported the effects of interventions on multiple outcomes were included provided that fatigue was an outcome of interest. Interventions including psychotherapy and psycho-education were included. Educational interventions included those that provided advice or information (verbal, written, audio-visual or computer delivered material) in order to help people understand and manage CrF, strategies such as cognitive restructuring, coping skill development, meditation, or relaxation techniques. In line with McGuire et al (2014),
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studies that combined psycho-behavioural and non-psychological methods were included only if the study had a predominant emphasis on a psychological element in the design. Studies were excluded if they did not employ a psychotherapeutic rationale or theory in the intervention design.

Types of outcome measures

Studies were required to have “fatigue” as an outcome of interest. This included those where fatigue was measured as a main outcome or as a discrete sub-scale within a more comprehensive scale of physical symptoms or quality of life.

Primary outcomes

In line with Goedendorp et al (2009), studies were included if fatigue was measured with a questionnaire specifically designed to evaluate fatigue. Fatigue subscales that were part of a broader quality-of-life measure were also included, if specific fatigue-related data were available. Fatigue could also be measured with a visual analogue scale (VAS) or as part of a symptom list and scored as ‘present’ or ‘absent’. Fatigue could be measured in terms of characteristics such as intensity, distress, duration, frequency, or as dimensions such as physical fatigue, mental fatigue, or general fatigue.

Secondary outcomes

Secondary outcomes included:

- functional impact of fatigue (self-report questionnaires measures assessing the impact of fatigue on daily functioning)
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- fatigue self-efficacy (self-reported scales of control or self-efficacy in relation to fatigue)
- mood (self-reported scales of depression, and/or anxiety, or distress)
- Global quality of life (self-report questionnaires measures assessing the impact of fatigue on quality of life).

2.2.2. Search methods for identification of studies

<table>
<thead>
<tr>
<th>Search term</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 'cancer survivors' OR 'neoplasm'/exp OR neoplasm OR surviv* OR 'cancer'/exp OR cancer OR 'remission'/exp OR remission OR 'post treatment'</td>
</tr>
<tr>
<td>2 psychology OR psych<em>or AND behaviour AND therapy OR hypnosis OR relaxation OR imagery OR cognition OR psychotherapy OR cognit</em></td>
</tr>
<tr>
<td>3 fatigue OR asthenic OR asthenia OR exhaustion OR exhausted OR 'loss of energy' OR 'loss of vitality' OR weary OR weariness OR weakness OR apathy OR apathetic OR lassitude OR lethargic OR lethargy OR sleepy OR sleepiness OR drowsy OR drowsiness OR tired OR tiredness</td>
</tr>
<tr>
<td>4 “randomized controlled trial” OR controlled OR clinical OR trial OR 'random assignment'</td>
</tr>
<tr>
<td>5 1 AND 2 AND 3 AND 4</td>
</tr>
</tbody>
</table>

Electronic searches

The following electronic databases were searched on October 6\textsuperscript{th} and 7\textsuperscript{th} 2015: Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, CINAHL PsycINFO, Web of Science, and CancerLit. Alterations were made to the search strategies as
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appropriate for each database interface. Details of the search strategy are provided in Table 2.1. Medical subject headings (MeSH) or equivalent and text word terms were used.

Searching other resources

Unpublished and ongoing trials were identified by checking appropriate databases of current ongoing clinical research studies. Grey literature was searched using the OpenGrey database (www.opengrey.eu), which includes technical or research reports or doctoral dissertations. Conference papers from annual American Society of Clinical Oncology (ASCO) or International Psycho Oncology Society World Congress (IPOS) conferences were also searched. Other published, unpublished, and ongoing trials were identified by checking trials and protocols published on the following clinical trials registers and websites.

• World Health Organization International Clinical Trials Registry Platform (WHO ICTRP; www.who.int/ictrp/en).

• metaRegister of Controlled Trials (mRCT; www.controlled-trials.com/mrct/).

• ClinicalTrials.gov (www.clinicaltrials.gov).

• www.cancer.gov/clinicaltrials.

2.2.3. Data collection and analysis

One review author (TC) conducted the initial search before screening titles. Titles that were clearly not relevant to this review were removed. Two review authors (TC and BMG) independently screened the remaining titles and abstracts for their eligibility for inclusion.
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Ineligible studies were excluded at this stage, with each author recording the reason for rejection.

2.2.4. Selection of studies

Cohen's Kappa (κ) was run to determine the extent of agreement between two independent raters' judgement on whether papers should be included, excluded or whether further information should be sought. There was moderate agreement between the two raters' judgments, κ = 0.594 (95% CI, .300 to .886), p < .0005. Based on the guidelines from Landis and Koch (1977), a kappa (κ) of 0.59 represents a moderate strength of agreement.

Full-text copies were retrieved and screened if the title and abstract did not provide sufficient information concerning the inclusion criteria for this review. Copies of all studies that possibly or definitely met the inclusion criteria were also retrieved. Disagreements between the two reviewers were resolved by discussion, with the involvement of a third reviewer (DD). Multiple reports of the same study were included as a single study, with each study identified by the lead author of the primary results paper.

2.2.5. Data extraction and management

Two review authors (TC and BMG) independently extracted data from the studies using a specifically designed data extraction form (see Appendix 1 for data extraction tables). The form was initially piloted by three review authors (TC, BMG, and DD) on a sample of three studies. Following this exercise, some minor changes were made to the data extraction form before full data extraction began. Discrepancies were resolved by discussion, with the involvement of a third reviewer (DD) where necessary. Authors were contacted where further
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clarity regarding the study was required, or in order to obtain missing data. Findings were extracted regardless of their direction or extent of intervention effect. The following information was extracted from the studies:

- Participant characteristics including demographic characteristics (e.g., age, gender)
- Disease-specific factors such as cancer type/stage and type of treatment
- Minimum time since completion of treatment
- Geographic location of study
- Psychological technique/therapy
- Intervention information for each arm of the study (Type of delivery; Content; Duration; Comparison/s)
- Descriptions of providers of the intervention and comparison intervention/s
- Timing of assessment for each outcome
- Adverse events as reported in studies were analysed. The absence of information about adverse events was not inferred to imply that the intervention was entirely safe. Adverse events occur with higher frequency in papers where such occurrences are sought more carefully than in studies in which they are left unreported (Loke, Price, & Herxheimer, 2008). Therefore, studies in which adverse effects were reported were not necessarily deemed unsafe.
- Other relevant information (such as funding sources or issues reported by the authors) was also noted.

2.2.6. Assessment of risk of bias in included studies

The following parameters were evaluated:
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- Adequate sequence generation,
- Allocation concealment,
- Masking or blinding,
- Methods of addressing incomplete outcome data,
- Selective reporting,
- Other bias.

The risk of bias of each trial was assessed as high risk, low risk, or unclear risk as per recommendations provided in Chapter 8 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al., 2011). The Cochrane Collaboration’s Review Manager Software, RevMan 5, was used for all analyses.

2.2.7. Measures of treatment effect

As there are many different measurement tools for assessing fatigue, the standardised mean difference (SMD) for continuous data was calculated and used as the common measure of effect across studies along with respective standard deviations (SD) and 95% confidence interval (95% CI). In each study, the mean within-condition difference was calculated by the change from pre-test to post-test. Mean differences were calculated such that negative values reflected a reduction in fatigue (i.e. improvement in symptoms). Where no standard deviations were reported, the standard deviation was calculated using the methods described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins, 2011). Where insufficient information was provided to calculate the standard deviation of the change in scores, the standard deviation of the group at final measurement point was used in the analysis.
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2.2.8. Unit of analysis issues

Continuous data were combined only where: (i) means and standard deviations were available or calculable. It was not appropriate to assess for evidence of skew in the distribution as the means and standard deviations reflected change scores from baseline to follow-up (Higgins, 2011).

2.2.9. Assessment of heterogeneity

Statistical heterogeneity was tested using $\chi^2$, $I^2$ and Tau$^2$. Statistical heterogeneity was regarded as substantial where Tau$^2$ was greater than 0.00 and the $\chi^2$ $p$-value was < 0.1 or $I^2$ was > 50%. As with Bourke (2014), funnel plots corresponding to meta-analysis of the primary outcomes were employed to test for small-study effects and publication bias. The plot should resemble a symmetrical (inverted) funnel in the absence of bias (Higgins, 2011).

A random effects model was chosen as it allows for differences in the treatment effect from study to study. Heterogeneity in treatment effects was predicted due to differences in study-related factors such as populations (such as cancer diagnosis, gender etc.), interventions received (such as type of psychological intervention), and study follow-up length. A summary result from a random effects meta-analysis may still be considered as clinically meaningful even when real study differences (heterogeneity) in treatment effects exist (Riley, Higgins, & Deeks, 2011). As each of the studies met the stringent inclusion criteria (i.e. similar type of treatment was used and patient characteristics were similar), it was decided it was clinically meaningful and appropriate to perform a random effects meta-analysis using RevMan 5.3.
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2.3. Results

2.3.1. Description of studies

Figure 2.1 depicts the PRISMA flow diagram of studies identified and excluded at each stage of the review. The literature search of 7 databases resulted in 4,212 potentially relevant articles. Following exclusion of duplicates, 3,285 articles remained. The titles and abstracts of these articles were screened and 60 full-text articles were selected to be retrieved and reviewed in detail. Following review of the full-text papers, a further 37 studies were excluded. Studies were excluded due to interventions not being regarded as psychological interventions (N = 16), some or all participants were undergoing active medical treatment for cancer (N = 7), fatigue was not an outcome of the study (N = 3), and studies were not RCTs (N = 3). Six of the articles were papers linked to studies that were already included, i.e. follow-up data or protocols. In cases where more than one paper was published relating to the same study, each cluster was counted as one paper. Five articles were found in the grey literature and full-texts were not available online. Study authors of each of these papers were contacted. Three study authors provided full-texts in preparation for publication. The other two papers were excluded at this point, as full-texts were not available. No articles were found in snowball search.

In total, 23 RCTs fulfilled all eligibility criteria for inclusion. A full description of these studies can be seen in Appendix 1.
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Figure 2.1. PRISMA Flow Diagram
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2.3.2. Included studies

Data were extracted from the included papers (See Table 2.2 for a description of the included studies). The 23 RCTs reported data on 2,930 cancer survivors (1,504 intervention and 1,426 controls).

Participants

Ten studies reported on outcomes of women with breast cancer (Bower et al., 2015; Dirksen & Epstein, 2008; Dolbeault et al., 2009; Fillion et al., 2008; Freeman et al., 2015; Hoffman et al., 2012; Lengacher, 2012; Matthews et al., 2014; Rogers et al., 2013; Savard, Simard, Ivers, & Morin, 2005). All other interventions reported on the outcomes of participants of both genders with various diagnoses (Bantum et al., 2014; Bennett, Lyons, Winters-Stone, Nail, & Scherer, 2007; Espie et al., 2008; Foster, Grimmett, et al., 2015; Gielissen, Verhagen, Witjes, & Bleijenberg, 2006; Johns et al., 2015; Prinsen et al., 2013; Reif, de Vries, Petermann, & Gorres, 2013; Ritterband et al., 2012; van der Lee & Garssen, 2012; van Weert et al., 2010; Willems, 2016; Yun et al., 2012).

In one study (Bennett et al., 2007), the authors specified that targeted patients were those who had received only radiotherapy. All other studies included participants who had received a variety of cancer treatments (e.g. surgery, chemotherapy, radiotherapy). Not all authors reported comprehensively on their samples. Six studies did not report the type of treatment that participants had received.

Participants must have had active medical treatment completed prior to taking part in the respective studies. However, there was little consistency across the studies regarding the timing of the intervention in relation to time elapsed since completion of cancer treatment. Reif et al. (2013) included those at any time point following active treatment and remission of
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acute toxic side effects. Foster et al., (2015) used similar criteria but did specify that the participants had received the diagnosis of cancer no more than 5 years previously. Dolbeault et al. (2009) specified that participants had completed primary treatment 15 days to 1 year before testing, whereas Lengacher et al. (2012) included those who had completed treatment within 18 months prior to study enrolment. In three studies, participants completed their initial cancer treatment no longer than 2 years before enrolment (Fillion et al., 2008; Hoffman et al., 2012; Yun et al., 2012). Hoffman et al. (2012) required participants to have completed treatment at least 2 months prior to the study. Six studies (Bantum et al., 2014; Espie et al., 2008; Matthews et al., 2014; Ritterband et al., 2012; Savard et al., 2005; Willems, 2016), included those who had completed treatment at least 4 weeks (or 1 month) prior. Willems et al. (2016) did not include those more than 56 weeks post-treatment. Likewise, Bantum et al. (2014) did not include those who had completed treatment more than 5 years before joining the study. Freeman et al. (2015) only included those at least 6 weeks after completing their major cancer treatments and Rogers et al. (2009) did not enroll participants until the patient was at least 8 weeks post-surgery. Four studies included only participants at least 3 months post-completion of primary cancer treatment (Bower et al., 2015; Dirksen & Epstein, 2008; Johns et al., 2015; van Weert et al., 2010). Bennett et al. (2007) included those at least 6 months post-treatment prior to enrollment. Three studies included those who had completed their last anti-cancer treatment at least 1 year previously (Gielissen et al., 2006; Prinsen et al., 2013; van der Lee & Garssen, 2012).

Interventions

Table 2.2 provides details of interventions including content, strategies employed, mode of delivery, duration, who delivered the intervention and the comparison or control group used.
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The interventions implemented in these trials were, in general, held on a weekly basis, and varied in length. Interventions were delivered by facilitators from a variety of different backgrounds and were presented in various modes (i.e., individual, group, video, or online-based).

Comparisons

Sixteen trials compared the intervention to waitlist control (Bantum et al., 2014; Bower et al., 2015; Dolbeault et al., 2009; Foster, Grimmett, et al., 2015; Freeman et al., 2015; Gielissen et al., 2006; Hoffman et al., 2012; Johns et al., 2015; Prinsen et al., 2013; Reif et al., 2013; Ritterband et al., 2012; Savard et al., 2005; van der Lee & Garssen, 2012; van Weert et al., 2010; Willems, 2016; Yun et al., 2012), five to treatment-as-usual (Bennett et al., 2007; Espie et al., 2008; Fillion et al., 2008; Lengacher, 2012; Rogers et al., 2013), one to sleep education (Dirksen & Epstein, 2008), and one to behavioral placebo (Matthews et al., 2014).
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Table 2.2. Details of Intervention Design and Comparison

<table>
<thead>
<tr>
<th>Study</th>
<th>Content</th>
<th>Strategies</th>
<th>Mode</th>
<th>Duration</th>
<th>Delivered by</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bantum 2014</td>
<td>Multiple health behaviour change program.</td>
<td>Skills building; information; encouragement; action planning; building self-efficacy; improving diet; increasing exercise; stress management via relaxation training; processing and communicating emotional experiences; fatigue management</td>
<td>Online</td>
<td>6 x weeks</td>
<td>Cancer survivors, mentored by the principal investigators.</td>
<td>Delayed-treatment control condition</td>
</tr>
<tr>
<td>Bennett 2007</td>
<td>Motivational interviewing</td>
<td>Careful listening; summarising; feedback; barrier identification; affirmation; building self-efficacy</td>
<td>In-person/Telephone</td>
<td>3 x 10-minute MI sessions.</td>
<td>Physical activity counsellor and master's-prepared research assistant</td>
<td>Usual care</td>
</tr>
<tr>
<td>Bower 2015</td>
<td>Mindfulness</td>
<td>Information; mindfulness; relaxation; meditation; gentle movement exercises (e.g., mindful walking); psychoeducation; problem solving; working with difficult thoughts and emotions; managing pain; cultivation of loving kindness.</td>
<td>Group</td>
<td>6 weekly x 2-hour sessions.</td>
<td>Master’s level Registered Nurse therapist</td>
<td>Wait list</td>
</tr>
<tr>
<td>Dirksen 2008</td>
<td>CBT-insomnia</td>
<td>Stimulus control instructions; sleep restriction therapy; sleep education and hygiene; cognitive strategies; sleep diaries; discussing progress.</td>
<td>Group</td>
<td>2-weeks pre-treatment 6-weeks x treatment : 4 x week classes (1-2 hour) and 2 x week telephone (15 mins) 2-weeks post-treatment</td>
<td>Master’s level Registered Nurse therapist</td>
<td>Sleep education</td>
</tr>
</tbody>
</table>
Table 2.2. Details of Intervention Design and Comparison (continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Content</th>
<th>Strategies</th>
<th>Mode</th>
<th>Duration</th>
<th>Delivered by</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dolbeault</td>
<td>Psycho-educational group based</td>
<td>Self-monitoring; problem-solving; cognitive restructuring; communicate; relaxation.</td>
<td>Group</td>
<td>8 weekly x 2-hour sessions,</td>
<td>Led by 2 therapists, either psychologists or psychiatrists trained in group therapy and BCT</td>
<td>Wait list</td>
</tr>
<tr>
<td>2009</td>
<td>on CBT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Espie 2008</td>
<td>CBT-insomnia</td>
<td>Stimulus control; sleep restriction; cognitive therapy strategies.</td>
<td>Group</td>
<td>5 x weekly, 50-minute sessions.</td>
<td>Cancer nurses, mentored by clinical psychologist</td>
<td>Usual care</td>
</tr>
<tr>
<td>Fillion 2008</td>
<td>Psycho-education and physical</td>
<td>Relaxation skills; coping strategies; links between thoughts, emotions, and fatigue; self-regulation techniques (e.g., self-recording and goal setting); decrease passive coping strategies (e.g., behavioural and social disengagement and naps); increase awareness of the benefits of exercise; adherence techniques; reinforcement self-efficacy, motivation, and positive outcomes.</td>
<td>Group</td>
<td>4 x weekly group meetings</td>
<td>Kinesiologist, trained research nurses,</td>
<td>Usual care</td>
</tr>
<tr>
<td></td>
<td>activity</td>
<td></td>
<td></td>
<td>of 2.5-hours and 1 x short</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>telephone booster session</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>(5-15 minutes)</td>
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### Table 2.2. Details of Intervention Design and Comparison (continued)

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<tr>
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<th>Duration</th>
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<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foster 2015</td>
<td>Self-efficacy to manage CrF.</td>
<td>Defines CRF (possible causes and effects); goal setting and planning; diet, sleep, exercise, home life and work; thoughts and feelings; strategies for talking to others; patient stories; self-monitoring; feedback; automated weekly emails; reminders.</td>
<td>Online</td>
<td>6 x weeks.</td>
<td></td>
<td>Wait list</td>
</tr>
<tr>
<td>Freeman 2015</td>
<td>Imagery-based intervention</td>
<td>Education on the mind–body connection; impact of mental imagery and the sensate experience on physiological processes; apply learning and receive peer-feedback; identify maladaptive ‘passive imagery’ (e.g., automatic thoughts focused on fear/loss of control); create adaptive ‘active imagery’ (e.g., thoughts focused on empowering, meaning–making themes); practice ‘targeted imagery’; monitor the effects of imagery on mind–body health.</td>
<td>Group/tele-medicine</td>
<td>5 x weekly 4-hour group sessions (live delivery or telemedicine delivery). First 4 x sessions separated into 3 x modules (25-minutes didactic education; 25-minutes of group interaction; 20–30 minutes guided imagery). Brief (&lt;10 min) weekly phone calls during intervention delivery and for 3 x months post-treatment.</td>
<td>Licensed professional counsellor, and a family medicine physician</td>
<td>Wait list</td>
</tr>
</tbody>
</table>
### Chapter 2. Systematic Review: The Effectiveness of Psychological Interventions for Fatigue in Cancer Survivors: Systematic Review and Meta-analysis

#### Table 2.2. Details of Intervention Design and Comparison (continued)

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<tr>
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<th>Duration</th>
<th>Delivered by</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gielissen</td>
<td>CBT</td>
<td>Focused on six perpetuating factors (six modules) of post-cancer fatigue, which were based on existing literature and experience in clinical practice: Coping with the experience of cancer; fear of disease recurrence; dysfunctional cognitions concerning fatigue; dysregulation of sleep and activity; focus on low social support and negative social interactions.</td>
<td>Individual</td>
<td>Number of sessions was determined by the number of modules used and whether the goal of the therapy was reached. 5-26 x 1-hour therapy sessions over 6-month period (M = 12.5 sessions; SD = 4.7 sessions).</td>
<td>3x therapists with previous CBT experience with patients with chronic fatigue</td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Wait list</td>
</tr>
<tr>
<td>Hoffman</td>
<td>Mindfulness</td>
<td>Body scan; yoga-based stretches; meditation; group discussions; perceptions of and reactions to life events; stress physiology; mindfulness in communication and everyday life; didactic teaching.</td>
<td>Group</td>
<td>8 weekly x 2 hour classes; first and last classes were 2.25 hours in length; 1 x 6-hour day of mindfulness in week 6; Home practice 40-45 minutes for 6 or 7 d/wk.</td>
<td>Qualified MBSR instructor</td>
<td>Wait list</td>
</tr>
<tr>
<td>2012</td>
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<td></td>
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<tr>
<td>Johns 2014</td>
<td>Mindfulness for CrF</td>
<td>Body scan; sitting/ walking/ compassion meditation; gentle hatha yoga; psycho-education related to CrF; class discussion; bedtime body scan; information (relationship of stress and fatigue, influence of the perception of exhaustion on subsequent diminished physical activity and that physical activity is helpful with CrF); mindful communication practice.</td>
<td>Group</td>
<td>7x weeks x 2-hour classes; Guided home practices (20 min)</td>
<td>MBSR teaching experience</td>
<td>Wait list</td>
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## Chapter 2. Systematic Review: The Effectiveness of Psychological Interventions for Fatigue in Cancer Survivors: Systematic Review and Meta-analysis

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<th>Delivered by</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lengacher 2012</td>
<td>Mindfulness</td>
<td>Awareness of thoughts and feelings through meditation practice (sitting and walking meditation, body scan, and gentle hatha yoga); informal mindfulness meditation; educational material related to relaxation, meditation, and the mind–body connection; pay attention and observe responses during stressful situations; group support sessions on emotional/ psychological responses and physical symptoms; discussion of barriers to the practice of meditation and application of mindfulness in daily situations; supportive interaction between group members.</td>
<td>Group</td>
<td>6 x weekly, 2-hour sessions; Formal exercises (15–45 min per day, 6 x days per week; increased per week); Informal home practice; 1x day x 8-hour silent retreat.</td>
<td>Licensed clinical psychologist trained in MBSR</td>
<td>Usual care</td>
</tr>
<tr>
<td>Matthews 2014</td>
<td>CBT-insomnia</td>
<td>Treatment rationale; conceptual model of insomnia; sleep restriction; stimulus control; sleep schedule; sleep hygiene; cognitive therapy: altering dysfunctional beliefs about sleep and the impact of sleep loss on daytime functioning; sleep titration and treatment gains; relapse prevention and skills to cope with setbacks.</td>
<td>3 x sessions in person</td>
<td>5 x weekly sessions: Session 1: 60 mins; Session 2, 3 and 6: 30–45 minutes; Session 4 and 5 (Telephone): 15–20 minutes.</td>
<td>An advanced practice nurse with specialized training in CBTI</td>
<td>Attention control placebo</td>
</tr>
</tbody>
</table>
### Table 2.2. Details of Intervention Design and Comparison (continued)

<table>
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<tr>
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<th>Duration</th>
<th>Delivered by</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prinsen 2013</td>
<td>CBT for post-cancer fatigue.</td>
<td>Information on coping with the experience of cancer; fear of disease recurrence; dysfunctional cognitions concerning fatigue;  dysregulation of sleep; dysregulation of activity; discussion of low social support and negative social interactions; tailored physical activity program of walking or cycling; gradually replace physical activities.</td>
<td>Group</td>
<td>12–14 x (50 min) individual sessions in 6 months. (M=12). 2 x daily sessions of tailored physical activity program (5 to 10 min to start, increased by 1-minute x day each time the activity was performed- maximum of 120-minutes per day).</td>
<td>Psychologists</td>
<td>Wait list</td>
</tr>
<tr>
<td>Reif 2012</td>
<td>Patient education program</td>
<td>Problem solving; goal setting and evaluation; other cognitive techniques; behaviour therapy-oriented strategies and techniques; diary-keeping; perform exercises and implement lifestyle changes.</td>
<td>Group</td>
<td>6 x weekly 90-minute sessions. 2 x additional meetings after 3 and 6 months.</td>
<td>Nurses/ psychologist</td>
<td>Wait list</td>
</tr>
<tr>
<td>Ritterband 2012</td>
<td>CBT-insomnia</td>
<td>Introduction and rationale; sleep restriction; stimulus control; sleep hygiene; identify and restructure unhelpful beliefs about sleep; relapse prevention; high degree of individual tailoring and feedback; interactive elements; automated emails; encourage adherence.</td>
<td>Online</td>
<td>Access to Shuti for 9 x weeks (6 x week programme). Each core: 45 and 60 minutes.</td>
<td>NA</td>
<td>Wait list</td>
</tr>
</tbody>
</table>
### Table 2.2. Details of Intervention Design and Comparison (continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Content</th>
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<th>Mode</th>
<th>Duration</th>
<th>Delivered by</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rogers 2009 (Rogers et al., 2013)</td>
<td>Physical activity behaviour change intervention</td>
<td>Self-efficacy; outcome expectations; behavioural capability; observational learning; self-control; social support; personal behavioural modification plan; overcoming exercise barriers; emotional coping (including stress management); exercise benefits; task self-efficacy by gradual advancement of the exercise prescription; self-monitoring with daily activity log; overcoming exercise barriers experienced by the participant; self-monitoring; use of the behavioural modification plan; providing positive reinforcement; setting up for maintenance</td>
<td>Group/individual</td>
<td>12-week programme: 6 x group sessions during the first 8 weeks; 12 x individual exercise sessions during the first 6 weeks; 3 x individual counselling sessions during the final 6 weeks.</td>
<td>Psychologist/exercise specialist</td>
<td>Usual care</td>
</tr>
<tr>
<td>Savard 2005</td>
<td>CBT-insomnia Multimodal</td>
<td>Stimulus control therapy; sleep restriction; cognitive restructuring; sleep hygiene; fatigue and stress management</td>
<td>Group</td>
<td>8 x weekly sessions of approximately 90 minutes</td>
<td>Master-level psychologist.</td>
<td>Wait list</td>
</tr>
<tr>
<td>Van Der Lee 2013</td>
<td>MBCT</td>
<td>Skills that enhance the ability to raise awareness to present experiences; information and instructions about various themes; home practice (CDs with breathing instruction and awareness exercises).</td>
<td>Group</td>
<td>9 x week group therapy, weekly sessions (2.5 hours); 1 x 6 hour session; 1 x 2.5 hours follow-up session 2 x months after the 9th session. Total duration = 28.5 hours.</td>
<td>Both therapists had followed MBSR training with Kabat Zinn.</td>
<td>Wait list</td>
</tr>
</tbody>
</table>
## Chapter 2. Systematic Review: The Effectiveness of Psychological Interventions for Fatigue in Cancer Survivors: Systematic Review and Meta-analysis

Table 2.2. Details of Intervention Design and Comparison (continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Content</th>
<th>Strategies</th>
<th>Mode</th>
<th>Duration</th>
<th>Delivered by</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Van Weert 2010</strong></td>
<td>CBT and physical</td>
<td>Self- management, goal setting, monitoring; norms and decision making; action, self-reflection; self-efficacy: mastery of experiences and perceived success, modelling, social persuasion, physiological feedback; discussion of irrational illness perceptions; finding effective and adaptive solutions to stressful problems; dysfunctional cognition, emotions, and behaviours; discussing distress, exercise physiology, and relaxation; homework assignment, and relaxation exercises; individual fitness goal- aerobic training muscle strength training, and information; information on the benefits of exercise; illustrative “model of fatigue,”; restore the balance between demand and capacity during tasks and activities.</td>
<td>Group</td>
<td>1x hour twice a week for 12 x weeks (24 x hours individual physical training and 24 x hours of group sports and games). 24 hours x Cognitive-behavioural therapy (once a week, 2 x hours per session).</td>
<td>2 x physical therapists experienced in the delivery of physical training interventions to patients with cancer. CBT was supervised by 2 x psychologists.</td>
<td>Wait list and Physical therapy only</td>
</tr>
<tr>
<td><strong>Willems 2016</strong></td>
<td>Psycho-social and lifestyle support</td>
<td>Self-management training; return-to-work; fatigue; anxiety and depression; social relationship and intimacy issues; physical activity, diet, smoking cessation; general information on the most common residual symptoms</td>
<td>Online</td>
<td>6 x months</td>
<td>Stand-alone online</td>
<td>Wait list</td>
</tr>
<tr>
<td><strong>Yun 2012</strong></td>
<td>CBT</td>
<td>Based on 2008 National Comprehensive Cancer Network &amp; on the transtheoretical model (TTM) of health behaviour change and social cognitive theory as developed by Bandura or on cognitive behavioural therapy (CBT). Personally tailored sections based on the TTM model; physical activity; sleep hygiene; pain control; general introduction; energy conservation; nutrition; distress management; self-assessment and graphic reports; health advice; online education, caregiver monitoring and support; health professional monitoring.</td>
<td>Online</td>
<td>12 x weeks</td>
<td>Independent research coordinator (nurse)</td>
<td>Wait list</td>
</tr>
</tbody>
</table>
Chapter 2. Systematic Review: The Effectiveness of Psychological Interventions for Fatigue in Cancer Survivors: Systematic Review and Meta-analysis

*Interventions that were specifically designed to treat fatigue*

We were interested to compare studies where fatigue was specifically targeted by the treatment with studies where fatigue was a secondary outcome or measured as one component of a broad outcome such as quality of life. Nine of the included trials were designed specifically for the treatment of fatigue in cancer survivors (Fillion et al., 2008; Foster et al., 2015; Gielissen et al., 2006; Johns et al., 2015; Prinsen et al., 2013; Reif et al., 2013; van der Lee & Garssen, 2012; van Weert et al., 2010; Yun et al., 2012). Five assessed fatigue as part of inclusion criteria for the study (Foster et al., 2015; Johns et al., 2015; Reif et al., 2013; van der Lee & Garssen, 2012; Yun et al., 2012). Eight assessed fatigue as part of a broader quality of life intervention for people after cancer (Bantum et al., 2014; Bower et al., 2015; Dolbeault et al., 2009; Freeman et al., 2015; Hoffman et al., 2012; Lengacher, 2012; Matthews et al., 2014; Willems, 2016). Four focused on insomnia or sleep disturbance (Dirksen & Epstein, 2008; Espie et al., 2012; Ritterband et al., 2012; Savard et al., 2005) and two of the studies aimed to increase physical activity after cancer (Bennett et al., 2007; Rogers et al., 2009).

*Geographic location of study*

The majority of studies were conducted in the United States (Bantum et al., 2014; Bennett et al., 2007; Bower et al., 2015; Dirksen & Epstein, 2008; Freeman et al., 2015; Johns et al., 2015; Lengacher, 2012; Matthews et al., 2014; Ritterband et al., 2012; Rogers et al., 2009). Five were carried out in the Netherlands (Gielissen et al., 2006; Prinsen et al., 2013; van der Lee & Garssen, 2012; van Weert et al., 2010; Willems, 2016), three in the United Kingdom (Espie et al., 2008; Foster et al., 2015; Hoffman et al., 2012). The remainder were conducted in Canada (Savard et al., 2005), Germany (Reif et al., 2013), France (Dolbeault et al., 2009; Fillion et al., 2008) and Korea (Yun et al., 2012).
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Timing of assessment for each outcome

Most included trials assessed the outcomes within 2 weeks pre- and 2 weeks post-treatment. A third measurement point (follow-up) was included in 12 of the studies. Foster et al. (2015) assessed participants at 6 and 12 weeks (T2) post-baseline. Three trials assessed participants for a third time within 1 or 2 weeks after the intervention (Bower et al., 2015; Dolbeault et al., 2009; Hoffman et al., 2012). Johns et al. (2015) included a 1-month follow-up (T3) and three studies conducted final assessments at 3 months after the intervention (Fillion et al., 2008; Freeman et al., 2015; Rogers et al., 2009).

Longer-term persistence of treatment effects was assessed in some of the studies. Bennett (2007) assessed participants at 3 and 6 months after baseline. Three other studies (Espie et al., 2008; Reif et al., 2013; Willems, 2016) included a follow-up assessment of outcomes at 6 months post-treatment. Savard et al. (2005) reported the results of a fourth assessment at 12 months. Three of the studies only collected data at baseline and at 6 months after the intervention (Bantum et al., 2014; Gielissen et al., 2006; van der Lee & Garssen, 2012).

Adverse events

Adverse events were reported by 9 of the included studies. In the study reported by Bennett et al. (2007), two participants withdrew due to a broken leg. However, this was not discussed by the authors and so was likely not an adverse effect of the intervention. In another study (van Weert et al., 2010), a participant collapsed at the start of a training session and died at the first-aid station. Physicians judged that the death was not related to the exercise programme. The other studies also concluded that any adverse events experienced by patients were not attributable to the study (Espie et al., 2008; Foster et al., 2015; Hoffman et al., 2012; Johns et
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al., 2015; van Weert et al., 2010; Willems, 2016). These studies were not necessarily deemed unsafe.

In cases where data on adverse effects was not provided, the absence of information could not be inferred to imply that the intervention was entirely safe.

2.3.3. Risk of bias in included studies

The included studies were assessed for risk of bias using the Cochrane ‘Risk of Bias’ Tool (Higgins et al., 2011). Some aspects of the studies were not reported with sufficient detail to assess bias and therefore were rated as unclear risk of bias for domains where insufficient information was provided. An overall assessment of risk of bias is presented in Figures 2.2a and 2.2b.

Allocation (selection bias)

Most studies described the process of allocating participants between study groups randomly, providing details about the method of randomization employed. Six of the studies were deemed to have an unclear risk of selection bias as insufficient detail about the generation of the random sequence was provided (Freeman et al., 2015; Gielissen et al., 2006; Lengacher, 2012; Matthews et al., 2014; Savard et al., 2005).

Thirteen studies were judged as having an unclear risk of bias, as the method of allocation concealment either was not described or not described in sufficient detail to allow a definite judgment. One study had a high risk of selection bias as the participants or investigators might have foreseen assignment to the study groups (van der Lee & Garssen, 2012).
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Figure 2.2a. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Figure 2.2b. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.
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**Blinding (performance bias and detection bias)**

Most of the trials included in this review were at high risk of performance bias because, owing to the nature of the intervention, it was not possible to blind the trial personnel and participants. Three studies were judged an unclear risk of performance bias (Dolbeault et al., 2009; Gielissen et al., 2006; Lengacher, 2012).

Most studies did not provide sufficient detail to judge detection bias. Six trials were at a low risk for detection bias because the outcome assessors were unaware about the group allocation of participants (Foster et al., 2015; Hoffman et al., 2012; Reif et al., 2013; Rogers et al., 2009; Willems, 2016; Yun et al., 2012). One study (van Weert et al., 2010) was at high risk for detection bias.

**Incomplete outcome data (attrition bias)**

All studies provided some details of study attrition. Many of the studies were at a low risk of attrition bias, with good completion rates. Two trials were considered to have an unclear risk for attrition bias (Espie et al., 2008; Freeman et al., 2015) and five were considered at high risk for attrition bias (Foster et al., 2015; Gielissen et al., 2006; Hoffman et al., 2012; Prinsen et al., 2013; Rogers et al., 2009).

**Selective reporting (reporting bias)**

The majority of studies were at a low risk of reporting bias as, based on the information provided by the trial authors and study protocols (where available), it was unlikely that there was selective reporting of the primary and secondary outcomes. Two trials were considered at high risk (Prinsen et al., 2013; van der Lee & Garssen, 2012). Functional impairment was not an outcome specified in the original protocol, but was reported as such in the Prinsen et al
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(2013 ) paper. Van der Lee et al. (2013) did not report the findings from the mood assessment.

*Other potential sources of bias*

Most trials were deemed to be at a low risk for other biases such as potential bias due to baseline differences, inappropriate influence of the study sponsor, and early stopping for benefit (Corbett et al., 2015). Four trials were at unclear risk for other biases (Bennett et al., 2007; Bower et al., 2015; Ritterband et al., 2012; Willems, 2016).

**2.3.4. Effects of interventions**

This review aimed to critically summarize the evidence about the effectiveness of specific psychological intervention strategies for fatigue in cancer survivors. We completed meta-analyses for outcomes for the follow-up assessment up to and including 6 months after baseline.

When we found heterogeneity, we investigated subgroups based on *a priori* assumptions outlined in the study protocol (Corbett et al., 2015). Although all studies showed a relatively high risk of bias, a sensitivity analysis was conducted of studies where the allocation concealment scored as low risk of bias versus unclear or with a high risk of bias.

*Overall effects*

Fifteen of the included studies reported a significant effect of the interventions on fatigue at a 0.05 level. The 15 studies and their results are briefly described in Table 2.3. The standardized mean difference for the interventions that showed a reduction in fatigue varied between -2.39 (95% C.I. [-3.29, -1.50]) (Johns et al., 2015) and -0.51 -0.51 (95% C.I. [-0.82, -0.21]) (Dolbeault et al., 2009). Of the 15 included trials that found a significant effect of the interventions on fatigue, 13 found significant time-by-group interaction effects at follow-up.
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Meta-analysis

A meta-analysis of the change in score from baseline to follow-up between psychological and control interventions demonstrated a significant improvement in fatigue at 6 month follow-up (SMD= -0.5; 95% CI [-0.7 to -0.31]; participants = 2,662; studies = 20; $I^2 = 82\%$). Statistical heterogeneity was regarded as substantial as $I^2$ was > 50%.

We compared the quality of studies that reported improvements in fatigue at follow-up and those that did not report significant improvements in fatigue. The quality of the seven studies that found improvements in participants’ fatigue at follow-up did not differ from those that did not report significant improvements in fatigue ($p = 0.88$). There was also no difference between these studies in terms of whether theory had been reported in the design of the study ($p = 0.9$). There was no difference (where reported) in the number of months since undergoing medical cancer treatment in the intervention participants ($p = 0.46$).

Chi-squared analysis revealed that there was no statistically significant difference between studies that were designed specifically to target fatigue in comparison to those that included fatigue as one outcome within a more general approach ($\chi^2 = 3.65, p = 0.06$).

2.3.5. Publication bias:

A funnel plot analysis was used to assess potential publication bias. The $P$ value for Egger’s test (Egger, Smith, Schneider, & Minder, 1997) was 0.12, so it was concluded that symmetry exists in the funnel plot. Therefore no apparent bias exists in the studies included in the meta-analysis (Sedgwick, 2013; Sterne et al., 2011).

2.3.6. Subgroup Analysis

As there was significant clinical and statistical heterogeneity when combining all studies, a priori subgroup analyses were conducted. Random-effects models were used for each
Chapter 2. Systematic Review: The Effectiveness of Psychological Interventions for Fatigue in Cancer Survivors: Systematic Review and Meta-analysis

subgroup analysis to consider sources of heterogeneity. These analyses did not reveal any clear effects related to any of the pre-specified variables (Higgins, 2011). These findings of the subgroup analyses can be seen in Appendix 2.

2.3.7. Sensitivity Analysis

All studies showed a relatively high risk of bias in some domains, so we conducted a sensitivity analysis of studies where the sequence generation, allocation concealment and attrition rates scored as low risk of bias versus unclear or with a high risk of bias. These aspects of bias apply to the trial as a whole rather than being inherently specific to different outcomes within the trial (Higgins et al., 2011). We found that the effect of psychological intervention on the change from baseline to 6 months follow-up no longer remained significant (SMD -0.28; 95% CI [-0.71 to 0.15]). However, this analysis only included 5 studies and significant heterogeneity was demonstrated ($I^2$ = 90%).

2.3.8. Trials for which we could not extract data

Among trials for which we could not extract data, Espie et al. (2008) reported that CBT participants had reduced symptoms of fatigue at follow-up, while Matthews et al. (2014) found no statistically significant intervention effects on fatigue.
Table 2.3 Summary of Findings for the Main Comparisons

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Measure</th>
<th>Final follow-up</th>
<th>Intervention</th>
<th>p</th>
<th>Standardized mean difference and 95% Confidence Intervals (Effect size reported in paper)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bantum 2014</td>
<td>Brief Fatigue Inventory (BFI)</td>
<td>6 months</td>
<td>Web-based multiple health behaviour change program</td>
<td>p=.56</td>
<td>.17 (Calculated by taking the differences of the means at 6 months predicted from the model, including adjustment factors, divided by the standard deviation for the difference computed from the within and between subject variance components.)</td>
</tr>
<tr>
<td>Bennett 2007</td>
<td>Schwartz Cancer Fatigue Scale</td>
<td>6 months</td>
<td>Motivational interviewing</td>
<td>p&gt;0.5</td>
<td></td>
</tr>
<tr>
<td>Bower 2015</td>
<td>Fatigue Symptom Inventory</td>
<td>3 months</td>
<td>Mindful Awareness Practices</td>
<td>p=.57</td>
<td></td>
</tr>
<tr>
<td>Dirksen 2008</td>
<td>Profile of Mood States Fatigue/Inertia Subscale (POMSF/I)</td>
<td>2 weeks</td>
<td>CBT- insomnia</td>
<td>p&gt;0.01</td>
<td>-0.61 [-1.09, -0.14]</td>
</tr>
<tr>
<td>Dolbeault 2009</td>
<td>Profile of Mood States Fatigue/Inertia Subscale (POMSF/I)*</td>
<td>6 months</td>
<td></td>
<td>&gt;0.01</td>
<td>-0.51 [-0.82, -0.21]</td>
</tr>
<tr>
<td>EORTC Fatigue</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>((Eta^2 =0.07))</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>p= 0.036 ((Eta^2 =0.03))</td>
</tr>
</tbody>
</table>
**Chapter 2. Systematic Review: The Effectiveness of Psychological Interventions for Fatigue in Cancer Survivors: Systematic Review and Meta-analysis**

Table 2.3 *Summary of Findings for the Main Comparisons (continued)*

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Measure</th>
<th>Final follow-up</th>
<th>Intervention</th>
<th>$p$</th>
<th>Standardized mean difference and 95% Confidence Intervals <em>(Effect size reported in paper)</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Espie 2008</td>
<td>FSI</td>
<td>6 months</td>
<td>CBT- insomnia</td>
<td>$&lt;.001$</td>
<td><em>(Standardized Effect = -0.82)</em></td>
</tr>
<tr>
<td>Fillion 2008</td>
<td>Multidimensional Fatigue Inventory,</td>
<td>3 months</td>
<td>Psycho-education and physical activity</td>
<td>$=.07$</td>
<td>-0.35 [-0.77, 0.08]</td>
</tr>
<tr>
<td>Foster (2015)</td>
<td>Brief Fatigue Inventory (BFI)</td>
<td>12 weeks</td>
<td>Online intervention to enhance self-efficacy to live with CrF</td>
<td>$=.50$</td>
<td>-0.24 (-0.94, 0.46)</td>
</tr>
<tr>
<td>Freeman 2015</td>
<td>FACIT-Fatigue Scale (FACIT-F, version 4), fatigue severity subscale of the CIS</td>
<td>3 months</td>
<td>Imagery-based intervention</td>
<td>$&lt;.001$</td>
<td>-0.89 [-1.28, -0.51]</td>
</tr>
<tr>
<td>Gielissen2006</td>
<td></td>
<td></td>
<td>CBT</td>
<td>$.001$</td>
<td>-0.23 [-0.49, 0.04]</td>
</tr>
<tr>
<td>Hoffman 2012</td>
<td>POMSF/I</td>
<td>12-14 weeks</td>
<td>Mindfulness</td>
<td>$.002$</td>
<td>-0.89 [-1.28, -0.51]</td>
</tr>
<tr>
<td>Lengacher 2012</td>
<td>M.D. Anderson Symptom Inventory (MDASI) (Cleeland et al., 2000)</td>
<td>6 Week</td>
<td>Mindfulness</td>
<td>$.5$</td>
<td>-0.41 [-0.84, 0.02]</td>
</tr>
</tbody>
</table>
Table 2.3 Summary of Findings for the Main Comparisons (continued)

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Measure</th>
<th>Final follow-up</th>
<th>Intervention</th>
<th>p</th>
<th>Standardized mean difference and 95% Confidence Intervals (Effect size reported in paper)</th>
</tr>
</thead>
<tbody>
<tr>
<td>. Johns 2014</td>
<td>Fatigue Symptom Inventory</td>
<td>1 month</td>
<td>Mindfulness</td>
<td>(p&lt;0.001)</td>
<td>-2.39 [-3.29, -1.50] (d=1.34)</td>
</tr>
<tr>
<td>. Matthews 2014</td>
<td>Piper Fatigue Scale</td>
<td>6 Week</td>
<td>CBT for Insomnia (CBTI)</td>
<td>(p=0.52)</td>
<td>(d=0.27)</td>
</tr>
<tr>
<td>. Prinsen 2013</td>
<td>Checklist Individual Strength (CIS-fatigue)</td>
<td>6 months</td>
<td>CBT</td>
<td>(p&lt;0.001)</td>
<td>-1.30 [-2.04, -0.57] (\eta^2=0.248)</td>
</tr>
<tr>
<td>. Reif 2012</td>
<td>Fatigue Assessment Questionnaire (FAQ).*</td>
<td></td>
<td>Patient education program</td>
<td>(p &lt; 0.001)</td>
<td>-1.06 [-1.33, -0.78] (\eta^2=0.200)</td>
</tr>
<tr>
<td></td>
<td>fatigue subscale of the EORTC-QLQ-C30</td>
<td></td>
<td></td>
<td>(p &lt; 0.001)</td>
<td></td>
</tr>
<tr>
<td>. Ritterband 2012</td>
<td>Multidimensional Fatigue Symptom Inventory-Short Form (MFSI-SF)</td>
<td>9 weeks</td>
<td>CBT- insomnia</td>
<td>(p &lt; 0.01)</td>
<td>-0.97 [-1.76, -0.18]</td>
</tr>
<tr>
<td>. Rogers 2009 (Rogers et al., 2009)</td>
<td>FACT-F</td>
<td>6 months</td>
<td>Physical activity behaviour change intervention</td>
<td>(p&lt;0.05)</td>
<td></td>
</tr>
<tr>
<td>. Savard 2005</td>
<td>Multidimensional Fatigue Inventory (MFI)</td>
<td>6 months</td>
<td>CBT</td>
<td>(p &lt; .001)</td>
<td>2.07 to 2.43</td>
</tr>
</tbody>
</table>
Table 2.3 Summary of Findings for the Main Comparisons (continued)

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Measure</th>
<th>Final follow-up</th>
<th>Intervention</th>
<th>p</th>
<th>Standardized mean difference and 95% Confidence Intervals (Effect size reported in paper)</th>
</tr>
</thead>
<tbody>
<tr>
<td>. Van Der Lee 2013</td>
<td>Fatigue severity subscale of the CIS</td>
<td>6 months</td>
<td>Mindfulness-Based Cognitive Therapy</td>
<td>p&lt; 0.001</td>
<td>-0.98 [-1.48, -0.48] (d=0.74)</td>
</tr>
<tr>
<td>. Van Weert 2010</td>
<td>Multidimensional Fatigue Inventory (MFI)-</td>
<td>12 weeks</td>
<td>Physical training combined with CBT</td>
<td>p=.01</td>
<td>-4.3 (-5.3 to -3.4) (d= -1.26)</td>
</tr>
<tr>
<td>. Willems</td>
<td>Checklist Individual Strength (CIS)</td>
<td>6 months</td>
<td>psychosocial and lifestyle support intervention</td>
<td>p=.020</td>
<td>-0.19 [-0.39, 0.00] (d=0.21)</td>
</tr>
<tr>
<td>. Yun 2012</td>
<td>Brief Fatigue Inventory (BFI) *</td>
<td>3 months</td>
<td>CBT</td>
<td>p &lt; 0.01</td>
<td>-0.27 [-0.51, -0.03] (d=0.29)</td>
</tr>
<tr>
<td></td>
<td>Fatigue Severity Scale (FSS)</td>
<td>3 months</td>
<td></td>
<td>p &lt; 0.01</td>
<td>d=0.27</td>
</tr>
</tbody>
</table>
Chapter 2. Systematic Review: The Effectiveness of Psychological Interventions for Fatigue in Cancer Survivors: Systematic Review and Meta-analysis

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Experimental Mean</th>
<th>SD</th>
<th>Total</th>
<th>Control Mean</th>
<th>SD</th>
<th>Total</th>
<th>Weight</th>
<th>IV, Random, 95% CI</th>
<th>Std. Mean Difference IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bantum 2014 (1)</td>
<td>-2.6</td>
<td>13.19</td>
<td>147</td>
<td>-0.1</td>
<td>12.98</td>
<td>156</td>
<td>6.2%</td>
<td>-0.19 [-0.42, 0.04]</td>
<td></td>
</tr>
<tr>
<td>Bennett 2007 (2)</td>
<td>-4.58</td>
<td>7.9</td>
<td>19</td>
<td>-4.06</td>
<td>3.64</td>
<td>26</td>
<td>4.2%</td>
<td>-0.15 [-0.74, 0.45]</td>
<td></td>
</tr>
<tr>
<td>Boxer 2015 (3)</td>
<td>-0.03</td>
<td>0.26</td>
<td>31</td>
<td>-0.26</td>
<td>0.27</td>
<td>28</td>
<td>4.5%</td>
<td>0.88 [0.32, 1.35]</td>
<td></td>
</tr>
<tr>
<td>Clarkson 2009 (4)</td>
<td>-5.4</td>
<td>6.3</td>
<td>34</td>
<td>-1.3</td>
<td>7.6</td>
<td>38</td>
<td>4.9%</td>
<td>-0.61 [1.09, -0.14]</td>
<td></td>
</tr>
<tr>
<td>Cotbeust 2009 (5)</td>
<td>-3.15</td>
<td>5.58</td>
<td>81</td>
<td>0.09</td>
<td>6.84</td>
<td>87</td>
<td>5.8%</td>
<td>-0.59 [-0.82, -0.21]</td>
<td></td>
</tr>
<tr>
<td>Cote 2009 (6)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Not estimable</td>
<td></td>
</tr>
<tr>
<td>Filion 2008 (7)</td>
<td>-0.57</td>
<td>0.84</td>
<td>44</td>
<td>-0.26</td>
<td>0.93</td>
<td>43</td>
<td>5.2%</td>
<td>-0.35 [-0.77, 0.08]</td>
<td></td>
</tr>
<tr>
<td>Foster (2015) (8)</td>
<td>-1.07</td>
<td>2.5</td>
<td>83</td>
<td>-1.05</td>
<td>2.36</td>
<td>76</td>
<td>5.9%</td>
<td>-0.81 [-0.32, 0.50]</td>
<td></td>
</tr>
<tr>
<td>Freeman 2015 (9)</td>
<td>-11.75</td>
<td>10.4</td>
<td>71</td>
<td>-2.3</td>
<td>11.23</td>
<td>47</td>
<td>5.4%</td>
<td>-0.89 [1.28, -0.51]</td>
<td></td>
</tr>
<tr>
<td>Gielissen 2008 (10)</td>
<td>-1.9</td>
<td>6.3</td>
<td>103</td>
<td>-0.36</td>
<td>6.73</td>
<td>111</td>
<td>6.0%</td>
<td>-0.23 [-0.49, 0.04]</td>
<td></td>
</tr>
<tr>
<td>Holland 2012 (11)</td>
<td>-18.6</td>
<td>16.7</td>
<td>50</td>
<td>-5.2</td>
<td>18.36</td>
<td>48</td>
<td>5.2%</td>
<td>-0.80 [1.32, -0.30]</td>
<td></td>
</tr>
<tr>
<td>Johns 2014 (12)</td>
<td>-2.47</td>
<td>1.68</td>
<td>18</td>
<td>0.13</td>
<td>1.04</td>
<td>17</td>
<td>2.8%</td>
<td>-2.39 [-3.29, -1.50]</td>
<td></td>
</tr>
<tr>
<td>Lengeler 2012 (13)</td>
<td>-1.6</td>
<td>2.2</td>
<td>41</td>
<td>-0.06</td>
<td>2.6</td>
<td>43</td>
<td>5.1%</td>
<td>-0.41 [-0.64, 0.02]</td>
<td></td>
</tr>
<tr>
<td>Matthews 2014</td>
<td>-1.74</td>
<td>0</td>
<td>30</td>
<td>-1.39</td>
<td>0</td>
<td>26</td>
<td>0</td>
<td>Not estimable</td>
<td></td>
</tr>
<tr>
<td>Prinson 2013 (14)</td>
<td>-21.0</td>
<td>10.2</td>
<td>23</td>
<td>-7.5</td>
<td>11.8</td>
<td>14</td>
<td>3.5%</td>
<td>-1.30 [2.04, -0.57]</td>
<td></td>
</tr>
<tr>
<td>Reit 2012 (15)</td>
<td>-19.57</td>
<td>15.7</td>
<td>120</td>
<td>0.97</td>
<td>22.53</td>
<td>114</td>
<td>6.0%</td>
<td>-1.06 [-1.33, -0.78]</td>
<td></td>
</tr>
<tr>
<td>Ritterband 2012 (16)</td>
<td>-13.36</td>
<td>10.3</td>
<td>14</td>
<td>9.08</td>
<td>20.64</td>
<td>14</td>
<td>3.2%</td>
<td>-0.97 [1.76, -0.18]</td>
<td></td>
</tr>
<tr>
<td>Rogers 2009 (17)</td>
<td>0.64</td>
<td>12.85</td>
<td>14</td>
<td>2.35</td>
<td>13.06</td>
<td>12</td>
<td>3.3%</td>
<td>-0.13 [-0.50, 0.64]</td>
<td></td>
</tr>
<tr>
<td>Savard 2005</td>
<td>-0.59</td>
<td>0</td>
<td>27</td>
<td>-0.14</td>
<td>0</td>
<td>30</td>
<td>0</td>
<td>Not estimable</td>
<td></td>
</tr>
<tr>
<td>Van Der Lee 2013</td>
<td>-11.9</td>
<td>9.02</td>
<td>59</td>
<td>-3.8</td>
<td>5.57</td>
<td>24</td>
<td>4.7%</td>
<td>0.08 [1.48, -0.36]</td>
<td></td>
</tr>
<tr>
<td>van Weel 2010</td>
<td>-4.3</td>
<td>3.98</td>
<td>70</td>
<td>-2.38</td>
<td>6.68</td>
<td>60</td>
<td>5.5%</td>
<td>-0.59 [0.95, -0.24]</td>
<td></td>
</tr>
<tr>
<td>Willems 2012 (submitted)</td>
<td>-6.85</td>
<td>2.72</td>
<td>189</td>
<td>-2.8</td>
<td>28.15</td>
<td>221</td>
<td>6.4%</td>
<td>-0.19 [0.39, 0.00]</td>
<td></td>
</tr>
<tr>
<td>Yun 2012</td>
<td>-0.68</td>
<td>1.28</td>
<td>136</td>
<td>-0.33</td>
<td>1.35</td>
<td>137</td>
<td>6.2%</td>
<td>-0.27 [-0.51, -0.03]</td>
<td></td>
</tr>
</tbody>
</table>

Total (95% CI) 1346 1316 100.0% -0.50 [-0.70, -0.31]  

Heterogeneity: Tau²= 0.15, Ch²= 105.62, df= 19 (P = 0.00001); I² = 92%

Test for overall effect Z = 4.99 (P < 0.00001)

Footnotes
1. SD of change calculated using CI reported
2. SD of change taken from SD at follow-up
3. SD of change taken from SD at follow-up
4. SD of change taken from SD at follow-up
5. SD of change taken from SD at follow-up
6. SD of change taken from SD at follow-up
7. SD of change taken from SD at follow-up
8. SD of change calculated using CI reported
9. Combined groups of telemicine and five intervention using formula in Table 7.7a. Formulae for combining groups. Reverse scoring used.
10. SD of change calculated using CI reported
11. SD of change from SD at follow-up
12. SD of change calculated using CI reported
13. SD of change calculated using CI reported
14. SD of change taken from SD at follow-up
15. SD of change taken from SD at follow-up
16. SD of change taken from SD at follow-up
17. Data made available upon request from author. Reverse scoring used.

Figure 2.3. Forest plot of comparison between psychological interventions and controls on primary outcome of fatigue.
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2.3.9. Secondary outcomes

Secondary outcomes of interest to this review were specified \textit{a priori} in the study protocol (Corbett et al., 2015). These included mood (self-reported scales of depression, and/or anxiety, or distress); global quality of life and functional impact of fatigue (self-report questionnaire measures assessing the impact of fatigue on quality of life and daily functioning); and fatigue self-efficacy. Most of the studies included a measure of mood, either as an outcome or a control variable. However, the mood outcomes were assessed by a wide range of psychometric tools which assessed various dimensions of mood including stress, depression, anxiety, and distress. Many of the studies also included a measure of global quality of life (QoL) and functional impact of fatigue. Only two of the studies assessed self-efficacy in relation to coping with fatigue (Fillion et al., 2008; Foster, Grimmett, et al., 2015).

In the review process, other frequently reported secondary outcomes that were not outlined in the review protocol were identified as relevant to this review. Insomnia or sleep quality outcomes were reported in 12 studies. Furthermore, 6 studies reported an assessment of pain. Studies that assessed sleep quality or insomnia tended to be designed with the aim of impacting insomnia or quality of life after cancer treatment. Only one of the studies that assessed sleep-related variables was specifically designed to address CrF (Johns et al., 2015). These interventions appeared to impact insomnia, but findings were mixed regarding their impact on sleep quality. The interventions did also not appear to impact pain in the three studies in which it was assessed.

Within the practical constraints of this review, it was not possible to conduct a meta-analysis of the secondary outcomes, but the findings are summarised below and in Table 2.4.
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Mood (self-reported scales of depression, and/or anxiety, or distress)

In the 23 studies, 12 different measures of mood were used. Four studies included more than one measure of mood (Bower et al., 2015; Dirksen & Epstein, 2008; Dolbeault et al., 2009; Johns et al., 2015). The most commonly used measure was the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983), which was used to assess mood in 7 studies. The Patient Health Questionnaire (PHQ) (Spitzer, Kroenke, Williams, & Group, 1999) (a measure of depression severity) and The Profile of Mood States (POMS) (Lorr & McNair, 1971) (a measure of psychological distress) were used in 3 studies. The State-Trait Anxiety Inventory (STAI) (Spielberger, Gorsuch, Lushene, & Vagg, 1970) was used twice. Five studies reported no evidence of statistically-significant differences between groups in mood (Bantum et al., 2014; Foster et al., 2015; Lengacher, 2012; Matthews et al., 2014; Ritterband et al., 2012; Yun et al., 2012). Group main effects in favour of the intervention were revealed were revealed in 9 studies (Bower et al., 2015; Dirksen & Epstein, 2008; Dolbeault et al., 2009; Espie et al., 2008; Fillion et al., 2008; Freeman et al., 2015; Gielissen et al., 2006; Hoffman et al., 2012; Johns et al., 2015). Three studies (Reif et al., 2013; Savard et al., 2005; Willems et al, 2016) reported significant interaction effects of the intervention on mood. There was no difference in the quality of the studies that reported an effect and those that did not.

Global quality of life/ Functional Impact of Fatigue

The two most commonly used scales used to assess quality of life were the European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) (Aaronson et al., 1993) and the Functional Assessment of Cancer Therapy—General (FACT-G) (Cella et al., 1993). In the study protocol, the reviewers aimed
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to delineate the concepts of “global quality of life” and “functional impact of fatigue” (Corbett et al., 2015). However, in line with Luckett (2011), this was not deemed appropriate in the final review. Both types of measures assess physical, emotional, social, and functional/role scales. The QLQ-C30 provides brief scales for cognitive functioning, financial impact, and a range of symptoms either not assessed by the FACT-G or else subsumed within its well-being scales. The FACT-G includes both symptoms and concerns within each scale (Luckett et al., 2011).

Six studies used the EORTC QLQ-C30 to assess quality of life. Savard (2005) reported a significant group-time interaction for global quality of life, in favour of the treatment condition. Matthews et al. (2014) found no statistically significant intervention effect on QOL but reported a significant interaction effect for physical function in favour of the intervention group. The remaining four studies reported significant improvements in the global health status of the intervention group compared to the control group (Dolbeault et al., 2009; Reif et al., 2013; Willems, 2016; Yun et al., 2012).

Four studies used the FACT-G to assess QoL. Foster (2015) reported no evidence of difference between groups in quality of life. Three studies (Dirksen & Epstein, 2008; Espie et al., 2008; Hoffman et al., 2012) reported a significant group-time interaction for QoL, in favour of the intervention. Dirksen (2008) did not find significant interaction effects in the physical, social, emotional, and functional well-being subscales. Similarly, Espie (2008) reported that changes were not observed in both groups over time on the social or emotional scales, whereas Hoffman (2012) found interaction effects for emotional wellbeing, functional well-being, and physical well-being at three time points. Rogers (2009) noted a significant group by time interaction for social well-being, but not overall quality of life, physical well-being, endocrine symptoms, or cognitive function.
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Three studies used the Medical Outcomes Study (MOS) (Stewart, Hays, & Ware, 1988), which measures of quality of life including physical, mental, and general health. All three studies (Bennett et al., 2007; Fillion et al., 2008; Freeman et al., 2015) noted that participants reported significantly more well-being and less functional impairment than at baseline, but found no interaction effects between groups over time.

The Sickness Impact Profile (SIP) (Bergner, Bobbitt, Carter, & Gilson, 1981) was used in three studies. Gielissen (2006) reported a significant group-time interaction for functional, in favour of the treatment condition. Prinsen et al. (2013) reported that the change score in functional impairment was significantly different in favour of the intervention group compared to the waiting list group. Van der Lee (2012) found no difference in impairment between groups, with all participants improving over time.

Using the M.D. Anderson Symptom Inventory (MDSAI) (Cleeland et al., 2000), Lengacher et al. (2012) found no evidence of difference between groups in quality of life. Ritterband et al. (2012) reported that there was not a significant interaction effect of the intervention on either the mental or physical subscales of the SF-12. Johns et al. (2015) assessed functional impairment using the Sheehan Disability Scale and reported a significant group-time interaction, in favour of the treatment condition.

Fatigue self-efficacy

Two studies (Bower et al., 2015; Foster et al., 2015) found that intervention group participants felt significantly more confident about their ability to manage fatigue and its impact on their lives than control group participants at posttreatment. However, this impact was lost by the final follow-up in the Foster et al study (2015).

Insomnia or sleep quality
Six different outcome measures were used in the 11 studies to assess sleep quality or insomnia. The Insomnia Severity Index (ISI) (Morin & Barlow, 1993) was the most commonly used, with 4 studies using the tool. Each of the studies reported a significant time by treatment interaction for insomnia severity (Johns et al., 2015; Matthews et al., 2014; Ritterband et al., 2012; Savard et al., 2005). Bantum et al. (2014) also reported that the intervention group experienced an improvement in insomnia from baseline to follow-up compared to the control group, as assessed using the Women's Health Initiative Insomnia Rating Scale (WHIIRS) (Levine et al., 2003).

Four studies used the Pittsburgh Sleep Quality Index (PSQI) (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). Freeman et al. (2015) reported a significant group by time interaction effect in favour of the intervention. However, three studies (Bower et al., 2015; Espie et al., 2008; Rogers et al., 2009) reported no significant effects.

Using the MDSAI, Lengacher et al. (2012) found that in the intervention group, statistically-significant reductions were observed for disturbed sleep. Dolbeault et al. (2009) observed changes in both groups over time in the EORTC QLQ-C30 sleep scores, with no effect of the intervention.

Of the studies that assessed sleep or insomnia, three focused on insomnia or sleep disturbance (Espie et al., 2012; Ritterband et al., 2012; Savard et al., 2005) and one sought to increase physical activity after cancer (Rogers et al., 2009). Six of these studies involved a quality of life intervention for people after cancer (Bantum et al., 2014; Bower et al., 2015; Dolbeault et al., 2009; Freeman et al., 2015; Lengacher, 2012; Matthews et al., 2014). Only one of the interventions that assessed sleep was designed to target CrF (Johns et al., 2015).

Pain
Dolbeault et al. (2009) reported no effect of the intervention group on pain. Lengacher et al. (2012) reported a group effect of the intervention on pain and Rogers et al. (2009) found a significant time effect for joint pain. However, the group by time interaction was not significant in both studies.
### Table 2.4. Summary of studies reporting on secondary outcomes

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Endpoint</th>
<th>Outcome Measure</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>. Bantum 2014</td>
<td>Mood</td>
<td>Patient Health Questionnaire (PHQ-8): depression</td>
<td>Non-significant ($p=.69$) difference in groups in change from baseline to 6 months.</td>
</tr>
<tr>
<td></td>
<td>Insomnia or sleep quality</td>
<td>Women’s Health Initiative Insomnia Rating Scale (WHIIRS)</td>
<td>The intervention group experienced an improvement from baseline to 6 months compared to the control group: reduced insomnia (9.6 to 9.2 compared to 9.6 to 10.1, $p=.03$),</td>
</tr>
<tr>
<td>. Bennett 2007</td>
<td>Global quality of life / Functional impact of fatigue</td>
<td>Health status variables were measured by the Medical Outcomes Study Short-Form 36 (SF-36, v.2) Physical Component Summary (PCS) and Mental Component Summary (MCS)</td>
<td>Physical and mental health status increased across the study. Group × Time interaction was not significant for either mental or physical health.</td>
</tr>
<tr>
<td>Bower 2015</td>
<td>Fatigue self-efficacy</td>
<td>Fatigue subscale of the HIV self-efficacy questionnaire.</td>
<td>Intervention group participants felt significantly more confident about their ability to manage fatigue and its impact on their lives than control group participants at posttreatment (intervention group mean = 7.9, education group mean = 6.1; $t (28) = -2.6$, $p = .017$).</td>
</tr>
<tr>
<td></td>
<td>Mood</td>
<td>Beck Depression Inventory-II (BDI-II)</td>
<td>Group × Time interaction ($p = .026$) post-treatment, not maintained at 3 month follow-up. Groups reported similar reductions in depressive symptom levels.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Perceived Stress Scale (PSS)</td>
<td>A significant time effect for perceived stress ($p = .015$); feelings of stress decreased over the assessment period in both groups.</td>
</tr>
<tr>
<td></td>
<td>Insomnia or sleep quality</td>
<td>Pittsburgh Sleep Quality Index (PSQI)</td>
<td>No significant effects for subjective sleep quality.</td>
</tr>
</tbody>
</table>
Table 2.4. Summary of studies reporting on secondary outcomes (continued)

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Endpoint</th>
<th>Outcome Measure</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dirksen</td>
<td>Global quality of life / Functional impact of fatigue</td>
<td>Functional Assessment of Cancer Therapy-Breast (FACT-B) (version 4): physical well-being (FACT-PWB); emotional well-being (FACT-EWB); social well-being (FACT-SWB), functional well-being; (FACT-FWB) and relationship with doctor (three items).</td>
<td>Mediational analysis determined that the intervention did not have a direct effect on psychosocial outcomes. Statistically significant interaction effects were found for quality of life. Both groups improved on quality of life, but the increase was greater in the CBT-I group. FACT-B: p = 0.02</td>
</tr>
<tr>
<td>Mood</td>
<td>State-Trait Anxiety Inventory (STAI) (state (STAI-S) and a trait anxiety scale (STAI-T))</td>
<td>From pre- to post-treatment, the CBT-I group improved on trait anxiety and depression.</td>
<td></td>
</tr>
</tbody>
</table>

**Group x Time interaction effects were non-significant**

- FACT-B PWB: p = 0.11
- FACT-B SWB: p = 0.10
- FACT-B EWB: p = 0.49
- FACT-B FWB: p = 0.11

STAI-S: p = 0.22
STAI-T: p = 0.14
CES-D: p = 0.29
### Table 2.4. Summary of studies reporting on secondary outcomes (continued)

<table>
<thead>
<tr>
<th>Study ID</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Dolbeault 2009</td>
<td>Global QoL</td>
<td>EORTC QLQ-C30; EORTC QLQ-BR23</td>
<td>Changes in both groups were observed over time in the EORTC QLQ-C30 scores for physical, emotional, cognitive, and social functioning, dyspnoea, and financial difficulties, and in the QLQ-BR23 body image, future prospects, and breast symptom scores. A greater improvement in quality of life functional or symptom scales were observed in the intervention group compared with the control group. EORTC QLQ-C30 scores, emotional functioning (9% of the variance explained by the model including the time/group interaction term), role functioning (3%), global health status (3%).</td>
</tr>
<tr>
<td>Mood</td>
<td>STAI</td>
<td></td>
<td>Changes in both groups were observed over time in the STAI trait and state anxiety scores, the POMS anxiety, anger, confusion, depression and global scores, the MAC helplessness–hopelessness and anxious preoccupations scores. Significant Group × Time interactions indicate a positive effect of the intervention on anxiety (STAI Y-A: ( p &lt; 0.001 ); STAI Y-B: ( p &lt; 0.01 )). A greater reduction of negative affect and improvement in positive affect and in quality of life functional or symptom scales were observed in the intervention group compared with the control group. POMS anxiety and global scores (8% of the variance explained by the model including the Group × Time interaction term, ( p &lt; 0.001 )), anger (5%, ( p &lt; 0.01 )), interpersonal relationships (4%, ( p &lt; 0.01 )), vigour (3%, ( p &lt; 0.05 )) and depression (2%, ( p &lt; 0.05 )). No effect of the intervention group was evidenced on the POMS confusion (( p = 0.15 )).</td>
</tr>
<tr>
<td>Insomnia or sleep quality</td>
<td>EORTC QLQ-C30 sleep scores.</td>
<td></td>
<td>In both groups changes were observed over time in the EORTC QLQ-C30 sleep scores. No effect of the intervention group was evidenced (( p = 0.14 )).</td>
</tr>
<tr>
<td>Pain</td>
<td>EORTC pain</td>
<td></td>
<td>No effect of the intervention group on pain (( p = 0.06 )).</td>
</tr>
</tbody>
</table>
### Table 2.4. Summary of studies reporting on secondary outcomes (continued)

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<tr>
<th>Study ID</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Espie 2008</td>
<td>Global quality of life / Functional impact of fatigue</td>
<td>Functional Assessment of Cancer Therapy Scale– general FACT-G</td>
<td>No statistically significant interactions were found: Functional Assessment of Cancer Therapy (FACT)-Physical ($p = .47$), FACT-Functional ($p = .19$). CBT was associated with increased physical and functional QoL relative to TAU, at post-treatment and at follow-up (FACT Physical ($p &lt; .004$); FACT Functional $p &lt; .001$). No effect of the intervention group was evidenced on the FACT Social ($p = 0.53$) or FACT Emotional ($p = 0.44$) scales</td>
</tr>
<tr>
<td>Mood</td>
<td>Hospitals Anxiety and Depression Scale [HADS]</td>
<td>CBT participants had reduced symptoms of anxiety, and depression relative to TAU. (HADS Anxiety $p&lt;0.05$; HADS Depression $p&lt;0.01$)</td>
<td></td>
</tr>
<tr>
<td>Insomnia or sleep quality</td>
<td>PSQI, Epworth sleepiness (baseline only) sleep diary assessed the central insomnia Dimensions of difficulty initiating (SOL) and maintaining (WASO) sleep.</td>
<td>CBT was associated with median reduction in insomnia symptoms of almost 1 hour (SOL &amp; WASO) compared with no change following TAU. A higher proportion of CBT participants achieved the criterion for the lower limit of normal sleep, 51% (51 of 100) versus 34% on TAU (17 of 50; $p &lt; .01$); at 6 months this difference was no longer significant (44% of patients on CBT; 48% on TAU; $p=0.97$). Baseline sleep quality ($p = .88$), insomnia duration ($p = .65$) did not mediate response.</td>
<td></td>
</tr>
</tbody>
</table>

Table 2.4. Summary of studies reporting on secondary outcomes (continued)
### Chapter 2. Systematic Review: The Effectiveness of Psychological Interventions for Fatigue in Cancer Survivors: Systematic Review and Meta-analysis

<table>
<thead>
<tr>
<th>Study ID</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Fillion 2008</td>
<td>Global quality of life / Functional impact of fatigue</td>
<td>Medical Outcomes Study Short Form 12</td>
<td>Group effect for physical quality of life ( p &lt; 0.05 ) (PCS-12 Group X Time interaction effect, ( p = 0.09 ))</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Menopause-Specific Quality of Life Questionnaire</td>
<td>Group X Time interaction effects emerged for (POMS vigour ( p &lt; 0.05 ))</td>
</tr>
<tr>
<td></td>
<td>Mood</td>
<td>Profile of Mood States: combined anxiety and depression subscales</td>
<td>No interaction or main effects on mental quality of life: both conditions improved in a similar manner on mental quality of life overtime (( p &gt; 0.05 )).</td>
</tr>
<tr>
<td></td>
<td>Pain</td>
<td>Brief Pain Inventory</td>
<td>Control variable: change not reported</td>
</tr>
<tr>
<td>Foster 2015</td>
<td>Global quality of life / Functional impact of fatigue</td>
<td>Functional Assessment of Cancer Therapy—General (FACT-G)</td>
<td>FACT-G: no evidence of difference between groups, ( p = 0.10 )</td>
</tr>
<tr>
<td></td>
<td>Fatigue self-efficacy</td>
<td>Personal Wellbeing Index (PWI)</td>
<td>PWI: no evidence of difference between groups, ( p = 0.94 )</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Perceived Self-efficacy for Fatigue Self-management (PSEFSM)</td>
<td>Improved fatigue self-efficacy at T1 (0.514, 95 % CI [−0.084, 1.112], ( p = 0.09 )), in the intervention group though the impact is lost by T2.</td>
</tr>
<tr>
<td></td>
<td>Mood</td>
<td>Patient Health Questionnaire (PHQ-9)</td>
<td>No evidence of difference between groups, ( p = 0.40 )</td>
</tr>
</tbody>
</table>

Table 2.4. Summary of studies reporting on secondary outcomes (continued)
## Chapter 2. Systematic Review: The Effectiveness of Psychological Interventions for Fatigue in Cancer Survivors: Systematic Review and Meta-analysis

<table>
<thead>
<tr>
<th>Study ID</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Freeman 2015</td>
<td>Global quality of life / Functional impact of fatigue</td>
<td>Medical Outcomes Study 36-item short form survey (SF-36); Physical component summary (PCS) and mental component Summary (MCS) scores; Breast cancer-specific subscale of the Functional Assessment of Cancer Therapy-Breast (FACT-B)</td>
<td>No Group x Time interaction effects. Intervention groups higher MCS scores compared with women in the WL group (p&lt;0.05).</td>
</tr>
<tr>
<td>Mood</td>
<td>Psychological distress: Brief Symptom Inventory-GLOBAL Severity Index (BSI-GSI)</td>
<td></td>
<td>No Group x Time interaction effects. Both live delivery (p &lt; 0.01) and telemedicine delivery (p &lt; 0.01) intervention groups reported lower BSI-GSI than WL at the 3-month follow-up.</td>
</tr>
<tr>
<td>Insomnia or sleep quality</td>
<td>Pittsburgh Sleep Quality Index (PSQI)</td>
<td></td>
<td>Intervention groups lower PSQI scores compared with individuals in the WL group (p&lt;0.01)</td>
</tr>
<tr>
<td>Gielissen 2006</td>
<td>Global quality of life / Functional impact of fatigue</td>
<td>Functional impairment was measured by the Sickness Impact Profile-8 (SIP-8).</td>
<td>Patients in the intervention condition reported a significantly greater decrease in functional impairment (difference, 383.2; 95% CI, 197.1 to 569.2, p&lt;0.001) than patients in the waiting list condition</td>
</tr>
<tr>
<td>Mood</td>
<td>Psychological distress: Symptom Check List 90</td>
<td></td>
<td>Patients in the intervention condition reported a significantly greater decrease in psychological distress (difference, 21.6; 95% CI, 12.7 to 30.4, p&lt;0.001) than patients in the waiting list condition</td>
</tr>
</tbody>
</table>
Table 2.4. Summary of studies reporting on secondary outcomes (continued)

<table>
<thead>
<tr>
<th>Study ID</th>
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<th>Outcome</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hoffman 2012</td>
<td>Global quality of life / Functional impact of fatigue</td>
<td>Functional Assessment of Cancer Therapy-Breast (FACT-B)</td>
<td>Statistically significant treatment effects for FACT-ES, FACT-B, physical well-being, social well-being, emotional well-being, and functional well-being. Mean scores in the experimental group compared with the control group were greater at both T2 and T3 for all six FACT measures (except social well-being which was significant at T2 only). For emotional well-being, there was some evidence that treatment effects at T3 were statistically significantly greater that at T2.</td>
</tr>
<tr>
<td></td>
<td>FACT, Functional Assessment of Cancer Therapy SUBScales</td>
<td>No other interactions were statistically significant.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• PWB Physical wellbeing,</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• SWB social wellbeing,</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• EWB emotional wellbeing,</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• FWB functional well-being.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Functional Assessment of Cancer Therapy-Endocrine Symptoms (FACT-ES)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>WHO five-item well-being questionnaire (WHO-5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mood</td>
<td>POMS</td>
<td>Statistically significant increases in the WHO-5 in the experimental group compared with controls, and these were apparent at T2 and T3. There were statistically significant differences between treatment groups for POMS total mood disturbance, anxiety, depression, anger, vigour, fatigue, and confusion. The T1-adjusted mean differences and 95% CIs at T2 and T3 suggested statistically significant lower mood-state scores in the experimental group than in the control group at both measurement occasions except for depression (T2 only), anger (T3 only), and confusion (T2 only). There were no statistically significant interactions between treatment group and measurement occasion.</td>
<td></td>
</tr>
</tbody>
</table>
### Table 2.4. Summary of studies reporting on secondary outcomes (continued)

<table>
<thead>
<tr>
<th>Study ID</th>
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<th>Outcome</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Johns</td>
<td>Functional impact of fatigue</td>
<td>Functional status: Sheehan Disability Scale (SDS)</td>
<td>At T3, the intervention group demonstrated significantly lower functional disability scores than controls ((p &lt; 0.01)) with a large effect size ((d = -1.22)).</td>
</tr>
<tr>
<td>2014</td>
<td>Mood</td>
<td>Anxiety: Patient Health Questionnaire</td>
<td>Anxiety scores in the intervention group at T3 were significantly lower than the control group ((p &lt;0.01)) with a large effect size ((d = -0.98)).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Generalized Anxiety Disorder Scale</td>
<td>Depression scores were significantly lower ((p&lt;0.001)) for intervention group than controls with large differences at T2 ((d =-1.30)) and T3 ((d =-1.71)).</td>
</tr>
<tr>
<td></td>
<td>Insomnia or sleep quality</td>
<td>Sleep disturbance: Insomnia Severity Index</td>
<td>Sleep disturbance was significantly improved for intervention group compared with the control condition at both T2 ((d =-0.74)) and T3 ((d =-1.00)).</td>
</tr>
<tr>
<td>Lengacher</td>
<td>Global quality of life /</td>
<td>M.D. Anderson Symptom Inventory (MDASI) (drowsiness, lack of appetite,</td>
<td>Participants in both groups tended to improve on MDASI symptoms when compared to baseline. The MBSR (BC) group showed greater improvement across symptoms, and especially symptom interference items, compared to the control group. General activity, work (including work around the house) and relations with other people improved following MBSR (BC).None of the between group comparisons differences reached the statistical significance criteria set for this study.</td>
</tr>
<tr>
<td>2012</td>
<td>Functional impact of fatigue</td>
<td>nausea, vomiting, shortness of breath, numbness, difficulty remembering, dry</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>mouth,) Symptom interference items (i.e., general activity, work (including work around the house) relations with other people, walking).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mood</td>
<td>MDASI mood, enjoyment of life, distress, and sadness</td>
<td>Sadness and enjoyment of life were statistically reduced in the control group. Mood and enjoyment of life improved following MBSR (BC). None of the between-group differences were statistically-significant.</td>
</tr>
<tr>
<td></td>
<td>Insomnia or sleep quality</td>
<td>MDASI sleep disturbance</td>
<td>MBSR (BC) group, statistically-significant reductions ((p&lt;.01)) were observed for disturbed sleep.</td>
</tr>
<tr>
<td></td>
<td>Pain</td>
<td>MDASI drowsiness</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>MDASI pain</td>
<td></td>
</tr>
</tbody>
</table>
Chapter 2. Systematic Review: The Effectiveness of Psychological Interventions for Fatigue in Cancer Survivors: Systematic Review and Meta-analysis

Table 2.4. Summary of studies reporting on secondary outcomes (continued)

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<tr>
<th>Study ID</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Matthews 2014</td>
<td>Global quality of life</td>
<td>European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire– Core 30 (EORTC QLQ-C30)</td>
<td>A significant time by Group x Time interaction for physical function. Post-hoc tests showed significant improvement from baseline to post-test/ follow-up for women in the intervention group relative to active control ($p&lt;0.05$, $d=0.79$). No statistically significant intervention effects were noted on scores over time for QOL.</td>
</tr>
<tr>
<td></td>
<td>Mood</td>
<td>Hospital Anxiety and Depression Scale (HADS)</td>
<td>No statistically significant intervention effects were noted on scores over time for depression, or anxiety.</td>
</tr>
<tr>
<td></td>
<td>Insomnia or sleep quality</td>
<td>Sleep parameters extracted from the diary included SL, SE, WASO, TST, and number of nocturnal awakenings.</td>
<td>A significant time by treatment interaction was observed for SE, SL, and TST. No statistically significant condition effects were noted on scores over time for WASO or number of awakenings. Scores were significantly greater by the follow-up period ($p &lt;0.01$) where those in the intervention group improved SE by 11.53 percentage points and those in the active control group only increased by 6.34 percentage points, a moderate effect ($d = 0.63$). The intervention group reduced the minutes to fall asleep by more minutes than those in the active control group. This improvement was maintained during the follow-up period ($p &lt; 0.01$, $d = 0.49$). Evidence found for greater increases in TST in the active control group compared to intervention was not maintained at the follow-up period ($p = 0.84$, $d = 0.03$). A significant time by treatment interaction was noted for insomnia severity ($p&lt;0.05$, $d= 0.67$)</td>
</tr>
<tr>
<td>Prinsen 2013</td>
<td>Global quality of life / Functional impact of fatigue</td>
<td>Sickness Impact Profile-8 (SIP-8), the influence of symptoms on daily functioning, using eight subscales (home management, mobility, alertness behaviour, ambulation, sleep/rest, social interactions, work, and recreation and pastimes)</td>
<td>The change score in functional impairment (SIP-8) was significantly different between the intervention and the waiting list group (respectively $-73.0\pm28.1%$ and $-9.5\pm47.1%$).</td>
</tr>
</tbody>
</table>
### Table 2.4. Summary of studies reporting on secondary outcomes (continued)

<table>
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<tr>
<th>Study ID</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Reif 2012</td>
<td>Global quality of life</td>
<td>EORTC QLQ-C30: Global Health Status; Physical functioning; Role functioning; Emotional functioning; Cognitive functioning; Social functioning</td>
<td>The changes in the quality of life questionnaire QLQ-C30 indicate a significant improvement in the global health status in the IG compared to the CG (Table 2.3). All functional and symptom scale values as well as single items values increased significantly (Group x time ( p \leq 0.001 )).</td>
</tr>
<tr>
<td></td>
<td>Mood</td>
<td>Hospital Anxiety and Depression Scale</td>
<td>Anxiety and depression could be reduced significantly in the IG while these parameters increased in the CG (Group x Time ( p = &lt;0.001 )).</td>
</tr>
<tr>
<td></td>
<td>Insomnia</td>
<td>EORTC QLQ-C30 insomnia subscale</td>
<td>Insomnia (Group x Time ( p = &lt;0.001 ))</td>
</tr>
<tr>
<td>Ritterband 2012</td>
<td>Functional impact of fatigue</td>
<td>SF-12</td>
<td>Group x Time interaction was not significant</td>
</tr>
<tr>
<td></td>
<td>Mood</td>
<td>The Hospital Anxiety and Depression Scale (HADS)</td>
<td>Group x Time interaction was not significant</td>
</tr>
<tr>
<td></td>
<td>Insomnia or sleep quality</td>
<td>Insomnia Severity Index</td>
<td>Significant Group x Time interaction effect with the intervention group showing a marked improvement in insomnia severity from pre- to post-assessment, and the control group showing no significant change ( F_{1,25}= 22.8; p&lt;0.01; d=1.85 )</td>
</tr>
<tr>
<td></td>
<td>Sleep diary</td>
<td>bedtime, sleep onset latency (SOL), number of awakenings, total length of awakenings, wake time, arising time, daytime naps, rating of soundness of previous night’s sleep, rating of feeling upon morning awakening, and information about sleep aids (medication and/or alcohol use details).</td>
<td>Significant Group x Time interaction: Sleep efficiency ( F_{1,24}=11.45; p&lt;0.01, d=0.72 ); SOL ( F_{1,24}=5.18; p=0.03 ); lsoundness of sleep ( 0(F_{1,24}=9.34, p&lt;0.01, d=1.21) ); Feeling restored ( F_{1,24}=11.95, p&lt;0.01, d=1.35 ). No significant interaction for wake after sleep onset (WASO), time in bed, or number of awakenings.</td>
</tr>
</tbody>
</table>
### Table 2.4. Summary of studies reporting on secondary outcomes (continued)

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<tbody>
<tr>
<td>Rogers 2009</td>
<td>Global quality of life / Functional impact of fatigue</td>
<td>Functional Assessment of Cancer Therapy (FACT)-Breast physical well-being, social well-being, emotional well-being, Functional well-being, and additional concerns; FACT-endocrine symptoms; FACT-cognitive</td>
<td>A significant group by time interaction was noted for social well-being ($F = 4.22; p = 0.02$). No significant group by time interactions were noted for overall quality of life (i.e., FACT-Breast and FACT-G) nor the remaining subscales. Physical well-being showed a significant time effect ($F = 3.90; p = 0.03$), and FACT-G showed a significant between group difference for mean change from baseline to 3 months post intervention ($p &lt; 0.05$). No significant group, time, or group by time interaction was noted for endocrine symptoms, or cognitive function (total or subscales).</td>
</tr>
<tr>
<td></td>
<td>Insomnia or sleep quality</td>
<td>Pittsburgh Sleep Quality Index</td>
<td>No significant group, time, or group by time interaction was noted for sleep (total or subscales) with the exception of a significant group effect for sleep latency ($F = 4.17; p = 0.048$).</td>
</tr>
<tr>
<td>Savard 2005</td>
<td>Pain</td>
<td>Western Ontario and McMaster Universities Osteoarthritis Index</td>
<td>A significant time effect was seen for joint pain ($F = 3.46; p = 0.037$). Group x Time was not significant</td>
</tr>
<tr>
<td></td>
<td>Mood</td>
<td>European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (QLQ-C30+3)</td>
<td>Significant Group x Time interaction global quality of life ($F_{1,48} = 5.69; p &lt; .05$). A priori contrasts revealed significant time effects in the treatment condition on the global quality-of-life scale ($F_{1,48} = 16.27; p &lt; .001$), whereas no significant time effect was found in the control condition.</td>
</tr>
<tr>
<td></td>
<td>Mood</td>
<td>Hospital Anxiety and Depression Scale.</td>
<td>Significant Group x Time interactions were obtained on scores of anxiety ($F_{1,45} = 5.19; p &lt; .05$), depression ($F_{1,48} = 4.14; p &lt; .05$). A priori contrasts revealed significant time effects in the treatment condition on anxiety ($F_{1,46} = 4.77; p &lt; .05$) and depression ($F_{1,49} = 9.03; p &lt; .01$). No significant time effect was found on any variable in the control condition</td>
</tr>
</tbody>
</table>
Table 2.4. Summary of studies reporting on secondary outcomes (continued)

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Endpoint</th>
<th>Outcome</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Savard 2005</td>
<td>Insomnia or sleep quality</td>
<td>The Insomnia Interview Schedule; Insomnia Severity Index; sleep diary: sleep onset latency (time to sleep after lights out), wake after sleep onset (summation of nocturnal awakenings), total wake time (summation of sleep onset latency, wake after sleep onset, and early morning awakening), total sleep time (time in bed minus total wake time), sleep efficiency (ratio of total sleep time to the actual time spent in bed multiplied by 100), and use of sleep-promoting medications (type, frequency, and quantity).</td>
<td>Significant Group x Time interactions were obtained on all sleep variables, with the exception of total sleep time: sleep efficiency ($F_{1.52} = 22.59; p &lt; .0001$), total wake time ($F_{1.52} = 22.77; p &lt; .001$), sleep onset latency $F_{1.53} = 4.16; p &lt; .05$), wake after sleep onset ($F_{1.52} = 16.70; p &lt; .001$), ISI-P ($F_{1.52} = 25.31; p &lt; .0001$), ISI-C ($F_{1.52} = 79.37; p &lt; .0001$), and ISI-SO ($F_{1.48} = 4.54; p &lt; .05$). A priori contrasts revealed significant time effects on all variables in the treatment condition and all variables with the exception of two in the control condition (sleep onset latency and wake after sleep onset). Significant time effects found in the control condition were always of a lower magnitude compared with those of the treatment condition.</td>
</tr>
<tr>
<td>Van Der Lee 2013</td>
<td>Global quality of life / Functional impact of fatigue</td>
<td>Sickness Impact Profile: home management, mobility, social interaction, walking, work and recreation and pastimes. Dutch Health and Disease Inventory questionnaire</td>
<td>Participants reported significantly more well-being and less functional impairment than at baseline. No difference was found in functional impairment between the two conditions. Mean well-being score at post-measurement was significantly higher in the intervention group than in the waiting list group corrected for pre-treatment level of well-being.</td>
</tr>
<tr>
<td>Mood</td>
<td></td>
<td>Hospital Anxiety Depression Scale</td>
<td>Control variable: change not assessed</td>
</tr>
<tr>
<td>Insomnia or sleep quality</td>
<td></td>
<td>Sleep Quality Scale—SQS</td>
<td>Control variable: change not assessed</td>
</tr>
</tbody>
</table>
Chapter 2. Systematic Review: The Effectiveness of Psychological Interventions for Fatigue in Cancer Survivors: Systematic Review
and Meta-analysis

Table 2.4. Summary of studies reporting on secondary outcomes (continued)

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Endpoint</th>
<th>Outcome</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Van Weert 2010</td>
<td>Global quality of life</td>
<td>EORTC Quality of Life Questionnaire (EORTC QLQ-C30)</td>
<td>Participants in the intervention group reported higher emotional ($B=3.47, p=0.022, f^2=0.013$) and social functioning ($B=3.95, p=0.011, f^2=0.017$) than the control group six months after the start of the intervention. Effects for emotional and social functioning did not remain significant after intention to treat analyses.</td>
</tr>
<tr>
<td>Willems 2016</td>
<td>Mood</td>
<td>Hospital Anxiety and Depression Scale (HADS)</td>
<td>Participants in the intervention group reported lower depression ($B=-0.63, p&lt;0.01, f^2=0.019$) than the control group six months after the start of the intervention. The results of the intention to treat analyses showed that the found effects for depression remained significant ($B=-0.49, p&lt;0.05$).</td>
</tr>
<tr>
<td>. Yun (2012) [43]</td>
<td>Global quality of life / functional impact of fatigue</td>
<td>EORTC QLQ-C30</td>
<td>Significantly greater increase in global QOL and in emotional, cognitive, and social functioning scores of EORTC QLQ-C30 scales. For those secondary end points, significance was lost after Bonferroni corrections were applied for 15 multiple comparisons, except for cognitive functioning scores of the EORTC QLQ-C30.</td>
</tr>
<tr>
<td></td>
<td>Mood</td>
<td>HADS</td>
<td>Intervention group had clinically more meaningful improvement than the control group in HADS anxiety score.</td>
</tr>
<tr>
<td></td>
<td>Insomnia or sleep quality</td>
<td>Medical Outcome Study–Sleep Scale (MOS-SS)</td>
<td>Significantly greater decrease in HADS anxiety score: significance was lost after Bonferroni corrections were applied for 15 multiple comparisons.</td>
</tr>
<tr>
<td></td>
<td>Sleep Quality Index I and II</td>
<td></td>
<td>Control variable: change not assessed</td>
</tr>
<tr>
<td>Pain</td>
<td>Brief Pain Inventory</td>
<td></td>
<td>Control variable: change not assessed</td>
</tr>
</tbody>
</table>
Chapter 2. Systematic Review: The Effectiveness of Psychological Interventions for Fatigue in Cancer Survivors: Systematic Review and Meta-analysis

2.4. Discussion

The aim of this review was to provide an overview of psychological interventions for fatigue after the completion of cancer treatment, and to evaluate the effectiveness of these interventions. In our search 23 psychological interventions were identified, in which the effect on fatigue was tested in a RCT. The sample size of the 23 included studies varied between 26 and 273, with 2,775 participants.

There is some evidence that psychological interventions are effective in reducing fatigue in cancer survivors. This is similar to findings of a previous review of interventions during treatment (Goedendorp et al., 2009). Thirteen of the included studies reported a significant effect of the interventions on fatigue at a 0.05 level. However, ten of the psychological interventions did not differ significantly from the control group in reducing fatigue.

Many aspects of trial procedures were not reported in sufficient detail to adequately assess risk of bias of all domains of all included trials. Only five studies were deemed to be low risk of bias for sequence generation, allocation concealment and attrition rates. While there was substantial heterogeneity across these studies, the findings suggest that there currently is insufficient high quality evidence at to conclude that psychological interventions are effective in reducing fatigue in cancer survivors.

Given that the studies were subject to stringent inclusion criteria, it was deemed appropriate to combine them into a meta-analysis. Most interventions were described as containing similar therapeutic content, with a focus on psychoeducation, stress reduction, communication skills training, problem-solving, identification of maladaptive cognitions and awareness of useful coping strategies.
Chapter 2. Systematic Review: The Effectiveness of Psychological Interventions for Fatigue in Cancer Survivors: Systematic Review and Meta-analysis

While most of the effective interventions comprised CBT and/or psychoeducation, it was not possible to establish if certain types of intervention are superior for reducing fatigue or to draw conclusions about the effectiveness of the interventions for specific cancer types. It could not be established if interventions should be based on face-to-face contact, or if online sessions might be an alternative. A previous review (Goedendorp et al., 2009), has suggested that interventions specifically designed to treat fatigue during cancer treatment may be superior to those not specifically targeting fatigue. This review did not find similar results, as treatments that were specifically developed for cancer fatigue were not significantly different from more general interventions addressing fatigue.

The studies differed widely in terms of duration and frequency of interventions. Most of the interventions were 4-12 weeks in duration. There were also differences in the amount of contact across the different interventions. Due to this variance, it was not possible to conduct subgroup analysis to investigate if this factor could potentially explain some of the heterogeneity across the studies.

While an overall moderate effect was found for psychological interventions to address persistent fatigue in cancer patients, a number of limitations reduced our ability to make strong recommendations about any of the intervention strategies. In some studies it was difficult to assess when exactly participants completed cancer treatment prior to participating in the study. Few studies described the cancer treatment received by participants in detail, such as types of treatments and total duration. It is also unclear when is the best time to intervene after treatment has ended. Most studies did not report on the adherence of participants to the intervention treatment, adverse effects or integrity checks that may allow further inferences to be made about the quality of the studies.
Chapter 2. Systematic Review: The Effectiveness of Psychological Interventions for Fatigue in Cancer Survivors: Systematic Review and Meta-analysis

In this review, RCTs were excluded if it was unclear if cancer patients were receiving ongoing medical treatment at the time of the intervention. Despite attempts to contact the authors, it was not always possible to obtain sufficient information to clarify this issue. Trials with negative results might not have been published at all, and therefore may have been missed during our search. Attempts were made to seek information on registered trials, unpublished trials, and studies reported in conference abstracts. We are unaware that relevant studies were missed.

To conclude, at present there is evidence of an overall moderate treatment effect for psychological interventions to ameliorate fatigue after cancer treatment. Our overall rating of the quality of the studies is moderate, with a notable absence of relevant information in many published studies. There is a lack of good quality studies and therefore the conclusion that there is evidence for a treatment effect must be tempered by concerns about study quality. These findings demonstrate the need for the publication of more detailed descriptions of complex interventions, promoting methodological rigour and transparency in the design and throughout the trial process (Chalmers et al., 2014; Craig et al., 2008).

It is important to identify why evidence for the effectiveness of these interventions was not maintained when a sensitivity analysis (based on study quality) was conducted. It may be the case that studies with unclear risk of bias were not actually of poor quality but that authors need to specify more clearly the details needed to evaluate quality, including how these interventions might work. The optimal duration of the intervention needs to be established, and the ideal timing of the intervention remains unclear.

As the included studies were heterogeneous, it was not possible to identify if these interventions are better suited to those treated in specific ways for specific malignancies. The
Chapter 2. Systematic Review: The Effectiveness of Psychological Interventions for Fatigue in Cancer Survivors: Systematic Review and Meta-analysis

prevalence of fatigue during treatment may depend on the diagnosis (Hickok, Morrow, Roscoe, Mustian, & Okunieff, 2005) and treatment received (Hartvig, Aulin, Hugerth, Wallenberg, & Wagenius, 2006). However, the process of fatigue in cancer survivorship is less clear. Persistent fatigue after treatment may be related to psychological factors such as a history of psychological disorder and elevated depressive symptoms and anxiety in the acute diagnostic and treatment phase, the tendency to catastrophize, loneliness, and early life adversity (Bower, 2014).

2.5. Conclusion

This review showed that there is some tentative support for psychological interventions for fatigue after cancer treatment. However, the RCTs were heterogeneous in nature and the number of high quality studies was limited. Regarding secondary outcomes, mood and quality of life factors appear to be somewhat positively impacted by the interventions. However, due to the variety of concepts and the nature of the measures used, it is difficult to draw firm conclusions about the effect of these interventions on these variables.
Chapter 3. Qualitative Research: Grounding the research in psychological theory

3.1. Background

Intervention development guidelines recommend that theory should inform intervention content design, as it allows the author to outline and specify potentially active intervention components (Bradbury et al., 2014; NICE, 2014). Evidence from systematic reviews suggest that more extensive use of theory in online interventions is associated with larger effect sizes (Webb et al., 2010). Psychological theory can offer guidance on the approach and appropriate targets for specific components of the website (Michie et al., 2012). In line with MRC guidelines, the use of theory in developing the content of an online intervention was predicted to facilitate understanding of the causal assumptions underpinning the intervention (Craig et al., 2008).

CrF should be approached as a complex psychosocial issue and considered from the patient perspective to facilitate better understanding and management of symptoms. Research into the subjective experience of fatigue in post-treatment cancer survivorship is required.

Recently there has been an increased focus on the needs associated with treatment-induced symptoms of post-treatment cancer survivors (Brennan & Houssami, 2011). These persistent negative effects delay the patients’ return to normal life (El-Shami et al., 2015).

Fatigue is often described as a medically-contested illness (Lian & Nettleton, 2014). Individuals with fatigue report that a ‘medicalised’ self-identity is unavailable to them, in contrast to those impaired due to medically- and socially-legitimated illnesses (Pertl, Quigley, & Hevey, 2014). The ‘invisible’ nature of fatigue may lead others to discredit patients’ illness experiences (Scott, Lasch, Barsevick, & Piault-Louis, 2011) and those with CrF have described a lack of understanding from family, friends and health professionals.
Chapter 3. Qualitative Research: Grounding the research in psychological theory

(Rosman, 2009). Consequently, they are often left to make sense of and manage CrF by themselves. A greater understanding of patient beliefs about their fatigue would be useful given evidence that certain types of thoughts (e.g. catastrophising) are associated with CrF (Andrykowski, Donovan, Laronga, & Jacobsen, 2010).

The underlying aetiology of CrF is not well understood (Berger, Mitchell, et al., 2015) but it is thought to be a complex process associated with physical, mental, and emotional aspects. Minton et al (2015) note that the processes that cause and maintain fatigue overtime remain unclear. An inflammatory response to both the cancer itself and the range of treatment modalities has been linked to fatigue. (Du et al, 2015). Given that those who are post-treatment would generally be expected to improve overtime (when disease and treatment side effects had abated), it is hypothesised that other factors may lead to prolonged fatigue during survivorship. A cognitive-behavioural model of CrF posits that biological insults such as cancer or its treatment may precipitate the initial experience of fatigue during cancer, but behavioural and cognitive factors may aggravate and prolong fatigue in survivorship (Andrykowski et al., 2010). Thus the aims of this study are to specifically address the experience of fatigue in those after treatment rather than discussing the cancer experience or trajectory more broadly. In some instances, experiences particular to the individuals’ cancer experience were mentioned. However as outlined in the interview schedule, unless the comments referred directly to fatigue after cancer, these were not the focus of the study (see Appendix 7).

Guidelines for the support of individuals with CrF following treatment recommend the use of cognitive-behavioural therapy (CBT) (Berger, Abernethy, & Atkinson, 2012; Runowicz et al., 2016). CBT aims to influence or change cognitions, emotions, behaviours, or a combination of these (Goedendorp et al., 2009). Interventions which target these processes
may improve symptom management in cancer-related fatigue (Adam et al., 2015). These interventions target knowledge, emotional adjustment, quality of life, coping skills, physical health and functional adjustment (Newell et al., 2002; White et al., 2011).

CBT interventions focus on similar cognitive, emotional and coping/behavioural factors as those outlined by Leventhal’s (Leventhal et al., 1997; Leventhal & Diefenbach, 1991) common sense model of self-regulation (or self-regulation model: SRM). The SRM addresses personal beliefs or mental representations—whether medically sound or unsubstantiated—that a person holds about a health issue. This theoretical framework may, therefore, provide a useful approach to understanding post-treatment CrF with potential for informing the design of interventions based on cognitive–behavioural principles (Hudson, Moss-Morris, Game, Carroll, & Chilcot, 2016).

The SRM suggests that illness information is evaluated and integrated by the individual to provide a ‘lay’ understanding of the symptom or illness. Illness representations may be guided by current and prior awareness of symptoms, or by social messages from perceived significant others or authoritative sources (H. Leventhal, 1984). Processing of information occurs in three stages: representation, coping, and appraisal.

The individual’s representation of illness is proposed to have 5 components (Leventhal & Diefenbach, 1991). These are: identity (the name or label applied to the symptoms), timeline (the perceived time trajectory for the symptoms), consequences (expected future effects and outcomes due to symptoms), causes (beliefs about aetiology of the symptoms) and control (the extent to which the patient believes that they can gain personal control over the symptoms). Coping is guided by illness representations (Karasz & Mckinley, 2007) and involves implementing responses for managing the symptoms or the emotional responses that follow. Viewing illness and symptoms as controllable is linked to active coping, whereas
perceptions that symptoms are uncontrollable and chronic have been found to be associated with avoidance and denial coping (Hagger & Orbell, 2003). An individual also appraises the effectiveness of their coping efforts (Diefenbach & Leventhal, 1996) and this evaluation may result in a change in coping strategy and/or a change in perception of the illness and its symptoms (Dempster, Howell, & McCorry, 2015).

The model has proved useful across many health conditions (Karasz & Mckinley, 2007) with considerable evidence linking elements of the SRM to psychological functioning in a wide range of illnesses (Dempster et al., 2015; Groarke, Curtis, Coughlan, & Gsel, 2005; Hagger & Orbell, 2003). Few studies, report on how survivors describe CrF, highlighting the need for research from the patient perspective (Scott et al., 2011) and only one study to date (Barsevick, Whitmer, & Walker, 2001) has examined the fit of the patient experience of CrF with the concepts from the SRM. In that study, the majority of patient statements were classified as mental representations of fatigue, with fewer references to coping and appraisal. The authors concluded that the SRM was a valid organizing framework for CrF in patients undergoing treatment (Barsevick et al., 2001). However, the experience of fatigue is likely to be different when the patient transitions into long-term survivorship (Terwee et al., 2007). The utility of the SRM at this later stage awaits investigation. Reviews of the literature have not reported on a study that has used the SRM as a theoretical framework underpinning research into CrF in cancer survivors (M.M. Goedendorp et al., 2009; Meneses-Echávez, González-Jiménez, & Ramírez-Vélez, 2015; Mustian, Sprod, Janselsins, Peppone, & Mohile, 2012).

Accordingly, this qualitative focus group research was conducted to assess if the SRM could be used as a theoretical framework for organising the experiences of people with CrF, with a view to identifying methods to address fatigue in cancer survivors. In turn, this model may
prove to be a useful integrated theoretical model for developing, evaluating and explaining the underlying mechanisms involved in CBT interventions for CrF. The use of such a model could enhance our understanding of the complex processes involved in the development and maintenance of CrF in some individuals.

3.2. Methods

3.2.1. Procedure

This study sought to establish a coherent theoretical basis that would underpin the design and testing of a psychological intervention for fatigue in post-treatment cancer survivors, in line with Medical Research Council (MRC) guidelines (Craig et al., 2013). Focus groups were used as they enable discussion about the subjective experience of persistent fatigue, and they facilitate conversation about a topic that is not often addressed (Bennett et al., 2007). The study protocol was approved by the Institutional University Research Ethics Committee of the National University of Ireland Galway, Ireland. Details of the research procedure can be seen in Table 1.

An interview script was designed in line with the questions asked by Barsevik et al (2001) (See Appendix 7).

Thematic analysis was employed to identify, analyse, and report themes within the data (Boyatzis, 1998). A contextualist approach was adopted to acknowledge the meanings applied to, and reality of, the experience of CrF, and to understand how the broader social context impacts on those meanings (Braun & Clarke, 2006). Further details of this process can be seen in Box 1.
Box 1. *Process of data analysis*

Coding was initially data-driven using an inductive approach to ensure that the data was analysed comprehensively, without trying to fit it into a pre-existing model or analytic preconceptions (Braun and Clarke, 2006). Two researchers (TC and AMG) processed initial features of the data that were of interest (codes). Each transcript was analysed separately and emerging codes were compared across groups. Discrepancies were discussed with co-authors (JW and BMG) until consensus was reached.

At the next stage of data analysis there was a shift towards the broader level of themes. Themes were items that represented some level of patterned meaning within the data (Braun & Clarke, 2006). Codes were organised using a theoretical thematic analysis, driven by SRM theory (Clarke & Braun 2013). The analysis of the codes was theory-driven in order to address the specific research question, “Do participants’ subjective accounts fit with the components of the SRM?”

As themes were refined, the data set was reviewed to ensure that selected themes ‘worked’ and to identify any data that may have been previously overlooked. A thematic map of the data was produced (See Figure 1).
Table 3.1. Consolidated criteria for reporting qualitative research (COREQ) checklist for focus groups

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domain 1: Research team and reflexivity</td>
<td></td>
</tr>
<tr>
<td>Personal Characteristics</td>
<td></td>
</tr>
<tr>
<td>1. Interviewer/facilitator</td>
<td>Two authors (TC and BMG) conducted the focus groups</td>
</tr>
</tbody>
</table>
| 2. Credentials | TC: BA, MSc  
BMG: BA, MClinPsych, DipCrim, DipHealthSc, PhD, AFPsSI, Reg Psychol (PsSI), AFBPsS, CPsychol |
| 3. Occupation | TC: PhD candidate  
BMG: Research Leader and Clinical Psychologist |
| 4. Gender | TC: female  
BMG: male |
| 5. Experience and training | TC: trained in qualitative research methods and design; experience in conducting focus groups; BMG: trained in qualitative research methods and design; experience in facilitating clinical groups |
| Relationship with participants | |
| 6. Relationship established | Participants contacted TC via email or telephone to discuss arrangements for the focus groups. Otherwise participants had no relationship with researchers |
| 7. Participant knowledge of the interviewer | Participants were informed that the researcher was conducting a PhD in the area of cancer related fatigue and that her goal was to understand the symptom better by discussing it with people who lived with it. |
| 8. Interviewer characteristics | Qualitative researcher and supervisor were both closely engaged in the research process and were therefore unable to completely avoid personal bias. This research sought to inform the content of an intervention. |
Table 3.1. Consolidated criteria for reporting qualitative research (COREQ) checklist for focus groups (continued)

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Domain 2: study design</strong></td>
<td></td>
</tr>
<tr>
<td>Theoretical framework</td>
<td></td>
</tr>
<tr>
<td>9. Methodological orientation and Theory</td>
<td>Thematic analysis was used in this study. A contextualist approach was adopted to acknowledge the meanings applied to, and reality of, the experience of CrF, and to understand how the broader social context impacts on these meanings (Braun &amp; Clarke, 2006).</td>
</tr>
<tr>
<td><strong>Participant selection</strong></td>
<td></td>
</tr>
<tr>
<td>10. Sampling</td>
<td>Cancer survivors who self-reported ‘significant fatigue or reduced energy’ were eligible to take part. Self-selected Irish cancer survivors from the general public participated in this research.</td>
</tr>
<tr>
<td>11. Method of approach</td>
<td>From February to June 2014, cancer support groups and associations in the region were contacted. A press release was distributed to local media groups advertising the study (See Appendix 4.).</td>
</tr>
<tr>
<td>12. Sample size</td>
<td>There were 18 participants in the study. There were four individuals in each of the first three focus groups and the final group had six attendees.</td>
</tr>
<tr>
<td>13. Non-participation</td>
<td>All participants who agreed on a date and time to attend took part in the focus groups.</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td></td>
</tr>
<tr>
<td>14. Setting of data collection</td>
<td>Data was collected in a meeting room in the School of Psychology at the University where the researcher is based.</td>
</tr>
<tr>
<td>15. Presence of non-participants</td>
<td>No one else was present besides the participants and researchers.</td>
</tr>
<tr>
<td>16. Description of sample</td>
<td>Demographic data can be seen in Table 3.2.</td>
</tr>
</tbody>
</table>
### Table 3.1. Consolidated criteria for reporting qualitative research (COREQ) checklist for focus groups (continued)

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data collection</strong></td>
<td></td>
</tr>
<tr>
<td>17. Interview guide</td>
<td>Questions based on a study by Barsevik et al. (2001) were utilised. These open-ended questions were posed to each of the groups: (a) what is your experience of fatigue? (b) What does the experience of fatigue mean to you? and (c) what do you do about your fatigue? These were the primary questions asked, with other topics being addressed as the conversation developed. If an opportune moment arose, other questions from Barsevik et al. (2001) were also included: (a) are there different types of fatigue? (b) How do other symptoms affect fatigue? and (c) what do you and/or your doctors and nurses recommend to manage fatigue? (See Appendix 7.)</td>
</tr>
<tr>
<td>18. Repeat interviews</td>
<td>No repeat interviews were carried out.</td>
</tr>
<tr>
<td>19. Audio/visual recording</td>
<td>Audio recording was used to collect the data.</td>
</tr>
<tr>
<td>20. Field notes</td>
<td>Field notes were made during and after the focus group.</td>
</tr>
<tr>
<td>21. Duration</td>
<td>Each of the focus groups was approximately 90 minutes in duration.</td>
</tr>
<tr>
<td>22. Data saturation</td>
<td>The researchers decided that data saturation had been achieved after the fourth focus group. The transcripts were reviewed as soon as possible after each interview. Saturation was achieved as no further additional new information began to emerge. It was agreed that the addition of new codes was unlikely after the fourth focus group (Fusch &amp; Ness, 2015).</td>
</tr>
<tr>
<td>23. Transcripts returned</td>
<td>Transcripts were not returned to participants for comment and/or correction.</td>
</tr>
</tbody>
</table>
## Chapter 3. Qualitative Research: Grounding the research in psychological theory

Table 3.1. Consolidated criteria for reporting qualitative research (COREQ) checklist for focus groups (continued)

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Domain 3: analysis and findings</strong></td>
<td></td>
</tr>
<tr>
<td>Data analysis</td>
<td></td>
</tr>
<tr>
<td>24. Number of data coders</td>
<td>Two data coders (TC and AMG) coded the data</td>
</tr>
<tr>
<td>25. Description of the coding tree</td>
<td>Coding Tree can be seen in Appendix 9.</td>
</tr>
<tr>
<td>26. Derivation of themes</td>
<td>Themes were identified in advance based on theory. The identified themes are reflective of patterns in the data and aim to provide a unified picture. Two researchers agreed on a clearly specified thematic coding manual which guided the interpretation of the data (See Appendix 8.)</td>
</tr>
<tr>
<td>27. Software</td>
<td>Data was managed by hand</td>
</tr>
<tr>
<td>28. Participant checking</td>
<td>Participants did not provide feedback on the findings.</td>
</tr>
<tr>
<td><strong>Reporting</strong></td>
<td></td>
</tr>
<tr>
<td>29. Quotations presented</td>
<td>Participant quotations were presented to illustrate the themes / findings. Each quotation identified using the participants’ age, gender, and cancer diagnosis.</td>
</tr>
<tr>
<td>30. Data and findings consistent</td>
<td>There is consistency between the data presented and the findings. The unit of analyses was the theme rather than the prevalence or frequency of statements. Some statements of quantification are included (e.g. statements such as often, sometimes), but do not always aim to provide estimates of prevalence.</td>
</tr>
<tr>
<td>31. Clarity of major themes</td>
<td>Codes identified in the open coding stage were discussed by two study authors until consensus was reached. A coding manual was developed (See Appendix 8.) to clarify and define each of the themes. In stage two, the codes were checked in relation to pre-defined themes based on SRM. All major themes clearly presented in the findings.</td>
</tr>
<tr>
<td>32. Clarity of minor themes</td>
<td>There is a description of minor themes in the findings.</td>
</tr>
</tbody>
</table>
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The study was reported using the consolidated criteria for reporting qualitative research (COREQ) checklist for focus groups to ensure rigor in reporting in how the study was conducted. Other features of the research that ensured validity (CASP, 2014) included:

- Clear statement of the aims of the research
- Justification of the methodology and research design used
- Ethical approval received for study
- Use of an interview schedule that was established a priori (Appendix 7)
- Rigor in data analysis achieved by following pre-defined steps of how to conduct thematic analysis
- Use of a coding manual for consistent analyses (Appendix 8)
- Use of interrater-coding in the data analyses

3.2.2. Participants

Irish cancer survivors who self-reported ‘significant fatigue or reduced energy’ were eligible to take part. All participants were Caucasian. Four focus groups were held with 18 participants (Mean age 59.83, SD= 10.34). (See Table 3.2). Smaller groups were selected as-given the somewhat sensitive nature of the topic- the researchers felt that it may be difficult to get meaningful interaction among the participants in a larger group. The smaller number of participants, therefore, allowed for greater in-depth discussion in this exploratory research. Analysis of these discussions is based on themes that were reflective of patterns in the overall data rather than a reporting of the proportion of participants or groups expressing a theme. Participants gave consent to take part in a discussion about their fatigue and were informed that the sessions would be recorded.
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3.3. Results

Participants reported that they valued the opportunity to discuss their experience with post-treatment CrF and enjoyed comparing their experiences with similar others. Individuals spoke freely, with little need for prompting from the facilitator. Analyses identified major themes that could be understood within the processes of the SRM: representation of symptoms; coping; appraisal of coping. The impact of the wider social context in the individual’s representation of their CrF was an overarching theme. These themes are described in further detail below and are illustrated in Figure 3.1.
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### Table 4.2. Demographic information for each of the participants

<table>
<thead>
<tr>
<th>Gender</th>
<th>Age</th>
<th>Cancer Type</th>
<th>Treatment Type</th>
<th>Time since treatment (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>77</td>
<td>Prostate</td>
<td>Chemotherapy</td>
<td>36</td>
</tr>
<tr>
<td>Male</td>
<td>67</td>
<td>Prostate</td>
<td>Radiotherapy</td>
<td>Decapeptyl injections 7</td>
</tr>
<tr>
<td>Male</td>
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<td>Prostate</td>
<td>Surgery</td>
<td>Brachytherapy 60</td>
</tr>
<tr>
<td>Female</td>
<td>60</td>
<td>Breast</td>
<td>Other</td>
<td>18</td>
</tr>
<tr>
<td>Female</td>
<td>68</td>
<td>Breast</td>
<td>Other</td>
<td>42</td>
</tr>
<tr>
<td>Female</td>
<td>53</td>
<td>Breast</td>
<td>Other</td>
<td>36</td>
</tr>
<tr>
<td>Female</td>
<td>66</td>
<td>Breast Stage III ductal</td>
<td>Other</td>
<td>72</td>
</tr>
<tr>
<td>Female</td>
<td>55</td>
<td>Breast</td>
<td>Other</td>
<td>18</td>
</tr>
<tr>
<td>Female</td>
<td>59</td>
<td>Breast</td>
<td>Other</td>
<td>9</td>
</tr>
<tr>
<td>Female</td>
<td>43</td>
<td>Breast</td>
<td>Other</td>
<td>24</td>
</tr>
<tr>
<td>Female</td>
<td>60</td>
<td>Triple Negative Breast</td>
<td>Other</td>
<td>36</td>
</tr>
<tr>
<td>Male</td>
<td>71</td>
<td>Bowel and liver</td>
<td>Other</td>
<td>18</td>
</tr>
<tr>
<td>Female</td>
<td>57</td>
<td>Stomach</td>
<td>Other</td>
<td>72</td>
</tr>
<tr>
<td>Male</td>
<td>76</td>
<td>Stomach</td>
<td>Other</td>
<td>24</td>
</tr>
<tr>
<td>Male</td>
<td>44</td>
<td>Testicular</td>
<td>Other</td>
<td>48</td>
</tr>
<tr>
<td>Male</td>
<td>58</td>
<td>Rectum</td>
<td>Other</td>
<td>26</td>
</tr>
<tr>
<td>Female</td>
<td>44</td>
<td>Non-Hodgkin Lymphoma</td>
<td>Other</td>
<td>72</td>
</tr>
<tr>
<td>Male</td>
<td>52</td>
<td>Lymphoma</td>
<td>Other</td>
<td>7</td>
</tr>
</tbody>
</table>
Social context of fatigue
A wide variety of social factors influence the formation and maintenance of illness representations.
- Attempts to cope with fatigue and “return to normal” were influenced by the individual’s social context.
- The general public was perceived as not having a good understanding of fatigue.
- Participants did not want to worry their family or friends. They felt under pressure not to appear to be complaining.
- Representations of fatigue were influenced by the reactions of healthcare professionals.
- The individual’s social role and identity, as well as their interactions with others, influenced their emotional and cognitive representation of fatigue.

Emotional and Cognitive Representation of fatigue
- Accessing a label for fatigue, or having an “identity of the symptom” influenced the perceived cause, timeline and controllability of CrF.
- Fatigue had far-reaching social and emotional consequences for participants.
- This affected ability to cope with fatigue. In particular, having a “label” or a name for symptoms was seen as a vehicle to accepting fatigue.

Appraisal of coping strategies
- Participants did not spontaneously appraise coping strategies to deal with fatigue.
- Participants spoke about how fatigue symptoms related to broader quality of life issues and attempts to “return to normal.”

Coping: Strategies used to alleviate fatigue
- Active coping strategies included positive reinterpretation, exercise, seeking social support and planning.
- Acceptance of fatigue was viewed as an important coping strategy.
- Distraction, resting and avoiding activity were used as coping strategies to deal with competing, distracting or tiring activities.

Figure 3.1. A Self-Regulation Model of Cancer-Related Fatigue.
3.3.1. Social context

The social context of fatigue was discussed. Participants were concerned that their symptoms were a deviation from the norm. The general public was perceived as not having a good understanding of fatigue. One participant (age 53, 36 months post-treatment) asserted that, “It’s more socially acceptable in society to say ‘I’m a cancer patient’, than ‘I suffer from fatigue’”.

Social Identity

The participants described the experience of CrF within the context of their own complex lives (Bennion & Molassiotis, 2013). Participants did not want to worry their family or friends, and felt under pressure not to appear to be complaining. One woman (age 44, 72 months post-treatment) said “you’re trying to explain to them that you’re tired and you’re flat and you just have no interest. Sometimes it’s hard to articulate.” Individuals reported frustration at platitudes offered by others. Failure of others to understand that CrF was different from ‘normal’ fatigue, aging, or being busy was a common problem. One man (age 58, 26 months post-treatment) said, “My friends and colleagues said “Look, we’re all getting old. It’s not you and your cancer at all. It’s just your age.” As with previous studies, the findings indicated that understanding and support from others could be beneficial, but many often felt misunderstood and isolated when the reality of the “new normal” was not fully appreciated (Bennion & Molassiotis, 2013; Boykoff, Moieni, & Subramanian, 2009). Comparisons were likely if participants knew of others who had not experienced fatigue after cancer treatment. One woman (age 44, 72 months post-treatment) said that it “makes you question it even more because you’re saying “why am I not like them?” Meeting similar others helped participants to accept their own fatigue. One man (age 67, 7 months post-
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treatment) described how “all of a sudden you realize that so many people have the same problem”.

Participants discussed relationships and responsibilities. One woman (age 44, 72 months post-treatment) described pressure from her family to return to ‘normal’ saying “It helps them cope as well. Because they see you as not being sick anymore and so they are indirectly pushing you to get back to your normal routine.” One man (age 52, 7 months post-treatment) lamented the impact that CrF had had on his relationship with his son saying, “I wouldn't be able to go playing ball with him. He’s gotten to where he doesn’t ask me. It's a loss.”

Interaction with healthcare service

Perceptions of fatigue were impacted by the reactions of healthcare professionals to CrF. Participants felt that they were not adequately forewarned that fatigue would persist after treatment. Many said that fatigue “was never mentioned.” One person (age 53, 36 months post-treatment) noted that although fatigue was mentioned, “nobody said 3 years down the line you’re still going to be nodding off.”

Participants thought that doctors were dismissive when they mentioned fatigue. One woman (age 60, 18 months post-treatment) felt that her G.P. “practically laughed” when fatigue was mentioned. She believed that doctors were “more into the treatment and you mention tiredness, they ignore you. It was swept under the carpet.” Others agreed that healthcare providers were slow to engage in a conversation about fatigue. One man (age 52, 7 months post-treatment) said “I feel like I’m telling her [the doctor] I’m tired all the time. She thinks I’m cuckoo.” Another man (age 77, 36 months post-treatment) described how his doctors carried out various tests when he complained about fatigue, “but not one of them has even acknowledged that it might be because I had cancer”.

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Positive experiences with healthcare professionals were also mentioned. One man (age 67, 7 months post-treatment) said he was “lucky that I’ve a very good GP and he does listen. We do talk about fatigue.” Many cited family members who worked in a healthcare profession as a support in terms of information provision and reassurance, especially in light of perceived gaps in care elsewhere.

Participants criticised a non-holistic approach to care, reporting that once physical causes of their fatigue were ruled out, their symptoms were often ignored. One participant (age 60, 18 months post-treatment) felt that healthcare professionals “were very quick about curing things but they never worry about side-effects.” Others considered fatigue “a psychological aspect of the illness and the treatment that’s been left open ended” (age 68, 42 months post-treatment). One man (age 67, 7 months post-treatment) said “You’re left lonely. You’re left not having that support that you thought the doctor might be able to give you.”

Participants believed that ‘quality of life’ was an emerging concept in cancer care and influenced the recognition of side-effects such as fatigue. One man (age 77, 36 months post-treatment) suggested that “maybe the reason the medical profession are in denial is that they don’t know how to cure it. They certainly don’t acknowledge it at all. It’s not within their competence to do anything about it so they just conveniently don’t recognise it.”

3.3.2. Cognitive and Emotional Representations of Health Threat

Identity

Participants voiced frustration that a label or definition of CrF was not provided to them. Acknowledgement of fatigue was viewed as a tool for acceptance that could reduce worry about the symptom and would justify the “right to be tired” (age 60, 18 months post-treatment). People emphasised the reality of fatigue, expressing the belief that fatigue was not something wholly psychological. One man (age 52, 7 months post-treatment) said “it’s not
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imaginary. You really feel it. This exhaustion is true. It’s too strong.” Another woman (age 53, 36 months post-treatment) echoed this sentiment saying “there is not something wrong with our heads. It is actually real.”

The lack of an available discourse for CrF influenced how people made sense of their symptoms, influencing the perceived cause, timeline, and controllability of CrF, in turn affecting their ability to cope with fatigue. One person (age 43, 24 months post-treatment) said, “I was beginning to think that I was going silently crazy or something.” Inadequate support was also raised as a potential causal factor in fatigue. One woman (age 60, 36 months post-treatment) believed that fatigue “hits later down the line because you’re not in any cocoon. There is nobody there to look after you for the fatigue.” Participants described having numerous medical tests that aimed to identify a physiological cause for the fatigue. These tests were often invasive and inconvenient. Importantly, they were also seen to reduce the validity of fatigue as an issue in and of itself, which led to feelings of confusion, uncertainty, and fear. Uncertainty about fatigue was also discussed in terms of the chronicity of fatigue. Participants wondered “is this the way it’s going to be? Or will this ease?” (Age 43, 24 months post-treatment). Some felt that they should be “better by now” (age 58, 26 months post-treatment). Doubt surrounding the prolonged experience of CrF led to emotional consequences. Many were uncertain if their fatigue was in line with their predicted time for recovery, with one saying “I keep thinking this can’t be right. I cannot be this tired after three and a half years” (age 60, 36 months post-treatment).

Cause

Fatigue was sometimes attributed to the culmination of stress during cancer. Others felt that they had taken on too much too soon after treatment, describing ‘pressure on yourself to get back to your normal routine” (age 60, 18 months post-treatment). Potential biological causes
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were also mentioned, including inflammation, endorphins, or cytokines. The role of cancer treatment in the development of symptoms was raised, with one noting “The treatment made me tired. Treatment is worse than illness in some cases” (age 67, 7 months post-treatment). A lack of concentration or ‘chemo-brain’ was also cited as a potential cause of fatigue. One participant (age 44, 72 months post-treatment) said “You can’t focus and that- mentally- is kind of just adding to the tiredness.”

Emotional responses, including fears of cancer recurrence, were also linked to the presence of fatigue. One woman worried that “the cancer must be back. I think sometimes is there a bit of a bad cell left floating around in me that’s causing it?” (Age 60, 36 months post-treatment).

Habits and mood were mentioned as possible causes of fatigue. One man (age 71, 18 months post-treatment) asked “would tiredness be related to worry?” Participants distinguished between fatigue and depression. Rather than attributing low mood to depressive symptoms, participants recognised low mood as being related by feeling “so tired, you feel down because you’re not going to be able to do anything today” (age 52, 7 months post-treatment)

Consequence

The impact of fatigue on quality of life and functional capacity was discussed, with one participant asking “Without energy what can you have?” (Age 55, 18 months post-treatment). Participants described learning to reconceptualise energy as a limited resource, as there was a ‘cost’ of activity and over-exertion. People avoided certain situations “because it just won’t be worth it” (age 44, 72 months post-treatment). One participant (age 53, 36 months post-treatment) said that “Cancer was not the worst ordeal of my life. The diagnosis, the treatment, the surgery wasn’t debilitating- didn’t stop me from doing anything. But the fatigue does…”

The persistence of fatigue delayed return to a sense of ‘normality.’
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Fatigue challenged the self-concept of many participants, with one noting “it impacts on me not being able to be who I am” (age 60, 36 months post-treatment). One woman (age 43, 24 months post-treatment) observed that “you’re not able to do the things you want to do or you’re not where you want to be”. Social lives were interrupted due to fatigue, resulting in “a feeling of isolation” (age 68, 42 months post-treatment). Some believed that fatigue was responsible for a lack of concentration and led to procrastination.

Fatigue had forced some individuals into early retirement, even when they “had no intention of retiring just yet” (age 67, 7 months post-treatment). One participant (age 44, 72 months post-treatment) said that she “just could not face going back to work. I just really didn’t have the energy.” One woman (age 60, 36 months post-treatment) described how retirement due to ill-health was “part of a kind of a rejection”.

Participants emphasised the “difference between being tired and fatigue” (age 53, 36 months post-treatment). One (age 60, 18 months post-treatment) spoke about how “sleeping doesn’t seem to cure it,” saying that “every day for me was a groundhog day”. Some reported heavy sleep at night. For others, getting to sleep posed a problem. One woman (age 68, 42 months post-treatment) stated that she had trouble “staying asleep and then nodding off during the day.

In terms of emotional representations, participants worried about fatigue, with one woman saying she found herself “fretting to high heaven about it” (age 60, 18 months post-treatment). Another described how “thinking about it brings on anxiety” (age 76, 24 months post-treatment). Distress as a consequence of CrF was addressed. One participant (age 57, 72 months post-treatment) pointed out that “no matter how you try to be positive about it, it does get you down. It affects you mentally.”
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Participants felt guilty and ashamed about functional limitations, low energy levels, and pressure from others. One woman (age 68, 42 months post-treatment) regretted "lost days". A mother in the group (age 44, 72 months post-treatment) said CrF affected her relationship with her children, feeling “guilty because I didn’t do more things with them”. Another participant (age 60, 36 months post-treatment) felt she was “a failure”, saying “it’s not that I’m depressed. I’m frustrated. The only time I was ever angry about having cancer is the fact that it’s left me with fatigue.” Another agreed that it was “quite frustrating, debilitating in ways” (age 43, 24 months post-treatment). A belief that participants ‘should’ be happy to have beaten cancer was also debated.

Timeline

Fatigue was described as having changed over time, and as being persistent. People described a “dead tiredness, all the time” (age 44, 72 months post-treatment) and how fatigue “won’t go. It lingers” (age 60, 36 months post-treatment). Another explained, “When you’re tired all the time it seems to drag on” (Age 43, 24 months post-treatment).

The onset of fatigue during the day was addressed by participants. One (age 60, 18 months post-treatment) described fatigue “creeping over me... gradually getting more and more tired. Until eventually you are flattened.” Another experienced “a weakness all over” upon waking and felt “very sluggish in the morning” (age 43, 24 months post-treatment).

Participants described a predictive pattern of fatigue, with one (age 67, 60 months post-treatment) saying “you could nearly time yourself by it”.

For certain individuals, fatigue symptoms had diminished over time. Some viewed fatigue as an acute symptom that would not go on forever. One (age 58, 26 months post-treatment) said “I’m hoping it’ll go away. I thought I’d be ok this year but maybe next year.”
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Cure/Control

Many participants believed that they had a lack of control over their tiredness. One (age 66, 72 months post-treatment) described her fatigue as “totally uncontrollable”. Another (age 52, 7 months post-treatment) mentioned that “Sometimes you would just have to go to sleep.” Conversely, others felt that they had gained control over their CrF, saying “I think that it’s in your own hands and you have to plan and you have to work your way out of this lethargy” (age 67, 7 months post-treatment).

3.3.3. Coping: strategies used to alleviate fatigue

Active coping strategies

Positive reinterpretation was discussed as a means of staying optimistic with persistent fatigue. One woman (age 66, 72 months post-treatment) said it was necessary to “be kinder to yourself. Be more forgiving.” Some considered fatigue a small price to pay for surviving cancer. One (age 68, 42 months post-treatment) said that she was “lucky to be here even though I feel wiped out”.

Participants preferred not to “give in” to their fatigue, with one participant (age 58, 26 months post-treatment) saying “whatever I do, I won’t sleep during the day because if I sleep during the day I won’t sleep at night.” Some used exercise to alleviate fatigue. One woman (age 53, 36 months post-treatment) said “If you do get really tired, don’t sit. Go for a walk. Go out and do something. It can be the antidote.” Another (age 57, 72 months post-treatment) said “the more energy you use the more you get to replace it.”

Participants sought advice, assistance, or information from doctors and support centres. For some, support received during cancer had extended into longer-term survivorship due to fatigue. One participant (age 59, 9 months post-treatment) noted “I had my sister when I was
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sick to keep the house ticking over and she’s still there.” Individuals sought out others for moral support, sympathy, or understanding. One participant felt “it’s important to be out among people. You can’t be isolated” (age 59, 9 months post-treatment). This included support from other fatigued cancer survivors, with one man (age 67, 60 months post-treatment) concluding that “we can learn from one another.”

Planning helped participants to prepare coping strategies. One woman (age 44, 72 months post-treatment) said “I just have to pace myself. You plan events. You have rest days before and afterwards. Make adjustments. You know you’re going to be flat.”

Acceptance and Emotion-Focused Coping

One participant described a process of learning “to pace yourself better” and to “recognize your own limits” (age 44, 72 months post-treatment). This was not always easy; one individual (age 60, 18 months post-treatment) said “I don’t do things because I know I’m going to be tired. I know the consequence of it.”

Acceptance of fatigue was difficult. One woman (age 60, 18 months post-treatment) voiced her frustration, saying “who wants to listen to their body? You just want to go out and enjoy yourself.” Another said that he “just can’t accept it” (age 52, 7 months post-treatment), whereas others felt it was important to acknowledge the reality of their situation. Another group member (age 60, 36 months post-treatment) reflected on how she felt she could cope better as a result of how she understood her symptoms, stating, “I can manage my life if I know I’m going to be tired.”

Distraction, Resting and Avoiding Activity as coping strategies

Individuals often disengaged from activity to cope with fatigue. Napping was mentioned as a coping strategy, with one woman (age 60, 18 months post-treatment) saying that she sleeps
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“on the couch every single evening”. Research on CrF suggests that it may be better to avoid long or late afternoon naps as the combination of less daytime activity and more daytime sleep is associated with increased levels of CrF (Berger & Farr, 1998; Hoffman, Robinson, & Weisbrod, 2014; Mustian et al., 2012).

Mental disengagement was employed by participants to distract themselves from fatigue and the stress of dealing with it. One (age 43, 24 months post-treatment) said that she tries to “forget about it and keep going”, but in turn, described how she then feels more tired later as a consequence. The groups discussed the importance of recognising physical limitations rather than disengaging from them. Taking breaks and rest were discussed as useful. One woman (age 68, 42 months post-treatment) said “Listen to your body. It’s saying slow down.” Another (age 71, 18 months post-treatment) suggested “if your body’s tired, just go away for five minutes and when you come back you’ll get through the day no problem.” However, this was contested with one participant (age 60, 18 months post-treatment) saying, “but when you raise your family... and you’re getting into your 60s and you want to go out and enjoy life... who wants to listen to their body? You just want to go out and enjoy yourself.” One man (age 52, 7 months post-treatment), stated, “Basically I don’t do things because I know I’m going to be tired. I just don’t do anything then because I know the consequence of it- that the recovery period is too long- and I say “sure it’s not worth it in the end”... so I don’t bother.” Participants felt it was sometimes best to avoid competing, distracting, or tiring activities. Learning to say “no” was recognised as an important skill for participants.

3.3.4. Appraisal of coping strategies

While participants were not asked explicitly to appraise the effectiveness of their coping, it was considered that certain questions could capture elements of this (“what do you do about your fatigue?” or “how do other symptoms affect fatigue?”)
In addition, in some instances the question “What have you found “works” for your fatigue” was included but these were not based on the Barsevik questions and arose naturally as the interviews progressed (See Appendix 7).

The impact of the coping styles or strategies adopted was discussed within that context. Participants discussed acceptance as a particularly important overall coping strategy. One woman (age 68, 42 months post-treatment) said “I find I accept it now. It’s there. Deal with it. You either have a solution or you learn to live with it.” Another (age 44, 72 months post-treatment) explained that “you can reason with it better once you know that it’s got a name.”

Some felt that their current coping strategies were ineffective. One woman (age 60, 18 months post-treatment) said “I don’t do anything. I sit down and get very depressed. I’m not a very accepting person. I want to be like the way I was before it happened.” Another (age 57, 72 months post-treatment) felt that her attitude prevented her from engaging in effective coping “I go walking if I think I’m only going for a mile. Maybe I can’t manage it. But I couldn’t do it if I thought I was going for three miles. I don’t know is it my legs or my mindset, you know? That’s the problem. Maybe my legs would take me the other two miles, but I can’t.”

One man (age 52, 7 months post-treatment) described how “some days you’d push yourself to do something and you knew you were tired but you’d achieve it. There is a great sense of achievement when you do something.” Another (age 58, 26 months post-treatment) said “I’m coping with it ok but I’m just finding time is long and I’d like to be back doing a full day’s work again but unfortunately just I’m not able for that yet.’ Participants identified challenges, with one woman (age 44, 72 months post-treatment) describing how initially she was "so tired and so flat”, and that “it was only when the fog lifted” that her family began to return to
their “own little routine and our own little life”. In appraising her coping, she felt that “it got
easier once I recognized that you can’t do everything that you used to do.”

These findings are depicted in Figure 3.1.

3.4. Discussion

These qualitative findings add to published quantitative research to provide a more thorough understanding of the subjective experience of CrF in post-treatment cancer survivors. The SRM was developed to represent ‘lay’ understanding of illness experiences across all populations, yet to date very little research has applied the model to the experience of cancer survivors (Dempster et al., 2015). Findings in the current study, demonstrate, for the first time, that subjective experiences of post-treatment cancer survivors with CrF fit with the constructs of cognitive and emotional representations, coping strategies and appraisal as outlined in the SRM. Fatigue was understood as a part of the cancer experience that extended into longer-term survivorship. Without access to an available narrative to describe their experience, individuals engaged in a process of making sense of the fatigue themselves (Pertl et al., 2014).

Participants emphasised the role of others, highlighting the influence of wider social discourse on their experience of fatigue. Dealing with social pressure to return to ‘normal’ after cancer was difficult for participants. Feelings of isolation associated with others’ lack of understanding regarding CrF might contribute to the symptom burden (Dickson, Knussen, & Flowers, 2007). The social response to symptoms influenced participant representations of and coping with CrF, with some participants reporting hesitations in discussing their symptoms and feeling distressed or guilty as a consequence of CrF. Research has previously indicated that the social context is extremely pertinent to how representations are formed (Sinding & Gray, 2005). As with previous studies, the findings indicated that the social
context of the “new normal” was crucial in how participants understood their symptoms. Reactions and support from others influenced these perceptions, and the coping response that followed (Bennion & Molassiotis, 2013; Boykoff et al., 2009). This serves to demonstrate the alignment of survivors’ views with the SRM. The individual’s coping with, and appraisal of, CrF can modify illness representations (i.e. in a feedback loop—See Figure 4.1.) (Hagger & Orbell, 2003).

These qualitative results provide further insight into the specific ways that both the individuals’ perspective and the influence of social factors should be acknowledged in those with CrF. Individual perceptions and social context, as well as disease and treatment characteristics are important in planning survivorship care (Donovan et al., 2005). The SRM could be a useful framework for healthcare professionals to apply in assessments of survivor’s physical and psychosocial characteristics in order to effectively tailor care (Sun et al., 2015).

Many statements focused on the “identity” of CrF. A label was seen as a vehicle to accepting fatigue. In line with previous research, recognition of symptoms was considered crucial in learning to cope with fatigue and articulating the experience to others, including health professionals (D. L. Hall, Mishel, & Germino, 2014). Barker et al (Barker, 2008) emphasised the significance of having a name for medically unexplained symptoms. The current study also showed that fatigue had far-reaching social and emotional consequences for participants. Many emotional consequences were associated with uncertainty that arose due to lack of recognition of CrF by others. Behavioural consequences such as the inconvenience of medical testing were also often linked to this uncertainty. Discussions relating to the timeline of CrF were similarly dominated by a sense of ambiguity. Likewise, individuals did not report a sense of control over their symptoms. Participants were not sure what to expect
because CrF had already persisted longer than anticipated after the end of treatment. Others have also noted the link between cancer-related uncertainty and psychophysiological disruptions, highlighting a need to target this ambiguity in interventions for CrF. Factors such as comprehensibility, manageability, and meaningfulness can influence symptom perception. A sense of coherence may serve as a protective psychological factor in the adaptation process (Rohani, Abedi, Omranipour, & Langius-Eklöf, 2015; Rohani, Abedi, Sundberg, & Langius-Eklöf, 2015).

The representations impacted on acceptance of fatigue and affected participants’ coping, as shown in previous research (McAndrew et al., 2008). Perceived lack of support from family members and healthcare providers, as well as difficulties in trying to understand CrF also influenced participants’ ability to cope. Some participants described engaging in “active” coping strategies, such as exercise in managing CRF. Others reported taking naps or avoiding activity. Thus, participants may choose more maladaptive strategies for fatigue (e.g. daily/frequent napping) rather than recommended strategies (e.g. exercise (Cramp & Daniel, 2008)) depending on their representation of CrF. Beliefs about fatigue management influence coping strategies following cancer treatment (Costanzo, Lutgendorf, & Roeder, 2011).

Participants did not spontaneously appraise or reflect on the particular coping strategies they used to manage CrF. Evaluations focused more on general appraisals of attempts to regain a sense of ‘normality’ after treatment. Whitaker, Scott and Wardle (Whitaker, Scott, & Wardle, 2015) note that factors such as high external demands (e.g. family and work commitments) can impact interpretation of symptoms. Co-morbidities, stereotypes, and perceptions of aging can also bias appraisal of coping and expectations.Acknowledgement of symptom seriousness from others may facilitate individual acceptance of fatigue and encourage appraisal of current coping strategies (Whitaker et al., 2015). Current results add to those of
Chapter 3. Qualitative Research: Grounding the research in psychological theory

A previous study which noted that appraisals of representations have been linked to seeking care in response to ambiguous (Cameron, Leventhal, & Leventhal, 1995) and prolonged symptoms (Mora, Halm, Leventhal, & Ceric, 2007). Understanding how individuals appraise coping could help guide the development of tailored, proactive interventions to improve well-being (Costanzo et al., 2011).

Taken overall, this study suggests that the structure of the SRM could serve as the basis for developing interventions for improving fatigue management (McAndrew et al., 2008). This study extends on previous research that applied the SRM to patients’ experiences during cancer treatment (A. Barsevick et al., 2010; Barsevick et al., 2001), providing insight into the unique representations of CrF in cancer survivors (Stanton et al., 2005). Persistent fatigue does not conform to generally accepted conceptualisations of survivorship, with treatment as an end-point of care (Kaiser, 2008).

The findings highlight a need for continued support to enhance quality of life after cancer treatment (Stanton et al., 2005; Terwee et al., 2007). Cancer itself and/or treatment initially trigger fatigue, but other factors may be responsible for persistence of CrF (Andrykowski et al., 2010). Exercise or psychosocial interventions are currently the treatment modalities of choice (Minton, Richardson, Sharpe, Hotopf, & Stone, 2011). Existing interventions for CrF have focused on perpetuating factors such as beliefs and behaviours associated with fatigue, often using strategies based on cognitive behaviour therapy (CBT) (Goedendorp et al., 2009; Kwekkeboom et al., 2012). CBT is a practical application of many of the theoretical constructs addressed in the SRM (Hudson et al., 2016; Moss-Morris, 2013). Very few randomized trials have explicitly applied the SRM to influence self-regulative symptom management (McAndrew et al., 2008). None have explored how the SRM could be applied in interventions for CrF after cancer. SRM-based strategies could target how individuals think,
Chapter 3. Qualitative Research: Grounding the research in psychological theory

feel, and cope with their fatigue (McAndrew et al., 2008). This study, therefore, concentrated solely on the fit of the discussions to the SRM rather than considering alternative models. Dempster et al (2015) found that illness perceptions and coping play an important role in studies that link the SRM to wellbeing outcomes. It is still unclear how illness representations relate to coping, and how this might be applied in interventions. The current study suggests that interventions for CrF should be two-fold, targeting and measuring both the representation of symptoms and coping strategies (A. Barsevick et al., 2010). A ‘top-down’ SRM approach to CrF would aim to create an overarching cognitive and emotional representation of fatigue as a manageable symptom, with coping and appraisal as targets for behaviour change (McAndrew et al., 2008). In line with calls for improved methods of identifying and reporting the components of interventions, such an approach would need to assess the theoretical constructs of the SRM as proposed mechanisms of any change in fatigue symptoms (Cane, Richardson, Johnston, Ladha, & Michie, 2015).

3.4.1. Limitations

Some limitations of this study should be acknowledged.

As the participants self-selected, this may have resulted in a biased sample not representing the wider population. Those frustrated with fatigue problems might have been more likely to self-nominate to participate in this research. Conversely, significantly fatigued people may have not felt well enough to participate. As this was an exploratory study of an under-researched symptom in Irish cancer survivors, it was decided that specific purposive sampling methods were not appropriate. This sampling method reflected the methods that would be used in any future intervention arising from the findings, and would give a sense of perceived need/interest in the topic from the community. However, the authors recognise that
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The current study may be susceptible to selection biases, in particular regarding the disproportionate number of breast cancer survivors who participated. For example, Wenger and Oliffe (2014) suggest that men may be less comfortable discussing distressing situations or symptoms, and may feel more cautious about who they consider a safe source of support.

The collection of data via focus groups means that participants may conform to the perspectives of others in the group and findings may not reflect the views of individual participants (Sim, 1998). Care was taken to ensure that each participant was given ample opportunity to express their perspective, however, some were naturally inclined to speak more than others. Researchers did make efforts to keep dominant respondents from taking over discussion.

The groups engaged in a free-flowing conversation with relatively little input from the researchers. However, issues raised by participants were likely to depend on their circumstances at the time of participation (Garcia, Evans, & Reshaw, 2004). Although a variety of cancer types and treatments were represented, a more heterogeneous sample would broaden the content of the representations, coping strategies, and appraisals. Furthermore, information relating to education level was not gathered. Some evidence published prior to this research had suggested that factors such as ethnicity, educational attainment, and employment status were not associated with fatigue (Bower et al., 2000; Petra Servaes, Verhagen, & Bleijenberg, 2002). However, recent evidence (published since the focus groups were conducted) suggests that lower education and pre-existing comorbidities may be associated with fatigue (Husson et al., 2015; Schmidt et al., 2015).

Attempts were made to avoid bias in how the data was collected and interpreted. The moderators of the groups were experienced in qualitative research and followed an interview
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schedule. Questions were designed to be neutral and answerable. General questions were asked before specific questions.

While there were advantages to conducting qualitative rather than quantitative survey-based methods to learn more about CrF, some limitations must be considered. The analysis of these discussions is based on themes that were reflective of patterns in the overall data rather than a reporting of the proportion of participants or groups expressing a theme. Using qualitative methods did not provide information regarding the proportion or frequency of particular responses (See Table 3.1. Point 30).

The first author of this paper analysed the data and was also a moderator in the focus groups. This may have resulted in bias when reporting the findings. Experiences, beliefs, goals of the researcher and personality could bias analysis and reporting. However, efforts were made to minimise this bias by specifying the questions a priori in an interview schedule and following a coding manual (Appendix 7 and Appendix 8). In addition, inter-rater reliability was used in the coding process.

3.5. Conclusion

Overall, results indicated that post-treatment CrF can be described using concepts from the SRM. The findings contribute to the literature on the reconceptualization of cancer as a chronic illness by identifying perceived inadequacies in support available to those left with lingering side-effects after the completion of cancer treatment. The study demonstrated the complexity of the individuals’ meaning-making processes when the legitimacy of the health concern is contested. The current research identified specific elements of the SRM that were very pertinent for those with CrF. Participants felt inadequately prepared for persistent fatigue after cancer and were left confused, isolated and frustrated as a result. CrF should be
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approached as a complex psychosocial issue and considered from the patient perspective to facilitate better understanding and management of symptoms.

Prevailing models of healthcare promote patient-centred care for control of chronic symptoms and highlight the need for evidence based practice (Craig et al., 2013; McAndrew et al., 2008). Importantly, this study highlights how the SRM could be applied to CrF in post-treatment cancer survivors by providing a theoretical framework for understanding individuals’ representations, and coping strategies, and thus identifying targets for intervention (Cane et al., 2015).
Chapter 4. Designing the content of the intervention

4.1. Introduction

This chapter describes the development of a theory-based, interactive web-based intervention designed to facilitate self-management of cancer-related fatigue (CrF) following cancer treatment. An open-source web-development platform, LifeGuide was used to develop the programme (www.lifeguideonline.org) in line with existing interventions of this nature (Grimmett, Armes, Breckons, Calman, Corner, Fenlon, Hulme, May, May, & Ream, 2013; Michie et al., 2012). The development of the intervention was informed by the Medical Research Council’s guidelines on developing complex interventions (MRC, 2008). Complex interventions are those that comprise multiple interacting components (Craig et al., 2008). Michie et al. (2012) reported that there is a need for more detailed descriptions of the foundations that underpin complex interventions, promoting methodological rigour and transparency in the design process (Chalmers et al., 2014; Craig et al., 2008). The aim of this chapter is to outline the rationale, decision-making processes, methods, and findings which led to the development of the content for the intervention (Hoddinott, 2015).

This research sought to incorporate the findings of the previous chapters by integrating psychological theory, existing evidence of effective interventions, empirically derived principles of web-design, and the views of potential users into the systematic planning and design of the intervention of an easy to use website for cancer survivors (Bradbury et al., 2014; Michie et al., 2012; Webb et al., 2010). In doing so, a thorough description of the content and principles used in the development process is provided (Michie et al., 2012), while also clarifying hypothesised causal mechanisms (Moore et al., 2015). This chapter will include a rationale for the chosen theory of behavioural change, the quality of the evidence on
Chapter 4. Designing the content of the intervention

which the intervention is based and guiding principles established with targeted groups (Maar et al., 2016; Waterlander et al., 2014).

4.2. Planning the Design of an Online Intervention

The Behaviour Change Model for Internet Interventions (Ritterband et al., 2009) proposes that effective internet interventions produce behaviour change and symptom improvement through various mechanisms of change (as documented in Figure 4.1). The primary factors to consider are the characteristics of the intended user and factors such as the problem being targeted. Change mechanisms function as the catalysts for symptom improvement and behaviour change (Ritterband et al., 2009). Deductive approaches (including reviews of the existing literature) are useful to ascertain what is already known about changing a behaviour and inform intervention design (Bradbury et al., 2014).

4.2.1 Existing Guidelines and interventions incorporated in the design process

As addressed in Chapter 2, a systematic review of psychological interventions for fatigue in cancer survivors was conducted. The aim of this review was to identify psychological interventions that were likely to impact CrF. The systematic review and meta-analysis found an overall positive effect of psychological interventions on fatigue in cancer survivors. However there was considerable heterogeneity, not only in design and outcomes, but also in the quality and usability of the specific interventions. Systematic reviews of trials are often complicated by variations in interventions and a paucity of information to allow replication, including how and when they were actually administered (Glasziou, Chalmers, Green, & Michie, 2014). Such interventions are highly suitable for the application of transparent design principles to begin the process of intervention optimisation (Michie et al., 2012).

The review identified five primary psychological intervention types. The most commonly used intervention strategies were CBT, mindfulness-based interventions and psycho-
Chapter 4. Designing the content of the intervention

education. Since no single intervention type emerged as superior in this review, a decision was made to base the current intervention on CBT. This decision was based on the quality and quantity of existing literature, as well as clinical expertise from study authors and stakeholders.

Existing practice recommendations were consulted to assess the applicability of CBT for this participant group. The National Comprehensive Cancer Net-work has published guidance on supporting patients with CrF following treatment. Recommendations include the use of CBT. (Berger, Abernethy, & Atkinson, 2012). CBT is also recommended by the American Cancer Society/American Society of Clinical Oncology Breast Cancer Survivorship Care Guidelines (Runowicz et al., 2016). These guidelines and similar interventions were consulted to facilitate selection of specific behaviours that users would be encouraged to perform (Hardeman et al., 2005; NICE, 2014).
Chapter 4. Designing the content of the intervention

Figure 4.1 Application of the Behaviour Change Model for Internet Interventions
Chapter 4. Designing the content of the intervention

CBT has also been found to be an effective therapy for fatigue symptoms associated with other conditions. Price, Mitchell, Tidy, and Hunot (2008) concluded that CBT is superior in reducing the symptoms of fatigue in those with chronic fatigue syndrome (CFS) compared with usual care, and may be more effective than alternative psychological therapies in reducing fatigue symptoms. Evidence on effectiveness of particular components suggest that activities such as self-monitoring of fatigue levels, education, stress management, relaxation and energy conservation should be included (Berger et al., 2012; Reif, de Vries, & Petermann, 2012). CBT also incorporates a theory of fear avoidance, that proposes that cognitive responses (fear of engaging in activity) and behavioural responses (avoidance of activity) may perpetuate fatigue (Chalder, Goldsmith, White, Sharpe, & Pickles, 2015; White et al., 2011). CBT strategies may therefore be useful in addressing the multifaceted nature of CrF.

Van Kessel and Moss-Morris (2006) developed cognitive behaviour model to explain fatigue in multiple sclerosis (MS). A CBT manual was written based on this model and van Kessel et al. (2008) conducted a randomized controlled trial of CBT for MS fatigue. The aim was to target behavioural, cognitive, emotional, and external factors that may contribute to MS fatigue symptoms. The manual enabled participants to focus on aspects which they felt were relevant to them and ignore aspects which were less relevant. The first two sessions introduced participants to the CBT model of MS fatigue, and provided a detailed treatment rationale. An individualized CBT model for fatigue was developed. Participants were instructed on goalsetting and monitoring of goals. Sessions 3 and 4 concentrated on behavioural strategies with cognitive strategies introduced in session 5 (while continuing with the graded activity, rest, and sleep goals). Strategies for dealing with setbacks were introduced in the final session. This manual-based intervention was shown to effectively reduce fatigue up to six month follow-up (van Kessel et al., 2008). An online version was
Chapter 4. Designing the content of the intervention

later trialled as a potentially beneficial means of delivering treatment (Moss-Morris et al., 2012). The self-management package for MS fatigue (“MS Invigor8: Breaking the Cycle of Fatigue”) was based on the therapist-delivered CBT programme and formalised feedback from patients with MS (Moss-Morris et al., 2012). The authors concluded that online CBT may be a clinically and cost-effective treatment for MS fatigue (Moss-Morris et al., 2012). For this study, the MS Invigor8 trial was utilised as an example of the translation of manual-based CBT into an online format.

A manual entitled “Understanding and Managing Persistent Cancer-Related Fatigue” is available for Irish individuals with fatigue after cancer (Collier, 2012). This manual is structured on cognitive behavioural therapy (CBT) techniques and is made up of eight different chapters tackling issues such as inactivity, low mood, sleep problems, worry, and reclaiming life after cancer. This manual has not been tested for effectiveness but was drawn upon as an example developed for use with an Irish sample.

Further information and specific components of the intervention were also informed by the available evidence on symptom focusing (Moss-Morris, Sharon, Tobin, & Baldi, 2005); activity scheduling, insomnia management (Thorndike et al., 2008) (Ritterband et al., 2012) (Vincent & Lewycky, 2009); and stress management (Antoni, 2003) in cancer patients. Relaxation techniques and descriptions on activity pacing from the “Feeling Better” manual developed by McManus (2010) were also incorporated.

The structure and layout was therefore compiled in line with previous CBT interventions, in particular, the Understanding and Managing Persistent Cancer-Related Fatigue manual (Collier, 2012) and the MSInvigor8 trial (Moss-Morris et al., 2012). Adjustment to, and self-regulation of, fatigue was specified as a primary focus of the intervention, with cognitive, behavioural, affective and social responses being addressed (Dennison, Moss-Morris, Yardley, Kirby, & Chalder, 2013; Moss-Morris et al., 2013).
Chapter 4. Designing the content of the intervention

4.2.2. Application of psychological theory

The use of theory reflects recent research which recognises self-management as essential components for recovery of health and well-being in cancer survivorship (Foster et al., 2015; Foster & Fenlon, 2011). The content of this intervention draws upon established cognitive–behavioural models of fatigue (van Kessel & Moss-Morris, 2006). Andrykowski et al. (2010) proposed that biological insults such as the cancer or its treatment may precipitate the initial experience of fatigue during cancer, whereas a cognitive-behavioural model of CrF may predict fatigue in survivorship. As discussed in Chapter 3. CBT models focus on similar cognitive, emotional, and coping/behavioural factors as those outlined by Leventhal et al. (2003). Using the SRM to describe fatigue after cancer provided an integrated theoretical model for developing the intervention based on cognitive–behavioural principles (See Figure 4.2). Principles of the SRM were therefore identified as key to informing intervention development from the intervention (Bradbury et al., 2014). These key influences on behaviour were linked to intervention sessions that were established based on previous research and CBT guidelines (Collier, 2012; Moss-Morris et al., 2013; Roth & Pilling, 2008). The intervention was focused on making changes in routines to minimise fatigue, developing specific coping strategies, and having clear expectations about the nature of challenges faced. Information and advice about managing expectations and how to use social support was included.

The aim was to outline the hypothesised mechanisms through which the intervention would bring about change in order to understand both how these effects might be replicated by similar future interventions (Grant, Treweek, Dreischulte, Foy, & Guthrie, 2013).

4.3. Specifying intervention content

In outlining intervention content, the authors aimed to hypothesise about a theorised link between CBT and behavioural determinants based on psychological theory (de Bruin,
Chapter 4. Designing the content of the intervention

Crutzen, & Peters, 2015). In order to describe intervention content and avoid the problems of lack of consistency across interventions, The Behaviour Change Technique Taxonomy (v1) was employed (Michie et al., 2013). A behaviour change technique (BCT) is an observable, replicable, and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour (Michie et al., 2013). CBT is a well-established therapeutic model (Price et al., 2008), that is non-summative (i.e. the whole is greater than the sum of its parts) (Roth & Pilling, 2008). The use of the Behaviour Change Technique Taxonomy (v1) was not intended to reflect the effectiveness of particular BCTs in this intervention (de Bruin et al., 2015), but rather as a tool to specify techniques of the CBT intervention as a whole.

As the BCT taxonomy had not yet been used to specify components of a CBT intervention, the content of each of the sessions was analysed independently by two coders. One of the coders was naïve to the content, theoretical basis or aims intervention. BCTs were coded with a “0” if absent and a “1” if present. The inter-rater reliability was found to be moderate across each of the sessions (average κ=.67, p<0.05) (See Table 4.1.). Disagreements between the two reviewers were resolved by discussion until 100% consensus was reached. A total of 60 different BCTs were present across the sessions. The sessions increased in complexity, with the number of change techniques increasing as the intervention progressed. The session with most BCTs was session 5. The most commonly used BCT was within the sessions was “13.2. Framing/reframing” which featured in every session. To ensure a comprehensive description of all aspects of the intervention was provided, content was also described with reference to the CBT competence framework for working with people with persistent physical health conditions (Roth & Pilling, 2008) (See Table 4.2).
**Figure 4.2.** From theory to practice: Applying the self-regulation model to a cognitive-behavioural therapy treatment mode
Chapter 4. Designing the content of the intervention

Table 4.1: *Inter-rater reliability of BCT coding for each session*

<table>
<thead>
<tr>
<th>Session</th>
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<tbody>
<tr>
<td>Session 1:</td>
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<td>Session 2:</td>
<td>.692</td>
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<tr>
<td>Session 3:</td>
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<td>Session 6:</td>
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<td>Session 7:</td>
<td>.669</td>
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<td>Session 8:</td>
<td>.668</td>
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<td><strong>Average</strong></td>
<td><strong>.668</strong></td>
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</table>
### Table 4.2. Intervention phases, CBT intervention techniques, proposed mechanisms of change and theoretical constructs targeted and behaviour change techniques employed

<table>
<thead>
<tr>
<th>Session</th>
<th>CBT intervention techniques</th>
<th>Theoretical Construct targeted</th>
<th>Behaviour Change Techniques used</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. CrF</td>
<td>Overview</td>
<td>Symptom perceptions; Emotional (mood); Illness (identity, timeline, consequences, control); Representations of symptoms; Inaccurate illness perceptions; Treatment outcome expectancies; Coherence/overall illness; understanding</td>
<td>2.4. Self-monitoring of outcome(s) of behaviour; 3.1. Social support (unspecified); 4.2. Information about Antecedents; 5.1. Information about health consequences; 5.2. Salience of consequences; 5.3. Information about social and environmental consequences; 5.6. Information about emotional consequences; 6.2. Social comparison; 13.2. Framing/reframing; 15.2. Mental rehearsal of successful performance</td>
</tr>
<tr>
<td></td>
<td>Elicit from participant their understanding of fatigue; Draw on knowledge about fatigue; Reflect information using patients’ own language</td>
<td></td>
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</tr>
<tr>
<td>2.</td>
<td>What is CBT?</td>
<td>Illness Representations (identity, timeline, consequences, cause, control) Emotional Representations (mood) Understanding of poor adjustment in the context of fatigue Coping Target specific triggers that the participant is concerned about. Fatigue management tasks and broader life goals</td>
<td>1.1. Goal setting (behaviour); 1.2. Problem solving; 1.3. Goal setting (outcome); 1.4. Action planning; 4.1. Instruction on how to perform the behaviour; 5.2. Salience of consequences; 5.4. Monitoring of emotional consequences; 6.1. Demonstration of the behaviour8.1. Behavioural practice/rehearsal; 8.2. Behaviour substitution; 8.4. Habit reversal; 13.2. Framing/reframing; 15.1. Verbal persuasion about capability;</td>
</tr>
<tr>
<td></td>
<td>Explanation about the CBT model of adjustment; Develop case conceptualisation with participant; Draw on information elicited to describe interaction between thoughts, feelings, behaviours, and physical symptoms in response to fatigue; Activity monitoring; Encouraging participants to record and evaluate behaviour patterns; Problem solving encourage participant to identify a specific problem that they are having difficulties with at the moment; SMART Goal Setting; Identify a goal they would like to work towards; Action plan how to implement steps defined within SMART goal acronym; Apply chunking: breaking goal down where necessary</td>
<td></td>
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<tr>
<td>3.</td>
<td>Thoughts and Fatigue</td>
<td>Challenging inaccurate illness perceptions (cause, control) Emotional Representations (mood) Coping Identifying and challenging Cognitive biases</td>
<td>1.2. Problem solving; 1.6. Discrepancy between current behaviour and goal; 1.7. Review outcome goal(s); 2.3. Self-monitoring of behaviour; 2.4. Self-monitoring of outcome(s) of behaviour; 2.5. Monitoring of outcome(s) of behaviour without feedback; 4.1. Instruction on how to perform the behaviour; 4.2. Information about Antecedents; 4.3. Re-attribution; 4.4. Behavioural experiments; 5.1. Information about health consequences; 5.2. Salience of consequences; 5.3. Information about social and environmental consequences; 5.4. Monitoring of emotional consequences; 5.6. Information about emotional consequences; 6.1. Demonstration of the behaviour; 6.2. Social comparison; 11.2. Reduce negative emotions; 12.4. Distraction; 13.2. Framing/reframing</td>
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</table>
### Chapter 4. Designing the content of the intervention

Table 4.2. Intervention phases, CBT intervention techniques, proposed mechanisms of change and theoretical constructs targeted and behaviour change techniques employed (continued)

<table>
<thead>
<tr>
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<th>Behaviour Change Techniques used</th>
</tr>
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<tbody>
<tr>
<td><strong>4. Activity Schedules</strong></td>
<td>Activity monitoring; Facilitate process of guided discovery by encouraging participants to record and evaluate behaviour patterns.; Activity scheduling; Rational for activity scheduling outlined in relation to fatigue.; Planning when to implement an activity.; Graded exposure; Generate graded exposure hierarchy; Allow exposure and habituation to a feared situation.; Exercise; Apply chunking: breaking goal down where necessary.; Encourage participants to implement an exercise routine that fits in with their physical demands and ability.</td>
<td>Illness representations (timeline, consequences, cause, control); Coping; Behavioural disengagement (distress); All or nothing behaviour (boom and bust cycles); Behavioural avoidance/social withdrawal in relation to feared situations; Fatigue management tasks and broader life goals</td>
<td>1.1. Goal setting (behaviour); 1.2. Problem solving; 1.3. Goal setting (outcome); 1.4. Action planning; 1.5. Review behaviour goals; 2.3. Self-monitoring of behaviour; 2.4. Self-monitoring of outcome(s) of behaviour; 4.1. Instruction on how to perform the behaviour; 4.2. Information about Antecedents; 4.3. Re-attrition; 5.1. Information about health consequences; 5.2. Salience of consequences; 5.3. Information about social and environmental consequences; 5.4. Monitoring of emotional consequences; 5.6. Information about emotional consequences; 6.2. Social comparison; 7.3. Exposure; 8.1. Behavioural practice/rehearsal; 8.2. Behaviour substitution; 8.3. Habit formation; 8.4. Habit reversal; 8.7. Graded tasks; 11.2. Reduce negative emotions; 13.2. Framing/reframing; 13.3. Incompatible beliefs; 15.1. Verbal persuasion about capability; 15.3. Focus on past success; 16.2. Imaginary reward</td>
</tr>
</tbody>
</table>

**5. Improving your sleep** | Attentional control and cognitive processes; Relaxation skills; Rationale for relaxation explained as a way of reducing tension and attentional processes towards threat; Provide participants with skills to implement relaxing strategies including breathing exercises.; Sleep routines; Implement changes to current sleeping patterns. | Illness representations (consequences, control); Coping; Impact of self-management techniques, threat of future complications or worry about fatigue.; Fatigue management tasks and broader life goals; Target increased arousal and “fight/flight response”; Altered sleep | 1.1. Goal setting (behaviour); 1.2. Problem solving; 1.3. Goal setting (outcome); 1.4. Action planning; 2.3. Self-monitoring of behaviour; 3.2. Social support (practical); 3.3. Social support (emotional); 4.1. Instruction on how to perform the behaviour; 4.2. Information about Antecedents; 4.3. Re-attrition; 5.1. Information about health consequences; 5.3. Information about social and environmental consequences; 5.6. Information about emotional consequences; 6.1. Demonstration of the behaviour; 6.2. Social comparison; 7.1. Prompts/cues; 7.5. Remove aversive stimulus; 7.8. Associative learning; 8.2. Behaviour substitution; 8.3. Habit formation; 8.4. Habit reversal; 8.7. Graded tasks; 11.2. Reduce negative emotions; 11.3. Conserving mental resources; 11.4. Paradoxical instructions; 12.1. Restructuring the physical environment; 12.3. Avoidance/reducing exposure to cues for the behaviour; 12.4. Distraction; 12.5. Adding objects to the environment; 13.2. Framing/reframing; 15.1. Verbal persuasion about capability; 15.2. Mental rehearsal of successful performance; 15.3. Focus on past success |

**6. Low mood-thinking** | Cognitive reappraisal; Participant guided to identify evidence for and against biased thoughts; Realistic thought generation, based on objective evidence is encouraged; Socratic questioning principles implemented; Acceptance; Alter functional relationship with thoughts. Thoughts experienced without letting thoughts control other aspects of behaviour; Participants supported with their acceptance using principles of Socratic questioning (e.g. prompting self-reflection, stimulate thought and increase awareness; Mindfulness. | Illness representations (identity, timeline, consequences, cause, control); Emotional representation; Coping; Acceptance used in the context of accurate illness perceptions.; Allows person to maintain levels of functioning with fatigue. | 1.2. Problem solving; 1.6. Discrepancy between current behaviour and goal; 2.3. Self-monitoring of behaviour; 3.2. Social support (practical); 3.3. Social support (emotional); 4.1. Instruction on how to perform the behaviour; 4.2. Information about Antecedents; 4.3. Re-attrition; 5.1. Information about health consequences; 5.3. Information about social and environmental consequences; 5.6. Information about emotional consequences; 6.1. Demonstration of the behaviour; 6.2. Social comparison; 8.1. Behavioural practice/rehearsal; 8.2. Behaviour substitution; 8.3. Habit formation; 8.4. Habit reversal; 9.3. Comparative imagining of future outcomes; 11.2. Reduce negative emotions; 11.3. Conserving mental resources; 12.4. Distraction; 13.2. Framing/reframing; 13.3. Incompatible beliefs; 15.4 Self-talk |
**Chapter 4. Designing the content of the intervention**

Table 4.2. Intervention phases, CBT intervention techniques, proposed mechanisms of change and theoretical constructs targeted and behaviour change techniques employed (continued)

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<tbody>
<tr>
<td>7. Worries and Anxiety/Stress Management</td>
<td>Problem solving; Pros and cons; Relaxation skills; Explain rationale for relaxation exercises; Provide participants with skills to implement relaxing strategies including breathing exercises; Emotional expression; Encourage participants to write about feelings during “worry time”</td>
<td>Illness representations (identity, timeline, consequences, cause, control) Emotional representations Coping Target increased arousal Processing emotions in a healthier manner</td>
<td>3.3. Social support (emotional); 4.1. Instruction on how to perform the behaviour; 4.2. Information about Antecedents; 5.1. Information about health consequences; 5.3. Information about social and environmental consequences; 5.4. Monitoring of emotional consequences; 5.6. Information about emotional consequences; 6.2. Social comparison; 8.2. Behaviour substitution; 8.3. Habit formation; 8.4. Habit reversal; 9.1. Credible source; 9.2. Pros and cons; 9.3. Comparative imagining of future outcomes; 11.2. Reduce negative emotions; 11.3. Conserving mental resources; 12.4. Distraction; 12.5. Adding objects to the environment; 13.2. Framing/reframing; 13.3. Incompatible beliefs; 15.4. Self-talk</td>
</tr>
<tr>
<td>8. Social Support and Preparing for the future</td>
<td>Assertiveness skills training; Facilitate participant expressing themselves with others; Explaining about lifestyle restrictions of fatigue; Practice scenarios of expressing themselves.</td>
<td>Coping Behavioural avoidance/social withdrawal in relation to feared situations Lack of assertion Increasing degree and type of social support. Evaluation</td>
<td>1.1. Goal setting (behaviour); 1.2. Problem solving; 1.3. Goal setting (outcome); 1.4. Action planning; 1.5. Review behaviour goal(s); 1.6. Discrepancy between current behaviour and goal; 1.7. Review outcome goal(s); 3.1. Social support (unspecified); 3.2. Social support (practical); 3.3. Social support (emotional); 4.1. Instruction on how to perform the behaviour; 4.3. Re-attrIBUTion; 6.1. Demonstration of the behaviour; 6.2. Social comparison; 6.3. Information about others’ approval; 8.1. Behavioural practice/rehearsal; 8.6. Generalisation of target behaviour; 9.2. Pros and cons; 12.2. Restructuring the social environment; 12.3. Avoidance/reducing exposure to cues for the behaviour; 13.2. Framing/reframing; 13.3. Incompatible beliefs; 13.4. Valued self-identify; 13.5. Identity associated with changed behaviour; 15.1. Verbal persuasion about capability; 15.2. Mental rehearsal of successful performance; 15.3. Focus on past success; 15.4. Self-talk; 16.3. Vicarious consequences</td>
</tr>
</tbody>
</table>
Chapter 4. Designing the content of the intervention

4.3.1. Preferences of potential users sought in design: Incorporating a Person-Based Approach

The Behaviour Change Model for Internet Interventions model proposes that the user is one of the most challenging variables to consider in the design on online interventions (Ritterband et al., 2009). In order to gain insight into user characteristics, qualitative research was used to identify the preferences of potential users. Inductive qualitative work can provide important information about which intervention features might be preferable to users. Qualitative research may also capture practical novel responses which have not been anticipated by the researcher (Bradbury et al., 2014; Yardley et al., 2012). The person-based approach was incorporated into intervention design to supplement principles derived from psychological theory (Yardley et al., 2015). Qualitative research was used in the development of “guiding principles” that state the key intervention design objectives and describe the features of the intervention designed to achieve each objective.

At the planning stage of developing the intervention, focus groups were carried out with survivors of cancer with fatigue (N= 18), to explore their perceptions of online interventions and the type of features that were viewed as acceptable or unacceptable. Participants were asked to discuss the following open-ended question: “How would you feel about participating in an online programme that would aim to help you with your fatigue?”

Developing a web-based resource to support self-management after cancer treatment was endorsed by the majority of participants. Important contributions were made regarding the need for some degree of personalisation, credibility, and recognition of the fatigued nature of those using the website. Drawing on personal experiences, participants highlighted important domains such as an emphasis on moving forward with life after cancer rather than focusing too much on the illness. Suggestions were also made pertaining to the need for the resource to be accessible in terms of literacy, comprehension, and level of computer skills required.
Chapter 4. Designing the content of the intervention

Unlike traditional usability testing, the person based approach extends beyond factors relating to usability, acceptability, and satisfaction (Yardley et al., 2015). The aim is to develop interventions that are effective at changing behaviours while also being motivating, enjoyable, informative, convincing (Yardley et al., 2012).

The findings were collated and a set of “guiding principles” were established (See Table 4.3.). These considerations allowed the researchers to focus on particular design objectives and key features. The guiding principles that were consulted throughout the planning and development phases. This helped to ensure that the intervention was founded on a consistent rationale that would optimize its acceptability, feasibility, and in turn, effectiveness. With this person-based approach to design, the intervention developers were able to access information that would complement the application of psychological theory in the design of the programme.

4.3.2. Application of Psychological theory in design process

In addition to the qualitative research, guidance based on established psychological theories was used to inform the optimal implementation of different design features and BCTs within different intervention contexts (Morrison, 2015; Morrison, Yardley, Powell, & Michie, 2012).

Personalisation

Personalisation was used throughout the website (e.g. inserting a person’s name) (Dijkstra & De Vries, 1999). Self-referent cues encoding are believed to be important in encouraging effortful processing (Morrison, 2015). While there is evidence for the use of tailored interventions, adaptive interventions require more time and technical expertise to develop and test. Some evidence suggests that increasing the personal relevance of information may have adverse effects on attitude and persuasion (Petty, 2004). The elaboration likelihood model (ELM) suggests that tailored arguments must be congruent with prior attitudes or beliefs, or else they may inadvertently promote careful critique of the arguments (Morrison, 2015).
Chapter 4. Designing the content of the intervention

Given that this intervention incorporates content that is designed to challenge maladaptive perceptions relating to fatigue, the incongruence between the message and prior attitudes may lead to a rejection of the content in highly tailored interventions. In turn, this may lead to early drop out. Providing untailored intervention content may better attract and retain users’ attention, thus encouraging continued usage (Morrison, 2015). Tailored online content has been perceived as less credible than non-tailored content (Yardley et al., 2015). Given that credibility was an issue raised in the focus groups, a non-tailored intervention may be more suited at this stage for this group.
Table 4.3. Guiding Principles And Design Objectives Based On Qualitative Interviews With Fatigued Cancer Survivors.

<table>
<thead>
<tr>
<th>Guiding principle</th>
<th>Illustrative participant quotes</th>
<th>Design objectives</th>
<th>Key features</th>
</tr>
</thead>
<tbody>
<tr>
<td>People are self-motivated to seek solutions.</td>
<td>“People are more proactive in looking for ways to improve their quality of life afterwards. If there was something out there or some kind of programme that they could do on cancer fatigue they would try it.”</td>
<td>Recruitment from general public.</td>
<td>Use of theory based recruitment strategies to engage potential participants.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Recruitment from print media and social media sites, as well as through healthcare professionals and cancer charities.</td>
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<td></td>
<td></td>
<td></td>
<td>Promote ease of use of website</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Users’ names would be presented at log-in and at various times throughout each session.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Participants would be given autonomy to identify times that they would find it convenient and appropriate to receive notifications about when to complete the next sessions.</td>
</tr>
<tr>
<td>Individual differences in the amount of in-person contact required</td>
<td>“I do think you have to be aware that you cannot beat human interaction especially for people who might feel a bit isolated because of their condition.”</td>
<td>Personalisation should be a key part of the intervention.</td>
<td></td>
</tr>
<tr>
<td>Participants disagreed with having a complete lack of contact, but noted that an online programme would suit those who did not have the time or energy to take part in an in-person intervention.</td>
<td>“There was so much going on and you’re trying to get back into your routine and you’re looking after the kids and you’re just so tired. I wouldn’t have signed up for a course to go anywhere. If I could have gone onto the internet and logged onto something I would. Because I could do that in my own time and 5 minutes here and there, whereas I wouldn’t sign up to physically talk to someone.”</td>
<td>Participants would have autonomy in choosing times and activities that fit with their routine.</td>
<td></td>
</tr>
<tr>
<td>Personal touch: personalised contact could motivate and engage participants.</td>
<td>“If you had a meeting or call with somebody initially and they said ‘we’re going to have this online programme. This is what it’s based on. We might check in on you every now and again.” ...Just to have a bit of a contact. You’d feel like that’s kind of especially for you. If it was only an email or something like that...”</td>
<td>Contact could garner trust in the programme while increasing engagement and continued use of the intervention.</td>
<td>Personalised emails would be sent to each participant at the beginning of the intervention, inviting them to contact the researchers if they had any questions.</td>
</tr>
<tr>
<td></td>
<td>“You’re not even looking for contact every week or whatever but if you knew somebody was going to check in you would make much more of an effort to actually finish it and get the benefits from it than just signing up and starting it.”</td>
<td></td>
<td>Phone calls would be made in the 3rd week and after the final session.</td>
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<td></td>
<td></td>
<td></td>
<td>Participants would also have access to a “Contact Us” tab with contact details so that they could contact the researchers with any personal queries.</td>
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</tbody>
</table>
## Chapter 4. Designing the content of the intervention

<table>
<thead>
<tr>
<th>Guiding principle</th>
<th>Illustrative participant quotes</th>
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<th>Key features</th>
</tr>
</thead>
</table>
| **Normalising symptoms:**  
website to raise awareness about CrF and to inform users about the symptoms.  
Focus on what participants can do. rather than emphasising limitations or the impact of the cancer experience.  
Preference for a skills-focused intervention:  
Enable participants to live their lives despite fatigue. | I think it’s very good that there would be a programme or some other support that would at least alert you to the fact that it’s not just you.”  
“You’re really questioning yourself and questioning why did all of this happen and all of that and you do need to learn to move beyond it and get into a, kind of a positive place. Step forward. It’s a way of focusing your own mind and. Getting out of it.”  
“I find it difficult. You want to do it in yourself but you need to make other people aware of it without being a whinge-bag. Just something I can say or do and just move on. It would be very useful. It’s not going to away. The next step is learning how to manage it.” | Ensure promotion of fatigue-reducing coping strategies does not stigmatise current behaviour  
Approach which promotes wellbeing and moving forward, rather than illness management  
Building a toolkit of skills that would enable the participant to achieve their personal goals. | Participants would be encouraged to seek out further information from their healthcare professional if necessary. Also, a list of useful information sources and contacts would be provided.  
Avoid language that criticises or blames users for their fatigue  
Promote benefits of behavioural changes.  
Friendly, welcoming tone – Avoid reference to illness, focus on moving forward  
Cancer and cancer treatment would not be emphasised, but would only be mentioned where it was deemed necessary to recognise causal factors in the development of fatigue or contributing factors such as negative thinking or low mood.  
Each session would be introduced by highlighting what would be learned and why it was important, in order to emphasise the gains of the intervention. Participants would be congratulated on achievements and progress throughout the sessions.  
Each session would build from an initial explanation of the topic towards developing coping strategies and skills to deal with the issues faced.  
Practicing newfound skills would be encouraged through the use of “To-Do” lists at the end of each session.  
Allow users to pick intervention elements and information which are most relevant to them personally.  
Linking out to existing resources. |
## Chapter 4. Designing the content of the intervention

<table>
<thead>
<tr>
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<th>Key features</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Length of the sessions:</strong> anything too tedious or tiring was unlikely to be attractive to users.</td>
<td>“You’re online. You’re sending emails; you’re sitting at a computer. but I find if I am on a, if I’m on a computer for a long time I’m exhausted, I find the computer it really drains you it really does drain you.”</td>
<td>Enabling easy, timely, non-intrusive access to brief information which can be read and acted on quickly when needed.</td>
<td>Short sessions, where possible that the user can take something away from within a few minutes. Make the sessions engaging and colourful. Each session would include a variety of images, vignettes, and videos to reduce monotonous presentation of information. Brief amount of text on page. Similar outline in each session so that participants would develop a sense of familiarity with the structure. Interactive reflective exercises would allow participants to note their thoughts or personal experiences during the session. Participants’ answers would be saved to re-load so that participants could pick up where they left off if they had to logout or take a break during any session. “Who developed REFRESH” tab on the website homepage: Each member of the team would be presented with a picture and brief biography highlighting their relevant expertise in the area. Logos of the university and the cancer charity that co-funded the research would straddle the website logo. The website logo would reflect the design of awareness ribbons often associated with cancer awareness. The university colours (white, purple, and green) would be used in the logo. A white, purple, and green colour scheme would be used throughout the website design.</td>
</tr>
<tr>
<td><strong>Credibility of the Information source</strong> Some participants were sceptical about using the internet as an information source, citing experiences where online searches had led to misinformation, increased anxiety and a heightened lack of clarity about fatigue.</td>
<td>“When someone mentions looking up stuff on the internet. I think you can put yourself into bother looking up things.”</td>
<td>Emphasise affiliations and expertise in information and intervention development.</td>
<td></td>
</tr>
</tbody>
</table>
Chapter 4. Designing the content of the intervention

Autonomy

Health behaviour change typically requires a considerable degree of self-regulatory effort and is therefore not usually considered an inherently enjoyable activity. This can undermine motivation to engage in the behaviour change process. Self-determination theory (SDT) proposes that if that behaviour is autonomously motivated, performance and maintenance of behaviour is more likely. The behaviour is more probable if it is performed out of a sense of choice rather than external pressure (Ryan & Deci, 2000).

A positive, affective experience will reinforce usage of the intervention in the short-term. In the longer-term, usage may naturally wane as users experience mastery and develop skills needed to sustain behavioural change (Morrison, 2015). In order to ensure that the website was attractive to users, a simple, clear design was used. The colour-scheme throughout reflected the affiliation with the University institution. The name “REFRESH” was chosen as suggested by participants in the qualitative research. This word was to reflect a new beginning (i.e. a fresh start), and focus on what people could do rather than the cancer experience.

Morrison (2015) notes that autonomous motivation can be improved by supporting individuals’ need for autonomy, relatedness (i.e. support from and connection to others) and competence (i.e. confidence and ability to perform a behaviour). Tunneled, session-based delivery such as that in this programme may not be compatible with the perceived advantages of technology such as quick, flexible, and on-the-go access to information (Danaher, McKay, & Seeley, 2005). However, where possible, strategies for providing choice and flexibility were identified to enhance users’ sense of autonomy (Morrison, 2015). Participants were encouraged to self-select their own health related goals and given the opportunity to select when to receive reminder emails. Optional supplementary supportive tools were also made available. This additional information was to ensure that users who desired greater support
Chapter 4. Designing the content of the intervention

would be successfully engaged without burdening users who desire more freedom and control (Yardley, Morrison, Andreou, Joseph, & Little, 2010). Optional contact with the intervention team was offered (Morrison, 2015). Participants were also invited to try out a variety of different strategies accompanied by a meaningful rationale, rather than instructed to follow specific behavioural directives (Yardley et al., 2015). Users were encouraged in every session to reflect on their own personal, intrinsic reasons for using the website and reflect on how suggested changes could be incorporated into their lives (Yardley et al., 2014).

The use of vignettes and quotes from the focus groups may meet users’ need for relatedness by ensuring that users feel listened to and by recognising the challenges faced by CrF. Further, during the phone calls, the user is provided with the opportunity to offer feedback to the research team which may also increase a sense of ownership and connection with the intervention (Morrison et al., 2012). A sense of relatedness was promoted through the use of videos and by introducing the research team via a ‘meet the team’ page. The phone calls made to participants were conducted by the same researcher that spoke in the video content to create a sense of continuity and connection. Competence was promoted by encouragement, task of graded levels of difficulty and available support from the team if the users had any questions.

Goal setting and self-monitoring

Goal setting and self-monitoring are commonly employed BCTs within health interventions (Morrison et al., 2012; NICE, 2014). Goal-setting theory and social cognitive theory (SCT) suggest that goals will be more effective when they are specific and learning focused (Morrison, 2015). In order to avoid the pursuit of inappropriate goals, a significant portion of the second session is devoted to learning about SMART goals (Specific, Measurable, Attainable, Realistic, and Time-bound) (Shahin & Mahbod, 2007). A clear rationale is provided to explain why goal setting is important and useful. Examples and templates are
Chapter 4. Designing the content of the intervention

provided (Yardley et al., 2012). Goals should be achievable in the short-term but sufficiently challenging, and linked to a longer-term, distal goal. In order to facilitate this, a “goal step-ladder” was introduced to participants. Each step on the ladder represents a short-term goal that leads to the ultimate distal goal (Anderson, 1997). Hall and Fong (2007) propose that behaviour is motivated by the comparison of the immediate costs of performing a behaviour against the longer-term benefits. According to this temporal self-regulation theory, feedback focused on the immediate benefits of a certain behaviour may be optimal during the early stages of behaviour change, gradually focusing on the longer-term benefits of health behaviour as time progresses (Hall & Fong, 2007; Morrison, 2015). As users progress through the sessions, the content changes from specific issues associated with fatigue management to broader issues associated with life after cancer.

Users’ satisfaction with their goal progress and feedback can influence their motivation to continue goal pursuit. In order to reduce goal conflict and increase goal salience users were supported to identify health goals that fit with highly valued personal goals or self-conceptions. Users are encouraged to reflect on these goals throughout the duration of the intervention.

The SRM emphasises the role of coherence and feedback on goal performance or self-monitoring (Morrison, 2015). As the intervention content is primarily focused on this theory, participants are encouraged to evaluate and reflect upon how planned or actual behaviour directly affects fatigue, with framing and reframing of beliefs occurring throughout the sessions (Leventhal et al., 2003; Morrison, 2015). This process of appraisal is also included in the phone calls with the intervention team.

Self-efficacy

The health action process approach proposes that individuals’ self-efficacy beliefs support the regulation of behaviour and feedback on goal performance. Communications should therefore
Chapter 4. Designing the content of the intervention

increase individuals’ perceptions of their capability to change behaviour rather than pointing to the implications of not changing (Schwarzer & Renner, 2000). This is in line with the findings of the focus group where participants requested that the website focus on what they are able to do rather than on the limitations imposed on them by their fatigue. Participants are congratulated on milestones throughout the programme, and emails include verbal persuasion to continue with the programme. Stories from similar others, including reflections on how to cope with fatigue develop a sense of self-efficacy through the use of vicarious experiences. The use of a fatigue diary to monitor fatigue and understand its pattern allows participants to recognise their symptoms, while the sessions on negative mood, stress management, and relaxation provide skills-training to enhance a sense of control over the symptoms. (Foster et al., 2015; Grimmett, et al. 2013).

Levels of Social Support

Some users may not feel confident to make health-related behavioural changes with only minimal, automated guidance. Unguided interventions require users to autonomously interpret, follow, and implement the intervention advice provided. Therefore, efforts were made to offer computer-mediated forms of social support through the intervention provider rather than providing a social networking facility for participants. Weak tie network theory further argues that computer-mediated communication or support will be particularly beneficial for users managing conditions that they associate with shame, as a result of fears and prejudices surrounding cultural conceptions (Wright & Bell, 2003). CrF has been described as an under-recognised symptom in cancer survivorship (Stone & Minton, 2008). Further, in the qualitative research conducted in the design of this programme, many participants alluded to a sense of guilt or shame associated with not being able to activities such as returning to work or attending social events after cancer. Thus, ‘weak tie’ relationships between participants and the intervention provider may enable the user to gain
access to diverse types of information which may be useful for fostering a sense of control over one’s fatigue (Wright & Bell, 2003). This may be better suited to this intervention where resources are limited given the inconsistency regarding the credibility and benefits of social support interventions and difficulties associated with ensuring that these tools are appropriately engaged with (Morrison, 2015).

4.4. Principles of website design

Gaining insight into how individuals in unique situations might perceive and engage with the behavioural elements of the programme led directly to the identification of some key behaviour change techniques (BCTs) that could make the content more attractive to users. Five principles of website design were identified by the user group. A further six were identified by the study team: personalisation, autonomy, goal setting, self-monitoring, self-efficacy, and social support. The participants highlighted some elements that may be particularly necessary or problematic to them. For example, the issue of lethargy and fatigue in participants must be considered in designing content and the length of the sessions. BCTs related to shaping knowledge, social support, goals and planning and feedback and monitoring. A list of intervention components resulting from the iterative process of applying principles and BCTs can be seen in Table 4.4.
### Chapter 4. Designing the content of the intervention

Table 4.4. *Principles of website design and associated BCTs included to promote the use of the REFRESH programme.*

<table>
<thead>
<tr>
<th>Principles Of Website Design</th>
<th>BCTs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social Support</td>
<td>3.1. Social support (unspecified)</td>
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<tr>
<td></td>
<td>3.2. Social support (practical)</td>
</tr>
<tr>
<td></td>
<td>3.3. Social support (emotional)</td>
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<td></td>
<td>6.3. Information about others’ approval</td>
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<tr>
<td></td>
<td>12.2. Restructuring the social environment</td>
</tr>
<tr>
<td>Autonomy</td>
<td>2.1. Monitoring of behaviour by others without feedback</td>
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<tr>
<td></td>
<td>10.7. Self-incentive</td>
</tr>
<tr>
<td></td>
<td>10.9. Self-reward</td>
</tr>
<tr>
<td>Goal Setting</td>
<td>1.1. Goal setting (behaviour)</td>
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<tr>
<td></td>
<td>1.2. Problem solving</td>
</tr>
<tr>
<td></td>
<td>1.3. Goal setting (outcome)</td>
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<td></td>
<td>1.4. Action planning</td>
</tr>
<tr>
<td></td>
<td>1.5. Review behaviour goal(s)</td>
</tr>
<tr>
<td></td>
<td>1.7. Review outcome goal(s)</td>
</tr>
<tr>
<td>Self-Monitoring</td>
<td>2.3. Self-monitoring of behaviour</td>
</tr>
<tr>
<td></td>
<td>2.4. Self-monitoring of outcome(s) of behaviour</td>
</tr>
<tr>
<td></td>
<td>5.4. Monitoring of emotional consequences</td>
</tr>
<tr>
<td></td>
<td>12.5. Adding objects to the environment</td>
</tr>
<tr>
<td>Self-Efficacy</td>
<td>6.3. Information about others’ approval</td>
</tr>
<tr>
<td></td>
<td>10.4. Social reward</td>
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<tr>
<td></td>
<td>14.4. Reward approximation</td>
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<tr>
<td></td>
<td>15.1. Verbal persuasion about capability</td>
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<tr>
<td>Personalisation</td>
<td>7.1. Prompts/cues</td>
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</table>
Chapter 4. Designing the content of the intervention

Table 4.4. Principles of website design and associated BCTs included to promote the use of the REFRESH programme. (continued)

<table>
<thead>
<tr>
<th>Principles Of Website Design</th>
<th>BCTs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normalising Symptoms</td>
<td>5.1. Information about health consequences</td>
</tr>
<tr>
<td></td>
<td>5.2. Salience of consequences</td>
</tr>
<tr>
<td></td>
<td>5.3. Information about social and environmental consequences</td>
</tr>
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<td></td>
<td>5.6. Information about emotional consequences</td>
</tr>
<tr>
<td></td>
<td>6.2. Social comparison</td>
</tr>
<tr>
<td></td>
<td>4.3. Re-attribution</td>
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<tr>
<td>Focus On Abilities</td>
<td>15.3. Focus on past success</td>
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<td></td>
<td>16.3. Vicarious consequences</td>
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<td></td>
<td>8.6. Generalisation of target behaviour</td>
</tr>
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<td></td>
<td>8.7. Graded tasks</td>
</tr>
<tr>
<td>Skills-Focused</td>
<td>4.1. Instruction on how to perform the behaviour</td>
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<tr>
<td></td>
<td>4.2. Information about Antecedents</td>
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<tr>
<td></td>
<td>6.1. Demonstration of the behaviour</td>
</tr>
<tr>
<td></td>
<td>8.1. Behavioural practice/rehearsal</td>
</tr>
<tr>
<td></td>
<td>8.2. Behaviour substitution</td>
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<tr>
<td></td>
<td>8.3. Habit formation</td>
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<tr>
<td></td>
<td>8.4. Habit reversal</td>
</tr>
<tr>
<td>Length Of The Sessions</td>
<td>7.1. Prompts/cues</td>
</tr>
<tr>
<td>Credibility</td>
<td>9.1. Credible source</td>
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</tbody>
</table>
Chapter 4. Designing the content of the intervention

4.5. Developing content

The findings of the preparatory deductive and inductive research were collated to create a plan of what the intervention should contain. Attempts were made to anticipate factors external to the intervention that may act as a barrier or facilitator to its implementation, or its effect (Moore et al., 2015).

Once the theoretical and empirical principles were established, the team reached consensus over the overarching theme and design of the proposed website (Michie et al., 2012). A draft content manual and plan for the structure of the intervention were designed (See Appendix 17). Due to the nature of online interventions, certain aspects of the content manual could not be translated as originally planned. A storyboard was made for each session to demonstrate how the information would be presented on each webpage (See Fig 4.4). These storyboards were then discussed among the research team. Time and staffing resources were limited and so certain aspects of the content were prioritised by the research team. Certain features that were considered “must-haves” and “should-have” were maintained (Bradbury et al., 2014). Other aspects were altered or delivered in a different way than originally planned. Some intervention features that were not deemed essential were removed where necessary (Bradbury et al., 2014; Van Velsen, Wentzel, & Van Gemert-Pijnen, 2013)

An iterative review process then took place with the design team examining the different sessions. Comments were made about the accuracy of information and relevance to the conceptual and theoretical framework. Other suggestions related to suggested activities, participant burden and design preferences. After discussion by the research team, amendments were incorporated, and pages were created. In Chapter 5. The process of translating the content into the website will be described.
Chapter 5. Designing the website

In this chapter, the process of usability testing and user-based design will be described. This is seen as a crucial part of the design process. Employing testing methods that allow for the exploration of user experiences allows researchers to better understand the processes involved (Bradbury et al., 2014; Michie et al., 2012; Yardley, Morrison, Bradbury, & Muller, 2015b).

The Essential guide to LifeGuide intervention development was used as a resource for planning practical aspects of the intervention (LifeGuide, 2014). All pages were created in Life-Guide’s Virtual Research Environment (VRE) (Yardley et al., 2009). This allowed the team to share online feedback, comments, and suggested amendments on each of the pages.

The early stages of the development process involved an iterative process of drafting sections of the website and revising sections based on comments from study team members and expert advisors. The original offline manual was useful as the website was extensively tunnelled and tailored throughout this process (Michie et al., 2012). The overall framework for developing the REFRESH website can be seen in Figure 5.1.

5.1. Design team

The development of REFRESH was supported by service users and stakeholders. The development process was also informed by academics, clinical psychologists, and health psychologists with experience working with individuals affected by CrF, cancer or fatigue. Specialists in the development and evaluation of web-based behaviour change interventions were also consulted during the design process. These included individuals with expertise in the design and implementation of interventions built using LifeGuide open-source software (Hare et al., 2009). In order to ensure that an acceptable and feasible intervention was developed, the views of stakeholders, such as healthcare staff were also considered (Bradbury
5.2. Understanding the context of online interventions

Despite the seeming uniformity of delivery of online programmes, implementation may often vary from one context to another (Shiell, Hawe, & Gold, 2008). Understanding context is therefore critical in interpreting the findings (Moore et al., 2015; Ritterband et al., 2009). Theoretical principles cannot explain the many factors that may impact a given intervention within a particular context.

Although online interventions for fatigue after cancer have been tested elsewhere (e.g. the RESTORE trial in the UK (Grimmett, et al., 2013), little research has been conducted in regions that do not offer free universal healthcare. In Ireland, while those with a medical card receive free GP care, the rest of the population pay at the point of delivery (Nolan, 1993). Without a medical card, paying the full cost fee (reported in most cases to be €50 per visit) appears to be a deterrent to seeking primary care (Barrett, Savva, Timonen, & Kenny, 2011). The perceived “need” of treatment for fatigue may influence an individual’s willingness to pay for a GP consultation (Barrett et al., 2011). Health professionals sometimes fail to appreciate the occurrence, duration and detrimental effects associated with CrF (Mackereth, Bardy, Finnegan-John, Farrell, & Molassiotis, 2015). Many fatigued individuals do not discuss their symptoms as they perceive fatigue as an untreatable symptom that is to be endured as a normal part of cancer (Passik et al., 2002). Many also believe that interventions for fatigue are not available, and cite this as a barrier to opening a conversation about CrF (Passik et al., 2002).

An online intervention may be particularly beneficial to Irish participants, given reported inequity in care provision (Barrett et al., 2011). The home-based setting of an online intervention may also allow participants to learn more about their symptoms and possible
Chapter 5. Designing the website

coping strategies, empowering them to begin a conversation about fatigue with their healthcare professional. Some survivors report a desire to move on with their lives and to no long identify as a cancer patient (Servaes et al, 2002). Therefore, the anonymity and privacy of an online programme may be appealing. Participants can practice and incorporate new skills more readily into their daily lives when the intervention is incorporated into their current routine (Myall et al., 2015; Wolvers, et al., 2015).
Chapter 5. Designing the website

**Figure 5.1.** The framework for developing the *REFRESH* website

- Systematic review of Psychological Interventions for fatigue
- Theoretical basis and principles underpinning of intervention content established
- Literature review and in-depth study of similar interventions
- Content Manual developed
- Design scheme, logo and graphics
- Overall flow-chart of website structure
- Application of Psychological theory in design process
- Preferences of potential users sought in design
- Draft versions of all pages in LifeGuide’s Virtual Research Environment (VRE)
- Iterative process of drafting sections of the website
  - Comments from team members and expert advisers
  - Revising sections based on feedback
- Testing content with panel of adults (including psychologists, cancer support staff, nurses, cancer survivor and spouse of cancer survivor).
- Linking sections together and applying the changes to larger sections until full website developed.
Chapter 5. Designing the website

5.3. Intervention structure

According to Danaher, McKay, and Seeley (2005) the information architecture (IA)—the structure of website information—is a key factor that is often overlooked in the design of behaviour change websites. The REFRESH programme utilises a hybrid IA design. The user starts out by accessing an initial Web page that contains a welcome and access to a sign-up page. Following the initial sign-up, participants will read about the benefits of engaging in a behavioural support programme.

Logging-in enables access to a page that provides matrix-like access to four content areas. Participants will be welcomed to the intervention site, where they will be able to find out more about the website in general. The user has free access to five different pages from the home page (a matrix design). This matrix design is also used on the “My sessions” and “Useful content pages”. However, on the “My sessions” page the user can choose to enter a program composed of a series of sequential steps (a tunnel design). This design permits the user to explore content while still maintaining the focused forward movement of the tunnel program during the CBT sessions (Danaher et al., 2005). The pages that use a tunnel design require few navigational controls other than the “back” and “next” buttons. Ancillary pages provide links to Web page resources outside of the programme, however these are programmed to open in a new tab to ensure that users do not need to leave the website to gain extra information. This design was used to facilitate user autonomy. The overall website structure and the sessions are shown in Figure 5.2.

Given the structured nature of traditional CBT, some tunnelling is necessary. A linear model is better suited for multi-session programs in which users are assigned tasks to do in between online sessions. This model also allows for an incremental increase in the amount of information and BCTs a user is exposed to, increasing the likelihood that the user learns and potentially uses the strategies. Ancillary pages in the hybrid design can enable the user to
Chapter 5. Designing the website

customize their experience, seeking out extra information if they choose and not being constrained by the tunnel design. Hybrid designs offer the user alternative (and potentially more engaging) ways of interacting with, or re-visiting content (Danaher et al., 2005). It was decided that this structure would be attractive as well as usable based on the reported preferences of participants in the qualitative study.
Chapter 5. Designing the website

Figure 5.2. Design Architecture of REFRESH website
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5.4. Page Design

Factors such as page/screen layout were also considered as participants encouraged consideration of the fatigue experienced by users. Content was to be clear and concise, in simple user-friendly language. The sessions were short in length and a brief amount of text was displayed on each page. Participants’ answers were saved to re-load at the end of each page so that participants could pick up where they left off if they have to logout or take a break during a session. “Next” buttons and “Back” buttons on pages were positioned in the same place on each page. Attempts were made to fit what needs to be conveyed on a page so that end-users would not need to scroll down if possible. Links to external websites were either available in folders external to the tunnelled sessions or appeared as pop-ups in a new tab in order to allow users to come back to the intervention easily. Other non-essential information was presented as an optional feature that facilitated autonomy by allowing interested users to seek out supplementary materials if they wished to do so.

People do not tend to read long pages of text in online interventions (Yardley, Morrison, Andreou, Joseph, & Little, 2010). Participants often scan the page, picking out individual words, sentences, or images. To improve clarity, short concise sentences were presented in a large, clear font styles. Text was chunked into short paragraphs to make the page feel less text heavy. Lots of empty space (e.g. between borders and text) and bullet pointed message were used to break up text. Bold font was used to highlight the main points on the page, with main points at the top of the page. To break up text and reinforce meaning, as well as to reduce monotony, a variety of media were used to deliver the content. These included illustrations, text, animated videos with music and voiceovers, and the use of vignettes based on testimonials from qualitative research participants (LifeGuide, 2014).

The layout allows for easy navigation to each of the main sections of the site.
Chapter 5. Designing the website

Once logged in, each user was presented with a personalized “Home Page” that provides information about the last time the user logged in. The screen allowed for easy navigation to each of the main sections of the site: “Useful Content”, “Sessions” and “About the programme”.

- The Useful Content tab contained useful links that were relevant to participants (links to cancer support service websites etc.); and printable elements of the program such as diaries and tips.
- The “Information about the programme” tab offered information about how to contact the research team. A “Frequently Asked Questions” (FAQ) page addressed technical issues.
- A “What is REFRESH” tab provided a brief introduction to the system. A “Who made REFRESH?” tab that introduced participants to the research team involved in developing the programme.

The website includes useful supplementary links that are relevant to participants (links to cancer support service websites etc.). Participants could access information about how to contact the research team, a “Frequently Asked Questions” (FAQ) page addressing technical issues, and a “What is REFRESH” tab that provides a brief introduction to the system. The “Disclaimer” tab reminds users that the information provided is for educational purposes only and should not replace or override a physician’s care.

Every session follows a similar structure: objectives and outline, main content, review and todo list. This can be seen in Table 5.1. Each of the 8 sessions acts as an online analogue for the weekly sessions conducted in traditional in-person CBT. Every session is introduced by highlighting what would be learned and why it was important, in order to emphasise the gains of the intervention. Sessions would build from an initial explanation of the topic towards developing coping strategies and skills to deal with the issues faced. Practicing newfound
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skills is encouraged through the use of “To-Do” lists at the end of each session. Participants were congratulated on achievements and progress throughout the sessions.

In the Behaviour Change Model for Internet Interventions, Ritterband et al. (2009), address the appearance of the website. This relates to the look and feel of the application. In qualitative research, potential users emphasised the need to develop an attractive and engaging programme (Yardley et al., 2010). Therefore, aspects such as appearance and the use of colour were considered throughout the design process.
Table 5.1. *Structure of each session in the REFRESH programme.*

<table>
<thead>
<tr>
<th>Structure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objectives and outline</td>
<td>The objectives and outline provides a rationale for learning the material from that session by reminding participants what has been covered to date and addressing the questions, “What will I learn in this session?” and “Why is this session important?”</td>
</tr>
<tr>
<td>Main content</td>
<td>Each session typically requires 30-45 minutes to complete. The main content screens for each session address a unique aspect of fatigue through a variety of interactive features, including vignettes, images, videos and interactive questions. “Learn more” buttons provide in-depth information about a topic by opening a pop-up window. “Key words” are highlighted in the text and definitions of these new concepts are presented in a box on the side of the page.</td>
</tr>
<tr>
<td>Summary</td>
<td>Every session has a summary page that provides a review of the 10 main points presented in the session.</td>
</tr>
<tr>
<td>Recap questions</td>
<td>A short recap quiz that prompts participants to reflect on what they learned in each session.</td>
</tr>
<tr>
<td>To-do list</td>
<td>Each session ends with a “To-Do List” page that reminds participants about the skills they have learned and how to improve fatigue coping skills in the coming week.</td>
</tr>
<tr>
<td>Well done!</td>
<td>Participants are congratulated on their progress to-date</td>
</tr>
<tr>
<td>Schedule next session</td>
<td>Participants are asked to schedule a time and date to receive an email reminder for their next session.</td>
</tr>
</tbody>
</table>
Chapter 5. Designing the website

Individuals emphasised the need to promote credibility to encourage use of the website. Source credibility was established by promoting a combination of trustworthiness and expertise. Participants were invited to read about the expertise of content developers. Content was presented in a friendly-style to promote likeability. The website logo reflects the design of awareness ribbons often associated with cancer awareness. The university colours (white, purple, and green) would be used in the logo (See Figure 5.3.). Logos of the university and the cancer charity that co-funded the research straddle the website logo. A white, purple, and green colour scheme was also used throughout the website design.

![REFRESH website logo](image)

Figure 5.3. REFRESH website logo

5.5. Usability Testing

Inductive qualitative research was conducted at this stage to answer questions relating to users’ engagement with an intervention, how acceptable the intervention is to users or why users might fail to adhere to the intervention (Bradbury et al., 2014). Usability testing was employed to further develop and improve the website by assessing preliminary functionality, acceptability, usability and engagement (Michie et al., 2012; Yardley et al., 2010). The data was analysed to examine beliefs of the users and information about specific content, format, and navigation-related feedback. This feedback was used to modify the relevant components of the intervention (Michie et al., 2012).
Chapter 5. Designing the website

Users were asked to ‘think aloud’ to enable the team to identify problems people might experience when working through the intervention (e.g. navigational difficulties or potential adverse reactions) (Yardley et al., 2015; Yardley et al., 2010). Participants (a testicular cancer survivor and a nurse) were presented with draft webpages and asked to comment on their reactions to every aspect of the intervention, focusing on the helpfulness of information provided, comprehension and ease of use (Yardley et al., 2015).

Other participants used the intervention alone as an end user and completed a survey about their experiences after completing some or all of the intervention. These participants included a cancer care assistant, a spouse of a cancer survivor with fatigue and 2 PhD students studying Health Psychology. This was to gather information about how people use the programme in the absence of a researcher. Participants were asked to note any aspects that they found particularly beneficial or not useful, easy to use or problematic and aspects which they particularly enjoyed or disliked (Bradbury et al., 2014).

The team encouraged users to provide critical feedback to guide improvements to the programme (Hinchliffe & Mummery, 2008; Yardley et al., 2015). Major changes to the intervention were not required at this stage. Some minor modifications were incorporated, and pages were re-drafted (See Table 5.2.).

5.6 Conclusion

Chapters 4 and 5 have described the development of REFRESH, an online CBT-based intervention for CrF after the completion of cancer treatment. The intervention was developed through the systematic application of theory, evidence, and user-testing (Michie et al., 2012). Despite being a complex and multifaceted intervention, transparency was sought by detailing the components of the intervention, the proposed mechanisms of change. Efforts were made to reduce the ‘black box’ criticism of interventions (Craig et al., 2013; Michie et
Chapter 5. Designing the website

al., 2012) by offering a clear description of the intended intervention, and how it is expected to work, prior to its evaluation (Moore et al., 2015).

The co-creation of the intervention with the experts and service users allowed the design team to ensure that an acceptable intervention was developed. Involving users from the target group at the design stage can significantly contribute to the development of interventions by highlighting aspects of the design that would have otherwise been missed (Foster, Calman, Grimmett, Breckons, Cotterell, & Yardley, 2015; Owens et al., 2011).

This evidence-based online programme is the first intervention of its kind based on SRM theory, with the primary aim of targeting the representations of fatigue and enhancing self-management of CrF specifically. It also provides the first systematic coding of a CBT intervention using the BCT taxonomy (v1). The content is based on CBT and provides evidence-based self-management strategies in addition to education and information provision.

Table 5.2. Changes to website design identified by user-testing

<table>
<thead>
<tr>
<th>Change</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change bright purple border around buttons. Use darker shade.</td>
<td></td>
</tr>
<tr>
<td>Use of bold font to emphasise key points and improve design.</td>
<td></td>
</tr>
<tr>
<td>Fix formatting issues relating to content layout.</td>
<td></td>
</tr>
<tr>
<td>Some videos not working, voiceover volume low.</td>
<td></td>
</tr>
<tr>
<td>Include an instruction video to introduce the site.</td>
<td></td>
</tr>
<tr>
<td>Change unhelpful jargon and terminology</td>
<td></td>
</tr>
<tr>
<td>Some typos identified</td>
<td></td>
</tr>
<tr>
<td>Remind people to scroll down on pages where it is necessary to do so</td>
<td></td>
</tr>
<tr>
<td>Email reminder should contain a link to the website for easy access.</td>
<td></td>
</tr>
<tr>
<td>Ensure that email reminders are sent on time</td>
<td></td>
</tr>
<tr>
<td>Increase font size in some parts of the website.</td>
<td></td>
</tr>
</tbody>
</table>
Chapter 6: Acceptability and Preliminary Feasibility of an Online Intervention for Post-Treatment Cancer Survivors with Persistent Fatigue

6.1. Introduction

This chapter describes a 2-armed randomized controlled trial that was designed to study the feasibility of an online intervention that aims to reduce the impact of fatigue in post-treatment cancer survivors (Moher et al., 2012).

A systematic review of the literature, described in Chapter 2. (Corbett et al., 2015) revealed that the most commonly used intervention strategies were CBT, mindfulness-based interventions and psycho-education. While no single intervention type emerged as superior in this review, and a decision (based on the quality and quantity of existing literature, as well as clinical expertise) was made to base the current intervention on CBT.

As outlined in Chapter 3. qualitative focus group research indicated that the participants’ descriptions mapped onto the Self-regulation Model of Health and Illness (SRM) (Leventhal & Diefenbach, 1991). The study demonstrated the complexity of the individuals’ meaning-making processes and identified specific factors that were important issues for those with CrF. This qualitative research indicated that the SRM could be applied to CrF in post-treatment cancer survivors and provides a theoretical framework for understanding individuals’ representations, and coping strategies, and thus identifying targets for intervention (Hudson et al., 2016; Skerrett & Moss-Morris, 2006).

CBT models focus on similar cognitive, emotional, and coping/behavioural factors as those outlined by Leventhal in the SRM (H. Leventhal et al., 1997). Using the SRM to describe fatigue after cancer provided an integrated theoretical model for developing interventions for fatigue based on cognitive–behavioural principles. The description of how this intervention was designed is outlined in Chapter 4. and Chapter 5 of this thesis.
Chapter 6: Acceptability and Preliminary Feasibility

The intervention aimed to build upon previous studies that have employed internet-based self-management programmes (Foster et al., 2015; Moss-Morris et al., 2012; Yun et al., 2012), while applying a novel theoretical approach that addresses both individuals’ understanding of, and coping with, CrF. The study employed Roth and Pilling’s competence framework for cognitive behavioural therapy for those with persistent physical health conditions (Roth & Pilling, 2008). Adjustment to fatigue was a primary focus of the intervention, with cognitive, behavioural, affective, and social responses being addressed (Moss-Morris, 2013). This evidence-based online programme was the first intervention of its kind based on the self-regulation model (SRM), with the primary aim of targeting the representations of fatigue and enhancing self-management of CrF specifically. The study also provided the first systematic coding of a CBT intervention using the BCT taxonomy (v1) (Craig et al., 2013). This was to reduce the ‘black box’ criticism of complex interventions (Craig et al., 2013) by providing a transparent description of the intended intervention, and how it is expected to work (Moore et al., 2015).

An online intervention designed using a theoretical, systematic and person-based approach may be successful in reducing the effects of fatigue in post-treatment cancer survivors. The hypothesis was that targeting cognitive and emotional representations of symptoms would lead to improvements in coping skills and in turn, reduce fatigue levels. These processes may be moderated by cancer-related factors (e.g. diagnosis, treatment type, time since treatment) and demographic factors (e.g. gender, socioeconomic circumstances, education).

The end-goal of this research is to improve functioning, and to enable the participants to make meaningful changes in their daily lives, rather than symptom reduction per se. The aim was to determine the feasibility of the “REFRESH (Recovery from Cancer-Related Fatigue)” intervention trial. The study also assessed the potential for the intervention to impact fatigue and proposed mediating factors in cancer survivors.
Chapter 6: Acceptability and Preliminary Feasibility

Once the intervention was considered acceptable to users in the initial testing phase, the researchers began to create a protocol for a feasibility study, a small scale randomised clinical trial (RCT). This study was designed to test the processes of carrying out a larger trial and to make final refinements to the intervention before its effectiveness is tested in a fully powered RCT (Arain, Campbell, Cooper, & Lancaster, 2010; Bradbury et al., 2014; Hoddinott, 2015). Further issues that may need to be addressed include training and support for end-users and communication or management structures (Moore et al., 2015). It is also necessary to assess the “reach” of the intervention (whether the intended audience comes into contact with the intervention, and how) (Glasgow, McKay, Boles, & Vogt, 1999).

6.1.1. Specific objectives

1. To conduct an evaluation of the feasibility of the intervention, looking at
   i. Recruitment (number of patients approached about the study, source of referral to the study, number consenting to participate and those eligible to be randomised)
   ii. Adherence and attrition to the intervention
   iii. Drop out from trial (i.e. follow-up questionnaires not completed)
   iv. Evaluation of functionality, acceptability and usability of website
   v. Participant satisfaction with the website.

2. To assess the potential efficacy of the “REFRESH programme” in adult survivors of cancer. Changes in fatigue will be assessed by comparing intervention and wait-list control groups at baseline and post-intervention in terms of the following outcome:
   i. Fatigue (primary outcome) - assessed using the Revised Piper Fatigue Scale (PFS-R) (Reeve et al., 2012).
   ii. Quality of Life (secondary outcome), as measured using the Quality of Life in Adult Cancer Survivors (QLACS) Scale.

3. To explore change in potential therapeutic mechanisms of change in relation to
Chapter 6: Acceptability and Preliminary Feasibility

fatigue outcomes. Changes will be assessed by comparing intervention and wait-list control groups at baseline and post-intervention in terms of the following outcomes:

i. Illness perceptions relating to CrF.

ii. Cognitive-behavioral coping strategies used in the management of fatigue.

iii. Coping with fatigue.

6.2. Ethical approval

This design and testing of the trial was approved by the Research Ethics Committee at National University of Ireland Galway in January 2013 (See Appendix 3.). Full written informed consent was sought from all participants for both their participation and the publication of the results of the research (See Appendix 10). Participants were reminded that they were free to withdraw at any time and that their data would be stored securely and anonymously. All data was stored on password protected hard drives in accordance with the Data Protection Act. All data was anonymised.

6.3. Method

The study was an exploratory, parallel-group pilot randomised controlled trial to determine the feasibility, potential effectiveness (as assessed using Piper Fatigue scale (Reeve et al., 2012) and acceptability of an online CBT intervention for cancer-related fatigue called REFRESH (Recovery from Cancer-Related Fatigue). The study protocol for this intervention has been published elsewhere (Corbett, Walsh, Groarke, Moss-Morris, & McGuire, 2016)

The study included 2 parallel conditions: experimental condition (online CBT for fatigue) and a wait-list control condition.

1. Wait-list control condition: Participants in this group were provided with a widely available leaflet comparator developed by the Irish Cancer society, called “Coping with Fatigue” (available online as a pdf) (Walker, 2013). This booklet is currently widely available as a
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source of information about fatigue.

2. Experimental condition: The intervention group accessed an interactive CBT for CrF intervention (REFRESH). Participants were asked to complete a session each week for 8 weeks. Assessments were conducted at baseline and immediately after intervention (at 10 weeks).

6.3.1. Inclusion and Exclusion Criteria

Participants were eligible for the study if they

1. Were over 18 years of age,
2. Had completed primary treatment with curative intent for non-metastatic cancer at least 3 months prior to baseline assessments
3. Were experiencing fatigue defined as scoring $\geq$4 on a unidimensional 11-point numeric rating for fatigue as suggested by the National Comprehensive Cancer Network (Mock et al., 2000),
4. Were able to complete written records in English,
5. Had or are were to create an email account and have access to the internet,
6. Had access to, and basic ability to use a computer
7. Had completed primary treatment for cancer (patients were eligible for the study if they were receiving maintenance therapy such as hormone therapies) at least 3 months prior to baseline assessment (Goedendorp et al, 2013)

Patients were excluded if they:

1. Did not provide informed consent or refuse to be randomized.
3. Did not confirm that they have received medical clearance for participation.
4. Were currently participating in any other psychosocial intervention for cancer survivors.
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6.3.2. Recruitment

The aim was to recruit a total of 80 Irish cancer survivors to be randomized to receive the intervention or usual care. Recruitment took place from September 2015- March 2016.

Online Recruitment

An online recruitment strategy ran separately and concurrently with the rest of the research recruitment campaign in order to broaden exposure (Yuan, Bare, Johnson, & Saberi, 2014). Social media sites were used to target cancer survivors engaged in online activity. Use of popular existing social network sites were expected to address issues of reach, engagement, and retention (Maher et al., 2014). Online social networks have been found to typically achieve high levels of user engagement and retention. Social media enables the researcher to actively generate engaging and novel content, which is likely to be more influential than traditional static and passive websites (O'Connor, Jackson, Goldsmith, & Skirton, 2014). They are a cost-effective means of recruitment that may engage potentially difficult-to-reach groups, providing participants a more accessible method by which to participate in health research (O'Connor et al., 2014). These websites informed potential participants of the study and provided a link to the survey.

i. WordPress® was used to develop a host website for the study. Participants were able to access the participant information sheet and links to the online questionnaire on this site. Another page gave a description of the study investigators. Pictures and engaging content were posted to build rapport and credibility with the audience (Yuan et al., 2014).

ii. A Facebook® fan page was created to recruit participants and raise awareness of the study (Yuan et al., 2014). Posts included study announcements, links to the WordPress® website, pictures, and videos featuring the primary researcher discussing the project. Posts were scheduled in advance, with about a new post per
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day during the recruitment period. Other Facebook fan pages with similar purpose
or interest were interacted with, by “liking” these organizations’ pages, which
were found using keyword searches for cancer, oncology and health care.
“Facebook Adverts ©” were used to advertise the study to a large number of social
media users.

iii. Twitter® was used to target individuals using short messages (tweets) to share
online material including links to the REFRESH WordPress® website. Users were
encouraged to share (i.e. ‘retweet’) these messages with their own followers
(O’Connor et al., 2014). Stakeholders and key influencers were targeted in
particular. These include patient advocates and healthcare professionals.
Organizations affiliated with cancer survivorship were ‘followed’. Hashtags (#)
related to cancer, fatigue and related topics were used to reach a large audience of
potential participants (Yuan et al., 2014).

iv. LinkedIn® groups that included content related to cancer survivorship were used
to reach potential participants. Again, these messages targeted those people living
with CrF, cancer survivorship advocates, and healthcare professionals working in
oncology and psycho-oncology, and other researchers. Group members were
asked to share the survey link with other potentially interested groups or
individuals (Yuan et al., 2014).

Offline Recruitment

The offline recruitment strategy centered on interaction with community organizations and
leaders (UyBico, Pavel, & Gross, 2007). Cancer support groups and national cancer charities
and organizations were contacted and asked to promote the study. Researchers also recruited
in-person at the Irish National Cancer Survivorship Conference in September 2015.
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Media outlets were contacted via press releases (See Appendix 11) with information about the study being promoted nationally in press and on the radio. Printed advertisements (such as leaflets) were distributed in local pharmacies and coffee shops (See Appendix 12).

Health system recruitment was also employed, given the importance of physician referrals as gatekeepers to patient research recruitment (UyBico et al., 2007). General practitioners and health care professionals were informed about the study. They were encouraged to share the information with any patients who may benefit from participating in the research (See Appendix 13).

6.4. Trial procedures

Interested participants were invited to access a recruitment website hosted on WordPress®. This website provided details about study procedures and inclusion/exclusion criteria. After reading this information, participants were invited to complete baseline assessments using an online survey tool (Survey Monkey®). Participants were then required to provide informed consent outlining their awareness of the trial protocol. Any participants who did not meet the inclusion/exclusion criteria following baseline assessment were excluded from the study.

6.4.1. Randomization and blinding

Upon completion of the baseline questionnaire, participants were randomised in a 1:1 ratio to receive either the REFRESH intervention, or a leaflet comparator. Participants were randomised in blocks of six, using a computer-generated number sequence that was created a priori using Random.org (Haahr, 2006). An independent research assistant emailed participants to inform them of their group allocation. The research team was made aware of group allocation in advance of the half-way contact point with participants. The nature of the trial is such that blinding of participants could not be achieved. No changes in assignment were possible. Figure 6.1 shows the flow of participants through the trial.
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6.4.2. Control group/usual care

The control group received an online copy of a booklet with brief general recommendations about fatigue management that was developed by the Irish Cancer Society, *Coping with Fatigue* (Walker, 2013). This contained some general information about CrF. After completion of this study, control participants were given the opportunity to access the *REFRESH* program. Online user data gathered in the post-assessment period was analysed to evaluate user processes such as engagement, and dose of intervention received (Moore et al., 2015).

6.4.3. Intervention

The intervention was a web-based online program that can be accessed from any location or device with Internet access (Yardley et al., 2009). The purpose of this intervention was to target individuals’ illness representations and coping strategies in order to facilitate coping with CRF (See Chapters 4 and 5 for further information on intervention content and design). The *REFRESH* intervention was created with the goal of providing participants with a user-friendly, engaging and effective online environment while affording them the opportunity to learn more about their fatigue symptoms and management.

6.4.3.1. Procedure of the intervention

Participants in the intervention group were asked to sign-up for the *REFRESH* programme with their email and unique password. New users received instructions on the “About *REFRESH*” page before logging in. The page included an introduction to the aims of CBT and step-by-step instructions for how to navigate the programme.

Participants were expected to complete one session per week for 8 weeks. Each session was expected to take approximately 45-60 minutes to complete. The online intervention was accessed through the main welcome page. Participants were encouraged to challenge
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cognitions and learn to prioritize certain behaviours in order to maintain a healthy energy balance.

*REFRESH* included a range of behaviour change techniques (BCTs) designed to enhance relevant information, motivation and behavioural skills. The programme utilised accessible and engaging delivery methods, in line with Ritterband’s theory of online interventions (Ritterband et al., 2009).

6.4.3.2. Telephone calls

The effectiveness of Internet-based interventions have been found to be enhanced by the use of additional methods of communicating with participants (Webb et al., 2010). A semi-structured interview guide was followed in each of these calls (See Appendix 14). The structure was outlined in a manual to enable replication. The calls were made by the primary researcher who has a background in Health Psychology and experience in working with patient groups. Every participant (in each group) received one phone call after 4 weeks of the programme (i.e. half-way). Each phone call lasted approximately 15-20 minutes. For the intervention group, the aim of these calls was to solve any problems with the sessions or content. Also, messages of encouragement were given to stimulate adherence to the program. The WLC group were called to remind them that they can gain access to the programme in the weeks that follow. Calls were audio recorded and checked for fidelity.

The content of these calls was transcribed so that the information provided could also be used to guide improvements for future iterations of the website (Yardley, 2015).

6.4.3.3. Intervention fidelity

A content manual was been developed to accompany this intervention. The ‘Intervention Manual’ described and defined the programme components for each module (See Appendix 17). The website included features to monitor adherence and completion rates of each
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module by each user. Individual factors which may affect fatigue and/or energy level (medication-use, comorbidities, physical disability etc.) were documented for both control and intervention groups.

6.5. Follow-up Measurement, Assessment and Outcomes

6.5.1. Timing of assessments

Participants were recruited and assessed at baseline from October 2015- March 2016. Outcomes were self-reported at baseline (T0), post-intervention (T1). Follow-up data was collected upon completion of the trial, 10 weeks post-baseline. Additional qualitative feedback was obtained through explorative open-ended questions at T1 for participants in the experimental condition. After completion of follow up assessments at T1, participants in the control condition were offered the experimental intervention. Participants (intervention and control group) continued to have access to the REFRESH programme for 2 months following completion of follow-up questionnaires.

6.5.2. Methods for dealing with loss to follow-up

This trial aimed to assess attrition rates for a future larger RCT. In order to reduce loss-to-follow up, the researchers aimed to foster trusting relationships, helping the participants to feel engaged in the research process (Bradbury et al., 2014; Maher et al., 2014). All participants were contacted via telephone in the fourth week of the programme to enhance this relationship. Familiarity with the researchers was promoted through the use of familiar and consistent voices on the narration of videos used in the online programme. Participants were able to access a page entitled “About us”, which included photographs and brief biographies of each the researchers.

Participants were reminded of their commitment to the programme at the outset of the intervention in order to promote a sense of self-responsibility (Morrison, Yardley, Powell, &
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Michie, 2012). Participants were congratulated upon completing a module in order to boost self-esteem and garner a sense of achievement (Morrison et al., 2012). At the end of each session, participants selected a time to receive one prompt email to continue to the next session in the week that follows. Emails that participants received throughout the trial can be seen in Appendix 15.

6.5.3. Outcome measurements

Assessments were undertaken online (See Appendix 16). Assessors of outcomes were blinded to group allocation until after baseline measures had been completed.

*The primary goal of this study was to assess the feasibility and functionality of an online CBT programme for this sample. Therefore, the following outcomes were assessed.*

I. Recruitment and uptake

II. Adherence and attrition

III. Evaluation of functionality and usability of website

IV. Participant satisfaction with website.

This feasibility trial aimed to provide insight into the way *REFRESH* is used by participants. Information on intervention uptake, delivery and experience were collected. Delivery and uptake were determined by assessing initial uptake to the programme and participation in each of the sessions.

Adherence to, and engagement with, the programme was also assessed. The ‘engagement’ of participants was assessed using data relating to pages visited and time spent on each page, collected via LifeGuide (Yardley et al., 2009). This data was used to gain a sense of how participants engaged with the programme. Criteria for assessing engagement for each individual were set *a priori* as:
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- Active participation in 90% of at least 4 of the REFRESH sessions.
- Completion of exercises within the sessions
- Level of engagement with course materials.

The Internet Evaluation and Utility Questionnaire was used to measure participants’ experiences and perceptions of the intervention. This measure has two main sections – generic and specific. In an earlier and shorter version of this measure (Thorndike et al., 2008), good internal reliability was found (α= .69). Patients respond to the questions on a 5-point Likert scale from 0 (“not at all”) to 4 (“very”), with 2 open-ended items requesting patients to identify “most helpful” and “least helpful” parts of the web program.

- The first 15 questions make up the generic section. The constructs measured by items 1-8 include ease of use, convenience, engagement, enjoyment, layout, privacy, satisfaction, and acceptability.
- Items 9 to 15 assess perceptions of the web program material in terms of usefulness, comprehension, credibility, likelihood of returning, mode of delivery, and helpfulness.
- Following these 15 items are questions specific to the REFRESH intervention.

Open-ended questions were also asked of all participants at follow-up to obtain further qualitative data on the barriers and facilitators to participation as well as to understand the experience of participating. These questions were included at the end of the follow-up questionnaire. Those who withdrew from the intervention were invited to participate in an exit interview/debrief with the principal investigator.

To assess the effectiveness of the “REFRESH (Recovery from Cancer-Related Fatigue) intervention” in long-term adult survivors of cancer, by comparing intervention and wait-list control groups:
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Primary outcome: Fatigue was measured using the Piper Fatigue Scale (revised) (PFS-R) (Reeve et al., 2012). This scale assesses adjustment and interference of fatigue. The scale is multidimensional and incorporates key dimensions of the fatigue experience including cognition, behaviours, affect, and sensory symptoms (Piper et al., 1998).

The revised PFS-R consists of 22 items measured on a 10-item numeric rating scale items. Higher mean scores represent greater fatigue. Four open-ended questions were also included as descriptive items. Reported Cronbach alphas have ranged from 0.98 for the total scale and 0.94 for subscales in women with fatigue after cancer treatment (Kluthcovsky et al., 2012) indicating good internal consistency. Research has demonstrated good psychometric properties, with high concurrent validity with the FQ (r=.80) and good test–retest reliability results (r=.98) (Dittner, Wessely, & Brown, 2004). The scale has been validated in a group of cancer survivors (Minton & Stone, 2008). This multidimensional measurement model is in keeping with the theoretical framework being assessed in the intervention, as well as reflecting the complex nature of the fatigue experience (Ahlberg, Ekman, Gaston-Johansson, & Mock, 2003). The scale is cited by the NCCN guidelines for the management of CrF as a commonly used scale (Mock et al., 2000).

6.4. 4 Secondary outcome:

Quality of Life was measured using the Quality of Life in Adult Cancer Survivors (QLACS) questionnaire (Avis et al., 2005)

The QLACS is a multi-dimensional measure with 47 items that assess 12 QOL domains. It includes: negative feelings; positive feelings; cognitive problems; pain, items; sexual interest; energy/fatigue; sexual function; social avoidance; financial problems; benefits; distress-family; appearance; and distress-recurrence. Participants are asked to rate how often they felt a certain way in the past 4 weeks (never, seldom, sometimes, about as often as not,
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frequently, very often, always). The scale is validated in a range of cancer types (Pearce, Sanson-Fisher, & Campbell, 2008) and has good internal consistency reliability, and adequate concurrent and retrospective validity (Avis, Ip, & Foley, 2006). Sohl et al (2015) concluded that the QLACS is consistent with other widely accepted measures in capturing QoL, while also assessing specific issues relevant to post-treatment cancer survivors.

To assess the relationship between therapy process and outcomes

In line with the recommendations of the competence framework for psychological interventions with people with persistent physical health conditions (Roth & Pilling, 2008), this trial also incorporated measures that aimed to further explore the relationship between therapy process and outcomes. Drawing on the theory of the self-regulatory model of illness (H. Leventhal et al., 1997) the following outcomes were also assessed:

Illness Perceptions Questionnaire for Cancer-Related Fatigue

The Illness Perceptions Questionnaire for Cancer-Related Fatigue (IPQ-CrF) was used to assess perceptions relating to CrF Cognitive and Emotional Representations. The IPQ-R for CrF (Pertl, Hevey, Donohoe, & Collier, 2012) is adapted from the IPQ-R (Moss-Morris et al., 2002). The scale is divided into three sections. Section A assesses CrF identity and asks respondents to report (a) whether they have experienced each of a list of 14 commonly experienced core symptoms and (b) whether they believe each of these symptoms is specifically related to their CrF using a yes/no response format. The list of symptoms included in the identity dimension is tailored to CrF by including 12 symptoms specifically associated with this condition based on the CrF diagnostic criteria (Pertl et al., 2012)

Section B contains 38 items that assess the timeline acute/chronic, timeline cyclical, consequences, personal control, treatment control, illness coherence, and emotional representation dimensions (Pertl et al., 2012). These items consist of statements that are rated
on five-point Likert scales ranging from 1 (strongly disagree) to 5 (strongly agree). The mean of the subscale items measures that illness dimension. Section C is concerned with the cause dimension. Respondents indicate whether they believe each of a list of items cause or contribute to their fatigue using the same five-point Likert scale. The scale has been validated on cancer patients and survivors (Pertl et al., 2012).

*Cognitive and Behavioural Responses to Symptoms Questionnaire*

The Cognitive and Behavioural Responses to Symptoms Questionnaire (CBSQ) was used to assess which cognitions and behaviours mediate the effect of cognitive behavioural therapy on fatigue in this group. The CBSQ consists of two behavioural subscales and five cognitive subscales. These subscales measure aspects of the response to (or coping strategy employed to manage) symptoms. The CBSQ subscales have an acceptable internal reliability. The scale has previously been used in MS patients (Knoop et al., 2012). All items are scored on a five-point frequency scale ranging from never (0) to all the time (4). Item scores are added from each subscale to obtain a total score (Knoop et al., 2012). The scale includes “Cognitive Subscales” which assess interpretation of the symptoms. These include: fear avoidance catastrophising, damaging beliefs, embarrassment avoidance and symptom focusing. It also includes “Behavioural Subscales” which measure all-or-nothing behavior (tendency of patients to overexert themselves, followed by periods of inactivity) and avoidance/resting behaviour.

*Appraisal of Coping*

The Coping Efficacy Scale (Zautra & Wrabetz, 1991) Coping efficacy was measured to assess respondents’ appraisal of coping with fatigue. Participants will be asked “How satisfied are you with how you coped with your fatigue?” referring to the past week. The second item will be, “If you had similar symptoms again, how certain are you that you would be able to adjust well to its negative aspects?” referring to the past week. Participants were
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asked to indicate on a 5-point Likert scale about how certain they were that they could cope with similar symptoms in the future. The scores of these items will be averaged to produce one composite score of coping efficacy. A score of 1 indicated low coping efficacy and 10 indicated high coping efficacy. Evidence for the validity of these measures of coping efficacy is strong (Johnson, Zautra, & Davis, 2006; Zautra & Wrabetz, 1991)

Demographic and cancer-related information

Baseline data in future, fully-powered iterations of the trial, could be used to explore possible moderating variables (individual demographic factors and medical-related factors). Demographic (age, gender, marital and employment status) and medical information (cancer type and treatment, time of diagnosis and treatment, comorbid medical conditions) were obtained via self-report.

6.6. Sample size for feasibility trials

The primary aim of this study was to assess initial uptake of the study and following attrition. Figure 6.1. shows the flow diagram of the study participants. This research sought to investigate how the intervention was delivered, as well as how it might be replicated and improved upon (Moore et al., 2015).

In line with guidelines for the calculation of sample size in pilot studies by Viechtbauer et al. (2015) an estimated sample size of 59 cancer survivors would be required for the identification of unforeseen problems, such as ambiguities in description of the trial or eligibility criteria, or misinterpretations of questionnaire items. If a problem was likely to occur with 5% probability in a participant, the issue would be identified (with 95% confidence) in a pilot study including 59 participants (Viechtbauer et al., 2015).

This research did not assess Cronbach’s alpha for the individual scales used. This was a feasibility trial that aimed to assess the processes of carrying out a larger trial. Assessing the
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reliability of the scales in a pilot study with a larger sample is likely to yield more useful information for future large RCTs of this intervention (Schmitt, 1996; Walter, Eliasziw, & Donner, 1998).

Mechanisms of impact and effectiveness were not assessed in this instance as a sufficient number of participants were not recruited (Moore et al., 2015). According to G*power (Faul, Erdfelder, Lang, & Buchner, 2007) 54 participants would be required to demonstrate statistically significant group differences over time at the .05 level (d=.25).

A mediational analysis exploring whether the effect of the intervention on the primary outcomes was mediated by illness perceptions and cognitive behavioral strategies using the analytic framework recommended for RCTs was not undertaken as the study was underpowered due to the small sample size.

6.7. Statistical analyses

Hypothesis tests were carried out at the 5% level for primary and secondary outcomes. All analyses were planned a priori and are reported in full. The primary comparative analysis was conducted on an intention-to-treat basis.

Means and standard deviation were used to represent the variable scores at baseline and follow-up measurements.

Initially, possible differences between groups at baseline were assessed using a one-way analysis of variance for continuous data (or equivalent statistical approach in the case of non-parametric data) and Chi-square for categorical data.

Comparisons of outcome measures were undertaken at baseline and 10 weeks for all available measures. Between-group comparisons will be made using a 2 (group) x 2 (time) mixed ANOVA.
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Although the trial was not powered to detect the influence of mediating and moderating factors on fatigue, we sought to explore patterns in the following secondary analyses:

(i) to investigate possible differences in intervention effects on the primary outcome by demographic and cancer-related factors;

(ii) engagement with REFRESH was determined and a comparison between those who meet the criteria for engagement versus those who do not was undertaken to assess ‘per protocol’ effectiveness;

6.8. Data Management and Access

The data was saved online through Surveygizmo (all questionnaires). This data was only accessible by the first author. When these data were collated, the co-authors also had access to the relevant data files. The data was saved in both .csv and .sav formats. These files were stored in encrypted Dropbox folders. In accordance with the NUI Galway data retention policy, these data will be retained for 5 years at the NUI Galway School of Psychology (as well as being backed up on Dropbox) and anonymised by replacing participant ID numbers and names with randomly generated subject ID numbers.

6.9. Results

6.9.1. Assessing the feasibility and functionality of an online CBT programme for post-treatment cancer survivors with persistent fatigue.

6.9.1.1. Recruitment and uptake

An overview of the reach and attrition of the intervention participants is provided in Fig. 2.

Chi-squared analysis did not reveal any differences across the groups in marital status; nationality; cancer type; whether healthcare costs were covered by either private health insurance or a medical card; employment status; how participants heard about the study; sex;
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highest level of education/training completed to date; or whether participants were currently receiving hormone therapy.

One-way ANOVAs did not indicate any differences between groups ANOVA in current age, Age at diagnosis (years); time (in months) is it since participants completed treatment for cancer; or number of comorbidities. Participants also did not differ in fatigue scores (the primary outcome) at baseline. The sample demographic and disease-related characteristics at baseline are displayed in Table 6.1.
Figure 6.1. Flow of participants through the REFRESH randomised controlled trial
### Demographic and disease-related characteristics at baseline

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>4</td>
<td>10.0</td>
</tr>
<tr>
<td>Female</td>
<td>36</td>
<td>90.0</td>
</tr>
<tr>
<td><strong>Nationality</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irish</td>
<td>34</td>
<td>85.0</td>
</tr>
<tr>
<td>British</td>
<td>4</td>
<td>10.0</td>
</tr>
<tr>
<td>American</td>
<td>2</td>
<td>5.0</td>
</tr>
<tr>
<td><strong>Highest level of education/training</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary school</td>
<td>10</td>
<td>25.0</td>
</tr>
<tr>
<td>3rd level non-degree</td>
<td>11</td>
<td>27.5</td>
</tr>
<tr>
<td>3rd level degree</td>
<td>9</td>
<td>22.5</td>
</tr>
<tr>
<td>Postgraduate</td>
<td>10</td>
<td>25.0</td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Homemaker</td>
<td>2</td>
<td>5.0</td>
</tr>
<tr>
<td>Unemployed due to health</td>
<td>6</td>
<td>15.0</td>
</tr>
<tr>
<td>Unemployed seeking employment</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>Part-time employment</td>
<td>9</td>
<td>22.5</td>
</tr>
<tr>
<td>Full-time employment</td>
<td>15</td>
<td>37.5</td>
</tr>
<tr>
<td>Retired</td>
<td>5</td>
<td>12.5</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>5.0</td>
</tr>
<tr>
<td><strong>Relationship status</strong></td>
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<td></td>
</tr>
<tr>
<td>Single</td>
<td>10</td>
<td>25.0</td>
</tr>
<tr>
<td>In a relationship</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>Married/Living as married</td>
<td>22</td>
<td>55.0</td>
</tr>
<tr>
<td>Separated</td>
<td>5</td>
<td>12.5</td>
</tr>
<tr>
<td>Divorced</td>
<td>2</td>
<td>5.0</td>
</tr>
<tr>
<td><strong>Healthcare costs covered by either private health insurance or a medical card</strong></td>
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<td></td>
</tr>
<tr>
<td>Medical card</td>
<td>9</td>
<td>22.5</td>
</tr>
<tr>
<td>Private health insurance</td>
<td>25</td>
<td>62.5</td>
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<tr>
<td>Other</td>
<td>6</td>
<td>15.0</td>
</tr>
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</table>
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Table 6.1. *Demographic and disease-related characteristics at baseline (continued)*

<table>
<thead>
<tr>
<th>Age</th>
<th>Youngest participant</th>
<th>Oldest participant</th>
<th>Mean</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>26</td>
<td>82</td>
<td>49.6</td>
<td>12.7</td>
</tr>
</tbody>
</table>

**How did you hear about the REFRESH: Recovery from Cancer-Related Fatigue programme?**

<table>
<thead>
<tr>
<th>Source</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social media (Facebook)</td>
<td>8</td>
<td>20.0</td>
</tr>
<tr>
<td>Social media (twitter)</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>Newspaper</td>
<td>15</td>
<td>37.5</td>
</tr>
<tr>
<td>Flyer</td>
<td>2</td>
<td>5.0</td>
</tr>
<tr>
<td>A friend</td>
<td>10</td>
<td>25.0</td>
</tr>
<tr>
<td>A healthcare professional</td>
<td>4</td>
<td>10.0</td>
</tr>
</tbody>
</table>

**Before taking part in this trial, have you tried any other strategies to help you to manage your fatigue?**

<table>
<thead>
<tr>
<th>Answer</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>21</td>
<td>52.5</td>
</tr>
<tr>
<td>No</td>
<td>19</td>
<td>47.5</td>
</tr>
</tbody>
</table>

**How long (in months) is it since you completed your treatment for cancer?**

<table>
<thead>
<tr>
<th>Range</th>
<th>Mean</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.00- 56 months</td>
<td>17.08</td>
<td>13.5</td>
</tr>
</tbody>
</table>

**Type of cancer**

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast cancer</td>
<td>24</td>
<td>60.0</td>
</tr>
<tr>
<td>Prostate cancer</td>
<td>2</td>
<td>5.0</td>
</tr>
<tr>
<td>Other cancer type</td>
<td>14</td>
<td>35</td>
</tr>
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</table>

**Stage at diagnosis**

<table>
<thead>
<tr>
<th>Stage</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Don't know</td>
<td>8</td>
<td>20.0</td>
</tr>
<tr>
<td>Stage I</td>
<td>8</td>
<td>20.0</td>
</tr>
<tr>
<td>Stage II</td>
<td>12</td>
<td>30.0</td>
</tr>
<tr>
<td>Stage III</td>
<td>12</td>
<td>30.0</td>
</tr>
</tbody>
</table>
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Table 6.1. *Demographic and disease-related characteristics at baseline (continued)*

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiotherapy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemotherapy</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Hormonal therapy</td>
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<td></td>
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<tr>
<td>Brachytherapy</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Currently receiving hormone therapy?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Don't know/prefer not to say</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-menopause</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First time you have been treated for cancer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First time</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treated before for the same cancer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treated before for a different cancer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other long standing health condition</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Comorbidities</td>
<td>Minimum</td>
<td>Maximum</td>
<td>Mean</td>
<td>Std. Deviation</td>
</tr>
<tr>
<td>.00</td>
<td>8.00</td>
<td>1.3</td>
<td>2.01</td>
<td></td>
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</table>
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#### Table 6.1. Demographic and disease-related characteristics at baseline (continued)

<table>
<thead>
<tr>
<th>Number of Comorbidities</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>Arthritis/osteoporosis</td>
<td>3</td>
<td>7.5</td>
</tr>
<tr>
<td>Asthma or other chronic chest problem</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>Blindness or visual impairment</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>Chronic kidney disease (CKD), including End-stage renal disease (ESRD)</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>Deafness or hearing impairment</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>Depression</td>
<td>3</td>
<td>7.5</td>
</tr>
<tr>
<td>Diabetes mellitus (DM), Type 2</td>
<td>5</td>
<td>12.5</td>
</tr>
<tr>
<td>Heart condition (including Hypertension (or Coronary artery disease (CAD), ischemic heart disease (IHD) or history of myocardial infarction (MI) or History of stroke (CVA) or transient ischemic attack (TIA)</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>High blood pressure</td>
<td>3</td>
<td>7.5</td>
</tr>
<tr>
<td>Insomnia</td>
<td>3</td>
<td>7.5</td>
</tr>
<tr>
<td>Liver disease</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>Obstructive sleep apnoea (OSA)</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>Obesity</td>
<td>2</td>
<td>5.0</td>
</tr>
<tr>
<td>Restless leg syndrome</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>Long term back problems</td>
<td>4</td>
<td>10.0</td>
</tr>
<tr>
<td>Long-standing neurological problem</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>Another long-standing condition</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td><strong>Number of Comorbidities per individual</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>.00</td>
<td>25</td>
<td>62.5</td>
</tr>
<tr>
<td>1.00</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>2.00</td>
<td>5</td>
<td>12.5</td>
</tr>
<tr>
<td>3.00</td>
<td>4</td>
<td>10.0</td>
</tr>
<tr>
<td>4.00</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>5.00</td>
<td>2</td>
<td>5.0</td>
</tr>
<tr>
<td>6.00</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>8.00</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td><strong>Medications for any of the conditions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>12</td>
<td>30.0</td>
</tr>
<tr>
<td>No</td>
<td>28</td>
<td>70.0</td>
</tr>
</tbody>
</table>
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6.9.1.2. Attrition

In total, 40 cancer survivors were included for analysis at baseline (intervention \( N = 21 \), control \( N = 19 \)), and 24 participants filled out the follow-up questionnaire (40% dropout).

In order to identify significant predictors for dropout, a logistic regression analysis was conducted. The dichotomous criterion variable was loss to follow-up (yes/no), and the predictor variables were group (dummy coded intervention/control), age, education level, and time since treatment. A test of the full model with all predictors was statistically reliable (\( \chi^2 = 15.35 \) (\( df = 1 \), \( p < .001 \)), indicating that the predictor variables of age, education level and time since treatment reliably predicted those people who were lost to follow-up.

The model correctly classified 80% of participants. The variance in dropout accounted for was quite good with a Cox & Snell \( R^2 = .32 \), indicating that the model contributed to the prediction of dropout. Examination of the Wald statistics indicated that the group that participants were in (Wald = 12.26, \( p < .001 \)) significantly added to the model. In the control group 78.9% of participants were lost to follow-up. However, only 19.0% of the intervention group did not complete the follow-up questionnaires.

A Chi-Squared test was carried out to see if there was an association between other categorical variables and drop-out in both groups. The analyses revealed that marriage, nationality, cancer type or employment status were not associated with loss to follow-up. It was also found that there was no significant association between loss to follow up and whether participant healthcare costs were covered by either private health insurance or a medical card.

6.9.1.3. Adherence

The average number of sessions completed was 4.65 sessions. Forty percent of participants actively participated in 90% of 4 or more of the REFRESH sessions. Four participants
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(10.3%) completed all 8 sessions. These participants completed each of the exercises within the sessions and were found to interact with course materials, as assessed by examining user data downloaded from the LifeGuide website and also through participant descriptions of the intervention process.

In total 31 participants visited the website (both intervention group and WLC). Pearson’s Product-Moment correlation coefficient was conducted to see if a correlation between website use and continuous demographic variables existed. Chi-Squared tests were carried out to see if there was an association between categorical variables and website use. It was found that website use was correlated with group assignment ($\chi^2 = 4.27, p = .04$). The majority of the intervention group accessed the website (90.5%), whereas only 63.2% of the control group proceeded to access the intervention when given access.

The analyses revealed that marriage, nationality, cancer type healthcare coverage, or employment status were not associated with website use.

An independent-samples t-test was conducted to evaluate if participants visited the website more in the intervention group as opposed to those in the control condition who gained access at the end of the study period. The results showed that there was no significant difference in the number of sessions visited ($t(28) = .19, p = .85$). Participants in intervention group ($N=19, M=7.74$ sessions) accessed a similar number of sessions as those in the control group who chose to access the website ($N=11, M=4.55$ sessions). These groups did not differ in the days or times of the day that they visited the website. There was also no difference in the number of times each individual session was visited. Data relating to website use can be seen in Table 6.2.

6.9.1.4. Evaluation of functionality and usability of website
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As shown in Table 6.3, the website was generally evaluated positively by participants. The website design, content and layout were rated favourably. Participants found the website easy to use, interesting, informative, understandable and trustworthy (See Table 6.3). Several participants answered the open-ended questions with positive evaluations of the website and described features that were particularly helpful to them. These evaluations often referred to their own process of changing their perceptions of fatigue and appropriate ways to cope with symptoms (in particular, activity pacing, planning and goal setting), but also related to their new understanding of fatigue as a common experience after cancer.

Some suggestions were made regarding additional contact with the researchers at the beginning of the intervention. Participants noted that the content was somewhat repetitive. Others experienced trouble with the website not functioning properly, or being unable to watch the videos on i-Pads or tablets. This was cited as a barrier as participants felt they were not able to engage fully with the content. Others found it difficult to make time to complete their sessions on a weekly basis, while some suggested that the website did not fully consider the difficulties posed by competing demands on individuals (e.g. financial strain or having to mind their young children).

6.9.1.5. Participant satisfaction with website.

Participants were mostly satisfied with the REFRESH program and indicated that they would be likely to use the programme again if their fatigue persists. Participants also agreed that the Internet was a good method for delivering the REFRESH intervention. The open-ended questions gave participants the opportunity to highlight that participation in the research served as validation of their CrF experiences. One participant (BC, age 53) noted, “It is reassuring to me (and I’m sure to others) that you’re even doing the research. CrF
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must be a problem”. Participants enjoyed the programme and described the intervention as “fruitful”, “helpful”, “realistic”, and “worthwhile”.

Table 6.2. Patterns of website use

<table>
<thead>
<tr>
<th>Number of unique logins per individual</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-5</td>
<td>11</td>
<td>34.4</td>
</tr>
<tr>
<td>6-10</td>
<td>11</td>
<td>34.4</td>
</tr>
<tr>
<td>11-16</td>
<td>5</td>
<td>15.6</td>
</tr>
<tr>
<td>18-23</td>
<td>4</td>
<td>12.5</td>
</tr>
<tr>
<td>51</td>
<td>1</td>
<td>3.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Day of the week that people visited the website</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fri</td>
<td>30</td>
<td>9.4</td>
</tr>
<tr>
<td>Mon</td>
<td>58</td>
<td>18.1</td>
</tr>
<tr>
<td>Sat</td>
<td>19</td>
<td>5.9</td>
</tr>
<tr>
<td>Sun</td>
<td>37</td>
<td>11.6</td>
</tr>
<tr>
<td>Thu</td>
<td>59</td>
<td>18.4</td>
</tr>
<tr>
<td>Tue</td>
<td>65</td>
<td>20.3</td>
</tr>
<tr>
<td>Wed</td>
<td>52</td>
<td>16.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time of the day</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before 9am</td>
<td>22</td>
<td>6.9</td>
</tr>
<tr>
<td>9am-12pm</td>
<td>68</td>
<td>21.2</td>
</tr>
<tr>
<td>12pm-6pm</td>
<td>115</td>
<td>35.8</td>
</tr>
<tr>
<td>6pm-9pm</td>
<td>41</td>
<td>12.8</td>
</tr>
<tr>
<td>After 9pm</td>
<td>70</td>
<td>21.8</td>
</tr>
</tbody>
</table>
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#### Table 6.2. (continued) Patterns of website use

<table>
<thead>
<tr>
<th>Number of participants who visited each session</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Session</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Overview of Cancer-related Fatigue.</td>
<td>28</td>
<td>87.5</td>
</tr>
<tr>
<td>What is Cognitive Behavioral Therapy (CBT)?</td>
<td>25</td>
<td>78.1</td>
</tr>
<tr>
<td>Thoughts and Fatigue</td>
<td>19</td>
<td>59.4</td>
</tr>
<tr>
<td>Activity Scheduling</td>
<td>20</td>
<td>62.5</td>
</tr>
<tr>
<td>Improving your sleep</td>
<td>15</td>
<td>46.9</td>
</tr>
<tr>
<td>Dealing with low mood and changing your thinking</td>
<td>16</td>
<td>50.0</td>
</tr>
<tr>
<td>Worries and Anxieties/Stress Management</td>
<td>13</td>
<td>40.6</td>
</tr>
<tr>
<td>Social Support and Preparing for the future</td>
<td>12</td>
<td>37.5</td>
</tr>
<tr>
<td><strong>Overall Mean number of sessions completed</strong></td>
<td><strong>M</strong></td>
<td><strong>SD</strong></td>
</tr>
<tr>
<td></td>
<td>4.65</td>
<td>2.6</td>
</tr>
</tbody>
</table>
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Table 6.3 Quantitative usability and evaluation data – N (%)

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at all</th>
<th>Slightly</th>
<th>Somewhat</th>
<th>Mostly</th>
<th>Very</th>
</tr>
</thead>
<tbody>
<tr>
<td>How much did the <em>REFRESH</em> program keep your interest and attention?</td>
<td>2 (18.2)</td>
<td>8 (72.7)</td>
<td>1 (9.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How much did you like the <em>REFRESH</em> program?</td>
<td>2 (18.2)</td>
<td>7 (63.6)</td>
<td>2 (18.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How much did you like the way the <em>REFRESH</em> program looked?</td>
<td>2 (18.2)</td>
<td>8 (72.7)</td>
<td>1 (9.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How worried were you about your privacy in using this <em>REFRESH</em> program?</td>
<td>4 (36.4)</td>
<td>4 (36.4)</td>
<td>1 (9.1)</td>
<td>1 (9.1)</td>
<td>1 (9.1)</td>
</tr>
<tr>
<td>How good of a fit was the <em>REFRESH</em> program for you?</td>
<td>1 (9.1)</td>
<td>2 (18.2)</td>
<td>7 (63.6)</td>
<td>1 (9.1)</td>
<td></td>
</tr>
<tr>
<td>How satisfied were you with the <em>REFRESH</em> program?</td>
<td>2 (18.2)</td>
<td>5 (45.5)</td>
<td>4 (36.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How useful did you find the information in the web program?</td>
<td>1 (9.1)</td>
<td>8 (72.7)</td>
<td>2 (18.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How easy was the information to understand?</td>
<td>3 (27.3)</td>
<td>8 (72.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How much did you feel you could trust the information?</td>
<td>4 (36.4)</td>
<td>7 (63.6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If your fatigue continues or return, how likely would you be to come back to the <em>REFRESH</em> program?</td>
<td>1 (9.1)</td>
<td>2 (18.2)</td>
<td>4 (36.4)</td>
<td>4 (36.4)</td>
<td></td>
</tr>
<tr>
<td>How good of a method was the Internet for delivering the <em>REFRESH</em> intervention?</td>
<td>1 (9.1)</td>
<td>1 (9.1)</td>
<td>5 (45.5)</td>
<td>4 (36.4)</td>
<td></td>
</tr>
</tbody>
</table>
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6.9.2. Assessing the effectiveness of the “REFRESH (Recovery from Cancer-Related Fatigue) intervention” in long-term adult survivors of cancer, by comparing intervention and wait-list control groups.

Missing data were handled using the last observation carried forward (LOCF) method. The last available measurement for each individual at the time point prior to withdrawal from the study (i.e. baseline score) was retained in the analysis. This type of intention to treat (ITT) analysis includes every participant who is randomized according to randomized treatment (Gupta, 2011).

Table 6.4 shows mean scores for all outcome measures over the two time points, as well as the results of investigations into possible differences in intervention effects the different groups.

There is evidence of a change in the PFS Behavioural scale, with both groups showing greater fatigue in relation to activities. There was a significant increase in scores in the identity, timeline, consequences, and cyclical dimensions of the IPQ-R. This indicates that over time, participants in both groups developed stronger beliefs about the number of symptoms attributed to the illness, the chronicity of the condition, the negative consequences of the illness, and the cyclical nature of the condition. Higher scores on coherence dimensions suggest an increase in positive beliefs about the participants’ personal understanding of the condition over time. At follow-up participants reported higher scores on the 4 of the generic subscales of the QLACS (Negative feelings; Cognitive Problems; Pain; Social Avoidance) and on two of the Cancer-Specific scales (Financial Problems and Distress Family). Higher scores represent more problems or lower QOL.
### Table 6.4. ANOVA Table for primary and secondary outcomes.

<table>
<thead>
<tr>
<th>Time</th>
<th>Intervention N= 21</th>
<th>Control N= 19</th>
<th>Time</th>
<th>Group</th>
<th>Time ⋆ Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>F</td>
</tr>
<tr>
<td>The Piper Fatigue Scale (revised) (PFS-R)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>Baseline</td>
<td>6.53</td>
<td>1.32</td>
<td>6.68</td>
<td>1.42</td>
</tr>
<tr>
<td></td>
<td>Follow-up</td>
<td>6.12</td>
<td>1.33</td>
<td>6.04</td>
<td>1.21</td>
</tr>
<tr>
<td><strong>Sensory</strong></td>
<td>Baseline</td>
<td>6.12</td>
<td>1.33</td>
<td>6.04</td>
<td>1.21</td>
</tr>
<tr>
<td></td>
<td>Follow-up</td>
<td>5.98</td>
<td>1.89</td>
<td>5.72</td>
<td>1.74</td>
</tr>
<tr>
<td><strong>Behavioural</strong></td>
<td>Baseline</td>
<td>5.79</td>
<td>2.05</td>
<td>5.77</td>
<td>1.53</td>
</tr>
<tr>
<td></td>
<td>Follow-up</td>
<td>6.77</td>
<td>1.58</td>
<td>7.00</td>
<td>1.51</td>
</tr>
<tr>
<td><strong>Cognitive/Mood</strong></td>
<td>Baseline</td>
<td>5.92</td>
<td>2.26</td>
<td>5.66</td>
<td>1.85</td>
</tr>
<tr>
<td></td>
<td>Follow-up</td>
<td>5.79</td>
<td>2.05</td>
<td>5.77</td>
<td>1.53</td>
</tr>
<tr>
<td><strong>Affective</strong></td>
<td>Baseline</td>
<td>7.14</td>
<td>1.45</td>
<td>7.19</td>
<td>1.75</td>
</tr>
<tr>
<td></td>
<td>Follow-up</td>
<td>6.77</td>
<td>1.58</td>
<td>7.00</td>
<td>1.51</td>
</tr>
</tbody>
</table>
Table 6.4. *ANOVA Table for primary and secondary outcomes.* (continued): The Illness Perceptions Questionnaire for Cancer-Related Fatigue (CRF)

<table>
<thead>
<tr>
<th>Time</th>
<th>Intervention N= 21</th>
<th>Control N= 19</th>
<th>Time</th>
<th>Group</th>
<th>Time * Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>F</td>
</tr>
<tr>
<td><strong>Identity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>17.10</td>
<td>3.42</td>
<td>16.00</td>
<td>2.33</td>
<td>12.18</td>
</tr>
<tr>
<td>Follow-up</td>
<td>45.75</td>
<td>58.92</td>
<td>60.32</td>
<td>70.92</td>
<td></td>
</tr>
<tr>
<td>Timeline</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>4.53</td>
<td>.62</td>
<td>4.13</td>
<td>.52</td>
<td>16.18</td>
</tr>
<tr>
<td>Follow-up</td>
<td>6.12</td>
<td>2.34</td>
<td>5.60</td>
<td>1.96</td>
<td></td>
</tr>
<tr>
<td>Timeline cyclical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>1.90</td>
<td>1.83</td>
<td>1.95</td>
<td>1.51</td>
<td>33.42</td>
</tr>
<tr>
<td>Follow-up</td>
<td>5.30</td>
<td>3.20</td>
<td>5.47</td>
<td>3.72</td>
<td></td>
</tr>
<tr>
<td><strong>Personal control</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>2.50</td>
<td>1.64</td>
<td>2.68</td>
<td>1.73</td>
<td>17.79</td>
</tr>
<tr>
<td>Follow-up</td>
<td>4.60</td>
<td>1.88</td>
<td>4.32</td>
<td>2.21</td>
<td></td>
</tr>
<tr>
<td>Treatment control</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>2.25</td>
<td>1.83</td>
<td>2.68</td>
<td>2.29</td>
<td>19.44</td>
</tr>
<tr>
<td>Follow-up</td>
<td>4.45</td>
<td>2.09</td>
<td>4.58</td>
<td>1.77</td>
<td></td>
</tr>
<tr>
<td><strong>Consequences</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>4.50</td>
<td>1.64</td>
<td>4.05</td>
<td>1.43</td>
<td>8.21</td>
</tr>
<tr>
<td>Follow-up</td>
<td>6.15</td>
<td>3.60</td>
<td>5.58</td>
<td>2.63</td>
<td></td>
</tr>
<tr>
<td><strong>Coherence</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>1.45</td>
<td>1.19</td>
<td>1.95</td>
<td>1.93</td>
<td>199.47</td>
</tr>
<tr>
<td>Follow-up</td>
<td>6.40</td>
<td>1.14</td>
<td>7.05</td>
<td>1.31</td>
<td></td>
</tr>
<tr>
<td><strong>Emotional representation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>4.10</td>
<td>.97</td>
<td>7.40</td>
<td>3.53</td>
<td>26.50</td>
</tr>
<tr>
<td>Follow-up</td>
<td>4.68</td>
<td>.95</td>
<td>7.32</td>
<td>3.23</td>
<td></td>
</tr>
</tbody>
</table>
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Table 6.4. ANOVA Table for primary and secondary outcomes. (continued): The Cognitive and Behavioural Responses to Symptoms Questionnaire

<table>
<thead>
<tr>
<th>Time</th>
<th>Intervention N= 21</th>
<th>Control N= 19</th>
<th>Time</th>
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### Table 6.4. ANOVA Table for primary and secondary outcomes. (continued): Quality of Life in Adult Cancer Survivors (QLACS) questionnaire

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### Table 6.4. ANOVA Table for primary and secondary outcomes. (continued): Quality of Life in Adult Cancer Survivors (QLACS) questionnaire

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**Appraisal of Coping: The Coping Efficacy Scale**

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Chapter 6: Acceptability and Preliminary Feasibility

Both groups indicated enhanced coping efficacy at follow-up. There was a significant effect of group on Financial Problems, with the control group reporting a great increase in cancer-specific financial concerns. However, there were no interaction effects.

6.9.2.1 Secondary outcomes

This feasibility trial was not powered to assess the hypothesis regarding the modelling of fatigue using the SRM. However, some exploratory correlational analyses indicate that higher levels of fatigue were negatively correlated with stronger beliefs about treatment control ($r = -.37, p > 0.05$) and participants’ sense of coherence relating to their fatigue symptoms ($r = -.37, p > 0.05$). Increased fatigue was positively correlated with perceived benefits as a consequence of cancer and its treatment ($r = .27, p > 0.05$).

A Mann-Whitney U test was used to establish if groups differed in their description of the nature of their symptoms at baseline. In the CBSQ, participants were asked to describe the nature of their symptoms by selecting one of the following responses:

- My symptoms are physical
- My symptoms are mainly physical
- Both physical and psychological factors are involved in my symptoms
- My symptoms are mainly psychological
- My symptoms are psychological in nature

The results of the test were not significant ($U = 200.00, p > 0.05$), indicating that the groups did not differ in the categories they used to describe the nature of their symptoms at baseline. In both groups, 20% ($N = 4$) described their symptoms as mainly physical, with a further 25% ($N = 5$) stating that their symptoms were mainly physical. Over half the participants in both of the groups (55% $N = 10$) said their symptoms involved both physical and psychological factors at baseline.
Chapter 6: Acceptability and Preliminary Feasibility

However, at follow-up the results of the test were significant ($U = 114.5, p < 0.05$), indicating that the groups did differ in the categories they used to describe the nature of their symptoms after the intervention period. In the intervention group, $20\%$ ($N=4$) described their symptoms as mainly physical. Most individuals $45\%$ ($N=9$) attributed both physical and psychological factors to their symptoms, with $35\%$ ($N=7$) stating their symptoms were mainly or wholly psychological in nature.

Conversely, $45\%$ ($N=9$) of those in the control group stated that their symptoms were mainly or wholly physical in nature. With $45\%$ ($N=9$) saying that both physical and psychological factors are involved, and $5\%$ ($N=1$) stating that symptoms are mainly psychological. None of the control group participants stated that their symptoms were wholly psychological in nature at follow-up.

6.10. Discussion

The primary aim of this research was to establish the feasibility and acceptability of the “REFRESH (Recovery from Cancer-Related Fatigue)” intervention trial. The intervention was found to be feasible and acceptable to participants. However, a follow-up pilot study with a larger sample size is warranted to establish the potential for the intervention as a means to help individuals to better manage fatigue after cancer treatment. If this potential is demonstrated, a full RCT is necessary to establish effectiveness.

Facilitators associated with the feasibility of REFRESH included the user-friendliness of the website and its informative nature. Ease of use was also determined in previous studies as an important factor for the acceptance of online interventions (Duman-Lubberding, 2015).

Barriers to use included the time required to engage with the website and competing life demands. This has also been reported in previous studies (Duman-Lubberding, 2015). Some participants reported having technical difficulties with the website and identified some issues
Chapter 6: Acceptability and Preliminary Feasibility

that would need to be remedied in advance of future trials. The duration of the sessions or the amount of information was not cited as a difficulty to participants. The positive feedback from participants in the qualitative open-ended questions and telephone data was an endorsement of the website (Bartlett et al., 2012).

The strength of the study is that a mixed methods approach was used, providing in-depth insight into the feasibility of the website in everyday life. Incorporating the views of potential participants in designing the intervention may have contributed to the favourable evaluations of the website (Bartlett et al., 2012). This strategy allowed for the views of cancer survivors to influence the design and content leading to a website that was both easy to use and useful. Inductive preparatory work ensured that participant needs were reflected in the intervention. The identified user requirements were combined with existing psychological theory relating to website use. Strategies including motivation, autonomy, goal setting, and action planning were incorporated in order to improve user acceptability and engagement with the intervention. In parallel, the SRM theory underpinning the content led to the inclusion of strategies for fatigue-management such as activity pacing, recognition of maladaptive coping strategies and cognitive reappraisal which were rated favourably by participants.

Budget and time constraints meant that the recruitment period was shorter than intended, however uptake of the intervention was relatively high (44%) (Foster et al., 2015). The data pertaining to actual use of the website indicate that the majority of participants (80%) in the trial- in both intervention and waitlist control groups- accessed the website at least once when given the opportunity to do so. Forty per cent of users accessed at least half of the sessions. These findings suggest that there is a demand for supportive materials for cancer survivors (Myall et al., 2015). Notably, as with other studies of this nature (Myall et al., 2015; Yun et al., 2012), individuals reported that participation in the trial was beneficial as they felt it validated their fatigue experience.
Chapter 6: Acceptability and Preliminary Feasibility

As described by Armes, Chalder, Addington-Hall, Richardson, and Hotopf (2007), it is quite difficult to develop a placebo intervention to control for behavioural interventions. The aim of this study was to explore the added benefit of CBT to the currently available leaflet comparator. However, it is unclear how many of the control group had accessed this information prior to the study. Further, control participants who were called at the mid-point of the study period echoed the intervention participants’ views that the study itself was an acknowledgement of their fatigue and its impact, which may have served as an intervention in itself. Some participants commented that the very act of completing the questionnaires had led them to reconsider their symptoms.

 Dropout was higher in the waitlist control arm. This may be because participants struggled with the lack of contact throughout the duration of the trial. Participants in the intervention group stated that they would have liked more input from the research team throughout the process. Personalised feedback is related to sustained intervention use and reduced attrition (Lubberding et al., 2015). This was mentioned by some participants who felt that tailored content or feedback would have been beneficial. Different individuals will require varying amounts of contact. In future iterations of the trial, efforts should be made to establish the optimum and most efficient level of contact required.

 There was very little difference between the groups and the intervention was not found to have significantly affected the scores on any of the primary outcome measures. An extension of the timing of the main outcome measure in future iterations of the trial will allow for the assessment of any sustained effect on outcomes.

 This study was not powered to detect change, and so a larger trial is required to establish if the website may be an effective means of enhancing coping with fatigue in this group. The primary outcome measure for REFRESH is fatigue as measured by the PFS-R at 10 weeks.
Chapter 6: Acceptability and Preliminary Feasibility

post-baseline for this pilot trial. In order to explore if, and the process by which, one variable affects another a mediation analysis would be required (Preacher, Rucker, & Hayes, 2007). Structural equation modelling (SEM), would allow researchers to examine how well the data fits with the proposed model that links hypothesised theoretical constructs to fatigue outcomes (Hayes, 2009). A complete theory testing of a complex models such as the SRM would require substantially larger sample sizes. Further, given the complex nature of fatigue, longer-term sustained behaviour change may be required before changes are evident.

The results from this trial have provided information regarding the potential of a novel theoretical approach to online interventions for cancer related fatigue in post-treatment cancer survivors. The research seeks to create supportive online environments at home to ameliorate fatigue and promote self-management of symptoms in this group. REFRESH was considered feasible, but our results also show that improvements can be made to enhance the feasibility and increase the satisfaction among cancer survivors.

The design of useful and user-friendly website for use is a key first step towards implementation of a means of supporting post-treatment cancer survivors. Future work should be undertaken to establish if the intervention could have an impact on clinical, psychological, and behavioural outcomes. Online theory-based approaches to self-management interventions may lead to enhanced coping and increased healthy behaviours in cancer survivors (Lee, Park, Yun, & Chang, 2013). If successful, an eHealth approach could prove to be an efficient and cost-effective means to deliver care to this group.
Chapter 7. General discussion

7.1 Chapter overview
This chapter will present a summary of the overall findings and evaluate the contribution made by this research to understanding the development of online interventions of cancer survivors with persistent fatigue. The findings will be discussed in relation to existing literature regarding cancer-related fatigue and the design of interventions targeting this group. The implications of the findings for future research and practice will be described. The limitations of each study will be outlined and approaches to addressing these limitations will be suggested. Finally, this chapter will end with concluding remarks.

7.2 Summary of the overall findings of this research

- It remains unclear if and how psychosocial interventions impact persistent fatigue after cancer. The systematic review indicated there is some tentative support for psychological interventions for fatigue after cancer treatment. However, the RCTs were very heterogeneous in nature and the number of high quality studies was limited. It appears that there is a lack of consistency in the literature regarding the extent of detailing intervention content and procedures. Clusters of factors that are expected to reduce fatigue should also be assessed for change during the intervention. Questions remain regarding the optimal duration of the intervention, and the ideal timing of the intervention.

- The qualitative study highlighted that the SRM could be applied to CrF in post-treatment cancer survivors by providing a theoretical framework for understanding individuals’ representations, and coping strategies, and thus identifying targets for intervention.

- The qualitative work also noted that the social context of CrF in adult survivors of cancer is complex. This impacts perceptions and self-management of the symptom. CrF also impacts the emotional wellbeing of cancer survivors. These contextual factors can negatively
Chapter 7. General discussion

influence decisions to discuss fatigue symptoms with a healthcare practitioner, particularly among those without a good relationship with a service provider. There are many perceived inadequacies in support available to those with lingering side-effects after the completion of cancer treatment. Participants are left feeling inadequately prepared for persistent fatigue after cancer and are confused, isolated, and frustrated as a result. CrF in cancer survivorship could be approached as a complex psychosocial issue and considered from the patient perspective to facilitate better understanding and management of symptoms.

- Collaborative methods of designing websites with experts and service-users allows researchers to link the perspectives of end-users with findings from the research literature. This helps to ensure that the website is usable, engaging, relevant, and understood by those who use it. Involving users from the target group at the design stage can significantly contribute to the development of interventions.

- The co-creation of the intervention allowed the design team to ensure that an acceptable intervention was developed. (Foster et al., 2015; Owens et al., 2011). The results from this trial indicated that the website was considered feasible, but our results also show that improvements can be made to enhance the feasibility and increase the satisfaction among cancer survivors. Further research is needed in order to establish if the intervention could have an impact on clinical, psychological, and behavioural outcomes.

7.3 Contribution of this research

There is some evidence that psychosocial interventions are effective in reducing fatigue in patients undergoing active treatment for cancer (Goedendorp et al 2009). However, the effectiveness of psychological interventions for fatigue in the specific cohort of post-treatment cancer survivors had not previously been investigated in depth. The findings of the systematic review suggest that there may be an overall positive effect of psychological interventions on fatigue in cancer survivors. However, there is considerable heterogeneity,
Chapter 7. General discussion

not only in design and outcomes, but also in the quality and usability of the specific interventions.

Although the systematic review did not definitively point to the use of CBT in intervention design, recent MRC guidance recommends that individuals select the “best bets” when applying systematic review evidence to intervention development (Glasziou, Chalmers, Green, & Michie, 2014). Published guidance on supporting patients with CrF following treatment recommend the use of CBT for the management of fatigue (Berger, Abernethy, & Atkinson, 2012; Runowicz et al., 2016). Furthermore, previous research has linked established psychological therapies such as CBT with improved fatigue-related outcomes in studies of people with cancer and other chronic conditions (Abrahams et al., 2013; Gielissen et al., 2006; van Kessel, Woudes, & Moss-Morris, 2015).

While the use of CBT for fatigue after cancer is not novel, the mechanism by which these interventions lead to improved self-management and outcomes remain unclear. The novelty of the approach used in the design of this intervention rests in the efforts to hypothesise about an underlying theory that may impact fatigue, and therefore could be impacted during the CBT process. A strong theoretical foundation was outlined, underpinned by proposed mechanisms of action (Craig et al., 2013). Outcomes were selected to reflect these proposed mechanisms. By incorporating qualitative research, the central role of the individual’s own understanding of their symptoms and its management was proposed, in keeping with a theory and person-based approach to intervention design (Bradbury et al., 2014; Yardley et al., 2015). This was the first online intervention for this group that aimed to specifically address components of the SRM. As with previous studies of this nature (Foster et al., 2015; Michie et al., 2012), a participatory and collaborative approach enabled the researchers to build an acceptable and feasible intervention, with efficient program delivery and evaluation (Yardley et al., 2015).
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The website was shown to have utility and was acceptable to users. Hoddinott (2015) notes that feasibility studies ask “Can this study be done?” Applying this definition, the trial described here was feasible. The components of the trial worked together and the operational aspects of trial design (e.g. recruitment, adherence, and assessment) functioned efficiently.

The table below outlines the results of the feasibility study that can be used to estimate important parameters that are needed to design the main study (Table 7.1). This study was not powered to estimate a standard deviation of the outcome measure, which is needed in some cases to estimate sample size (Viechtbauer et al, 2015). Sample size estimates will be calculated following a pilot study of the current trial.

7.4 Logic Model
A Logic Model based on the findings of the systematic review, qualitative interviews and the feasibility study is illustrated below. The logic model was based on Ritterband’s Behaviour change model of internet interventions, which suggests that changes in health outcomes would be mediated by the content of the intervention, as well as use of the intervention (Ritterband, 2012). This systematic review and qualitative research facilitated the identification of the SRM as the theoretical basis for the intervention. The intervention content is based on CBT techniques that aim to address constructs of the SRM theory. It is hypothesised that certain key CBT techniques are likely to influence symptom representation and coping with fatigue and that, an intervention addressing these factors is likely to change an individual’s appraisal of symptoms and coping responses. Changes in symptom appraisal and coping are hypothesised to lead to improvements in adjustment to, and interference of, fatigue. This is in line with previous work that proposes it is likely that beliefs about symptoms will influence beliefs about recovery behaviours and behavioural health outcomes (Molloy et al 2009; Dixon & Johnston, 2008; Kaplan, 1990).
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Table 7.1. *Feasibility study parameters that will be used to design a larger trial of the REFRESH Programme.*

<table>
<thead>
<tr>
<th>Parameters that are needed to design the main study</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Willingness of participants to be randomised;</td>
<td>Participants were willing to be randomised, with 116 participants consenting to take part in the study after reading the participant information sheet. Qualitative research indicated that participants understood the process of the intervention and were happy to wait to access the website. The majority of the intervention group accessed the website (90.5%), and 63.2% of the control group proceeded to access the intervention when given access. Participants in intervention group accessed a similar number of sessions as those in the control group who chose to access the website.</td>
</tr>
<tr>
<td>Willingness of clinicians to recruit participants;</td>
<td>An overview of the reach and attrition of the intervention participants is provided in Fig. 2. Four participants (10%) were informed about the study by a healthcare professional (HCP). As healthcare professionals were not a primary recruitment source, this was deemed promising. Links with HCPs will be developed in future iterations of the trial. Participants were also recruited from newspapers (37.5%) or social media (22.5%). Some heard about the study from a friend (25%) or saw flyers/ advertisements distributed (5%).</td>
</tr>
<tr>
<td>Number of eligible patients</td>
<td>30 eligible participants completed the baseline questionnaire.</td>
</tr>
</tbody>
</table>
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Characteristics of the proposed outcome measure

Fatigue was measured using the Piper Fatigue Scale (revised) (PFS-R) (Reeve et al., 2012). This scale assesses adjustment and interference of fatigue. The scale is multidimensional and incorporates key dimensions of the fatigue experience including cognition, behaviours, affect, and sensory symptoms (Piper et al., 1998).

Preliminary evidence showed evidence of a change in the PFS Behavioural scale, but a pilot study with a larger sample is needed to conclude that this measure would be suitable for use in a larger RCT trial. In line with guidelines for the calculation of sample size in pilot studies by Viechtbauer et al. (2015) an estimated sample size of 59 cancer survivors would be required for the identification of unforeseen problems, such as ambiguities in description of the trial or eligibility criteria, or misinterpretations of questionnaire items.

Follow-up rates, response rates to questionnaires, adherence/compliance rates

31 participants did not complete the initial baseline questionnaire. Ten (5 per group) were lost to follow-up. See Figure 6.1 for further details.

Forty percent of participants actively participated in 90% of 4 or more of the REFRESH sessions. Four participants (10.3%) completed all 8 sessions.

Availability of data needed or the usefulness and limitations of a particular database

Surveygizmo allowed the researcher to export outcome variables and data directly to SPSS. As data and variable names were set up prior to study completion this facilitated the prompt creation of a complete database.

Time needed to collect and analyse data

The researcher suggests that a longer period is required for recruitment and baseline data collection. In this study, data was collected over a 4 month period. A further 2-3 months of recruitment is recommended.

Once all data is collected, data can be analysed within 1 month.
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7.5 Behavioural outcomes in Fatigue research

Describing fatigue in terms of a limited ability to perform particular actions is in keeping with conceptualisations of disability as behaviour (Dixon & Johnston, 2008; Kaplan, 1990). Psychological theories recognise that individuals’ personal representations are important determinants of the response to symptoms; including their overall behaviour pattern comprising of lifestyle, habits, coping styles, and other individual psychological characteristics (Johnston & Dixon, 2014). Previous research has indicated that psychological theory can explain functional impairment, by addressing emotional factors such as catastrophising or fear-avoidance (Johnston & Dixon, 2014). These factors (among others) are implicated in perpetuating CrF (Weis and Horneber, 2016). Therefore, a model that addresses these factors is expected to have an impact on behavioural outcomes such as functional impairment and participation in activities (Dixon & Johnston, 2008; Kaplan, 1990).

Theories that address behaviour usually suggest that a set of cognitions or emotions leads to behaviour. In our logic model, we propose that a change in fatigue will be impacted by the individual’s representation, symptom appraisal and coping responses related to their fatigue. The feasibility trial described in this thesis showed evidence of a change in the PFS Behavioural scale, related to fatigue associated with activity interference. Likewise, the functional impact of fatigue was frequently addressed as an important issue for participants in the qualitative research. It may therefore, be most appropriate to specifically target behavioural outcomes in future trials (Kaplan, 1990). Future pilot studies will be used to gain further insight into these preliminary patterns and to further model the processes and outcomes of the intervention in line with MRC guidance. However, at this stage with limited data, the logic model presented refers to overall adjustment and interference of fatigue as assessed by all subscales of the PFS.
Figure 7.1. Logic model which includes theoretical model, the processes to be targeted, interventions, used to target specific processes and outcomes to be used in an efficacy RCT.
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7.5 Fatigue during survivorship as a unique experience

This study aimed to distinguish between the factors influencing fatigue during cancer and focusing particularly on the issues facing individuals faced with persistent fatigue after cancer treatment ends. The findings of this research indicate that prioritising the needs of cancer survivors is of key importance. The qualitative findings provide a thorough understanding of the subjective experience of CrF in post-treatment cancer survivors. Fatigue was considered as a long-term part of the cancer experience that had persisted after treatment. Participants emphasised the influence of wider social discourse on their experience of fatigue and in particular, discussed pressure to return to ‘normal’ after cancer. This was in keeping with research that has previously indicated that the social context is extremely pertinent to how representations are formed (Sinding & Gray, 2005). Participants discussed issues such as fear of recurrence, and how a symptom such as fatigue heightened these concerns.

The issue of support after cancer was frequently raised. During cancer, patients felt supported by their care providers. Without access to an available narrative to describe their experience, individuals engaged in a process of making sense of the fatigue themselves (Pertl et al., 2014). These sentiments were also echoed in the response to the trial, with many participants highlighting that the trial in itself was validation of their symptoms and a much needed support during this period of transition. This is in keeping with studies of a similar nature (Foster et al., 2015). Importantly, it raises questions about the timing of supportive care services for those after cancer, with some indicating that it may be best to begin the process of rehabilitating patients as treatment draws to a close, rather than waiting for treatment side effects to abate (Myall et al., 2015).

The experience of fatigue is at odds with some popularised schemas of the cancer ‘survivor’ as someone who is the embodiment of strength in the face of adversity. Social narratives of survivorship often describe cancer as being ‘beaten’ or ‘conquered’ by those with a ‘fighting spirit’ (Kaiser, 2008). Pertl et al. (2014) suggests that this may put pressure on patients to behave in line with these ideals. Further, CrF impinges the process for the individual of negotiating changes in their own self-concept as the transition from patient self to the new, post-cancer self (Miller, 2015). As a result of their fatigue, people found it difficult to adapt to social roles and experienced reduced functional capacity (Aziz & Rowland, 2003). People did not want to burden family members with concern about their symptoms, and often felt isolated and misunderstood as a result.
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It is, therefore, necessary to understand post-treatment fatigue as an issue that can impact, and be impacted by, the demands faced at this particular stage of the cancer trajectory.

7.6 A critical reflection on the use of the BCT taxonomy:

In this research, the components of the intervention were outlined using the BCT taxonomy (BCTT V1; developed by Michie et al (2013). This taxonomy aims to provide a systematic and precise method of describing the active content of interventions with specificity. This approach also aims to promote clarity in intervention design so that studies could be more easily replicated (2013). Johnston (2016) proposes that this shared vocabulary is crucial to advance scientific understanding.

Although widely used, recent debates in the health psychology literature have encouraged a more critical reflection on BCT taxonomy (e.g. Johnston, 2016; Ogden, 2016; Peters & Kok, 2016). Ogden (2016) for example, argues that the systemisation of behaviour change intervention neglects individual variability and contextual responses. The BCTT is also promoted as a means of identifying which techniques are most effective (2013). Ogden (2016) argues that there is a whole array of intrapersonal, interpersonal, and external factors that must also be considered.

Hagger and Hardcastle (2014) suggest that current use of the BCT taxonomy (BCTT V1, Michie et al 2013) have not addressed the role that interpersonal factors play in promoting behaviour change. In particular, research in clinical settings has highlighted the importance of the therapeutic or working alliance between client and therapist (i.e. not just what the therapist ‘does’) (Godfrey et al, 2007; Cook et al 2015). Researchers must also be cognisant of individual idiosyncrasies in how participants feel, think, look, behave or respond at any particular time. Variability will still exist in how persons interpret, and act upon, the information received (Ogden, 2016a). BCTs are therefore, only one component of multidimensional interventions. Hardcastle (2016) suggests that some key intervention approaches are not captured by BCT taxonomies. These include cognitive and interpersonal strategies such as the use of open-ended questions, affirmation, and reflections. She suggests that these approaches could complement BCTs that focus solely on content rather than on interpersonal factors (2016).

Online interventions can overcome some of these issues surrounding individual variability, by facilitating the provision of targeted and specific material. Albarracin & Glasman (2016)
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suggest that obtaining systematic information about the impact of particular key BCTs in interventions would enable enhanced tailoring, thus reducing variability. Further, as the online content is uniform, all individuals receive the same information as intended. Analyses of engagement patterns could help us to discern what components of the intervention are frequently used or which elements might be associated with behaviour change.

One can also hypothesise about variability between persons by linking the proposed BCTs to relevant psychological theory (Peters & Kok, 2016). However, interventions are often based on partial and often inappropriate use of theories (Johnston, 2015). Approaches such as Intervention Mapping promote the translation theory-based techniques for practical use such that it fits with the population and the context of the intervention (Kok et al., 2016; Peters, de Bruin, & Crutzen, 2015). The aim is to specify conditions that are hypothesised to be crucial for the effective delivery of the intervention to be effective in practical applications (Kok et al., 2016). While recognising the limitations of the BCT taxonomy to fully capture key intervention approaches, in this thesis the taxonomy was used as a descriptive tool to clarify intervention content, and supplemented with a theoretical basis (H. Leventhal et al., 1997) and a framework of therapeutic competencies (Roth & Pilling, 2008). Together, these frameworks allow us to define not only what was delivered, but the underlying rationale for each component.

Table 4.2 outlines all BCTs employed for the purpose of comprehensive description and clarity. However, the logic model above highlights key CBT strategies hypothesised to promote adaptive symptom representations, to reduce negative emotional representations, to target specific triggers of fatigue and to enhance coping with fatigue. With this logic model in mind, BCTs which are likely to be particularly important in delivering the REFRESH intervention are outlined in Table 7.2. below.
### Behavour change techniques

<table>
<thead>
<tr>
<th>BCTs which are likely to be particularly important in delivering the REFRESH Programme.</th>
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<tr>
<th>Table 7.2. BCTs which are likely to be particularly important in delivering the REFRESH Programme.</th>
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<tr>
<th>Behaviour change techniques</th>
<th>Key CBT strategies hypothesised to promote adaptive symptom representations, to reduce negative emotional representations, to target specific triggers of fatigue and to enhance coping with fatigue</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.2. Information about antecedents</td>
<td>• Draw on knowledge about fatigue</td>
</tr>
<tr>
<td>5.1. Information about health consequences</td>
<td>• Explanation about the interaction between thoughts, feelings, behaviours, and physical symptoms in response to fatigue</td>
</tr>
<tr>
<td>5.3. Information about social and environmental consequences</td>
<td>• Patients encouraged to keep a thought record. Thought record used as prompt to identify biased thinking patterns.</td>
</tr>
<tr>
<td>5.6. Information about emotional consequences</td>
<td>• Participant guided to identify evidence for and against biased thoughts</td>
</tr>
<tr>
<td>4.1. Instruction on how to perform the behaviour</td>
<td>• Activity monitoring</td>
</tr>
<tr>
<td>2.3. Self-monitoring of behaviour</td>
<td>• Encouraging participants to record and evaluate behaviour patterns.</td>
</tr>
<tr>
<td>2.4. Self-monitoring of outcome(s) of behaviour</td>
<td>• Encourage participant to identify a specific problem that they are having difficulties with at the moment and engage in problem solving</td>
</tr>
<tr>
<td>5.4. Monitoring of emotional consequences</td>
<td>• Setting goals and action plan how to implement goal.</td>
</tr>
<tr>
<td>9.2. Pros and cons</td>
<td>• Activity scheduling outlined in relation to fatigue.</td>
</tr>
<tr>
<td>1.1. Goal setting (behaviour)</td>
<td>• Graded exposure and planning when to implement an activity.</td>
</tr>
<tr>
<td>1.3. Goal setting (outcome)</td>
<td>• Apply chunking: breaking goal down where necessary.</td>
</tr>
<tr>
<td>1.4. Action planning</td>
<td>• Encourage exercise routine that fits in with physical demands and ability.</td>
</tr>
<tr>
<td>1.6. Discrepancy between current behaviour and goal</td>
<td>• Attentional control and cognitive processes</td>
</tr>
<tr>
<td>8.7. Graded tasks</td>
<td>• Implement changes to current sleeping patterns.</td>
</tr>
<tr>
<td>11.2. Reduce negative emotions</td>
<td>• Relaxation skills</td>
</tr>
<tr>
<td>12.1. Restructuring the physical environment</td>
<td>• Mindfulness-based exercises promote present moment awareness</td>
</tr>
<tr>
<td>12.4. Distraction</td>
<td>• Facilitate participant expressing themselves with others.</td>
</tr>
<tr>
<td>12.5. Adding objects to the environment</td>
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</table>
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7.7 A patient-centred model for intervention development

The website was developed in an Irish population, working with cancer care teams, clinical psychologists and cancer survivors suffering with fatigue. This collaboration helped to understand the needs of potential users and provide important information on which intervention features might be preferable to users. In turn, this guided the study design, and study implementation.

In the qualitative research, participants emphasised the need to establish an understanding of their symptoms. In particular, many participant statements focused on the “identity” of CrF. A label was seen as a vehicle to accepting fatigue. In line with previous research, recognition of symptoms was considered crucial in learning to cope with fatigue and articulating the experience to others, including health professionals (D. L. Hall et al., 2014). Fatigue had far-reaching social and emotional consequences for participants. Discussions relating to CrF were dominated by a sense of ambiguity, uncertainty and a lack of understanding of CrF by the individual themselves, and by others. Participants were not sure what to expect because CrF had already persisted longer than anticipated after the end of treatment. Factors such as comprehensibility, manageability, and meaningfulness can influence symptom perception. A sense of coherence may serve as a protective psychological factor in the adaptation process (Rohani, Abedi, Omranipour, et al., 2015; Rohani, Abedi, Sundberg, et al., 2015).

These representations impacted on acceptance of fatigue and affected participants’ coping, as shown in previous research (McAndrew et al., 2008). Beliefs about fatigue management influenced coping strategies following cancer treatment (Costanzo et al., 2011). Acknowledgement of symptom seriousness from others may facilitate individual acceptance of fatigue and encourage appraisal of current coping strategies (Whitaker et al., 2015).

Appraisals of representations have been linked to seeking care in response to ambiguous
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(Cameron et al., 1995) and prolonged symptoms (Mora et al., 2007). Understanding how individuals appraise coping could help guide the development of tailored, proactive interventions to improve well-being (Costanzo et al., 2011).

These factors were considered throughout the website development process, working with cancer care teams, clinical psychologists and cancer survivors suffering with fatigue. Individuals made suggestions regarding the need for some degree of personalisation, credibility, and recognition of the fatigued nature of those using the website. Important factors such as an emphasis on moving forward with life after cancer rather than focusing too much on the illness were also recommended. There was an emphasis on promoting active self-management that would motivate and engage participants.

Once the website was designed and ready to be tested, usability testing enabled the research team to further develop and improve the website by assessing preliminary functionality, acceptability, usability and engagement (Michie et al., 2012; Pagliari, 2007; Yardley et al., 2010). Major changes to the intervention were not required at this stage, but some minor modifications were suggested and incorporated. This participatory and collaborative approach enabled the researchers to build a relevant, acceptable, and feasible intervention, with efficient program delivery and evaluation (Yardley, Morrison, Bradbury, & Muller, 2015a).

7.8 Online interventions for cancer survivors

CrF is a multidimensional and complex symptom (Stone & Minton, 2008), and therefore, an intervention mode that could incorporate multiple and complex behaviour change techniques was required (Bradbury et al., 2014). The internet is increasingly being used as a resource by cancer survivors (Chou, Liu, Post, & Hesse, 2011) and so may serve survivors’ information and support needs (Fosteret al., 2015). A web-based resource to support self-management of CrF was endorsed by the majority of participants in the preliminary qualitative research. The
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home-based setting of an online intervention may be particularly beneficial to Irish participants, given inequity in care provision (Barrett et al., 2011), the reported unmet needs relating to post-treatment support and geographical barriers to accessing care. Participants can practice and incorporate new skills more readily into their daily lives when the intervention is incorporated into their current routine (Myall et al., 2015; Wolvers et al., 2015). The intervention described aimed to build upon previous studies that have employed internet-based self-management programmes (Foster et al., 2015; Moss-Morris et al., 2012; Yun et al., 2012), while applying a novel theoretical approach that addresses both individuals’ understanding of, and coping with, CrF.

This study fills an important gap in the cancer survivorship literature. There are limited online resources available for individuals dealing with posttreatment CrF that incorporate clinical recommendations for best practice. The program serves as a prototype for designing and assessing theory-based online cancer survivorship programs that address users’ needs (Griffiths et al., 2006; Yardley et al., 2015). The findings highlight the importance of incorporating the views of potential participants as well as expert input to enhance the development and personal relevance of the multimedia content and approach. This study has additional insight into the use of the intervention and allowed the researchers to understand the experience of the participants. These findings will inform any necessary post-trial modifications or remodeling in order to explore the potential effectiveness of REFRESH prior to the development of a larger scale RCT.

7.9 Difficulties associated with conducting research on fatigue

The aim of this trial was to help participants to better understand fatigue symptoms, yet the very act of answering questions about fatigue may change participants’ interpretations of their symptoms. This could lead to altered or biased fatigue scores. Further, it could also lead
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to maladaptive focusing on symptoms. These were two of the most prominent challenges in conducting this research and are discussed below.

7.9.1 The complex and subjective nature of fatigue

Aaronson et al. (1999) raise concerns about defining and measuring fatigue given issues relating to its complexity. In particular, the authors note the subjective quantification of fatigue; subjective distress as a result of fatigue; personal interpretations of the impact of fatigue on everyday life; the many wide-ranging correlates of fatigue and biological parameters of symptoms (Aaronson et al., 1999). Given the complex multidimensional and subject nature of fatigue, it is, therefore, particularly difficult to assess symptoms (Aaronson et al., 1999). No one tool can address each of these issues, but the use of validated multidimensional methods is recommended as a sophisticated way of assessing fatigue (Ahlberg et al., 2003). It is, therefore, necessary to obtain information relating to exacerbating and relieving factors, the impact of fatigue on day-to-day activities, individuals perceptions of fatigue, and the socio-cultural factors that influence fatigue (Winningham et al., 1994).

In order to gain such an extensive understanding of fatigue, a mixed-methods approach was adopted. In assessing fatigue in the trial a self-report measure of fatigue was used. As fatigue is primarily a subjectively experienced symptom and given the importance of the individuals’ own perceptions of their functional status, such scales are frequently used for measuring fatigue (Chalder et al., 2015; Piper, 1997). A multidimensional measurement model that assesses subjective dimensions of fatigue (cognitive, behavioural, sensory, and affective) was selected (Ahlberg et al., 2003; Piper et al., 1998; Reeve et al., 2012). These dimensions are in keeping with the CBT approach that was applied throughout the design of the trial. The Piper Fatigue scale also includes open-ended questions that assess cause, other symptoms, and relief strategies (Ahlberg et al., 2003; Piper et al., 1998).
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In future iterations of the trial it may be of use to supplement the subjective measures of fatigue with objective instruments and outcomes that are associated with fatigue (i.e. proxy measures) to increase validity and reliability—e.g., actigraphy to measure activity and sleep, biochemical markers for fatigue (Ahlberg et al., 2003). However, Aaronson et al. (1999) recommend that researchers should consider the relevant features of fatigue that are pertinent to a study when selecting a specific measure.

7.9.2 The potential harm of symptom focusing

Ogden (2016) notes that health behaviour change interventions have the potential for harm as well as their intended benefits. It is, therefore, important to highlight how researching this issue may have inadvertently contributed to psychological harms.

One of these potential harms relates to symptom focusing. Symptom focusing relates to excessive focusing on bodily sensations (Skerrett & Moss-Morris, 2006) and has been linked to poor patient and outcomes and negative affect in those with fatigue (Band, Wearden, & Barrowclough, 2015; Hughes, Hirsch, Chalder, & Moss-Morris, 2016). While encouraging participants to become aware of the behaviours associated with their fatigue, it was important that they did not become preoccupied with their symptoms. Therefore, self-monitoring fatigue was only advised to be carried over the course of two weeks. This allowed participants to gain an understanding of their symptoms over a short period. The topic of symptom focusing was raised in 3 of the sessions. This was to provide individuals with an insight into both the potential benefits and harms of monitoring symptoms. Participants were encouraged to focus on what they could do, and what they wanted to achieve rather than on their fatigue per se. Participants were also advised on how to distract themselves and disengage from symptom focusing. Graded activity was recommended throughout the programme, in order to facilitate reductions in the extent to which patients focus on their
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symptoms (Moss-Morris et al., 2005). Moss-Morris et al. (2005) has previously reported that the combined impact of decreasing symptom focusing and increasing beliefs in treatment control were associated with decreases in mental and physical fatigue and increased physical functioning in individuals with MS. Finally, the use of the Cognitive and Behavioural Responses to Symptoms Questionnaire (CBSQ) (Skerrett & Moss-Morris, 2006) allowed the researchers to assess how much patients focus on their symptoms.

As fatigue is a symptom of cancer and recurrence, it was particularly important that participants were encouraged to recognise the intervention as supplementary support to their standard care, rather than as a stand-alone treatment of any kind. A disclaimer was placed on the website homepage to this effect, and participants were regularly reminded to discuss any persistent symptoms with their healthcare providers at regular intervals.

7.10 Implications for research and practice

The purpose of this research was to provide a basis for future intervention research targeting the self-management of CrF in post-treatment cancer survivors. Based on the findings of this research, a robust case can be made for the potential clinical importance of the intervention and of subsequent larger scale pilot studies (Hoddinott, 2015). Future interventions should be designed to incorporate the views of potential end-users. This may benefit intervention development by highlighting unmet needs, identifying theoretical frameworks, and enabling iterative design of websites based on a person-centred approach (Craig et al., 2013; Yardley et al., 2015).

In addition, future interventions may reduce barriers to care provision by further engaging service providers, such as oncology nurses and GPs in the design of the intervention and in recruiting participants. Service providers and service users may not always succeed in the collaborative management of chronic symptoms such as fatigue (J. A. Hall, Stein, Roter, &
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Rieser, 1999; Piredda et al., 2007). Future interventions could aim to address the patient-carer dynamic by addressing factors such as knowledge, skills, and expectations. Such interventions could target health care professionals as well as patients, in order to promote non-judgemental discussion of survivorship-related issues and support for self-management.

7.11 Strengths and limitations

This study has a number of strengths and limitations which are addressed below.

A systematic review and meta-analysis of studies related to psychological interventions for CrF in post-treatment cancer survivors was conducted. This review was based on a pre-established review protocol that was registered and published in advance of the review being undertaken (Corbett et al, 2015). Study risk of bias/quality assessment was performed and incorporated into the analysis. The review also searched sources of unpublished data, and the risk of publication bias was considered. Study authors were contacted about conference proceedings and any necessary information that was not reported in the paper. However, methodological issues existed across the studies in this review. A meta-analysis was conducted as each study met the stringent pre-specified inclusion criteria. While these studies contributed to answering the review question, the studies were quite heterogeneous in design and quality. Therefore a narrative synthesis was conducted in conjunction with the presentation of meta-analytic findings. The issues relating to heterogeneity and study quality should be considered in interpreting the findings and applying them to future studies. The findings of this review served to identify gaps in the literature related to the review topic and provided an overview of existing knowledge.

In the focus group study, attempts were made to avoid bias in how the data was collected and interpreted. The moderators of the groups were experienced in qualitative research and followed an interview schedule. Questions were designed to be neutral and answerable.
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General questions were asked before specific questions. Factors such the moderator’s age, social status, race, and gender may have led to bias. The university setting of the interviews may have affected how comfortable participants were in discussing sensitive matters in the group. Efforts were made to ensure comfort by having a brief informal introduction over tea and coffee before the interviews started.

The author of this thesis analysed the data and was also a moderator in the focus groups. This may have resulted in bias when reporting the findings. Experiences, beliefs, goals of the research and personality could bias analysis and reporting. However, efforts were made to minimise this bias by specifying the questions a priori in an interview schedule and following a coding manual (Appendix 7 and Appendix 8). The author was assisted in the focus groups by another moderator (BMG) and the data was analysed with a co-author (AMG), with any further issues discussed with all study co-authors. However, one interview only was conducted with each group. The study aimed to be exploratory and descriptive in nature, but it may have been of benefit to check the validity of emerging themes by pursuing clarification and follow-up interviews with participants.

In the feasibility trial there are a few limitations to note. These are related to the sample size, the use of self-report to collect fatigue-related data, and lack of insight into reasons for self-selection into the study and loss-to-follow-up.

The study lacked important qualitative insight about reasons to discontinue use of the intervention. Stopping with the intervention might be related to individual characteristics (e.g. preference), content of the website (e.g., too burdensome or sensitive information), or the other factors (e.g., concurrent life events). Participants were invited to contact the study authors if they did not want to proceed, but few chose to notify the authors about
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discontinuation. Efforts were made to identify characteristics of completers compared to non-completers of the study and no differences were identified. However, overall there was a lack of sufficient data to specify the causes of attrition. Some specific intervention have been linked to improved adherence. These include a strong theoretical foundation; user perceptions that the intervention is relevant, credible, and effective; use of strategies such as tailoring, prompting, and social support (Murray, 2012). However, it is less clear what user characteristics might predict adherence or engagement.

As this was a feasibility study, our sample size was too small to determine the effectiveness of the study. However, the small numbers also limit the representativeness of the study sample compared to the wider population. A larger sample may have resulted in more reliable conclusions in this study (Muthén & Muthén, 2002). Factors that were not impacted by this intervention but were hypothesised to do so, such as CrF-related perceptions and behaviour, may be impacted in future iterations of the trial with a larger sample size. Further, the favourable response to the website may have been linked to participants’ initial motivation to take part in the study and contribute to research.

It is still unclear what level of engagement is required for individuals to benefit from the intervention (i.e. “effective dose”). Further, it is unclear what factors might explain how the level of required “effective dose” differs between users.

Participants were recruited online and through cancer support services and GPs in the Republic of Ireland. Online recruitment was an important feature of this study given that participants often do not discuss fatigue symptoms with healthcare providers (Scott et al., 2011). Further, it allowed for the recruitment of those who are already engaged online. The study was linked to local charity, Cancer Care West who co-funded the research. This link was promoted to enhance trust. The website was formally launched with the support of the
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charity Director and the charity logo appeared on each page of the REFRESH website. However, the study was not formally linked to any other cancer services or GP clinics. The study was promoted by some small local cancer support organisations, but recruitment could have been further boosted by promotion of the research by the national services such as the Marie Keating Foundation or the Irish Cancer Society. Regarding healthcare professionals, in some cases nurses and GPs found out about the study online (via Twitter) or in local media, and recommended the study to their patient. In other cases, the GPs had been contacted by the researcher. Establishing formal links with particular charities or GP surgeries may have been a more productive approach to recruitment. This way, the service providers would have become more familiar with the research aims and the recruitment criteria of the study, and may have been in a better position to support the recruitment process. Further, it may have enhanced the credibility of the study for any potential participants who were unsure about the online nature of the study.

Some participants indicated that it would have been useful to incorporate some of the website content into a mobile application for use on a smartphone. However, Martin et al (2016) have recently found that cancer survivors were very interested in computer-based programmes, with 69% of 847 breast, prostate and colorectal cancer survivors stating that they were ‘not at all interested’ in smartphone interventions. However, in future iterations of this trial, it may be useful to develop a supportive mobile application that would allow participants to complete the printable elements of the programme (i.e. online diaries or planners), while still accessing the full computer-based website for other parts of the intervention (e.g. sessions, videos etc.).
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7.12 Conclusions

The complexity of CrF has been acknowledged in previous research (Mitchell et al., 2007; Weis & Horneber, 2015a), however, few interventions have explored the psychological factors that may potentially underpin effective interventions for the management of fatigue in cancer survivors. Post-treatment CrF should be understood in terms of the social context of individuals who are confronted with an ambiguous and unexplained symptom as they are trying to ‘return to normal’ after cancer treatment. Interventions should aim to address their ‘common-sense’ representations and understanding of fatigue, while supporting appropriate self-management and coping strategies. In addition, these interventions need to be developed in collaboration with those they are designed for.

This thesis has outlined the development of REFRESH, an online CBT-based intervention for CrF after the completion of cancer treatment that was developed through the systematic application of theory, evidence, and user-testing (Michie et al., 2012). Despite being a complex and multifaceted intervention, transparency was sought by detailing the components of the intervention, the proposed mechanisms of change. Efforts were made to reduce the ‘black box’ criticism of interventions (Craig et al., 2008; Michie et al., 2012) by offering a clear description of the intended intervention, and how it is expected to work, prior to its evaluation (Moore et al., 2015). The co-creation of the intervention with the experts and service users allowed the design team to ensure that an acceptable intervention was developed. Involving users from the target group at the design stage can significantly contribute to the development of interventions by highlighting aspects of the design that would have otherwise been missed (Foster et al., 2015; Owens et al., 2011).

This evidence-based online programme is the first intervention of its kind based on SRM theory, with the primary aim of targeting the representations of fatigue and enhancing self-
Chapter 7. General discussion

management of CrF specifically. It also provides the first systematic coding of a CBT intervention using the BCT taxonomy (v1). The content is based on CBT and provides evidence-based self-management strategies in addition to education and information provision.

The evidence offers a unique contribution to the cancer survivorship literature focused on the comprehensive psychosocial management of fatigue in cancer survivors. This research may influence practice related to cancer survivorship care. This type of online programme may have the potential to provide supplementary support to individuals after they have completed their treatment for cancer.
References


References


References


References


References


References


References


References


211

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References


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References


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References


The development of an online intervention for post-treatment cancer survivors with cancer-related fatigue: Appendices

Volume II of thesis submitted for the Degree of Doctor of Philosophy

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Submitted August 2016
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Appendix 1. Characteristics of studies in systematic review
Bantum 2014

<table>
<thead>
<tr>
<th>Methods</th>
<th>Web-Based Health Behaviour Change Intervention: Randomized Controlled Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Eligibility requirements for the STC trial were intentionally broad and included age (18 years of age or older), completion of primary treatment at least four weeks prior, but not more than 5 years before joining the study, diagnosis with only one cancer and no recurrence, access to the Internet, and ability to read English</td>
</tr>
<tr>
<td>Intervention Details</td>
<td>“Surviving and Thriving with Cancer” (STC) intervention, adapted from Chronic Disease Self-Management Program (CDSM), a patient education course adopting the underlying principle that people with similar health conditions can help each other improve their health behaviours. Modules on the changes in body, sleep, and other side effects associated with post-treatment recovery were added to the program. Each session of the six-week course included approximately 30-35 webpages of didactic material (in the “Learning Centre” of the STC) that is geared towards skills building, information about specific content, and the encouragement of weekly action plans to build self-efficacy. Examples of content include improving diet by making healthier food choices, increasing exercise, stress management via relaxation training, improving communication with health care providers, processing and communicating emotional experiences to people inside of one’s existing social network, as well as group members, and fatigue management. Users were invited to identify a health behaviour they would like to change and were guided, in both the didactic materials, as well as by facilitators on how to set realistic, achievable goals, which were called action plans. These weekly action plans were posted on the “Discussion Centre” (see below) and facilitators provided feedback and help. Participants were prompted both in the middle and at the end of a given week, via an automated message, to update the group on their progress as well as provide feedback to other group members.</td>
</tr>
<tr>
<td>Cohort (group)</td>
<td>consisted of approximately 20-25 survivors, nine groups</td>
</tr>
<tr>
<td>Quantum of Treatment:</td>
<td>a six-week course. 30-35 webpages per module. Survey data were collected at two time points: baseline and six months later</td>
</tr>
<tr>
<td>Intervention provider/therapist:</td>
<td>two facilitators who were cancer survivors: intensive online training about both the content of the intervention materials and how to respond to users’ comments and goals. Mentored by PIs, who during the course of the intervention also read all posts and gave feedback and help to the facilitators as needed. the mean number of sessions ever attended (logged on at least once) was 5.3 (SD 1.28) with the range being 0-6, and 67.0% (203/303) of participants attended all six sessions, with 86.8% (263/303) attending 4 or more</td>
</tr>
</tbody>
</table>
sessions. There were 8016 total posts by treatment participants for an average of 46 posts per participant over the six-week intervention period.

**Comparison:** Wait-list control: The delayed treatment control condition received no information or materials until after second data collection point.

**Outcomes**

The Brief Fatigue Inventory (BFI); Women’s Health Initiative Insomnia Rating Scale (WHIIRS); The Godin Exercise Questionnaire; Patient Health Questionnaire

**Notes**

All participants received a US $10.00 Amazon voucher for completing each questionnaire.

Less education (OR 0.84, 95% CI 0.75-0.95, per one year increase) and having long-term back pain (OR 2.31, 95% CI 1.13-4.75) was associated with dropout between baseline and 6 month follow-up.

With the exception of age, no significant differences were found among the two groups.

both groups reported mild levels of fatigue

a large percentage of female breast cancer survivors (47%)

---

**Risk of bias table**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Once 40 to 50 participants had completed their baseline questionnaire, they were numbered in the order of completion and then randomized.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Randomization was conducted on a group-by-group basis. Randomized, using a random number table, half to treatment, and half to wait-list control.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Not possible</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>Not specified</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>(&lt;20%) Roughly 14% (13.9%, 49/352) of participants who were randomized did not provide any data at 6 months, which did not differ by condition (11.4%, 20/176 and 16.5%, 29/176) for control and intervention, respectively).</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>The trial appears to be free of other problems that could put it at a high risk of bias</td>
</tr>
</tbody>
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4
Development of an online intervention for cancer survivors with cancer-related fatigue:

Appendices

*Bennett 2007*

<table>
<thead>
<tr>
<th>Methods</th>
<th>Motivational Interviewing to Increase Physical Activity in Long-Term Cancer Survivors: A Randomized Controlled Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participants</strong></td>
<td><strong>Inclusion criteria:</strong> cancer survivors aged 18 years or older; who completed treatment at least 6 months prior to enrolment; and who were fatigued, under active (engaged in planned exercise fewer than 3 days a week for 20 minutes per session), and willing to try to increase their regular physical activity. <strong>Exclusion criteria:</strong> prior transplant treatment for cancer, current immunosuppressive therapy, medical conditions that contraindicated moderate exercise, cognitive difficulties, or psychiatric disorders</td>
</tr>
<tr>
<td><strong>Intervention Details</strong></td>
<td>· Tailored Motivational Interviewing · Measurements taken: Baseline, 3 months and 6 months · Participants received counselling session during enrolment appointment immediately following group assignment. 2 weeks later the participants were called by physical activity counsellor, and again at 2 months and 4.5 months after enrolment <strong>Quantum of Treatment:</strong> · Duration of each MI session: approximately 10 minutes x3; Duration of each phone call: 20 minutes <strong>Intervention provider/therapist:</strong> a master's-prepared research assistant who received 8 hours of group training and 6 hours of individual training by an experienced MI trainer who had met the requirements of the Motivational Interviewing Network of Trainers. <strong>Comparison:</strong> control group asked to maintain current level of physical activity, received 2x phone calls at 2 and 4.5 months. Calls used to set time for 3 and 6 month measurement appointments and for brief social conversations but MI strategies were not used</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td><strong>Physical Health Status and Mental Health Status</strong> variables were measured by the Medical Outcomes Study Short-Form 36 (SF-36, v.2) Physical Component Summary (PCS) and Mental Component Summary (MCS; <em>Ware, 2005</em>). <strong>Fatigue</strong> was measured by the Schwartz Cancer Fatigue Scale (<em>Schwartz &amp; Meek, 1999</em>).</td>
</tr>
</tbody>
</table>
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Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>“A physical activity counsellor assigned each participant to either the intervention or the control group according to a computer-generated randomization scheme.”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>“Assignments were placed in sealed envelopes prior to study.”</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>“The physical activity counsellor who conducted the MI intervention was not blinded to group assignment.”</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>“The physical activity counsellor who conducted the outcome measurements was not blinded to group assignment.”</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>&gt;20% attrition from both arms at follow-up</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>2 intervention participants withdrew due to broken leg</td>
</tr>
</tbody>
</table>

Bower 2015

Methods

Mindfulness Meditation for Younger Breast Cancer Survivors: A Randomized Controlled Trial

Participants

Inclusion criteria were: 1) diagnosis with stage 0, I, II, or III breast cancer at or before age 50 years; and 2) completed local and/or adjuvant cancer therapy (except hormone therapy) at least 3 months previously. Exclusion criteria were: 1) breast cancer recurrence, metastasis, or another cancer diagnosis (excluding non-melanoma skin cancer); 2) active, uncontrolled medical illness that could impact inflammation; and 3) inability to commit to the intervention schedule.

Intervention Details

The intervention was based on the Mindful Awareness Practices (MAPs) program at UCLA tailored for younger survivors by including information about maintaining health and preventing breast cancer recurrence. Mindfulness, relaxation, and the mind-body connection; experiential practice of meditation and gentle movement exercises (e.g., mindful walking); and a psychoeducational component for cancer survivors. Lectures, discussions, and group processes focused on solving problems concerning impediments to effective practice, working with difficult
Development of an online intervention for cancer survivors with cancer-related fatigue:

Appendices

thoughts and emotions, managing pain, and cultivation of loving kindness. Home practice on a daily basis.

**Quantum of Treatment** 6 weekly, 2-hour group sessions. Daily home-practice 5-20mins. mean number of classes attended was 5.24 (range, 2-6 classes), mindfulness practice during the 6-week intervention period (including time spent in the mindfulness classes and home practice) was 897 minutes (range, 305-1527 minutes)

**Intervention provider/therapist:**

**Comparison:** wait-list condition

**Outcomes** Fatigue, sleep quality, perceived stress, and depressive symptoms.

**Notes**
- Included women up to 10 years after cancer treatment, because the need for and benefits from stress management are not time-limited.
- intent-to-treat analyses were conducted
- Intervention group were less likely to be married and were more likely to have received radiation and/or to have history of smoking than control. Control higher depressive symptoms
- Assessments were conducted before and within 1 or 2 weeks after the intervention. A follow-up questionnaire packet was mailed to participants 3 months after the intervention to assess the persistence of treatment effects

**Risk of bias table**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Once a sufficient number of participants to comprise the mindfulness and control groups (8-14 women) had been screened as eligible and had completed the baseline assessment, they were randomized (4:3) to the intervention group or the wait-list control group, with slightly more women allocated to the intervention group to maintain adequate group size. Participants were recruited through invitations to women who had enrolled in an earlier study</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>condition assignments were kept in sealed envelopes in the research office,</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Not possible</td>
</tr>
<tr>
<td>Blinding of outcome</td>
<td>Unclear risk</td>
<td>Baseline assessment prior to randomisation</td>
</tr>
</tbody>
</table>
Development of an online intervention for cancer survivors with cancer-related fatigue:

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Assessment (detection bias)

Incomplete outcome data (attrition bias)

Low risk

Follow-up of 92% at the primary endpoint. 83% completed the 3-month follow-up questionnaire

Selective reporting (reporting bias)

Low risk

All pre-specified outcomes reported

Other bias

Unclear risk

Participants were recruited through invitations to women who had enrolled in an earlier study

Dirksen 2008

Methods

Insomnia intervention on fatigue, mood and quality of life in breast cancer survivors

Participants

Inclusion criteria:

· Stage I, II or III breast cancer
· at least 3 months post completion of primary cancer treatment
· Without current evidence of disease.
· concerned about their sleep, reported impaired daytime functioning and disturbed sleep
· The insomnia inclusion criteria: the International Classification of Sleep Disorders (American Sleep Disorders Association 1997) and the insomnia intervention research literature.
· Women who were taking a stable dose of antidepressants and sleep medications were not excluded.

Exclusion criteria: Cognitive impairment as determined by the Mini-Mental State Examination (Folstein et al. 1975) and/or suspicion of sleep apnoea, restless leg syndrome, or periodic limb movement disorder based on a screening interview.

Intervention Details

· CBT for insomnia with stimulus control instructions (SCI), sleep restriction therapy (SRT), and sleep education and hygiene (SEH) content including cognitive strategies.
· sleep diaries, discussing progress and encouraging adherence
· Participants wore the wrist actigraph.

Quantum of Treatment:

· The first class was approximately 2 hours in length, the remaining three classes were an hour or less
· Telephone sessions lasted approximately 15 minutes.
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**Intervention provider/therapist:** Master’s level Registered Nurse therapist.

**Comparison:**
- sleep education and hygiene (SEH)
- Participants in the CC group were offered CBT-I after the post-treatment measurement phase.

**Outcomes**
- Fatigue
- Mood
- Quality of life
- General quality of life
- Physical well-being
- Emotional well-being
- Social well-being
- Functional well-being

**Risk of bias table**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>“Participants were randomly assigned to treatment groups by the research assistant through the use of a random numbers table.”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Not specified</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>“The research assistant was not blinded to the group assignment”</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>Participants: due to the nature of the intervention content, participants could not have been blinded</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>&gt;20% attrition</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All outcomes specified in methods reported in results</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>The trial appears to be free of other problems that could put it at a high risk of bias</td>
</tr>
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</table>

*Dolbeault 2009*
Development of an online intervention for cancer survivors with cancer-related fatigue:

Appendices

<table>
<thead>
<tr>
<th>Methods</th>
<th>Psycho-educational group after early-stage breast cancer treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td><strong>Inclusion criteria:</strong> women (1) were 18 or older, (2) had completed primary breast cancer treatment (radiation alone or combined chemo-radiotherapy 15 days to 1 year before testing), (3) had working knowledge of French</td>
</tr>
<tr>
<td></td>
<td><strong>Exclusion criteria:</strong> (1) Psychiatric diagnosis such as severe cognitive disorders, mood disorders (ongoing or recent history of depression requiring hospitalization) or serious personality disorders. (2) recurrence or metastases,</td>
</tr>
<tr>
<td>Intervention Details</td>
<td>Psychoeducational structured model based on CBT principles. Taught to routinely use thought records, to practise problem-solving and cognitive restructuring, to communicate better with caregivers and health professionals through role-play, and to practice relaxation. All PEG exercises were combined with general medical information and peer exchanges on defined themes (causes and significance of cancer, impact of treatments on body image, managing uncertainty, improving communication with loved ones, etc.).</td>
</tr>
<tr>
<td>Quantum of Treatment</td>
<td>8 weekly 2 h sessions, groups were composed of 8–12 participants</td>
</tr>
<tr>
<td>Intervention provider/therapist</td>
<td>led by 2 therapists, either psychologists or psychiatrists trained in group therapy and BCT</td>
</tr>
<tr>
<td>Comparison</td>
<td>‘deferred group’</td>
</tr>
<tr>
<td>Outcomes</td>
<td><strong>Fatigue</strong> (POMS and EORTC)</td>
</tr>
<tr>
<td></td>
<td><strong>functional impact of fatigue</strong> (POMS Vigour, POMS Interpersonal Relationships, EORTC Physical Functioning, EORTC Role Functioning, EORTC Emotional Functioning, EORTC Cognitive Functioning, EORTC Social Functioning)</td>
</tr>
<tr>
<td></td>
<td><strong>mood</strong> (STAI Y-A, STAI Y-B, POMS Anxiety, POMS Anger, POMS Confusion, POMS Depression, MAC Hopelessness/Helplessness, MAC Anxious Preoccupation)</td>
</tr>
<tr>
<td></td>
<td><strong>perceived coping with fatigue</strong> (POMS Global score, EORTC Sleep)</td>
</tr>
<tr>
<td></td>
<td><strong>global quality of life</strong> (EORTC Health Status)</td>
</tr>
<tr>
<td>Include?</td>
<td>EORTC Nausea (<em>functional impact of fatigue</em>)</td>
</tr>
<tr>
<td></td>
<td>EORTC Pain (<em>functional impact of fatigue</em>)</td>
</tr>
<tr>
<td></td>
<td>EORTC Dyspnoea (<em>functional impact of fatigue</em>)</td>
</tr>
<tr>
<td></td>
<td>EORTC Financial Difficulties (<em>functional impact of fatigue</em>)</td>
</tr>
</tbody>
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Development of an online intervention for cancer survivors with cancer-related fatigue:

Appendices

EORTC Body image (functional impact of fatigue?)
EORTC Future Prospects (functional impact of fatigue?)
EORTC Breast Symptoms (functional impact of fatigue?)

Notes
Monthly meetings were organised with leaders, co-leaders, and investigators to ensure the coherence of intervention delivery.

The intervention was free of charge for patients, therapists being paid by hospital and research funding.

Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation</td>
<td>Low risk</td>
<td>Randomized between the ‘immediate’ treated group (TG: n=102) and the ‘deferred’ control group (CG: n=101). Randomization by sealed letter was performed at each site, with a readjustment of the number of subjects in each group after every eighth subject. After randomization, patients who dropped out were not replaced</td>
</tr>
<tr>
<td>Allocation concealment</td>
<td>Low risk</td>
<td>Randomization was performed to distribute the eligible patients after an interview to clarify their motivations.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Unclear risk</td>
<td>Not possible</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>Not specified</td>
</tr>
<tr>
<td>Incomplete outcome data</td>
<td>High risk</td>
<td>Patients who missed four group sessions were excluded from the analyses.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Completed in treatment group n = 81 (79 %)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Completed in control group n = 87 (86 %)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>lack of complete data for one-fifth of the patients, who did not complete the questionnaires at all three evaluation times</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported</td>
</tr>
</tbody>
</table>
Other bias: Low risk. The trial appears to be free of other problems that could put it at a high risk of bias.

Espie 2008

Methods: Randomized Controlled Clinical Effectiveness Trial of Cognitive Behaviour Therapy Compared With Treatment As Usual for Persistent Insomnia in Patients With Cancer.

Participants:
- **Inclusion criteria**: diagnosis of breast, prostate, bowel, or gynaecological cancer, and to satisfy diagnostic criteria for chronic insomnia; mean value longer than 30 minutes for complaint of delayed sleep-onset latency (SOL) and/or wake time after sleep onset (WASO), occurring 3 nights per week for 3 months and affecting daytime function. Participants also had to screen more than 5 on the Pittsburgh Sleep Quality Index (PSQI), a psychometrically robust instrument that identifies clinically significant sleep disturbance.

- **Exclusion criteria**: acute insomnia and transient effects associated with cancer treatment/adverse effects were excluded. Treatment (radiation therapy or chemotherapy) had to be completed by 1 month with no further anticancer therapy planned (excepting adjuvant hormone therapy). Participants with acute illness, estimated prognosis fewer than 6 months, confusional problems or drug misuse, or with evidence of other sleep disorders (e.g., sleep apnoea; screened by reports of nightly snoring and nocturnal breathing pauses, plus Epworth sleepiness scale more than 10) or of untreated psychiatric disorder, were excluded.

Intervention Details:

- The intervention included standard CBT components such as stimulus control, sleep restriction, and cognitive therapy strategies. A CBT plus TAU condition because the protocol explicitly permitted normal continuation of health care.

- **Quantum of Treatment**: five, weekly, 50-minute sessions during the early afternoon or early evening.

- **Intervention provider/therapist**: trained four experienced cancer nurses, who were released on a part-time basis from oncology nursing duties, to deliver CBT. Ongoing mentoring by an experienced clinical psychologist.

- **Comparison**: Represented normal clinical practice, where physicians were free to offer appointments, to prescribe, and to maintain/discontinue prescriptions. No additional help for their insomnia. At the end of the protocol, the TAU group was provided with The Good Sleep Guide.

Outcomes:

- Evaluation of audiotapes from randomly selected sessions.

Notes:

- Stratified for centre, pre-randomization PSQI scores, existing treatment for insomnia, and tumour type using the minimization method.
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A 2:1 treatment allocation, in favour of the intervention, was selected because this made efficient use of available CBT sessions and minimized the time a patient had to wait before starting CBT, thereby, reducing patient dropout.

Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation</td>
<td>Low risk</td>
<td>Centralized computer-based registration/randomization service available within the Cancer Research UK Clinical Trials Unit, Glasgow.</td>
</tr>
<tr>
<td>(selection bias)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allocation concealment</td>
<td>Unclear risk</td>
<td>Not specified</td>
</tr>
<tr>
<td>(selection bias)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blinding of participants and</td>
<td>High risk</td>
<td>Due to the nature of the intervention, it was not possible to blind participants or therapists to allocation.</td>
</tr>
<tr>
<td>personnel (performance bias)</td>
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</tr>
<tr>
<td>Blinding of outcome assessment</td>
<td>Unclear risk</td>
<td>Not specified</td>
</tr>
<tr>
<td>(detection bias)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data</td>
<td>Unclear risk</td>
<td>Not specified</td>
</tr>
<tr>
<td>(attrition bias)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selective reporting</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported</td>
</tr>
<tr>
<td>(reporting bias)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>The trial appears to be free of other problems that could put it at a high risk of bias</td>
</tr>
</tbody>
</table>

Fillion 2008

Methods
randomized control trial of a brief group intervention that combines stress management psycho-education and physical activity

Participants
Inclusion criteria: (1) being a woman diagnosed with an initial non-metastatic breast cancer (breast cancer survivor); (2) having completed their initial breast cancer treatment no longer than 2 years before enrolment; (3) having received 1 series of adjuvant treatments of radiotherapy, or having received radiotherapy in combination with other adjuvant treatments (e.g., chemotherapy or hormonal therapy); (4) understanding and speaking French; (5) passing the revised Physical Activity Readiness Medical Examination53 to obtain the authorization of the supervising physician before performing the fitness assessment; (6) living near the cancer centre
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and being available to take part in a series of 4 weekly sessions; and (7) accepting the randomization procedure.

Exclusion criteria: (1) showed clinical levels of depression symptoms, as measured by the Hospital Anxiety and Depression Scale (score higher than 10); (2) had insomnia, as defined by the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition56;a (3) presented any symptoms of recurrence; and (4) had any known severe health problems other than cancer.

Intervention Details

The purpose of the stress/fatigue management program were (1) to acquire a broader definition of fatigue, (2) to develop relaxation skills, (3) to gain knowledge of effective coping strategies to deal with physical factors associated with fatigue (e.g., circadian cycle and sleep hygiene), (4) to discover the links between thoughts, emotions, and fatigue; (5) to articulate ways to increase self-regulation techniques (e.g., self-recording and goal setting) and apply them to individualized walking programs; and (6) to inform on how to further decrease passive coping strategies (e.g., behavioural and social disengagement and naps). As home-based assignments for the stress/fatigue management component, participants were invited to practice relaxation and complete self-rating records of it. The walking portion of the program included behavioural strategies and cognitive strategies. The behavioural strategies included (1) a personal-physical exercise program was established by the kinesiologist for each participant according to their physical condition and personal goal; (2) a written contractual agreement to try out a new strategy for a short period of time constituted the starting prescription (e.g., frequency and intensity were indicated); (3) an initial training session and supervision of the exercise intensity (i.e., using a Polar heart rate monitor for objective feedback) was first done at the hospital after the initial physical assessment and the contract agreement; (4) participants were encouraged to perform their home-based assignments (e.g., walking program individualized in terms of intensity and frequency); (5) an ambulatory device was provided to each participant to self-monitor his or her cardiac function during home-based exercises and complete his or her personal log between sessions (i.e., the Polar heart rate wristwatch); and (6) the contractual agreement was revised each week by the kinesiologist during the walking session.

The walking prescription progressed differently for each participant according to their physical condition and personal goal. The cognitive strategies included (1) awareness of the benefits of exercise, focus on the benefits rather than the elimination of negative life circumstances (e.g., exercise can be promoted as an activity that will result in more energy, rather than one that will reduce fatigue); (2) awareness of immediate outcomes from exercising (e.g., enhance mood and energy, rather than long-term changes such as weight); (3) adherence techniques and focusing on the fact that one has considerable choice and control related to exercise; and (4) feedback on
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Physical activity from nurses at each management session and support to reinforce self-efficacy, motivation, and positive outcomes. The cognitive strategies were mostly included in the psycho-education management sessions co-led by nurses. Alongside the individually prescribed walking program, another behavioural active coping strategy was proposed: Participants received 20-minute, muscle-relaxation recordings and were invited to listen to them daily. The only booster telephone session occurred midway between the end of the intervention and the follow-up measurement at 3 months, that is, between the seventh and eighth week after completing the intervention. This booster telephone session was conducted by facilitating nurse and its purpose was to verify whether the participants pursued their walking program, encourage them to do so, and identify obstacles to walking if they were not.

Quantum of Treatment: 4 weekly group meetings of 2.5 hours and 1 short telephone Booster session (5Y15 minutes). One hour was devoted to the supervision of walking training by a kinesiologist or a trained research nurse, and 1.5 hours to the psycho-educative, fatigue management sessions, which were codirected by 2 oncology nurses. The nurses were trained in cognitive behavioural approaches and were supervised by a health psychologist (approximately 10 hours, in addition to 6 hours of reading).

Intervention provider/therapist: kinesiologist, trained research nurses,

Comparison:
Usual-care (control) condition.
Conventional medical follow-up for breast cancer treatments.

Outcomes
Fatigue

Secondary outcomes:
energy level
quality of life (mental and physical)
emotional distress

Notes
The stress management sessions were audiotaped in order to validate the information provided, that is, to ensure that the content was as planned. The audiotapes were listened to by 2 research assistants, and inter-reliability was verified. 100% of the sessions were reviewed for validation; 96% of the planned content was taught.

Baseline (T0), immediately after the intervention (T1), and a 3-month follow-up (T2).

Intention-to-treat basis (i.e., all participants with complete interview setsV3 times) according to their assigned conditions regardless of adherence.

Risk of bias table
Appendices

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>The sequence of randomization was computer generated, after a preliminary stratification, according to the adjuvant treatments received.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>The research assistant assessed eligibility, explained the study and the randomization procedure, and obtained informed consent for those who agreed to participate.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Not possible in this study</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>Not reported</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk (&lt;20%)</td>
<td>3 x control group lost to follow up</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 x experimental group lost to follow up</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>The trial appears to be free of other problems that could put it at a high risk of bias</td>
</tr>
</tbody>
</table>

Foster (2015)

Methods web-based intervention (RESTORE) to support self-management of cancer-related fatigue following primary cancer treatment: a multi-centre proof of concept randomised controlled trial

Participants Eligible participants were: ≥18 years; with clinical diagnosis of invasive cancer ≤ 5 years previously; had completed curative intent treatment (surgery/cytotoxic chemotherapy/radiotherapy); had no evidence of metastatic disease; self-reported moderate to severe fatigue (fatigue of ≥ 4 on 11-point rating scale) [26]; with access to the internet and with/willing to create an email account. Individuals were excluded if their clinical care team deemed them unable to give informed consent, had a mental health condition likely to be exacerbated by participation or were too ill to engage in the study

Intervention Details Online intervention named RESTORE informed by Macmillan Cancer Backup’s leaflet, *Coping with Fatigue* [24], self-efficacy theory, cognitive behavioural therapy, and evidence of fatigue management in cancer survivors. Presented with 5 sessions at weekly intervals. Sessions 1 and 2 were mandatory and introduced CRF and goal setting. For the next 3 weeks
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participants chose from: i) diet, sleep, exercise, home and work life; ii) thoughts and feelings; iii) talking to others. Participants can choose to complete all available sessions or spend more time on the area/s most important to them. Structured activities were available throughout including goal setting, automated tailored feedback on achievement of goals and fatigue level, and videos of patient stories. Participants were also encouraged to download and complete a fatigue diary.

Quantum of Treatment: 6 weeks. The RESTORE group received automated weekly emails announcing the availability of their next session, and reminders if they had not accessed the session within 7 days

Intervention provider/therapist:

Comparison:

Macmillan Cancer Backup’s leaflet, Coping with Fatigue. RESTORE was available to both groups after completion of T2 questionnaires.

Outcomes

Brief Fatigue Inventory (BFI)


Personal Wellbeing Index (PWI) Patient Health Questionnaire (PHQ-9)

Notes

Unpublished paper sought from author

Based on self-efficacy theory.

Participants completed further questionnaires at 6 (T1) and 12 weeks (T2) post baseline.

Intervention adherence was examined by usage data. Accessing session three was chosen as the cut-off for adherence as this is where participants begin to set goals and engage with other activities not available in the leaflet.

the intervention group had: a higher proportion ‘not working’ (48.8% vs. 36.0%), primarily due to more retired people in this group; and a greater number of days since last cytotoxic treatment (577.71 vs. 484.61)

Missing data were handled using multiple imputation where appropriate

Risk of bias table

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Random sequence generation</td>
<td>Low risk</td>
<td>A statistician independently generated a random allocation sequence, using ‘R’ for each NHS Centre, and participants were randomised in blocks of four</td>
</tr>
<tr>
<td>(selection bias)</td>
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</table>
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<table>
<thead>
<tr>
<th>Allocation concealment (selection bias)</th>
<th>Low risk</th>
<th>Participants were randomised by the research team after completion of T0 questionnaires.</th>
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<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Not possible</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Statisticians and members of the research team not involved in recruitment were blinded during analysis.</td>
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<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>High risk</td>
<td>36% attrition</td>
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<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>The trial appears to be free of other problems that could put it at a high risk of bias</td>
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</table>

Freeman 2015

Methods randomized trial comparing live and telemedicine deliveries of an imagery-based behavioural intervention for breast cancer survivors: reducing symptoms and barriers to care

Participants Confirmed diagnosis of breast cancer, 18 years of age or older, and with no major psychiatric illness. Participants were required to be visual and hearing capable, able to read, write and speak English, and demonstrate an orientation to person, place, and time.

Intervention Details Live delivery (LD) and telemedicine delivery (TD) group. Format followed a manual developed by the first author, and was identical for both delivery types. First four sessions were separated into three modules. Education on the mind–body connection; impact of mental imagery and the sensate experience (e.g., sounds, scent, taste, and touch) on physiological processes (e.g., psychoneuroimmunology processes, heart rate variability (HRV), temperature, and circadian rhythms) [[15-18]]. The interactive portion of sessions enabled participants to apply what they just learned and receive feedback from their small group and the therapist, who briefly visited with each triad during the interactive group time. Participants identified maladaptive ‘passive imagery’ (e.g., automatic thoughts focused on fear/loss of control), created adaptive ‘active imagery’ (e.g., thoughts focused on empowering, meaning–making themes), and practiced ‘targeted imagery’ (e.g., imagining healthy physiological processes such as HRV, circadian rhythms, and immune function). Participants were instructed to engage all five senses during active and targeted imagery and to monitor
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the effects of imagery on their own mind–body health. Participants received a guided imagery compact disc related to each week's topic- instructed to engage in daily formal (using compact discs) and informal (using brief targeted imagery when under stress) practice. Participants received weekly phone calls from their group therapist, designed to encourage participants to engage in practice and troubleshoot barriers to practice. All sessions were videotaped, and 10% was randomly chosen for evaluation of ongoing treatment fidelity. Participants who missed a session were encouraged to attend a one-on-one make-up session with the group therapist, who presented the didactic lessons using the same materials and format as were used in the group session.

Quantum of Treatment Participants in LD and TD had five 4-h weekly group sessions and received brief (<10 min) weekly phone calls to encourage at-home practice that began at the start of treatment and continued for 3-month post-treatment. Each module 25 min of didactic education followed by 25 min of interaction with fellow group members (in triads). Participants received a 20–30 min guided imagery compact disc related to each week's topic- instructed to engage in daily formal (using compact discs) and informal (using brief targeted imagery when under stress) practice. Participants received weekly phone calls from their group therapist (approximately 10 min) during intervention delivery and for 3-month post-treatment.

Intervention provider/therapist: first and second authors, a licensed professional counsellor, and a family medicine physician

Comparison:

WL group were offered ERL intervention delivered with a therapist present after they completed the 3-month follow-up.

Outcomes

General health-related QOL was measured using the Medical Outcomes Study 36-item short form survey (SF-36); Functional Assessment of Cancer Therapy-Breast (FACT-B) [20] assessed breast cancer-specific QOL. Fatigue was assessed using the FACIT-Fatigue Scale (FACIT-F, version 4), Perceived cognitive function was assessed with the FACT-Cog (version 2); Spiritual well-being was measured with the Functional Assessment of Chronic Illness Therapy Spiritual Well-Being Expanded Scale (FACIT-Spa-Ex; version 4); Psychological distress was assessed using the Brief Symptom Inventory-Global Severity Index (BSI-GSI) ; Sleep disturbances were assessed using the Pittsburgh Sleep Quality Index (PSQI

Notes

All self-report questionnaires were completed in the presence of a research assistant and were collected at baseline and 1-month and 3-month post-treatment.
Development of an online intervention for cancer survivors with cancer-related fatigue:

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Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
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<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Assignment by adaptive randomization (minimization) was balanced by age, gender, stage, chemotherapy, surgery, radiation, and hormone use.</td>
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<tr>
<td>Allocation concealment (selection bias)</td>
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<tr>
<td>Blinding of participants and personnel (performance bias)</td>
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<tr>
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</tr>
</tbody>
</table>

Gielissen 2006

Methods

Cognitive behaviour therapy in severely fatigued disease-free cancer patients compared with patients waiting for cognitive behaviour therapy

Participants

Inclusion criteria: If a physician was certain that the fatigue had no somatic cause. Patients completed curative treatment for cancer at least 1 year previously and had no evidence of disease recurrence at the time of participation. The minimum age at disease onset was 18 years, and patients were no older than 65 years and had no current psychological or psychiatric treatment when participating in the study.

Intervention Details

CBT was focused on six perpetuating factors (six modules) of post cancer fatigue, which were based on existing literature and experience in clinical practice. They involve insufficient coping with the experience of cancer, fear of disease recurrence, dysfunctional cognitions concerning fatigue, dysregulation of sleep, dysregulation of activity, and low social support and negative social interactions. therapy was adapted to each individual

Quantum of Treatment: The therapy only varied in the number of modules, but within each module the therapy is standardized. The number of sessions was determined by the number of modules used and whether the
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goal of the therapy was reached. Therapy sessions varied between five and 26 sessions (mean, 12.5 sessions; standard deviation [SD], 4.7 sessions) with a duration of 1 hour during a 6-month period. Patients were offered a maximum of two sessions during a 6-month follow-up period.

**Intervention provider/therapist:** Three therapists with previous CBT experience with patients with chronic fatigue (e.g., patients with chronic fatigue syndrome [CFS], neuromuscular diseases, and other chronic diseases) treated the patients.

**Comparison:** Patients in the waiting list condition were informed beforehand that, if desired, they could start therapy after the second assessment.

**Outcomes**

Fatigue severity: fatigue severity subscale of the CIS.

Functional impairment: Sickness Impact Profile-8 (SIP-8).

Psychological distress: Symptom Check List 90

**Notes**

The therapists were trained in the use of instruments to determine which module should be included in the therapy. Role-playing was an important part of this training. The therapists were supervised throughout the study by one author (G.B.).

**Risk of bias table**

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</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear</td>
<td>Random assignment was done by means of a sequence of labelled cards contained in sealed, numbered envelopes prepared by a statistical adviser.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear</td>
<td>Envelopes prepared by a statistical adviser. The envelopes were opened by the researcher (M.G.) in the presence of the patient.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
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<td>Not possible in this study</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear</td>
<td>Not specified</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>High risk</td>
<td>Experimental group: 9 lost to follow-up (&lt;20%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control group: 12 lost to follow-up (44 out of 56... 20% = 11 people)</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported</td>
</tr>
<tr>
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</table>
**Development of an online intervention for cancer survivors with cancer-related fatigue:**

**Appendices**

**Hoffman 2012**

**Methods**

**Participants**

Inclusion criteria: women diagnosed with stage 0 to III breast cancer, aged between 18 and 80 years, who were aware of their cancer diagnosis, able to complete questionnaires, within 2 months to 2 years after the completion of surgery, chemotherapy, and/or radiotherapy. Patients excluded were diagnosed with stage IV breast cancer, men, did not speak English, could not give informed consent as a result of psychosis or intellectual impairment, or suffered from substance misuse, suicidal thoughts, or current psychosis.

**Intervention Details**

The 8-week MSBR program. The program aims to cultivate mindfulness, which is defined as bringing complete attention of the individual to the experience that occurs in the present moment in a non-judgemental or accepting way. The classes consisted of the following formal mindfulness practices: a body scan, gentle and appropriate lying and standing yoga-based stretches, sitting meditation, some group discussions, didactic teaching, and home practice on topics including perceptions of and reactions to life events, stress physiology, and mindfulness in communication and everyday life. Home practice was delivered by four 45-minute compact discs of formal mindfulness practices and a manual.

**Quantum of Treatment**

8 weekly classes of 2 hours in length, except the first and last classes were 2.25 hours in length, plus one 6-hour day of mindfulness in week 6. Participants were asked to practice for 40 to 45 minutes for 6 or 7 d/wk.

**Intervention provider/therapist:**

The clinician/researcher was qualified as an MBSR instructor at the University of Massachusetts Centre for Mindfulness in 2004 and the Senior Teacher Trainer of the clinician/researcher provided clinical supervision during the study.

**Comparison:**

Wait-listed controls continued with their lives as usual before participating MSBR after the study period. Controls were offered measurement tools at T1, T2, and T3 while the experimental group had their MBSR program.

**Outcomes**

Primary was mood and measured by using the POMS; POMS total mood disturbance comprises subscales that evaluate anxiety, depression, anger, vigour, fatigue, and confusion.

Functional Assessment of Cancer Therapy-Breast (FACT-B)

The Functional Assessment of Cancer Therapy-Endocrine Symptoms (FACT-ES)

WHO five-item well-being questionnaire (WHO-5)

**Notes**

Baseline (T1; weeks 2 to 0), weeks 8 to 12 (T2), and weeks 12 to 14 (T3).
## Development of an online intervention for cancer survivors with cancer-related fatigue:

### Appendices

## Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Random assignment was performed by operations director of the organization, who was independent from the study, by using an externally computer generated randomization program in blocks of four, which ensured allocation concealment because no clinician/researcher could anticipate or direct the allocation of participants.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>No clinician/researcher could anticipate or direct the allocation of participants.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>The clinician-researcher conducting the study and delivering MBSR could not be blinded to the allocation of participants to either the treatment or control group</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Anonymized data were collected by a research assistant who was blinded to group assignment and independent from MBSR deliver.</td>
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<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>High risk</td>
<td>There were three instances (two patients in the intervention group and one patient in the control group) in which more than 20% of data was missing from participants at T1, and thus, according to rules set by the questionnaire manuals, their data was excluded because it was too sparse to analyse.</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported.</td>
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Johns 2014

<table>
<thead>
<tr>
<th>Method</th>
<th>Randomized controlled pilot study of mindfulness-based stress reduction for persistently fatigued cancer survivors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>At least 18 years of age, had a cancer diagnosis, reported experiencing persistent CRF for the previous 8 weeks or longer, and reported clinically significant CRF at the time of eligibility screening. Clinically significant CRF was defined by a cut-off mean score of ≥4 across the three-item Fatigue Symptom Inventory (FSI) severity composite [22]. Participants were excluded if they had cancer treatment (other than endocrine therapy for breast cancer) in the prior 3 months, were enrolled in hospice care, had severe hearing impairment, were experiencing severe depression (Patient Health Questionnaire eight-item depression scale (PHQ-8) ≥ 20), had previously participated in a mindfulness meditation class, or did not understand English. Figure 1 represents the participant flow of the study.</td>
</tr>
<tr>
<td>Intervention Details</td>
<td>The MBSR-CRF program tested in this study maintained fidelity to standard MBSR [13]. It featured training in the mindfulness practices of the body scan, sitting meditation, gentle hatha yoga, walking meditation, and compassion meditation. The protocol was adapted for the cancer context, a practice that has precedent in previous studies [23]. MBSR-CRF adaptations included 2-h classes, seven classes instead of eight, no retreat, brief psycho-education related to CRF, and shorter guided home practices (20 min) to accommodate fatigued participants; however, all of the core content of the standard MBSR curriculum was included. Recordings of guided meditations of body scan, sitting meditation, gentle hatha yoga with chair adaptations, and compassion meditation were created by the facilitator for home practice. Guidance was to acknowledge associated thoughts, emotions, and sensations in non-judgmental compassion, while offering the possibility of grounding in sensations of lesser valence such as those of the breath or contact with body support (e.g., chair and floor). Class discussion included the contrast between catastrophizing and being willing to connect with present moment experience of transient thoughts, emotions, and sensations. Given the high rates of sleep disturbance in the sample, an optional 8-min bedtime body scan variant, ‘Arriving for Sleep’, was provided to lessen pre-sleep rumination and difficulties initiating sleep. Information on the human stress reaction routinely presented in MBSR was expanded to include evidence of the relationship of stress and fatigue [24]. Information regarding the influence of the perception of exhaustion on subsequent diminished physical activity [25] and ample evidence that physical activity is helpful with CRF [9] were included. Mindful communication practice based in insight dialog [26] was used as a vehicle for participants to explore how newly developing strategies learned in mindfulness meet the interpersonal challenges of CRF.</td>
</tr>
<tr>
<td>Quantum of Treatment</td>
<td>7x 2-h classes; shorter guided home practices (20 min)</td>
</tr>
</tbody>
</table>
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Intervention provider/therapist: The instructor had 6 years of MBSR teaching experience, completing all components of professional training leading to eligibility for MBSR Teacher Certification Review (phase 4, Oasis Institute at the Centre for Mindfulness in Medicine, Health Care and Society

Comparison: The wait-list participants were offered the 7-week MBSR course following completion of the T3 assessment, and all elected to participate. The wait-list participants completed the self-report measures immediately after the MBSR course (T4). Both groups completed a final assessment 6 months after completing their respective MBSR courses (T5).

Outcomes

Fatigue Symptom Inventory (FSI); Sheehan Disability Scale (SDS); Patient Health Questionnaire Generalized Anxiety Disorder Scale; Insomnia Severity Index

Notes

Participants received $5 for each weekly diary card submitted, regardless of the logged amount of home practice. The course instructor was blinded to patient logs and outcomes during the class. Participants completed self-report measures at baseline (T1) and then were randomized. Subsequent assessments were completed at the end of the intervention (T2) and at 1-month follow-up (T3)

Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>The randomization sequence was generated by coin toss in blocks of four by the principal investigator.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Research assistants and participants were blinded to the randomization sequence using sequentially numbered and sealed envelopes.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Not possible</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>All outcomes were self-reported on study questionnaires and therefore not subject to bias by assessor interpretation.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>No drop-out</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>The trial appears to be free of other problems that could put it at a high risk of bias</td>
</tr>
</tbody>
</table>
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Lengacher 2012

Methods

Participants

Inclusion criteria: women age 21 or older with a previous diagnosis of stage 0, I, II, or III breast cancer and who had undergone surgery, received adjuvant radiation and/or chemotherapy and completed treatment within 18 months prior to study enrolment. All subjects had to be able to read and speak English at the 8th grade level.

Exclusion criteria: included stage IV breast cancer, history of mastectomy, severe psychiatric diagnosis (e.g. bipolar disorder) and treatment for recurrent breast cancer

Intervention Details

The goal of MBSR training is to teach participants to become more aware of their thoughts and feelings through meditation practice and to pay attention and observe their responses during stressful situations (Kabat-Zinn et al., 1985). The MBSR (BC) program was condensed to a 6-week format from the original 8-week program developed by Kabat-Zinn and excluded the 1 day, 8-h silent retreat. The 6 weekly, MBSR (BC) program were 2-h sessions taught by a licensed clinical psychologist trained in MBSR and included all the original content of the 8-week program. In addition, the program included group support sessions focused on emotional/psychological responses (e.g., anxiety, depression, and fear of recurrence) and physical symptoms (e.g., pain and sleep) that are common concerns to women with breast cancer. MBSR (BC) included: (a) educational material related to relaxation, meditation, and the mind–body connection; (b) meditation practice in weekly group sessions and homework assignments; and (c) group discussion of barriers to the practice of meditation and application of mindfulness in daily situations; and (d) supportive interaction between group members. The formal meditative training consisted of 4 types of techniques (sitting and walking meditation, body scan, and gentle Hatha yoga) that focus attention on the breath (Kabat-Zinn et al., 1985). Informal mindfulness meditation was used to teach participants how to practice mindfulness in everyday life, and included being aware of pleasant and unpleasant events, routine activities, and everyday events.

Quantum of Treatment: weekly 2-hour sessions + formally meditate and perform yoga exercises for a minimum of 15–45 min per day, 6 days per week; this time increased per week as participants became more experienced. They were also asked to informally practice 15–45 min per day.

Intervention provider/therapist: a psychologist certified and trained in MBSR.

Comparison: The control regimen consisted of standard post-treatment clinic visits with their practitioners, and varied depending on the patients’ treatment plan. Participants in the control group were asked not to use or
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Practice meditation, yoga techniques, or MBSR throughout the study period, although actual compliance was not recorded. Upon completing the study, each control participant was provided with a brief overview of MBSR (BC), study materials including an MBSR (BC) manual, and 4 CDs for practice, and was offered optional scheduled classes.

Outcomes

M.D. Anderson Symptom Inventory (MDASI) (Cleeland et al., 2000) at baseline and within 2 weeks after the 6-week MBSR intervention.

The MDASI includes 13 core symptom severity items (i.e., pain, fatigue, sleep disturbance, drowsiness, lack of appetite, nausea, vomiting, shortness of breath, numbness, difficulty remembering, dry mouth, distress, and sadness) and 6 symptom interference items (i.e., general activity, mood, work (including work around the house) relations with other people, walking and enjoyment of life).

Notes

Class sizes ranged from four to eight with seven groups in total completing the sessions over 15 months. All the sessions were standardized and followed the training manual developed to maintain consistency in the program. A single trained psychologist delivered the intervention. An independent observer monitored the weekly sessions for consistency by recording the timing of the intervention activities, and the quality of each session was assessed in a qualitative post-observation report. Homework discussion, enhancing group interaction.

Week 1: overview of the intervention to establish a learning contract and to learn initial meditation and body scan procedures.

Week 2: visualization and introduced to sitting meditation with awareness of breathing as primary object of attention.

Week 3: understanding of one’s reaction to a pleasant event, body scan with response to stress, introduction of yoga postures, and how physiological correlates.

Week 4: understanding of one’s reaction to unpleasant events.

Week 5: expanded their field of awareness to allow for modification of stress inducing patterns, and continued to monitor their awareness to allow for modification of stress inducing patterns, such as mountain meditation/and or lake meditation; awareness was expanded to include objects such as bodily sensations, sounds, thoughts, and feelings.

Week 6: encouraged to internalize practice sessions and develop a pattern for themselves. A non-parametric approach was chosen because many MDASI items were positively skewed leading to high Anderson–Darling statistics (indicating non-normal distributions). Because a relatively conservative alpha level reduces the power to detect significant effects, the decision was made to additionally make within-groups comparisons (repeated measures). Given a sample size of 40 women per group, this decision reduced the detectable effect size from .8 to .6 (an improvement in power).
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Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation</td>
<td>Unclear risk</td>
<td>A two-armed randomized controlled design, with randomization stratified by stage of cancer (0, I, III, and III) and treatment received (radiation treatment only or radiation treatment and chemotherapy), was used to randomly assign enrolled participants to either an MBSR (BC) group or a wait-listed control group.</td>
</tr>
<tr>
<td>Allocation concealment</td>
<td>Unclear risk</td>
<td>Not possible</td>
</tr>
<tr>
<td>Blinding of participants and personnel</td>
<td>Unclear risk</td>
<td>patients were not blinded to treatment group,</td>
</tr>
<tr>
<td>Blinding of outcome assessment</td>
<td>Unclear risk</td>
<td>Data on measures of presence of symptoms (MDASI), patient demographics, and clinical history were collected at baseline (1 week prior to the MBSR (BC) intervention) and within 2 weeks after the 6-week MBSR (BC) intervention. Participant randomization was done after baseline assessments were complete.</td>
</tr>
<tr>
<td>Incomplete outcome data</td>
<td>Low risk</td>
<td>1 per group loss to follow-up</td>
</tr>
<tr>
<td>Selective reporting</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>The trial appears to be free of other problems that could put it at a high risk of bias</td>
</tr>
</tbody>
</table>

Matthews 2014

Methods  Cognitive Behavioural Therapy for Insomnia Outcomes in Women After Primary Breast Cancer Treatment:

Participants  Women were eligible if they completed primary treatment for stage I–III breast cancer within 1–36 months and met study criteria for chronic insomnia, including a self-reported SL or WASO greater than 30 minutes on three or more nights per week for one month or longer plus score of 8 or higher on the Insomnia Severity Index (ISI) (scores range from 0–28; a score of 8 indicates subthreshold insomnia) (Morin, 1993; Savard, Savard, Simard, & Ivers, 2005). Other inclusion criteria were being aged 21–65 years, having insomnia that started or worsened at diagnosis as determined by a clinical interview, and being fluent in English. Women using hypnotic
medications were eligible because these medications have not been shown to significantly modify the effect of CBTI (Savard, Simard, et al., 2005). Exclusion criteria were unstable, major psychiatric or non-cancer medical illness, primary sleep disorder(s) other than insomnia, unstable doses of medications that affect sleep, and night-shift employment.

Intervention Details

Individual, weekly CBTI sessions consisted of education about sleep restriction, stimulus control, sleep hygiene education, and cognitive therapy derived from existing protocols. All sessions began by reviewing the participant’s sleep diary data, which determined the prescribed sleep schedule. Session 1 included a CBTI overview, conceptual model of insomnia, sleep restriction, and stimulus control. Sleep restriction limits the amount of time in bed to the patient’s estimated TST. The rationale for the sleep restriction is to consolidate sleep and gradually increase it until an optimal sleep time is achieved (Spielman et al., 1987). Stimulus control provides instructions designed to discourage sleep-incompatible behaviours and reinforce a regular sleep-wake schedule. To help “set” the biologic clock, participants were instructed to adhere within 15 minutes of the prescribed sleep schedule. Sessions 2 and 3 addressed sleep hygiene principles, and cognitive therapy aimed at altering dysfunctional beliefs about sleep and the impact of sleep loss on daytime functioning. Sleep hygiene education promotes good sleep habits such as regular meals and a light bedtime snack; habitual exercise; limited use of caffeine, nicotine, and liquids in the evening; and a sleep-promoting bedroom (quiet, dark, and comfortable) (Edinger & Carney, 2008). Cognitive therapy is designed to alter dysfunctional thoughts and beliefs about sleep and help develop realistic sleep expectations. For example, faulty beliefs include unrealistic sleep expectations and exaggeration of the consequences of sleep loss (Edinger, Wohlgemuth, Radtke, Marsh, & Quillian, 2001b). During sessions 4 and 5, CBTI principles were reinforced and sleep schedules adjusted based on sleep diary data. Session 6 focused on relapse prevention and skills to cope with setbacks.

Quantum of Treatment: in person (30–60 minutes each) and phone (15–20 minutes each).

Intervention provider/therapist: advanced practice nurse with specialized training in CBTI, first author

Comparison: BPT is based on the concept of desensitization BPT aims to reduce the conditioned arousal that develops in response to repeated pairings of frustration about not sleeping with difficulties initiating and maintaining sleep. Each individual BPT session began by recording diary data. In the first session, the therapist presented a BPT overview, conceptual model of insomnia, and helped women develop a 10-item arousal hierarchy of behavioural and cognitive activities that occur during poor sleep (e.g., clock watching, worrying about sleep). Each item was ranked from least to most arousing. A five-item neutral hierarchy was developed (e.g., taking a walk, listening to soothing music). Over the
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course of BPT, each item on the arousal hierarchy was paired with the neutral hierarchy items. Women were instructed to practice the exercise once daily at home, but not within 2–3 hours of bedtime to avoid unintended arousal.

Outcomes

Piper Fatigue Scale (PFS); Attentional Function Index (AFI); European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire–Core 30 (EORTC QLQ-C30; ISI; Hospital Anxiety and Depression Scale (HADS); Dysfunctional Beliefs and Attitudes About Sleep–16 (DBAS-16); Patient Knowledge Test (PKT)

Notes

baseline, post-intervention, and at three- and six-month follow-ups. CBTI and BPT were conducted in parallel; session duration and schedule were the same for each group. Sessions 1–3 and 6 were conducted in person (30–60 minutes each) and sessions 4 and 5 were conducted by phone (15–20 minutes each). Women received an $80 honorarium in three divided amounts and reimbursement for parking or public transportation. Treatment sessions were audiotaped with participant consent and a portion was reviewed for treatment integrity by an independent consultant certified in behavioural sleep medicine. Fidelity checklists were completed at the conclusion of each session

Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Adaptive randomization program, controlling for age, insomnia severity, recruitment site, and breast cancer stage.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Not specified</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Participants, but not the study therapist, were blind to treatment condition.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>Not specified</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>2 loss to follow up in each group</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>The trial appears to be free of other problems that could put it at a high risk of bias</td>
</tr>
</tbody>
</table>

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Prinsen 2013

<table>
<thead>
<tr>
<th>Methods</th>
<th>Cognitive behaviour therapy, for post cancer fatigue, on physical activity and physical fitness</th>
</tr>
</thead>
</table>
| Participants | **Inclusion criteria:** Had completed curative treatment of a malignant, solid tumour or of a non-Hodgkin’s lymphoma minimum of 1 year earlier, and had no evidence of disease recurrence at the time of the study. The minimum age of disease onset was 18 years and patients were no older than 65 years of age when entering the study.  
**Exclusion criteria:** Current psychological or psychiatric treatment and used no anti-depressive drugs, antiepileptic drugs, or benzodiazepines while participating in the study. Physical comorbidity (e.g., anaemia, poor kidney function, etc.) that could explain the fatigue. |
| Intervention Details | CBT for post cancer fatigue. Focused on six perpetuating factors of post cancer fatigue, including insufficient coping with the experience of cancer, fear of disease recurrence, dysfunctional cognitions concerning fatigue, dysregulation of sleep, dysregulation of activity, and low social support and negative social interactions. Therapy was adapted to the individual patient. Focusing on dysregulation of activity was part of their tailored treatment, which started with setting a base level of physical activity. Once this base level was set, a physical activity program was stated, usually twice a day, starting with 5 to 10 min of walking or cycling. The activity was increased by 1 min per day each time the activity was performed, ending at a maximum of 120 min per day. Gradually, physical activities were replaced by other activities.  
**Quantum of Treatment:** The mean number of (50 min) sessions of CBT for post cancer fatigue is 12. Treatment consists of 12–14 individual sessions in six months.  
**Intervention provider/therapist:**  
**Comparison:** Patients randomized to the control group waited 6 months for CBT and received this treatment. |
| Outcomes | Functional impairment was measured using the Sickness Impact Profile-8 (SIP-8)  
Fatigue severity: CIS-fatigue |
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Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
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<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Random assignment was done by means of a sequence of labelled cards contained in sealed, numbered envelopes prepared by a statistical adviser. The envelopes were opened by the psychologists in the presence of the patient. Randomization took place per patient</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>The envelopes were opened by the psychologists in the presence of the patient.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>The envelopes were opened by the psychologists in the presence of the patient.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>Not reported</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>High risk</td>
<td>Control: 0 loss to follow-up</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>High risk</td>
<td>Experimental: 27 lost to follow-up (&gt;20%)</td>
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<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>The trial appears to be free of other problems that could put it at a high risk of bias</td>
</tr>
</tbody>
</table>

Reif 2012

Methods

A patient education program: A multi-centre randomised two-group waiting-list controlled intervention trial

Participants

Inclusion criteria: a sufficient level of functioning and motivation to be able to participate in a multi-part seminar. Patients with depression were not excluded. 18 years or older and diagnosed with malignant tumours. They had to be in a stable condition (ECOG Performance Status 0e2) (Oken et al., 1982) at any time point following active treatment and remission of acute toxic side effects. The patients’ CRF level had to be rated as moderate (4e6) or severe (7e10) on a scale from 0 to 10

Exclusion criteria: excluded if their life expectancy was less than 12 months, if they had brain tumours or brain Metastases, cognitive disorders, or psychiatric conditions.
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**Intervention Details**
The intervention was a structured patient education program. FIBS aims at impacting on health-related self-efficacy as it is known that knowledge by itself hasn’t proved to achieve behaviour modifications. This was realized by implementing a training of problem solving, including goal setting and evaluation, and other cognitive techniques into the program.

Utilized behaviour therapy-oriented strategies and techniques and designed the program to be effective in the cognitive, emotional, and behavioural aspect. The structure of the sessions was scheduled so that short periods of lecture activity by the trainer and longer periods of controlled participant activity alternated.

Between sessions, the patients were encouraged to keep a diary, perform exercises, and implement lifestyle changes.

Two additional meetings after 3 and 6 months were offered to patients to share their experiences in daily life.

**Quantum of Treatment:** six weekly sessions à 90 min designed for groups of 8 cancer survivors.

**Intervention provider/therapist:** The program was administered by nurses and psychologists but can also be carried out by other health care professionals.

**Comparison:** Patients in the control group (CG) were put on a waiting-list. They participated in the program after the IG had completed their follow-up.

All patients received standard information on fatigue as a lecture. For all patients medical care, e.g. routine follow-up, continued as usual and no additional intervention was provided.

**Outcomes**
CRF was measured by the Fatigue Assessment Questionnaire (FAQ).

Quality of life was measured with the EORTC QLQ-C30

Anxiety and depression were measured by the German version of the Hospital Anxiety and Depression Scale (HADS-D)

**Notes**
Data collection was scheduled at baseline (t0), post-treatment (t1) and at a follow-up of 6 months (t2). Baseline measures (t0) were obtained prior to randomisation.

All trainers attended a specialized train-the-trainer workshop held by the authors to ensure that the program is conducted in each centre in the same way.

Patients in the intervention group (IG) were highly satisfied with the program (Reif et al., 2010).

Since there were no scales for measuring CRF knowledge the Fatigue Knowledge Test (F-WT) was developed. The concepts were drawn from
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clinical recommendations with emphasis on self-care. The items are based on a systematic review (de Vries et al., 2009). The F-WT is a 34-item instrument with true/false questions containing 9 items about aetiology and signs of CRF, 6 items about treatment, 3 items about exercise, 6 items about exercise motivation, 5 items about scheduling daily activities and 5 items about improvement of the sleep-wake rhythm. Cronbach’s alpha calculated from our study was 0.82. A questionnaire to measure the patients’ satisfaction was developed, the “Fatigue education satisfaction scale”, based on a scale for asthma education. The original scale contained 28 items. Cronbach’s alpha for the total scale was 0.92 and ranged from 0.47 to 0.91 for subscales (de Vries et al., 2008). This questionnaire was modified for use in FIBS.

Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Computer-generated randomisation lists were used for concealed allocation by central telephone calls. Baseline measures (t0) were obtained prior to randomisation.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Not specified</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Patients and tutors could not be blinded to treatment allocation for practical reasons.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>data entry and analysis was performed by blinded researchers</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>6% loss to intervention, 15% loss to control</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>The trial appears to be free of other problems that could put it at a high risk of bias</td>
</tr>
</tbody>
</table>
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Ritterband 2012

<table>
<thead>
<tr>
<th>Methods</th>
<th>Initial evaluation of an Internet intervention to improve the sleep of cancer survivors with insomnia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Inclusion criteria: DSM-IV criteria for insomnia, participants had to report poor sleep for at least 6 months, difficulty sleeping at least three nights per week, daytime consequences of sleep disturbance (e.g. fatigue, performance deficits, and mood disturbance), and no more than 6.5 h of sleep per Night on average over the past month. To be eligible, participants’ cancer diagnosis or cancer treatment had to either cause the insomnia or worsen existing sleep problems based on self-report.</td>
</tr>
<tr>
<td>Exclusion criteria: having a diagnosis of a sleep disorder other than insomnia (e.g. sleep apnoea, restless legs syndrome, narcolepsy) or a major psychiatric or medical condition other than cancer suspected to contribute to their sleep disturbance. Participants undergoing psychotherapy could enrol as long as they had not started psychotherapy within the past 3 months and were not receiving treatment specifically for insomnia. Other exclusion criteria included an unstable medication regimen, shift work schedule or other irregular sleep pattern, and pregnancy</td>
<td></td>
</tr>
<tr>
<td>Intervention Details</td>
<td>Based on well-validated face to-face CBT-I includes six interactive cores. The first core, ‘Overview’, provides an introduction to SHUTi and builds rationale for the intervention. The next two cores, ‘Behaviour 1’ and ‘Behaviour 2’, introduce sleep restriction (e.g. following an algorithmically determined sleep window) and stimulus control (e.g. limiting time spent awake in bed in order to re-associate the bed and bedroom with sleep). The ‘Education’ core focuses on sleep hygiene, and the ‘Sleep Thoughts’ core helps users to identify and restructure unhelpful beliefs about sleep. The final core, ‘Problem Prevention’, covers relapse prevention The SHUTi program provides a high degree of individual tailoring and feedback. Each core contains numerous interactive elements and includes a combination of text, graphics, vignettes, and animation. Automated emails are sent throughout the program to inform the users as to next steps (e.g. time to begin new cores or fill in diaries) as well as to encourage adherence (e.g. notifications that new cores will be available in a specified number of days; encouragement to log back in after periods of time without logins). The program was developed and evaluated based on the behaviour change model for Internet interventions. Quantum of Treatment: core content of SHUTi can be reviewed in as few as 6 weeks, Internet participants were provided access to SHUTi for 9 weeks. Each core takes between 45 and 60 min to complete</td>
</tr>
</tbody>
</table>
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Intervention provider/therapist:

Comparison: Following study completion, control participants were provided access to the SHUTi program, but no follow-up data were collected.

Outcomes

Fatigue: The Multidimensional Fatigue Symptom Inventory- Short Form (MFSI-SF)

Mood: The Hospital Anxiety and Depression Scale (HADS)

Quality of life: SF-12,

Notes

All participants completed the informed consent process and were paid $100 upon study completion.

Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Random group assignment was based on a computer-generated randomization schedule managed by the project coordinator</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Not specified</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Participants received an email with notification of their assignment to either the experimental (Internet) or waitlist control group.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>Not specified</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>No dropout</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Drs. Ritterband and Thorndike are equity holders of BeHealth Solutions, Inc, which is negotiating a license for the software described in this paper.</td>
</tr>
</tbody>
</table>

Rogers 2009

Methods

BEAT Cancer physical activity behaviour change intervention on physical activity, aerobic fitness, and quality of life in breast cancer survivors: a multicentre randomized controlled

Participants

Inclusion criteria: female, age 18 to 70 y with history of stage I, II, or IIIA breast cancer; (b) English speaking; (c) currently taking an aromatase inhibitor or oestrogen receptor modulator; and (d) medical clearance
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provided by physician. Although surgery within the past 8 wk. was not an exclusion criteria, enrolment was postponed until the patient was at least 8 wk. post-surgery.

**Exclusion criteria:** dementia, inability to fully participate in all intervention activities (e.g., inability to ambulate, plans to relocate outside the study area during the study period, etc.), contraindication to regular physical activity participation, breast cancer recurrence or metastasis, or engaging in z150 min of moderate plus vigorous activity or z60 min of vigorous physical activity per week for the prior month.

**Intervention Details**

Based on exercise programming preferences and social cognitive theory correlates (e.g., self-efficacy, emotional coping, perceived barriers, outcome expectations, behavioural capability, environment, observational learning, and self-control) among breast cancer survivors

The group sessions provided social support, speakers who were regularly active breast cancer survivors, and a personal behavioural modification plan to facilitate regular exercise participation. Group counselling related to overcoming exercise barriers (including barriers self-efficacy and time management), emotional coping (including stress management), exercise benefits, and importance of such benefits, and physical activity enjoyment was also included.

The 12 supervised exercise sessions focused on improving task self-efficacy by gradual advancement of the exercise prescription, self-monitoring with daily activity log, and overcoming exercise barriers experienced by the participant. The final three individual counselling sessions reinforced self-monitoring, use of the behavioural modification plan, and exercise benefits while assisting with overcoming barriers, providing positive reinforcement for those reaching their exercise goal, and updating the exercise prescription if indicated. The program objective was to gradually transition the participant to a home-based program with the goal of engaging in 150 min of moderate intensity activity (primarily walking) by the final weeks of the intervention. At the completion of the intervention, participants were told to continue the exercise prescription they had been following during the final weeks of the intervention.

**Quantum of Treatment:** 12-wk program. Participants completed 6 discussion group sessions with a clinical psychologist during the first 8 wk., 12 individual exercise sessions with an exercise specialist during the first 6 wk., and 3 individual counselling sessions with an exercise specialist during the final 6 wk. of the intervention.

**Intervention provider/therapist:**

**Comparison:** the usual care group received written materials about physical activity available through the American Cancer Society. Usual care participants were not given any other specific instructions related to
Development of an online intervention for cancer survivors with cancer-related fatigue:

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physical activity behaviour at the time of randomization or at the immediate post intervention assessment.

Outcomes Quality of life was assessed with the 37-item Functional Assessment of Cancer Therapy (FACT)-Breast

fatigue FACT-fatigue

Notes Neither the intervention nor the usual care group received staff or intervention contact during the 3 months between the immediate post intervention testing and the 3-mo follow-up assessments reported here.

<table>
<thead>
<tr>
<th>Risk of bias table</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Randomization was based on computer-generated numbers, stored in sealed, opaque envelopes, and done in the order in which participants completed baseline assessments</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>“sealed envelopes”</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Not possible</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Data entry is occurring at the coordinating centre and is performed by individuals blinded to the participant’s group allocation.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>High risk</td>
<td>93% (i.e., 38) completing the immediate post-intervention follow-up and 88% (i.e., 36) completing the full 6 months of the study. Among the 5 participants who withdrew, 3 were in the usual care group and withdrew due to unrelated illness (n = 1), distance (n = 1), and ill spouse (n = 1). Two withdrew from the intervention group due to unrelated medical problems (n = 1) and lost to follow-up (n = 1). Missing data reported for the FACT-ES and the FACT-Cog exceeded the pre-specified amount for imputation of values.</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported. Fatigue data not presented in paper, provided by author.</td>
</tr>
</tbody>
</table>
### Development of an online intervention for cancer survivors with cancer-related fatigue:

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<table>
<thead>
<tr>
<th>Other bias</th>
<th>Low risk</th>
<th>The trial appears to be free of other problems that could put it at a high risk of bias</th>
</tr>
</thead>
</table>

**Savard 2005**

**Methods**


**Participants**

Participants had to have completed radiotherapy and chemotherapy for a stage I to III breast cancer at least 1 month prior to enrolment onto the study, and had to meet diagnostic criteria for a chronic insomnia syndrome, as defined by the combined criteria of the International Classification of Sleep Disorders and of the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV), as well as those commonly used in insomnia research. Those criteria included difficulty in initiating and/or maintaining sleep, whereby sleep-onset latency and/or wake after sleep onset is greater than 30 minutes; sleep efficiency (ratio of total sleep time to total time spent in bed) lower than 85%; difficulties occurring at least 3 nights per week; difficulties occurring for at least 6 months; and difficulties causing marked distress or significant impairment in daytime functioning (e.g., fatigue, disturbed mood, performance deficits). Only patients whose insomnia was judged to be secondary to cancer were included in the study (i.e., those whose sleep difficulties were caused or aggravated by the cancer diagnosis or treatment). The following exclusion criteria were also used: presence of severe major depression or another serious psychiatric disorder; presence of a sleep disorder other than insomnia (e.g., sleep apnoea, periodic limb movements); presence of another illness affecting the immune system (e.g., HIV infection); regular use of a psychotropic medication other than hypnotics (e.g., antidepressants), unless the dosage used was stable in the last month and did not increase during the study; and current involvement in psychotherapy.

**Intervention Details**

The insomnia treatment protocol was based on clinical procedures developed by Morin and slightly adapted for the cancer population. This multimodal approach combined behavioural (i.e., stimulus control therapy, sleep restriction), cognitive (i.e., cognitive restructuring), and educational (i.e., sleep hygiene, fatigue and stress management) strategies that were described in a treatment manual given to all participants. Participants were instructed to continue completing the daily sleep diary throughout the treatment for clinical purposes. The treatment content is described in more detail elsewhere. An optional booster session was offered to participants 1 month after the end of the treatment. Participants interested in reducing their use of sleep-promoting medication were advised to consult a physician or pharmacist for supervision of medication withdrawal.

**Quantum of Treatment**

Eight weekly sessions of approximately 90 minutes, offered in groups of four to six patients. Because missed treatment sessions (n = 8) were rescheduled, all patients received the entire treatment.
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Appendices

program, excluding the four patients who dropped out of the study during the course of the intervention

**Intervention provider/therapist:** master-level psychologist with experience in the administration of this particular treatment protocol.

**Comparison:** Participants assigned to the control group waited a minimum of 8 weeks, which corresponded to the duration of the intervention, were assessed again on study variables, including completion of a sleep diary for a 2-week period, and then received CBT

**Outcomes**

- Insomnia Severity Index
- Multidimensional Fatigue Inventory
- Hospital Anxiety and Depression Scale
- The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire

**Notes**

- Only group difference at pre-treatment was for the proportion of patients with a comorbid physical illness (e.g., cardiovascular disease, arthritis), which was greater in the treatment (59%) than in the control condition

- After the intervention, as well as 3, 6, and 12 months after the end of treatment, the participants again completed the battery of self-report scales and completed daily sleep diaries for another 2-week period.

<table>
<thead>
<tr>
<th>Risk of bias table</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bias</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Not clear: &quot;randomly assigned&quot;</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Not specified</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Not possible</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>Not specified</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>&lt;20%</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported.</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>The trial appears to be free of other problems that could put it at a high risk of bias</td>
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</tbody>
</table>
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Van Der Lee 2013

<table>
<thead>
<tr>
<th>Methods</th>
<th>Mindfulness-based cognitive therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td><strong>Inclusion criteria:</strong> they completed their last anti-cancer treatment (all cancer types were accepted) at least 1 year previously; were curatively treated; older than 18 years; scored X35 on the severity of fatigue subscale of the self-report Checklist Individual Strength (CIS); had no other somatic disease or medicine use that could explain or influence their fatigue.</td>
</tr>
<tr>
<td></td>
<td><strong>Exclusion criteria:</strong> persons at risk for psychosis or severe depression/taking part in any other therapy directed at fatigue simultaneously</td>
</tr>
<tr>
<td>Intervention Details</td>
<td>The aim of mindfulness-based training is to teach skills that enhance the ability to raise awareness to present experiences. Participants received information and instructions about a particular theme each week and were encouraged to practice at home for 45 min, 6 days a week. Patients were given compact disks with breathing instruction and awareness exercises to facilitate practice at home.</td>
</tr>
<tr>
<td></td>
<td><strong>Quantum of Treatment:</strong> 9-weeks protocolised group therapy, including eight weekly sessions of 2.5 h and one 6 h session, plus one 2.5 h follow-up session 2 months after the ninth session. The total duration of the intervention was 28.5 h.</td>
</tr>
<tr>
<td></td>
<td><strong>Intervention provider/therapist:</strong> Both therapists had followed mindfulness-based stress reduction training courses with Kabat Zinn who developed the mindfulness training. One therapist had led MBCT groups with cancer patients 40 times the last 16 years; the first 5 years under supervision of an experienced trainer. The other therapist had led MBCT groups with cancer patients 30 times the last 8 years, initially under supervision of the first therapist.</td>
</tr>
<tr>
<td></td>
<td><strong>Comparison:</strong> Patients in the waiting list condition were informed that they could take part in a MBCT group after their post-measurement (9 weeks later).</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Fatigue severity, functional impairment and wellbeing, anxiety and depression</td>
</tr>
<tr>
<td>Notes</td>
<td>Follow-up values only given for intervention group (see Table 3 of the paper). Author Emailed on 28/10/2014: HADS scores not given</td>
</tr>
</tbody>
</table>
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Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation</td>
<td>Low risk</td>
<td>First, the researcher used SPSS syntax to randomly select 12 participants out of all</td>
</tr>
<tr>
<td>(selection bias)</td>
<td></td>
<td>eligible candidates in file at that moment. The number of eligible candidates varied</td>
</tr>
<tr>
<td></td>
<td></td>
<td>from 14 to 22. This approach ensured that each intervention group would start with</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12 participants</td>
</tr>
<tr>
<td>Allocation concealment</td>
<td>High risk</td>
<td>Not concealed</td>
</tr>
<tr>
<td>(selection bias)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blinding of participants and</td>
<td>High risk</td>
<td>Not possible</td>
</tr>
<tr>
<td>personnel (performance bias)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blinding of outcome assessment</td>
<td>Unclear risk</td>
<td>Not reported</td>
</tr>
<tr>
<td>(detection bias)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data</td>
<td>Low risk</td>
<td>(&gt;20%)</td>
</tr>
<tr>
<td>(attrition bias)</td>
<td></td>
<td>Intervention: 82% completed T2 questionnaire</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control: 97% completed T2 questionnaire</td>
</tr>
<tr>
<td>Selective reporting</td>
<td>High risk</td>
<td>HADs means not reported</td>
</tr>
<tr>
<td>(reporting bias)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>The trial appears to be free of other problems that could put it at a high risk of bias</td>
</tr>
</tbody>
</table>

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Van Weert 2010

Methods
A Randomized Controlled Multicentre Trial Comparing Cognitive-Behavioural Therapy Combined With Physical Training With Physical Training

Participants

Inclusion criteria: age ≥_18 years; last cancer-related treatment at least 3 months before study entry; estimated life expectancy of at least 1 year; knowledge of the Dutch language; and a minimum of 3 positive findings, as judged by the physician who referred the patient, for physical complaints, reduced physical capacity, psychological problems, increased fatigue, sleep disturbances, or problems in coping with reduced physical and psychosocial functioning.

Exclusion criteria: had a very low level of activity (i.e., category 3 or 4 according to the classification of Winningham*,24), were unable to travel independently to the rehabilitation centre, had cognitive disturbances or serious psychopathology or emotional instability that might impede participation in the rehabilitation program, or were in need of intensive medical treatment or rehabilitation.

Intervention Details

Physical training and CBT rehabilitation program based on the principles of self-management, including goal setting, monitoring, norms and decision making, action, and self-reflection. Sources of self-efficacy were enhanced through mastery of experiences and perceived success, modelling, social persuasion, and physiological feedback, in line with Bandura. Attention was paid to the role of irrational illness perceptions in both components because of their impeding effect on coping and functioning.

CBT was aimed at training self-management skills based on the cognitive-behavioural problem-solving approach of Nezu et al.35 This psychotherapeutic, systematic, goal-oriented approach is aimed at finding effective and adaptive solutions to stressful problems and at changing dysfunctional cognition, emotions, and behaviours. 36 Topics such as distress, exercise physiology, and relaxation were discussed during the first 4 sessions.

In sessions 5 to 12, participants primarily were trained to apply self-management skills to realize personal goals by practicing the steps in the circular problem-solving process.

The structure of each session consisted of recapitulation of the previous week’s session and exchange of everyday life experiences, discussion of the homework assignment, introduction of a new topic or self-management skill, self-management skills practice, introduction of the next homework assignment, and relaxation exercises.

Physical training. It was established whether and to what extent a patient had decreased aerobic capacity, reduced muscle strength, fatigue, or limited
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physical role functioning. Patients chose their individual goal (i.e., improving exercise capacity, improving muscle strength, coping with fatigue, or coping with physical role limitations) in collaboration with the physical therapist. In accordance with patients’ goals, 4 treatment modules were available. All modules consisted of individual aerobic training (20–30 minutes), muscle strength training (20–30 minutes), and information. Modules slightly differed in increase in training intensity and in the content of information provided. During the first 4 weeks, aerobic training was performed at a training heart rate. From week 5 onward, the training intensity gradually increased to a HRtrof HRrest _ 50%–80% of (HRmax _ HRrest) at week 12, in accordance with training guidelines. The increase was incremental for patients whose primary goal was to improve exercise capacity and more gradual for patients with other goals.

Progressive resistance muscle training of the trunk and the lower and upper extremities was based on the individual 1-repetition maximum (1-RM).

All patients received information on the benefits of exercise. Additionally, patients who aimed at coping with fatigue received an illustrative “model of fatigue”, and patients who aimed to improve role functioning were taught how to restore the balance between demand and capacity during tasks and activities.

**Quantum of Treatment:** 12 week. Physical training consisted in total of 24 hours of individual physical training and 24 hours of group sports and games, each conducted twice a week for 1 hour. Cognitive-behavioural therapy was conducted for a total of 24 hours (once a week, 2 hours per session).

**Intervention provider/therapist:** The individual physical training was supervised by 2 physical therapists who were experienced in the delivery of physical training interventions to patients with cancer. CBT was supervised by 2 psychologists.

**Comparison:**

1. A non-intervention control group (WLC group) consisted of patients who were referred for oncological rehabilitation at other Dutch centres that used the same inclusion and exclusion criteria as in the present study and who had to wait to start rehabilitation for at least 3 months. The WLC group filled in questionnaires upon enrolment and 12 weeks later.

2. Physical training alone

**Outcomes**

Fatigue was measured with the MFI,

**Notes**

All therapists received a manual and were trained to ensure that the standardized intervention was delivered as intended.

To monitor adherence to the intervention and to record adverse events, the exercise trainers and psychologists completed a case record form for each
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participant after each session. After each visit, the investigator obtained data about the health of the participants.

One participant in the PT group collapsed at the start of a training session during low-intensity warmup and died at the first-aid station. An autopsy showed that death was caused by cardiac arrest resulting from a haemorrhage from a residual carcinoma in the participant’s left primary bronchi. The physicians judged that the death was not related to the exercise program. No further adverse events were reported.

Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Randomization was conducted at the group level by an independent researcher using a randomization list. Consecutive groups of 8 to 12 patients were randomly assigned to each group. Both interventions were balanced in each centre.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Not specified</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Therapists could not be blinded, as they had to schedule the intervention sessions. Until the first session, participants were blinded to the intervention they were allocated to receive.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Main investigators were not blinded to group assignment</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>&lt;20% for all groups</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported.</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>The trial appears to be free of other problems that could put it at a high risk of bias</td>
</tr>
</tbody>
</table>
**Development of an online intervention for cancer survivors with cancer-related fatigue:**

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**Willems (2016)**

<table>
<thead>
<tr>
<th><strong>Methods</strong></th>
<th>a web-based tailored intervention for cancer survivors on quality of life, anxiety, depression, and fatigue: Randomized Controlled Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participants</strong></td>
<td>18 years or older; had been diagnosed with any type of cancer; primary treatment (surgery, chemotherapy, and/or radiotherapy) had been completed successfully for at least 4 weeks but no more than 56 weeks; there was no sign of recurrence in the latest follow-up visit; they were able to speak and read Dutch; and there was no serious medical, psychiatric, or cognitive illness that would interfere participation.</td>
</tr>
<tr>
<td><strong>Intervention Details</strong></td>
<td>Systematically developed, theory-based, web-based, computer tailored intervention aimed at providing psychosocial and lifestyle support for cancer survivors</td>
</tr>
<tr>
<td></td>
<td>Problem solving therapy (PST) and cognitive behavioural therapy (CBT).</td>
</tr>
<tr>
<td></td>
<td>Self-management training modules. These training modules cover the following topics: return-to-work, fatigue, anxiety and depression, social relationship and intimacy issues, physical activity, diet, and smoking cessation. The eighth module provides general information on the most common residual symptoms. Basic CBT principles are covered by providing psycho-education and assignments, such as monitoring behaviour or thoughts, challenging dysfunctional cognitions, and encouraging patients to set new goals. The information provided in the modules is supported by videos of fellow survivors and professionals from different fields discussing recovery after cancer and dealing with problems and daily troubles. The KNW is programmed to be an open and unrestricted program: users can choose which modules they want to visit. Assignments can be skipped if participants choose to receive general advice.</td>
</tr>
<tr>
<td><strong>Quantum of Treatment</strong></td>
<td>eight modules/6 months</td>
</tr>
<tr>
<td><strong>Intervention provider/therapist:</strong></td>
<td>fully automated.</td>
</tr>
<tr>
<td><strong>Comparison:</strong></td>
<td>Wait list</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td>CIS Global health status, Physical functioning, Role functioning, Emotional functioning, Cognitive functioning, Social functioning, Depression, Anxiety, Fatigue</td>
</tr>
<tr>
<td><strong>Notes</strong></td>
<td>At baseline and after three, six, and twelve months</td>
</tr>
</tbody>
</table>
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Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>the computer randomly assigned</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Fully automated</td>
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<tr>
<td>Blinding of participants and personnel (performance bias)</td>
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<td>Not possible</td>
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<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Fully automated</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
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</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported</td>
</tr>
</tbody>
</table>
| Other bias                                | Unclear risk       | Change to protocol: “Originally, this criterion was set to 6-52 weeks. After recruitment, we noted that participants were included outside this criterion. The lower limit of 6 weeks was set so participants had had a sufficient recovery period after treatment before participating in the study; the upper limit of one year was set to include participants highest in their distress. Since participants voluntarily participated and can decide whether they are able to participate and levels of distress are still high 56 weeks after treatment, we adjusted this criterion to 4-56 weeks. This led to an additional 13 participants in the control condition and 7 in the intervention condition”.

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Yun 2012

<table>
<thead>
<tr>
<th>Methods</th>
<th>Web-Based Tailored Education Program for Disease-Free Cancer Survivors With Cancer-Related Fatigue: A Randomized Controlled Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Inclusion criteria: moderate to severe fatigue (worst fatigue in Brief Fatigue Inventory 4) for at least 1 week, cancer stages I to III, primary treatment completed within the past 24 months, and age 20 to 65 years. Exclusion criteria: undergoing or planning surgery, radiotherapy, or chemotherapy; they had a major health problem that might cause fatigue; exercise or nutrition intervention was contraindicated; they had cardiovascular disease (congestive heart failure, angina), pulmonary disease (chronic obstructive pulmonary disease, restrictive pulmonary disease), uncontrolled hypertension, or poorly controlled diabetes or severe musculoskeletal disease; their body temperature was 37.2°C and WBC 11,000, platelet count 100,000/mcl, haemoglobin 10 g/dL, AST or ALT 40 IU/L, or creatinine level 1.4 mg/dL; they had severe psychiatric disorders such as major depression or suicidal tendencies; they had dyspnoea; they showed evidence of metastases or recurrence; their Eastern Cooperation and Oncology Group performance status was 3 to 4; or they did not use the Internet or a mobile telephone.</td>
</tr>
</tbody>
</table>
| Intervention Details | The intervention group was encouraged to participate in Health Navigation regularly. Components of the 12-week, individually tailored intervention program were based on 2008 National Comprehensive Cancer Network guidelines and covered six strategic areas: energy conservation, physical activity, nutrition, sleep hygiene, pain control, and distress management. They added an additional area—general introduction to CRF—to introduce the topic and allow the participants to evaluate their CRF status. Detailed sessions of seven areas were based on the transtheoretical model (TTM) of health behaviour change and social cognitive theory as developed by Bandura or on cognitive behavioural therapy (CBT). Health Navigation consists of the following five components: self-assessment and graphic reports, health advice and online education, enhanced and short message services, caregiver monitoring and support, and health professional monitoring. The user’s Web page covers seven education areas that contain personally tailored sections based on the TTM model (physical activity, sleep hygiene, and pain control) and education sections based on the CBT model (general introduction, energy conservation, nutrition, and distress management). Quantum of Treatment: 12 weeks Intervention provider/therapist: online Comparison: The waiting-list control group waited a minimum of 12 weeks, which corresponded to the duration of the Health Navigation intervention, but was encouraged to continue routine care and routine medication. A personalized letter reminded them of the upcoming }
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assessment points and invited them to access Health Navigation in 12 weeks.

Outcomes

Fatigue, HRQOL, Distress, Energy conservation, pain

Notes

Only change scores reported

Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation</td>
<td>Low risk</td>
<td>An independent statistician generated a randomization table with NQuery Advisor 6.01 (Statistical Solutions, Saugus, MA) and used the table to assign each patient to either the intervention group or the usual care group. To balance the number of patients in each group by potentially confounding variables, patients were stratified by factors previously reported to be associated with CRF: age (50 and 50 years), sex, and cancer type (three categories: stomach or colon; cervix, breast, or thyroid; and lung).</td>
</tr>
<tr>
<td>Allocation concealment</td>
<td>Low risk</td>
<td></td>
</tr>
<tr>
<td>Blinding of participants and personnel</td>
<td>High risk</td>
<td>Not possible</td>
</tr>
<tr>
<td>Blinding of outcome assessment</td>
<td>Low risk</td>
<td>An independent research coordinator (nurse) managed both groups</td>
</tr>
<tr>
<td>Incomplete outcome data</td>
<td>Low risk</td>
<td>23 of 136 loss to follow-up on intervention arm</td>
</tr>
<tr>
<td>Selective reporting</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>The trial appears to be free of other problems that could put it at a high risk of bias</td>
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</table>
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<table>
<thead>
<tr>
<th>Study</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Armes 2007</td>
<td>During treatment</td>
</tr>
<tr>
<td>Baker 2012</td>
<td>During treatment</td>
</tr>
<tr>
<td>Banasik, 2011</td>
<td>No psychology component to treatment</td>
</tr>
<tr>
<td>Bjorneklett 2012</td>
<td>During treatment</td>
</tr>
<tr>
<td>Bower 2011</td>
<td>No psychology component to treatment</td>
</tr>
<tr>
<td>Carson 2009</td>
<td>No psychology component to treatment</td>
</tr>
<tr>
<td>Culos-Reed 2006</td>
<td>No psychology component to treatment</td>
</tr>
<tr>
<td>Deckx 2015</td>
<td>During treatment</td>
</tr>
<tr>
<td>Donnelly 2011</td>
<td>During treatment</td>
</tr>
<tr>
<td>Gil 2005</td>
<td>No isolated measure of fatigue reported</td>
</tr>
<tr>
<td>James 2012</td>
<td>Full text not available</td>
</tr>
<tr>
<td>Johnston 2011</td>
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<tr>
<td>Kolidas 2013</td>
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<tr>
<td>Kwekkeboom 2012</td>
<td>During treatment</td>
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<td>Liu 2012</td>
<td>Not RCT</td>
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<td>May 2008</td>
<td>During treatment</td>
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<td>Moadel 2007</td>
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<td>Mustian 2013</td>
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<tr>
<td>Penttinen 2011</td>
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<td>Pinto 2005</td>
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<tr>
<td>Sandler 2015</td>
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<td>Servaes 2007</td>
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<tr>
<td>Sprod 2015</td>
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<td>Wagner 2011</td>
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<td>White et al (in preparation)</td>
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<td>Yousaf 2012</td>
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Appendix 2. Subgroup Analyses from Systematic Review

<table>
<thead>
<tr>
<th>Subgroup analyses</th>
<th>Comparison</th>
<th>Subgroup</th>
<th>Studies</th>
<th>Pts.</th>
<th>Effect Estimate</th>
<th>Std. Mean Difference (IV, Random, 95% CI)</th>
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<td>Psychological intervention type A vs psychological intervention type B</td>
<td>CBT vs. control</td>
<td>9</td>
<td>811</td>
<td>-0.24 [-0.64, 0.15]</td>
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<td></td>
<td>Mindfulness based intervention vs. control</td>
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<td>-0.70 [-1.49, 0.10]</td>
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<td>Psychoeducation or behaviour change vs. control</td>
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<td>1386</td>
<td>-0.40 [-0.75, -0.05]</td>
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<td>Motivational Interviewing vs. control</td>
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<td></td>
<td>Imagery vs. Control</td>
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<td>In-person interventions vs remote interventions</td>
<td>Online</td>
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<td>Group</td>
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<td></td>
<td>Individual</td>
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<td>Intervention for specific cancer type only vs intervention for any cancer type</td>
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<td>More than one cancer type</td>
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<td>Interventions specifically designed to treat fatigue after cancer treatment vs interventions not specific for fatigue</td>
<td>Aim of intervention</td>
<td>Insomnia intervention</td>
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<td>CRF intervention</td>
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<td>Physical activity intervention</td>
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<td>Quality of Life intervention</td>
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<td>Inclusion criteria</td>
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<td>Fatigue not measured as part of inclusion criteria</td>
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<td>Fatigue assessment</td>
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<td>Fatigue subscale as part of broader QoL measure</td>
<td>7</td>
<td>733</td>
<td>-0.30 [-0.68, 0.08]</td>
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</table>

Overall meta-analysis: 20 studies; 2662 participants; Std. Mean Difference (IV, Random, 95% CI): -0.50 [-0.70, -0.31]
Appendix 3. Ethical Approval for Ph.D. Research

Date: 20th January 2014
Ref: 13/NOV/16

Ms. Teresa Corbett
PhD Candidate Psychology and Health
Arts Millennium Building Extension (AMBE)
School of Psychology
National University of Ireland, Galway

Dear Ms Corbett

Re. Ethics Application:

A Web-based Tailored Program for Disease-free Cancer Survivors with Cancer-related Fatigue: A Randomized Controlled Trial

I write to you regarding the above proposal which was submitted for Ethical review. Having reviewed your response to my letter, I am pleased to inform you that your proposal has been granted APPROVAL.

All NUI Galway Research Ethics Committee approval is given subject to the Principal Investigator submitting annual and final statements of compliance. The first statement is due on or before 31st November 2014. Please see section 7 of the REC’s Standard Operating Procedures for further details which also includes other instances where you are required to report to the REC.

Yours Sincerely

[Signature]

Allyson Fyves
Chair, Research Ethics Committee
Appendix 4. Press Release for Focus Groups

Participants Needed for NUI Galway Research Project on Cancer-Related Fatigue

**Monday, 24 February, 2014:** The School of Psychology at NUI Galway is currently inviting adults who have completed their treatment for cancer at least six months ago, for a series of focus groups on the experience of cancer-related fatigue in cancer survivors.

The group discussions will offer participants the opportunity to share their experiences with, and thoughts about cancer-related fatigue, in a casual environment and with complete confidentiality. Persistent fatigue is often a common consequence of cancer treatment. Participant views and personal experiences are extremely valuable and their input will greatly help the researcher in the development of an intervention for individuals who suffer with fatigue after their treatment has ended. They may also benefit from discussing their fatigue with others who also experience persistent fatigue.

The focus groups are part of a PhD research project being carried out at NUI Galway by student Teresa Corbett with Dr Jane Walsh, Dr Brian McGuire and Dr AnnMarie Groarke of the University’s School of Psychology. The study is supported by Cancer Care West and Galway University Foundation.

The focus group session will include 4-6 other volunteer participants and will be led by Ms Corbett. Refreshments will be provided to participants and each session is scheduled to last approximately 90 minutes. The focus groups will be held in the School of Psychology in the Arts Millennium Building Extension at NUI Galway.

NUI Galway PhD student and facilitator of the focus groups, Teresa Corbett, said: “Persistent cancer-related fatigue is a common complaint. With an increasing focus on quality of life in survivorship, we believe that it is essential that people have the opportunity to discuss this often debilitating consequence of cancer. Participation is voluntary and anything you say during the focus group will be kept strictly confidential. The focus groups will give individuals the chance to inform our research by telling us of their own personal everyday experiences with fatigue.”

For further information or to participate in the focus groups contact Teresa Corbett,

-Ends
Appendix 5. Consent Form For Focus Groups

Consent Form

If you have any questions regarding this consent form or any other questions pertaining to this study, please contact Teresa Corbett (t.corbett2@nuigalway.ie) or one of her supervisors:

• Dr. Jane Walsh (jane.walsh@nuigalway.ie)
• Dr. Brian McGuire (Brian.Mcguire@nuigalway.ie)
• Dr. AnnMarie Groarke (annmarie.groarke@nuigalway.ie)

If Ms. Corbett or her supervisors are unable to address your concerns satisfactorily, please contact the Head of the School of Psychology, National University of Ireland, Galway.

Purpose: The purpose of this focus group interview is to discuss personal experiences of cancer-related fatigue from adult survivors of cancer.

Requirements: You will take part in casual discussions about cancer related fatigue.

Anonymity/Confidentiality: All of the information that is gathered in this study WILL BE KEPT STRICTLY CONFIDENTIAL. In addition, neither your name nor any other identifying information will be noted. The data gathered by the researcher may be presented at academic conferences and/or submitted for publication in scientific journals. However, data will not identify any person, but instead will be presented in aggregate (i.e., group) form.

Duration: Participation will take approximately 90 minutes.

Potential Risks: Participation in this study is unlikely to compromise the psychological and/or physical well-being of participants. However, some individuals may consider some of the issues raised to be sensitive in nature. Therefore, if you have any concerns about this study, please do not hesitate to contact Ms. Corbett or one of her supervisors.

Potential Benefits: It is hoped the current research will improve understanding of cancer related fatigue in adult survivors of cancer.

Right to Withdraw: If you wish to withdraw from this study, you may do so at any time without penalty or consequence. In addition, you may omit any items you wish; again, without penalty or consequence.

Participant Support: A detailed report outlining the major findings of this study will be available to participants when all data have been collected. However, should you have specific questions concerning your involvement in this study, please do not hesitate to contact...
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Teresa Corbett.

If you have any other queries relating to your cancer experience or any of the issues raised in this study, please contact

• Irish Cancer Society, 43/45 Northumberland Road, Dublin 4. Tel: 01 231 0500 Email: info@irishcancer.ie Website: www.cancer.ie

• National Cancer Helpline (Freephone) 1800 200 700 (Monday-Thursday 9-7 and Fridays 9-5)

• Samaritans Ireland 1850 60 90 90

Or visit www.cancersurvivorshipireland.com

PARTICIPATION IS STRICTLY VOLUNTARY.

Please tick EACH box and sign your name in the space below

1. I confirm that I have read the document entitled ‘Participant Information Sheet’ and have had the opportunity to ask questions. ☐

2. I am satisfied that I understand the information provided and have had enough time to consider the information. ☐

3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected. ☐

4. I agree to take part in the above study. ☐

Name: _________________________________ (Please use block capitals)

Signature: ______________________________

Date: ______ / ______ / ______
Appendix 6. Participant Information Sheet for Qualitative Study

Persistent fatigue is often a common consequence of cancer treatment. If you are an adult who was diagnosed with any stage I to IIIA cancer, and have completed your last anti-cancer treatment at least 6 months ago, we would like to get your views on the experience of cancer-related fatigue in cancer survivors.

What?
The focus group session will include 4-6 other volunteer participants and will be led by the primary researcher. During this meeting, you will have the opportunity to share your experiences with and thoughts about cancer related fatigue, in a casual environment and with complete confidentiality. refreshments will be provided to participants. Each session is scheduled to last approximately 90 minutes.

Where?
The focus groups will be held at the Psychology Department in the Arts Millennium Building Extension at the National University of Galway.

Why?
Your views and personal experiences are extremely valuable and your input will greatly help the researcher in the development of an intervention for individuals who suffer with fatigue after their treatment has ended. To compensate you for your time, all attendees will be entered into a draw with a chance to win one of two €50 An Post All-4-One vouchers. You may benefit from discussing your fatigue with others who also experience persistent fatigue.

Confidentiality
Although we hope you will join us, participation is voluntary. Please be assured that anything you say during the focus group will be kept strictly confidential, and that researchers will not release any information that can be linked to you.

How?
In order to participate we ask that you contact the researcher (via email or phone). Please give us your name, age and if you have a preference for a morning or evening session. We will try to accommodate you as best we can.

If you would like more details about this event, or if you have any questions about the study, you are also welcome to email us using the contact details below. We hope that you will be able to join us for this important discussion.

Best wishes
Teresa Corbett (t.corbett2@nuigalway.ie -Primary researcher)

Supervisors:
Dr. Jane Walsh (jane.walsh@nuigalway.ie )
Dr. Brian McGuire (Brian.Mcguire@nuigalway.ie )
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Dr. AnnMarie Groarke (annmarie.groarke@nuigalway.ie)

If you have any concerns about this study and wish to contact someone in confidence, you may contact: The Head, School of Psychology, National University of Ireland, Galway.
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Appendix 7. Interview Schedule Focus Groups 2014 - Cancer-Related Fatigue

The purpose of these focus group interviews is to discuss personal experiences of CRF from adult survivors of cancer. In particular, the study will aim to gather descriptions of the patients’ understanding of CRF and examine the fit of their descriptions to a theoretical model.

Does want to know:

1. How adults represent and understand their fatigue symptoms.
2. How adults cope with CRF
3. How adults appraise the impact of CRF.

Does not want to know:

1. how cancer in general has impacted their life
2. how they think others deal with or cope with fatigue

Goals of the research

General
➢ Develop a general understanding of target groups’ perceptions of CRF
➢ Identify the language and key concepts that the group uses to discuss CRF
➢ To frame the theoretical basis of the intervention. (i.e. To establish if Illness Perception theory could be applied in an Irish discussion of CRF )

Specific
➢ Key ideas that relate to the topic are identified
➢ The importance or significance of these key ideas can be described
➢ How strongly the participants feel about these key ideas can be identified
➢ Language and vocabulary are identified that relate to CRF and can be used in communication with participants.
➢ Solicit ideas in relation to the potential for an online intervention for CRF
➢ Questions and information from participants are available to assist with the further development of the research questions and purposes.
➢ Information from participants will verify hypothesis or help in refining hypotheses.

Moderators’ Guide: Interview Schedule

a) Introduction
   a. Welcome
      i. “Welcome and thank you for coming to this focus group. Each of you has been invited to participate because your view is important to us. We know that you are very busy and we greatly appreciate your contribution to this project. This interview is not a test, nor should it in any way be viewed as a series of questions with right or wrong answers. Remember, we are very interested in what you think and feel. We want to know your opinions on these issues, and we are certainly not interested in your agreeing with the opinions and feelings of others. There may be times, however, when you do, and it is appropriate for you to let us know that as well.”
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ii. *Here I have a participant information sheet for you to read. Once you’re happy that you’re clear on what is expected of you, you can sign our consent form. I can answer any questions you have.*

b. **Purpose**
   i. *“The purpose of this focus group interview is to discuss your personal experiences of cancer-related fatigue, as survivors of cancer.”*

c. **Guidelines**
   i. *“There are a few guidelines I would like to ask you to follow during the focus group interview. First, you do not need to speak in any particular order. When you have something to say, please do so.*
   ii. *Second, please do not speak while someone else is talking. Sometimes, the exchanges get emotional, and it is tempting to ‘jump in’ when someone is talking, but we ask you to refrain from doing so.*
   iii. *Third, remember that there are many people in the group and it is important that we obtain the point of view of each one of you. Fourth, you do not need to agree with what everyone or anyone in the group says, but you do need to state your point of view without making any negative comments or ‘put downs’.*
   iv. *Finally, because we have limited time together, I may need to stop you and to redirect our discussion. Does anyone have any questions? Ok, let’s begin*

b) **Warm-up**
   a. **Set the tone**
      i. *During the reception you had an opportunity to meet each other and to ask each other questions. To get the ball rolling, let’s start off with a brief introduction about yourself. Maybe tell us what type of cancer you had and how long it’s been since your treatment finished.*

   b. **Set participants at ease**

c) **Clarification of terms**
   a. **Establish the knowledge base of key terms through questions**
   b. **Provide definitions of key terms**
      i. *Just so that we’re all clear, I’m going to give you the standard textbook definition of cancer-related fatigue before we begin. It is defined as "a distressing persistent sense of tiredness or exhaustion related to cancer that is not proportional to recent activity and interferes with usual functioning."*
      ii. *What is your experience of fatigue?*

d) **Establish Easy and non-threatening questions**
   a. The initial questions should be general and less threatening
      i. *What does the experience of fatigue mean to you*
      ii. *What do you do about your fatigue*

e) **Establish More difficult questions**
   a. The more difficult or personal questions should be determined
      i. *Are there different types of fatigue*
      ii. *How do other symptoms affect fatigue*

f) **Wrap-up**
   a. Identify and organize the major themes from the participant’s responses
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i. Ok so from today it seems that we’ve covered quite a lot and heard some interesting points.

b. Ensure that any conversational points not completed are mentioned

i. Unfortunately we didn’t have time to discuss..... further, but if you want to find out more you can contact some of the services on your Participant Information sheet

g) Member-Check

a. Determine how each member perceives selected issues

h) Closing statements

a. Request anonymity of information

b. Answer any remaining questions

i. Has anyone any remaining questions about anything we’ve discussed today?

c. Express thanks

i. Great! Thank you very much for coming today. Your help is greatly appreciated

Other questions

- What is fatigue
- Signs of fatigue
- What causes fatigue in cancer survivors...treatment? Or other causes such as pain, emotional distress, sleep problems, medications, nutrition, lack of exercise etc.?
- How to manage fatigue?
- How to cope with fatigue?
- How to find out more about fatigue? - Newspaper? Doctor? Online? Nurse? etc.?
- When did the fatigue first start?
- When did you notice that this fatigue is different from usual?
- Does anything make it better? Worse?
- Do you have any other problems or concerns?
- How has the fatigue affected the things you do every day?
- Do you use the internet to find out about symptoms?
- What do you and/or your doctors and nurses recommend to manage fatigue?
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Appendix 8. Code Book for Thematic Analysis

The SRM hypothesises that individuals create mental representations of their illness based on the concrete and abstract sources of information available to them in order to make sense of and manage the problem. It is the interpretation of this information that forms the first step in the process of seeking help, engaging in a coping strategy, or adopting an illness management regimen (Bishop and Converse, 1986).

**Social Context**

Abstract and concrete sources of information

The perception and interpretation of the different sources of information influence other aspects of the participants’ perception of fatigue, including representations, coping with and appraisal of fatigue via symmetrical conceptual (abstract and prepositional) and schematic (concrete and perceptual) processes.

**Label**

**Social Messages**

**Definition**

The first source is information from the external social environment from perceived significant others. This refers to the general pool of ‘lay’ information already assimilated by the individual from previous social communication and cultural knowledge of the illness.

**Description**

- Deviation from norm
- Source: Media/ Similar others/family/ friends
- Type: vague/inaccurate/extensive/detailed

Includes: how social response to the reports of their fatigue symptom is assimilated by the individual and in turn, impacts their acceptance and representation of the symptoms:

- Reactions of and support offered by healthcare professionals
- Reactions of and support offered by family and friends

**Label**

**Social Identity**

**Definition**

This source of information relates to participants’ social role and identity. The expectations of others are included, as well issues that arise due to difficulties in articulating the experience of symptoms.

**Description**

- Expectations of others; Social comparisons (comparison to similar others); Individuals role as parent/ friend/ employee

**Representation**

Health Threat (cognitive and emotional)

**Label**

**Identity**

**Definition**

The name or description applied to symptoms

**Description**

- Label
- Concrete signs/symptoms

**Label**

**Cause**

**Definition**

Dimension represents the beliefs regarding the factors that are responsible for causing the illness or disease.
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<thead>
<tr>
<th>Description</th>
<th>Label</th>
<th>Definition</th>
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<th>Label</th>
<th>Definition</th>
<th>Description</th>
<th>Label</th>
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<tbody>
<tr>
<td>• Biological; Genetic; Psychological; Environmental; Emotion; Own behaviour</td>
<td><strong>Consequence</strong></td>
<td>imagined and real refers to beliefs regarding the impact of the illness on overall quality of life or how it may affect functional capacity</td>
<td>• Physical; Emotional; Social; Economic; Psychological</td>
<td><strong>Timeline</strong></td>
<td>i.e., the time for the development of the disease, its duration, and time for recovery; Refers to the individual’s beliefs about the course of the illness (e.g. “My illness is chronic”) and time scale of illness symptoms (e.g. “The pain is persistent”).</td>
<td>• Acute; Episodic; Cyclical; Chronic</td>
<td><strong>Cure/Control</strong></td>
<td>Degree to which the disease can be prevented, cured, and kept from progressing. Refers to the sensation of empowerment regarding performance of coping behaviours or the efficacy of treatment</td>
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</table>
Appendix 9. Coding Trees for Thematic Analysis
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Appendix 10: Consent forms for Trial

REFRESH

Consent Form

Page description:
1. If you have any questions regarding this consent form or any other questions pertaining to this study, please contact Teresa Corbett (t.corbett2@nuigalway.ie) or one of her supervisors: Dr. Jane Walsh (jane.walsh@nuigalway.ie) Dr. Brian McGuire (Brian.Mcguire@nuigalway.ie) Dr. AnnMarie Groarke (annmarie.groarke@nuigalway.ie)
If Ms. Corbett or her supervisors are unable to address your concerns satisfactorily, please contact the Head of the School of Psychology, National University of Ireland, Galway.

1. Purpose
This study is concerned with the experience of cancer-related fatigue in people after the completion of curative treatment for cancer.

Requirements
You will be randomly assigned to either group 1 or group 2.
If you are assigned to group 1, you will take part in a trial of an online programme designed for people with fatigue after cancer. At the end of the 8 weeks, you will be asked to complete another brief questionnaire. Each questionnaire session is may take up to 30 minutes.
If you are assigned to group 2, you will have to wait 8 weeks to participate in online sessions. You will be contacted via telephone during the first 4 weeks. At the end of the 8 weeks, you will be asked to complete another brief questionnaire. Each questionnaire session is may take up to 30 minutes.
Please note, once allocated to one of the two groups, participants will remain in those groups for the remainder of the study. Therefore, not all participants will immediately gain access to the website content, but everyone will have a chance to access it at some stage.

Anonymity/Confidentiality: All of the information that is gathered in this study WILL BE KEPT STRICTLY CONFIDENTIAL. In addition, neither your name nor any other identifying information will be noted. The data gathered by the researcher may be presented at academic conferences and/or submitted for publication in scientific journals. However, data will not identify any person, but instead will be presented in aggregate (i.e., group) form.

Duration: This study will last for approximately 8-10 weeks (from the start of this questionnaire until you have completed the follow-up questionnaire).

Potential Risks
Participation in this study is unlikely to compromise the psychological and/or physical wellbeing of participants. However, some individuals may consider some of the issues raised to be sensitive in nature. Therefore, if you have any concerns about this study, please do not hesitate to contact Ms. Corbett or one of her supervisors.

Potential Benefits
It is hoped the current research will improve understanding of cancer related fatigue in adult survivors of cancer.

Right to Withdraw
If you wish to withdraw from this study, you may do so at any time without penalty or consequence. In addition, you may omit any items you wish; again, without penalty or consequence.
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Participant Support
A detailed report outlining the major findings of this study will be available to participants when all data have been collected. However, should you have specific questions concerning your involvement in this study, please do not hesitate to contact Teresa Corbett. If you have any other queries relating to your cancer experience or any of the issues raised in this study, please contact

• Irish Cancer Society, 43/45 Northumberland Road, Dublin 4. Tel: 01 231 0500 Email: info@irishcancer.ie Website: www.cancer.ie
• National Cancer Helpline (Freephone) 1800 200 700 (Monday-Thursday 9-7 and Fridays 9-5)
• Samaritans Ireland 1850 60 90 90

Or visit www.cancersurvivorshipireland.com

PARTICIPATION IS STRICTLY VOLUNTARY.
I confirm that I have read the information sheet for the above study and have had the opportunity to ask questions.
I am satisfied that I understand the information provided and have had enough time to consider the information.
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.
I confirm that I agree to be randomly assigned to either group 1 or group 2 (as per descriptions outlined above)
I confirm that I have completed curative treatment for cancer at least 3 months ago.
I agree to take part in the above study.

Please sign here if you consent to participate in this study and are happy to proceed. *

______________________________________________________________
Sign name using mouse or touch pad
Signature of ______________________________
Appendix 11. Press Release for Trial
New online programme aims to help people to cope with persistent fatigue after cancer.

The School of Psychology at NUI Galway, with the support of Cancer Care West is currently recruiting people with persistent fatigue since the completion of cancer treatment (completed treatment at least three months ago).

Fatigue is one of the most debilitating and frustrating symptoms faced by individuals after cancer treatment. For some, these symptoms can last for months or even years after treatment. This can have an emotional and functional impact peoples’ lives. Such overwhelming fatigue can hold people back from resuming ‘normal life’ after cancer.

A new online programme called “REFRESH: Recovery from Cancer-Related Fatigue” has been developed at the National University of Ireland Galway to help people to learn how to better manage fatigue symptoms after cancer. The programme was developed as part of 4 years of research into cancer-related fatigue by Cancer Care West Hardiman Scholar Teresa Corbett. Over the last 3 years, Teresa has met with Irish individuals who have persistent and lingering fatigue after cancer.

Cancer-related fatigue is still relatively under-recognised and under-treated. “REFRESH: Recovery from Cancer-Related Fatigue” aims to address this unmet need of cancer survivors by raising awareness about what might cause fatigue and how people can learn to cope with it effectively. The programme is based on the most up-to-date research on fatigue, while also incorporating the thoughts and stories of those who experience fatigue.

The REFRESH: Recovery from Cancer-Related Fatigue trial will provide eight online sessions to people in the comfort of their own home. The content is based on the principles of cognitive-behavioural therapy, a psychological therapy that has been proven to be effective in the management of symptoms such as fatigue. The free online sessions in the programme will focus on what people do and think in response to their fatigue symptoms. Participants will be provided with instructions on a range of activity-pacing techniques to encourage more consistent levels of activity from day-to-day. Useful relaxation techniques and how to sleep better will also be addressed.

The study is open to people all over Ireland and will take place over the coming months. GPs and cancer support networks around the country are being encouraged to refer suitable people with fatigue to the study.

Teresa Corbett, coordinator of the study at NUI Galway, says “I’ve met so many people who are fatigued after cancer treatment. Often they feel frustrated and confused about their symptoms. We know that programmes like this can be beneficial. Unfortunately, people often feel that they do not get the support they need to re-adjust to life after cancer. We want to help people to learn skills to enable them to move on with their lives. In this trial, we will offer our programme to adults who have completed anti-cancer treatment for any type of cancer.”
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People who take part in the REFRESH trial will not need to attend any clinic or the University at any stage. All materials are available online for those wishing to learn effective ways of managing their fatigue; however some telephone contact with Teresa will also be included. “We are very keen to keep this online programme personal, so that people know that there is a supportive team behind it. Online programmes can allow many people to access high quality care from their own home, but we know how important it is to have human contact as well.” Participants can access all medical services as usual while involved in the trial. Study supervisor Dr Jane Walsh, NUI Galway, said: “This is a promising new online fatigue management programme and we are hopeful it will be of benefit to people with persistent fatigue after cancer”.

For further information, please contact Teresa Corbett, School of Psychology, NUI Galway, email nuigREFRESH@gmail.com, or see the website https://nuigREFRESH.wordpress.com/. GPs or cancer services who are interested in referring suitable patients to the trial can also use these contact details.

______________________________ ENDS ________________________________
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Appendix 12. Leaflet Advertising Trial

Have you had persistent fatigue since the completion of your cancer treatment?

We have developed an online programme called REFRESH: Recovery from Cancer-Related Fatigue and now we are looking for some volunteers to take part in a trial study.

This programme is based on psychological theories and involves taking part in 8 weekly online sessions that will cover topics including:

- what cancer-related fatigue is
- how to manage it effectively
- how to reclaim your life after cancer treatment

Who can take part in this study?

You are invited to participate if you are an adult who was diagnosed with any stage I to IIIA cancer and have completed your last anti-cancer treatment at least 3 months ago.

If you would like to learn more about what this study entails, please contact **Teresa** by emailing **nuigrefresh@gmail.com**.

Or visit one of the websites below:

- Website: nuigrefresh.wordpress.com
- Facebook: www.facebook.com/nuigrefresh
- Twitter: @nuigrefresh
Appendix 13. Telephone Call interview schedule

Phone call in REFRESH Trial – Script ( Intervention group)

The purpose of this phone call is to discuss the participants’ personal experiences of the REFRESH: Recovery from Cancer-Related Fatigue website. In particular, the study will aim to gather descriptions of the participants’ use of the website and to answer any questions that they have.

Does want to know:

1. If and how individuals are using the programme
2. If the individuals have set SMART goals and how they have been working to achieve them.
3. If individuals have done any of the recommended exercises (e.g. fatigue thought charts etc.).
4. If there have been any problems with the website, or if anything has been unclear.

Does not want to know:

1. Specific personal stories or beliefs about cancer related fatigue
2. how they think others deal with or cope with fatigue

Goals of the phone call

General

➢ Develop a general understanding of if and how the website is being used
➢ Identify the key barriers and facilitators of using the programme
➢ To answer any questions that the participants may have

Specific

➢ Key problems and related goals are identified
➢ Technical issues are identified
➢ Misunderstandings are clarified
➢ Participants’ given the opportunity to ask questions
➢ Reduce drop-out/ increase retention through communication with participants.
➢ Questions and information from participants may assist with the further development future iterations of the website.

Guide: Telephone Call Script

i) Introduction

a. “Hi could I please speak with <name> please?
   i. This is Teresa from the “REFRESH: Recovery from Cancer-Related Fatigue” study. You might recognise my voice from the videos in the sessions.
   ii. With your permission, we are going to record this call so that we can take your opinions on board. This recording would only be used for research purposes and would be kept confidential. Are you happy for us to record the conversation?
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iii. Thank you for taking this call. We know that you are very busy and we greatly appreciate your contribution to this project. We are very interested in what you think and feel about the website. We want to know your opinions on the design and content.

b. Purpose
   i. We just wanted to ask a few questions to make sure that everything is going ok with the website. The purpose of this call is to discuss your experience using the website and I can also answer any questions you have.

c. Guidelines
   i. Don’t be afraid to say something negative about the website. We are hoping to learn more from this study and your input is really valuable.
   ii. Also, I don’t want to keep you all day, so I may need to stop you and to redirect our discussion at some stage.
   iii. Ok, let’s begin

j) Warm-up
   a. Set the tone
      i. Maybe before we start taking about the website, let’s start off with a brief introduction about yourself. Why did you decide to take part in the REFRESH study?
   b. Set participants at ease

k) Clarification of terms
   a. Establish the knowledge base of key terms through questions
      i. I can see that you have completed <number of sessions> sessions, did you have any questions about anything that you’ve covered so far?

l) Establish Easy and non-threatening questions
   a. The initial questions should be general and less threatening
      i. Which of these have you found most useful?
      ii. Have you completed any of the homework exercises?

m) Establish More difficult questions
   a. The more difficult or personal questions should be determined
      i. In session 2 you were asked to identify some key problems and set SMART goals. What SMART goals did you set?

n) Wrap-up
   a. Identify and organize the major themes from the participant’s responses
      i. Ok so from today it seems that we’ve covered quite a lot and heard some interesting points.
   b. Ensure that any conversational points not completed are mentioned
      i. So, over the next few weeks, we would like you to continue with the programme. Try to complete one session each week and to incorporate some of the recommended changes into your everyday life.
      ii. We will contact you at the beginning of December with a follow-up questionnaire.

o) Participant-Check
   a. Are you happy to proceed with the study?

p) Closing statements
   a. Request anonymity of information
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i. We do ask that you don’t share the website link with anyone until after the follow-up questionnaires have been completed in December.

b. Answer any remaining questions
   i. Do you have remaining questions about anything we’ve discussed today?
   ii. You can email me at any stage with any other questions you have.

c. Express thanks
   i. Great! Thank you very much for taking the call today. Your help is greatly appreciated.

Other comments

Revisiting contents

i. Each of the sessions has a lot of information in it. Most of it will be covered and explained as you work through it. However, you may choose to read it again afterwards. Some of the material will apply to you more than other parts. You can access any of the sessions as many times as you like.

Doing homework activities

ii. Each session also combines specific information with a series of activities to fit into your day-to-day schedule. The time to do some of these tasks may vary from person to person, but should often take no more than 20 minutes per day. It is important that you try to make the commitment to fit these into your daily life. Previous studies have shown that even simple changes may make a difference to your symptoms. How much your symptoms change can partly depend on how much you can stick to your personal goals and to the programme?

Printing materials

iii. To help you do this we have provided coloured homework task sheets for you to print in each session. These will allow you to record your progress and fill in information that is personal to you. You may find it easier to print the relevant task sheet each week and place it in a plastic folder. This will allow you to easily access the sheet each day.

iv. We can send you copies of the handouts if you do not have a printer.

Not wanting to fill out information

v. This information is important for the study, and will not reflect on you in any way. If you feel that any information is too personal you can choose not to share it with us. Instead of typing your answer in the box, you can simply type NA. We do encourage you to complete as many of the tasks as possible, as they are a very important part of the programme and will help you to get as much as you can from taking part.

Phone call in REFRESH Trial – Script (Control group)

The purpose of this phone call is to discuss any questions that the control participants may have about the REFRESH trial.
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Does want to know:

1. If participants have any questions, or if anything has been unclear.
2. If participants are happy to proceed with the study.

Does not want to know:

1. Specific personal stories or beliefs about cancer related fatigue
2. how they think others deal with or cope with fatigue

Goals of the phone call
General
➢ To answer any questions that the participants may have
Specific
➢ Misunderstandings are clarified
➢ Participants’ given the opportunity to ask questions
➢ Reduce drop-out/ increase retention through communication with participants.

Guide: Telephone Call Script

q) Introduction
   a. “Hi could I please speak with <name> please?
      i. This is Teresa from the “REFRESH: Recovery from Cancer-Related Fatigue” study.
      ii. With your permission, we are going to record this call so that we can take your opinions on board. This recording would only be used for research purposes and would be kept confidential. Are you happy for us to record the conversation?
      iii. Thank you for taking this call. We know that you are very busy and we greatly appreciate your contribution to this project.

b. Purpose
   i. We just wanted to answer any questions you have about this research and how the trial is progressing.

c. Guidelines
   i. We are hoping to learn more from this study and your input is really valuable.
   ii. Also, I don’t want to keep you all day, so I may need to stop you and to redirect our discussion at some stage.
   iii. Ok, let’s begin

r) Warm-up
   a. Set the tone
      i. Maybe before we start taking about the website, let’s start off with a brief introduction about yourself. Why did you decide to take part in the REFRESH study?

b. Set participants at ease

s) Clarification of terms
   a. Establish the knowledge base of key terms through questions
      i. Did you have any questions about the study?
Development of an online intervention for cancer survivors with cancer-related fatigue:

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t) Establish Easy and non-threatening questions
   a. The initial questions should be general and less threatening
      i. Was there anything that was unclear about how the trial is being run?

u) Wrap-up
   a. Identify and organize the major themes from the participant’s responses
      i. Ok so from today it seems that we’ve covered quite a lot and heard some interesting points.
   b. Ensure that any conversational points not completed are mentioned
      i. Over the next few weeks, we would like you to keep in touch with our study.
      ii. We will contact you at the beginning of December with a follow-up questionnaire. You will then be sent a link and you can access the website.

v) Participant-Check
   a. Are you happy to proceed with the study?

w) Closing statements
   a. Request anonymity of information
   b. Answer any remaining questions
      i. Do you have remaining questions about anything we’ve discussed today?
      ii. You can email me at any stage with any other questions you have.
   c. Express thanks
      i. Great! Thank you very much for taking the call today. Your help is greatly appreciated.

Other comments

Revisiting contents

vi. Each of the sessions has a lot of information in it. Most of it will be covered and explained as you work through it. However, you may choose to read it again afterwards. Some of the material will apply to you more than other parts. You can access any of the sessions as many times as you like.

Doing homework activities

vii. Each session also combines specific information with a series of activities to fit into your day-to-day schedule. The time to do some of these tasks may vary from person to person, but should often take no more than 20 minutes per day. It is important that you try to make the commitment to fit these into your daily life. Previous studies have shown that even simple changes may make a difference to your symptoms. How much your symptoms change can partly depend on how much you can stick to your personal goals and to the programme?

Printing materials

viii. To help you do this we have provided coloured homework task sheets for you to print in each session. These will allow you to record your progress and fill in information that is personal to you. You may find it easier to print the relevant task sheet each
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Not wanting to fill out information

x. This information is important for the study, and will not reflect on you in any way. If you feel that any information is too personal you can choose not to share it with us. Instead of typing your answer in the box, you can simply type NA. We do encourage you to complete as many of the tasks as possible, as they are a very important part of the programme.

week and place it in a plastic folder. This will allow you to easily access the sheet each day.

ix. We can send you copies of the handouts if you do not have a printer.
Appendix 14. Emails to participants

REFRESH: Recovery from Cancer-related Fatigue study emails

<table>
<thead>
<tr>
<th>Email type</th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group Allocation</td>
<td>Hi &lt;name&gt;</td>
<td>Hi &lt;name&gt;</td>
</tr>
<tr>
<td></td>
<td><strong>Thank you for completing the first questionnaire in the REFRESH: Recovery from</strong></td>
<td><strong>Thank you for completing the first questionnaire in the REFRESH: Recovery from</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Cancer-Related Fatigue trial.</strong></td>
<td><strong>Cancer-Related Fatigue trial.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>You have been assigned to Group 1.</strong></td>
<td><strong>You have been assigned to Group 2.</strong></td>
</tr>
<tr>
<td></td>
<td>Below is the link to the REFRESH: Recovery from Cancer-Related Fatigue website.</td>
<td>Below is the link to the Irish Cancer Society’s “Coping with Fatigue” Booklet.</td>
</tr>
<tr>
<td></td>
<td>This website will give you information on techniques to help you to deal with your</td>
<td>The link below will give you some information about fatigue.</td>
</tr>
<tr>
<td></td>
<td>fatigue. You are asked to complete 1 session a week for 8 weeks. Each online session</td>
<td>You will be able to participate in online sessions of the REFRESH: Recovery from</td>
</tr>
<tr>
<td></td>
<td>is scheduled to last approximately 30-45 minutes and will consist of reflection</td>
<td>Cancer-Related Fatigue website from December 2015. You will be sent an email</td>
</tr>
<tr>
<td></td>
<td>activities and educational information.</td>
<td>once a week from the REFRESH team. You will be contacted via telephone in the</td>
</tr>
<tr>
<td></td>
<td>You will be sent an email reminder once a week. You will be contacted via</td>
<td>next four weeks.</td>
</tr>
<tr>
<td></td>
<td>telephone during the first 4 weeks to make sure that you are not having any</td>
<td>It is important for our study that some people do not access the REFRESH:</td>
</tr>
<tr>
<td></td>
<td>difficulties with the programme.</td>
<td>Recovery from Cancer-Related Fatigue website immediately. However, everyone</td>
</tr>
<tr>
<td></td>
<td>Further instructions about the programme can be found on the website. When you</td>
<td>will have a chance to access it at some stage.</td>
</tr>
<tr>
<td></td>
<td>visit the website for the first time, click “REGISTER” to create your account and</td>
<td>In 8 weeks, you will be asked to complete another questionnaire. At the end of</td>
</tr>
<tr>
<td></td>
<td>log in for your first session of the REFRESH: Recovery from Cancer-Related Fatigue</td>
<td>this questionnaire you</td>
</tr>
<tr>
<td></td>
<td>website.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>You can access the website at any stage by entering <a href="https://lifeguide.ecs.soton.ac">https://lifeguide.ecs.soton.ac</a></td>
<td></td>
</tr>
<tr>
<td></td>
<td>.</td>
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</tr>
</tbody>
</table>
Please do not share this link with anyone. It is important for our study that only those assigned to group 1 access the website.

In 8 weeks, you will be asked to complete another questionnaire. At the end of this questionnaire you can continue to access the REFRESH: Recovery from Cancer-Related Fatigue website.

You are free to withdraw from the study at any stage without penalty. Please contact the research team and let them know if you do not wish to proceed for any reason.

If you have any questions, please email Teresa at nuigREFRESH@gmail.com.

Click here to access the website

We wish you all the best for the coming weeks,

---

**Check-in email – Week 1**

**Hi <name>**

Welcome to the REFRESH: Recovery from Cancer-related Fatigue programme. Thank you for completing the questionnaire and setting up your account.

To ensure that the momentum of the programme is kept up, please do make sure to regularly login. This will help you learn more about your fatigue and to monitor your progress over the coming weeks.

Your login details are as follows:

Username: <username>

---

**Hi <name>**

Welcome to the REFRESH: Recovery from Cancer-related Fatigue study. Thank you for completing the questionnaire.

To ensure that you are kept up-to-date with the programme, please do make sure to regularly check your emails. We will contact you about the next stage of the study in coming weeks.
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Password: <password>

You can access the website at any stage by visiting https://lifeguide.ecs.soton.ac.uk/player/play/REFRESH

If you have any questions about the study, or no longer wish to take part, please contact Teresa at nuigREFRESH@gmail.com

We wish you all the best for the coming weeks,
The REFRESH Study Team.

We aim to reply as soon as possible. Please do contact us again if you do not receive a reply within five working days.

| Second email – Week 2 | Hi <name>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>We are now in the 2nd week of the REFRESH: Recovery from Cancer-related Fatigue programme. We will call you via telephone after 4 weeks so that you can ask us any questions you may have about the study and your progress.</td>
</tr>
<tr>
<td></td>
<td>To ensure that the momentum of the programme is kept up, please do make sure to regularly login. This will help you learn more about your fatigue and to monitor your progress over the coming weeks.</td>
</tr>
<tr>
<td></td>
<td>Your login details are as follows:</td>
</tr>
<tr>
<td></td>
<td>Username: &lt;username&gt;</td>
</tr>
<tr>
<td></td>
<td>Password: &lt;password&gt;</td>
</tr>
<tr>
<td></td>
<td>Hi &lt;name&gt;</td>
</tr>
<tr>
<td></td>
<td>We are now in the 2nd week of the REFRESH: Recovery from Cancer-related Fatigue programme. We will call you via telephone after 4 weeks so that you can ask us any questions you may have about the study. You will gain access to the website in December.</td>
</tr>
<tr>
<td></td>
<td>To ensure that you are kept up-to-date with the programme, please do make sure to regularly check your emails. We will contact you about the next stage of the study in coming weeks.</td>
</tr>
<tr>
<td></td>
<td>If you have any questions about the study, or no longer wish to take part, please contact Teresa at <a href="mailto:nuigREFRESH@gmail.com">nuigREFRESH@gmail.com</a></td>
</tr>
</tbody>
</table>
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

You can access the website at any stage by visiting https://lifeguide.ecs.soton.ac.uk/player/play/REFRESH.

If you have any questions about the study, or no longer wish to take part, please contact Teresa at nuigREFRESH@gmail.com

We wish you all the best for the coming weeks,

The REFRESH Study Team.

We aim to reply as soon as possible. Please do contact us again if you do not receive a reply within five working days.

Third email – Half-way prompt for phone call

Hi <name>

We are now almost half-way through the REFRESH: Recovery from Cancer-related Fatigue programme. This week, we would like to call via telephone so that we can hear about how you are finding the programme. Also, you can ask us any questions you may have about the study.

We appreciate that you have many other things going on in your life, and so we will try our best to call at a time that suits you. Could you please reply to this email with details about what time and day would suit you best for this short (approximately 5-10 minute) phone call?

To ensure that the momentum of the programme is kept up, please do make sure to regularly login. This will help you learn more about your fatigue and to monitor your progress over the coming weeks.

Your login details are as follows:

We are now almost half-way through the REFRESH: Recovery from Cancer-related Fatigue programme. This week, we would like to call via telephone so that we can discuss any questions you may have about the study. You will gain access to the website in December.

We appreciate that you have many other things going on in your life, and so we will try our best to call at a time that suits you. Could you please reply to this email with details about what time and day would suit you best for this short (approximately 5-10 minute) phone call?

To ensure that you are kept up-to-date with the programme, please do make sure to regularly...
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

Username: <username>
Password: <password>

You can access the website at any stage by visiting https://lifeguide.ecs.soton.ac.uk/player/play/REFRESH.

If you have any questions about the study, or no longer wish to take part, please contact Teresa at nuigREFRESH@gmail.com

We wish you all the best for the coming weeks.
The REFRESH Study Team.

We aim to reply as soon as possible. Please do contact us again if you do not receive a reply within five working days.

Follow-up questionnaire
Hi <name>

We are now in the final week of the trial period of the REFRESH: Recovery from Cancer-related Fatigue programme.

When you have completed all 8 sessions, could you please complete the follow-up questionnaire by clicking this link: <link>

The information you provide will be kept strictly anonymous and your participation in the study will be private. The information will be stored securely and in a way that protects your identity. Upon completion of this questionnaire, you will still be able to access the REFRESH: Recovery from Cancer-related Fatigue website and revisit any of the content.

Hi <name>

We are now in the final week of the trial period of the REFRESH: Recovery from Cancer-related Fatigue programme.

Could you please complete the follow-up questionnaire by clicking this link: <link>

The information you provide will be kept strictly anonymous and your participation in the study will be private. The information will be stored securely and in a way that protects your identity. Upon completion of this questionnaire, you will
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

Your participation in this research is greatly appreciated. When all participants have completed the study (this should be within 12 months of your participation), you will receive a summary of one or 2 pages of the main findings.

If you have any questions about the study, or no longer wish to take part, please contact Teresa at nuigREFRESH@gmail.com

We wish you all the best for the coming weeks,

The REFRESH Study Team.

We aim to reply as soon as possible. Please do contact us again if you do not receive a reply within five working days.

---

Fifth and final email - Follow-up questionnaire:

Hi <name>

We are now in the final week of the trial period of the REFRESH: Recovery from Cancer-related Fatigue programme.

When you have completed all 8 sessions, could you please complete the follow-up questionnaire by clicking this link: <link>

The information you provide will be kept strictly anonymous and your participation in the study will be private. The information will be stored

---

We are now in the final week of the trial period of the REFRESH: Recovery from Cancer-related Fatigue programme.

Could you please complete the follow-up questionnaire by clicking this link: <link>
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

The information you provide will be kept strictly anonymous and your participation in the study will be private. The information will be stored securely and in a way that protects your identity. Upon completion of this questionnaire, you will be able to access the REFRESH: Recovery from Cancer-related Fatigue website.

Your participation in this research is greatly appreciated. When all participants have completed the study (this should be within 12 months of your participation), you will receive a summary of one or 2 pages of the main findings.

If you have any questions about the study, or no longer wish to take part, please contact Teresa at nuigREFRESH@gmail.com

We wish you all the best for the coming weeks.

The REFRESH Study Team.

We aim to reply as soon as possible. Please do contact us again if you do not receive a reply within five working days.
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Appendix 15. Questionnaires for intervention

Contact details
1 – What is your email address? (Please ensure that this is the same email address that you use for all correspondence with this study)

2 – What is your phone number?

Demographic Characteristics
What Sex are you?

- Male
- Female
- Other, please specify

What age are you today?

What is your Height?

- ___metres
- Don’t know / can’t say

What is your Weight?

- ______Kg
- Don’t know / can’t say

What is your current marital status?

- Single
- Married
- Separated
- Divorced
- Widowed
- Other

What is your nationality?

- Irish
- Other nationality, please specify

What is the highest level of education/training (full-time or part-time) which you have completed to date?

- Primary
- Secondary
- 3rd level Non-degree
- 3rd level Degree
- Postgraduate
- Still at school/college
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What is your main employment status? (If on maternity or sick leave answer in relation to your usual employment status)

- Full time employment
- Part time employment
- Homemaker
- Student (in education)
- Retired
- Unemployed – and seeking work
- Unemployed – unable to work for health reasons
- Other

Are your healthcare costs covered by either private health insurance or a medical card?

- Private health insurance
- Medical Card
- Other

If you are female, what is your menopausal status?

- Premenopausal
- Postmenopausal
- Don’t know / can’t say

Information about Cancer and Cancer treatment

Age at diagnosis (years) ______________

What type of cancer were you diagnosed with

- Female breast
- Prostate
- Colorectal
- Lung
- Melanoma
- Lymphoma
- Stomach
- Pancreas
- Bladder
- Kidney
- Leukaemia
- Oesophagus
- Corpus uteri
- Ovary
- Brain & other C.N.S
- Cervix
- Head & neck
- Multiple myeloma
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- Testis
- Other, please specify

What stage was your cancer at diagnosis?

- 0
- I
- II
- III
- Don’t know / can’t say
- Other, please specify

What treatments have you received for your cancer? (Tick all that apply)

- Radiotherapy
- Surgery
- Hormone treatment
- Chemotherapy
- Brachytherapy
- Cryotherapy
- Other, please specify

Are you currently receiving hormone therapy?

- Yes (please specify)
- No

How long is it since you completed your treatment for cancer?

(Treatment includes any chemotherapy, radiotherapy, or surgery for cancer. When answering this question please do not include hormone treatments.)

- It is less than 3 months since my treatment ended
- It is ________ months since my treatment ended

Was this the first time you have been treated for cancer?

- Yes, this is the first time I have been treated for cancer
- No, I have been treated for the same type of cancer before but it has now come back
- No, I have been treated for a different type of cancer before

Information about Other Health Conditions

Do you have a long standing health condition? Please include anything other than your cancer that has troubled you over a period of time or that could affect you over a period of time.

- Yes
- No
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- Don’t know / can’t say

Which, if any, of the following conditions do you have (diagnosed by a health professional)? (Tick all that apply)

- Alzheimer’s disease or dementia
- Angina
- Anxiety
- Arthritis/Osteoporosis
- Asthma or other chronic chest problem
- Blindness or visual impairment
- Chronic kidney disease (CKD), including End-stage renal disease (ESRD)
- Deafness or hearing impairment
- Depression
- Diabetes mellitus (DM), Type 1
- Diabetes mellitus (DM), Type 2
- Epilepsy
- Heart condition (including Hypertension (or Coronary artery disease (CAD), ischemic heart disease (IHD) or history of myocardial infarction (MI) or History of stroke (CVA) or transient ischemic attack (TIA)
- High blood pressure
- Insomnia
- Kidney disease
- Learning difficulty
- Liver disease
- Narcolepsy
- Obstructive sleep Apnoea (OSA)
- Obesity
- Substance abuse or dependence (including Alcohol misuse, abuse or dependence)
- Long term back problems
- Long-standing mental health problem other than depression or anxiety
- Long-standing neurological problem
- Restless leg syndrome
- Another long-standing condition
- I do not have any of these conditions

Are you on medications for any of the conditions listed?

- Yes (please elaborate)
- No

**Standardised measures used:**

- Piper Fatigue Scale (PFS) (Primary Outcome)
- Illness Perception Questionnaire for Cancer-Related Fatigue (IPQ-CRF)
- Cognitive behaviour symptoms questionnaire
Development of an online intervention for cancer survivors with cancer-related fatigue:

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- Quality of Life in Adult Cancer Survivors (QLACS)

Follow-up only: Internet Evaluation and Utility Questionnaire

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Slightly</th>
<th>Somewhat</th>
<th>Mostly</th>
<th>Very</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

These questions are about your use of the REFRESH program. Please read the items and tell us how you felt about using the REFRESH program. If the item does not apply, please choose “NA”.

1. How easy was the REFRESH program to use?
2. How convenient was the REFRESH program to use?
3. How much did the REFRESH program keep your interest and attention?
4. How much did you like the REFRESH program?
5. How much did you like the way the REFRESH program looked?
6. How worried were you about your privacy in using this REFRESH program?
7. How satisfied were you with the REFRESH program?
8. How good of a fit was the REFRESH program for you?
9. How useful did you find the information in the web program?
10. How easy was the information to understand?
11. How much did you feel you could trust the information?
12. If difficulties continue or return, how likely would you be to come back to the REFRESH program?
13. How good of a method was the Internet for delivering the REFRESH intervention?
14. What was the most helpful part of the REFRESH program?
15. What was the least helpful part of the REFRESH program?
Content Manual for the *REFRESH* intervention

Teresa Corbett, BA, MSc.

**Introduction**

This manual provides information on the content of the *REFRESH*: Recovery from Cancer-Related Fatigue intervention. It provides detail on the content of this online intervention designed to help post-treatment cancer survivors to self-manage persistent cancer-related fatigue. There is no one treatment for cancer-related fatigue. However, evidence indicates that lifestyle factors, such as cognitions and behaviours might play a role in the maintenance of symptoms triggered by cancer and cancer treatment.

The information provided in this manual is based on research conducted by the author as part of a PhD thesis at the National University of Ireland. It draws on the findings of a systematic review of the literature relating to psychosocial interventions for cancer-related fatigue. The content is also based on qualitative research conducted with cancer survivors suffering with persistent fatigue after the completion of curative treatment. The structure and layout has been designed in line with previous CBT interventions, in particular, the *Understanding and Managing Persistent Cancer-Related Fatigue* manual (Collier & O’Dwyer, 2011) and the *MSInvigor8* trial conducted by Moss-Morris et al (2012).

Cancer-related fatigue is a complex symptom that is not yet fully understood. The biological factors contributing to persistent fatigue in some individuals is unclear, yet many factors have been recognised as contributing to and/or exacerbating fatigue symptoms. The information
Development of an online intervention for cancer survivors with cancer-related fatigue:

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presented in this manual is based on a theoretical framework known as the Common Sense Model of Health and Illness Representations (CSM) developed by Leventhal et al. This model proposes that the individuals’ understanding and interpretation of their fatigue is a key factor in predicting the coping strategies that they will engage in.

Following on from this model, and in line with traditional CBT techniques, this intervention will include material and activities based on the contributing factors to cancer-related fatigue, with the aim of assisting people to manage their symptoms and reduce their fatigue.

Outline and description of each of the sessions

Session 1. Overview of CRF.

Description: The overall objective of this module is to help participants to gain an understanding of what cancer-related fatigue is and what causes fatigue to persist. The module will emphasise the complex aetiology of cancer-related fatigue, in terms of predisposing and maintaining factors. Specifically, participants will learn the difference between cancer-related fatigue and "ordinary" fatigue. Participants will also identify biological, behavioural cognitive and emotional factors linked to fatigue.

Learning outcomes: On completion of this module, participants will be able to distinguish between “normal” fatigue and cancer related fatigue; identify symptoms of CRF and how they relate to mood/depression; recognise consequences of CRF; recognise causes of CRF

Session 2. What is cognitive behavioural therapy (CBT)?

Description: The overall objective of this module is to help participants to gain an understanding of what CBT is and why it might be useful for cancer-related fatigue. The module will emphasise the importance of goal setting. This module will help the participant to assess ‘where am I now?’

Learning outcomes: On completion of this module, participants will be able to describe what CBT is. They will learn to identify the problems that fatigue causes for them and reflect on their current situation. Participants will be able to set SMART goals for what they would like to achieve upon completion of the programme. They will learn how to keep a fatigue diary to assist them in self-monitoring their progress.

Session 3. Thoughts and Fatigue

Description: The overall objective of this module is to emphasise the power that thoughts can have on feelings and behaviours. In particular, this module will help the participant to assess their own beliefs about the cause of their fatigue and their ability to control or change how they cope with, and think about their fatigue.

Learning outcomes: On completion of this module, participants will understand that fatigue is a complex symptom that is likely to be a result of numerous different factors. Participants will learn to reflect on their thoughts about the cause of their fatigue using “Why Pie-charts”. They will then look at how these thoughts can impact their emotions, physical feelings and behaviours. At the end of the session participants will learn the importance on recognising unhelpful thoughts.
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Session 4. Activity Scheduling

Description: The overall objective of this module is to explore the links between inactivity, deconditioning and fatigue. Specifically this module will help the participant to be ‘economical’ in terms of energy expenditure and help them to learn to schedule activity in a manner that enables them to better manage their fatigue.

Learning outcomes: On completion of this module, participants will understand that fatigue is linked to inactivity and loss of fitness. Participants will learn about ‘energy economics’ and to reflect on their activity levels. Patterns of rest and activity will be discussed with reference to its effects on the body. They will then look at how they can plan activity and rest through the use of goal setting and planning.

Session 5. Improving your sleep

Description: The overall objective of this module is to help the participant to manage their sleep difficulties. This module will highlight the links between cancer, insomnia and cancer-related fatigue.

Learning outcomes: On completion of this module, participants will understand what insomnia and sleep disturbances are. They will be able to identify factors that contribute to sleep problems. Participants will learn ways to improve sleep. Relaxation techniques will be discussed with reference to their impact on sleep, stress and on the body. They will then look at how they can tackle unhelpful thoughts that might disrupt their sleep.

Session 6. Dealing with low mood and changing your thinking

Description: The overall objective of this module is to help the participant to explore the relationship between low mood, negative thinking, and cancer related fatigue. In particular, this module will highlight how our thoughts can make us feel and what we can do to change these thoughts.

Learning outcomes: On completion of this module, participants will be able to identify unhelpful thinking patterns. They will learn to challenge thoughts that drive low mood and to replace maladaptive cognitions with realistic helpful thoughts. Participants will also learn to cope with realistic thoughts that can drive low mood. Finally participants will be introduced to the concept of mindfulness and how this might help them to deal with negative thoughts.

Session 7. Worries and Anxieties/Stress Management

Description: The overall objective of this module is to help the participant to learn more about worry and anxiety. Participants explore why people with cancer related fatigue might worry. In particular this module will highlight strategies that people engage in to manage stress and determine a sense of control.

Learning outcomes: On completion of this module, participants will be able to describe what worry is. They will learn to identify the cause of their worry and stress. Finally participants will be introduced to coping strategies to help them deal with uncertainties that drive worry and anxiety.
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Session 8. Social Support and Preparing for the future

Description: The overall objective of this module is to help the participant to learn how to reclaim their life despite the difficulties associated with cancer-related fatigue. Participants will review their cancer journey and see if there are any positives that they gained from the experience. In particular this module will highlight strategies that people to overcome obstacles that hinder the return to a good quality of life.

Learning outcomes: On completion of this module, participants will be able to identify any positive impact that cancer may have had on their lives. They will learn to appreciate the importance of social support in overcoming the challenges they face. Participants will learn how to prepare for their future beyond the completion of the programme. Finally, they will be encouraged to plan for any setbacks that might arise as they move forward.
## Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

**Intervention Content**

### Session One Content

<table>
<thead>
<tr>
<th>Page Name</th>
<th>Format</th>
<th>Content Written</th>
<th>Content Spoken/ video</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Session 1.</strong>&lt;br&gt;Page 1.</td>
<td>Video and Text</td>
<td>Persistent cancer-related fatigue affects many people in Ireland. However, this problem is often neglected, and underreported despite its profound impact on quality of life. Click on the video to learn more about cancer related fatigue.</td>
<td>Frame 1. Normal everyday tiredness may be seen as a useful and appropriate response to what is going on in our lives. This type of fatigue can help us to keep a healthy balance between rest and activity. It protects us against over-doing things. Fatigue can remind us to make time to recover. When a healthy person is tired, this normal tiredness is made better by rest, and afterwards they feel ready to face the demands of their daily life once more.</td>
</tr>
<tr>
<td><strong>What is Persistent Cancer-related fatigue?</strong></td>
<td></td>
<td></td>
<td>Frame 2. People experience a huge range and variety of symptoms during and after cancer treatment, but fatigue is particularly common. It is one of the most distressing and frustrating symptoms described by those who have been through cancer. People report that it is different from other fatigue that they have experienced in the past. They describe it as more severe than ‘normal fatigue’. This type of persistent or long-lasting fatigue can affect many aspects of a person’s wellbeing. It can be an overwhelming sense of tiredness, lack of energy or feeling of exhaustion.</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Frame 3. Cancer-related fatigue is different for everyone. It can vary both between people and in the same person over time. People with cancer related fatigue may have some symptoms in common. Just as each person's reaction to cancer and its treatment is very individual, so is their experience of fatigue. Some may not get fatigued at all, while others people may feel like their lives are taken over by fatigue. Those with cancer-related fatigue might feel tired even while resting, and it can be made worse by physical or mental work. This might include everyday tasks like going to the shop, reading a book or even just chatting with a friend. Those with cancer related fatigue might also find that rest does not restore their energy. Sometimes people can continue to feel tired even after resting and sleeping.</td>
</tr>
</tbody>
</table>
Many people find themselves having to cut down, change or give up on some activities altogether. People may find themselves needing to rest more before and/or after any effort.

**Frame 4.** The causes, symptoms and impact of fatigue can vary at different stages. The tiredness that someone feels at diagnosis may be very different to that which they feel at the start of their treatment, or when treatment ends.

At any of these times a person might experience no fatigue at all; whereas others will report mild, moderate or severe fatigue. The feeling of being fatigued at any one stage does not predict how tired the person will be at a later point.

**Persistent CRF** is fatigue that lasts for more than 6 months following your treatment.

**Frame 5.** Cancer-related fatigue changes the way a person feels, both emotionally and physically, and can also affect how they think and act. The symptoms of cancer-related fatigue can vary from one person to the next. However, there are some key symptoms that many individuals describe.

We met some people and asked them how it felt to have CRF...

**Frame 6.** People with cancer-related fatigue described their physical feelings of fatigue and spoke about a sense of tiredness or absence of energy. Fatigue was explained as a feeling of “Mugginess” or being “Worn out.”

Some described fatigue as “Weakness” or feeling “Exhausted” or “Weary.”

People described having aches and pains and feeling like their limbs were heavy. Some people described cancer-related fatigue as being a “dull tiredness” that was not improved by rest.

**Frame 7.** Actions in response to CRF included sleeping for longer than usual, or having an irregular sleep pattern. For some this included napping during the day.
Many people spoke about how they reduced socialising or cut-down on hobbies as a consequence of being tired.

In some cases fatigue led to an avoidance of activity or decreased work.

People worried about their fatigue and had less motivation to complete tasks.

Some spoke about visiting their doctor often with many questions about fatigue, in the hope of finding a cause and cure for their fatigue.

**Frame 8.** Emotions described by people we spoke to included worry and anxiety. Some people felt guilty or disappointed about being tired. Others were frustrated, annoyed, or irritated with their fatigue.

However, many people described their hope for the future and their expectation that their energy levels would improve.

**Frame 9.** Some people that we spoke to described the unhelpful, groundless thoughts they have about their fatigue. These included:

- "It's only me"
- "I'm going mad"
- "Fatigue is inevitable"
- "There is nothing I can do about fatigue"
- "Sometimes I worry that my fatigue means that my cancer has come back"
- "I must save my energy"
- "I must sleep as much as possible"

Feeling easily distracted/unable to concentrate

Indecisiveness
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

Self-critical: "I should be able to do more"
"I am not coping well enough"

Frame 10. If this sounds familiar to you and it is at least 6 months since your active treatment ended, then you may be one of the many people who struggle with persistent CRF.

<table>
<thead>
<tr>
<th>Page Name</th>
<th>Format</th>
<th>Content Written</th>
<th>Questionnaire statements (FACT-F, 1997)</th>
<th>Content to be filled in</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 1. Page 2.</td>
<td>Image and Text</td>
<td>Here is a list of statements that other people who have had cancer have said are important. This questionnaire was developed to help measure fatigue by Clinical Psychologist Dr. David Cella and his colleagues. Take some time to read through the statements and note how true each statement has been for YOU during the past 7 days.</td>
<td>1. I feel fatigued 2. I feel weak all over 3. I feel listless (“washed out”) 4. I feel tired 5. I have trouble starting things because I am tired 6. I have trouble finishing things because I am tired 7. I have energy 8. I am able to do my activities 9. I need to sleep during the day 10. I am too tired to eat 11. I need help doing my usual activities 12. I am frustrated by being too tired to do things I want to do 13. I have to limit my social activity because I am tired</td>
<td>Participant fills in score ranging from 0-52 (52 = no fatigue at all, 0 = worst possible fatigue)</td>
</tr>
</tbody>
</table>

Frame 1. Being fatigued can make us feel bad. Over a long period of time, this can lead to negative emotions such as fear, anxiety, guilt, shame and depression. Each of these emotions can also worsen fatigue. These feelings are common in many long-term conditions and can affect how we experience symptoms. Most negative moods can lead
**Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices**

<table>
<thead>
<tr>
<th>CRF and Mood</th>
<th>affects your mood in many ways.</th>
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<tbody>
<tr>
<td></td>
<td>Click on the video to learn more about the relationship between mood and cancer related fatigue.</td>
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<tr>
<td></td>
<td>to changes in the body that can actually increase fatigue. We will discuss this further in Session 3.</td>
</tr>
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</table>

**Frame 2.** It is important to be aware that many of the symptoms used to describe cancer-related fatigue are also common in depression. In fact, fatigue and depression are sometimes confused in people with and after cancer.

Not only is fatigue sometimes mistaken for depression and vice versa but the two conditions can also be very closely related. Fatigue may cause or contribute to the development of depression. In turn, depression may lead to the development and maintenance of fatigue.

**Frame 3.** It is very important that cancer-related fatigue and depression are not confused. Problems with depression should not be ignored. The signs of clinical depression include:

- Depressed mood (or feeling down or sad) most of the day, most days;
- Ongoing loss of interest or pleasure in activities you had previously enjoyed;
- Significant change in your weight or appetite;
- Sleep disturbance;
- Agitation or feeling "slowed down";
- Loss of energy;
- Feelings of worthlessness or excessive feelings of guilt;
- Poor concentration and decision making;
- Feelings of hopelessness;
- Recurrent thoughts of death or suicide;

Because many of these symptoms, for example changes in weight, appetite and sleep, are common in people with cancer it can be difficult to notice depression. However, if you have 5 or more of these symptoms including low mood and or loss of interest for 2+ weeks, or if you are concerned that your symptoms may be caused by or made worse by depression or persistent low mood, it is important to discuss this with your GP.
There is no need to feel worried about talking about depression. Problems with low mood or anxiety are extremely common, especially after an illness. There is nothing shameful about discussing emotional or psychological difficulties with a professional. Depression and anxiety are also highly treatable with appropriate help.

Frame 4. So is CRF a physical or a psychological problem?

There is no doubt that cancer and its treatment can reduce energy and lead to reduced activity. However, our psychological or emotional response - both to having cancer and to this reduced energy - can cause a further drop in our energy and activity levels.

Our psychological response typically includes:

- How we feel - emotionally and physically about the situation
- How we think about the situation
- What we do in the situation

Frame 8. This part of session one is now complete. On the next page we will review what we will look at an example of how our thoughts can affect our quality of life. Please hit "NEXT" to progress with the session.

<table>
<thead>
<tr>
<th>Page Name</th>
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<th>Content Spoken/ video</th>
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<tbody>
<tr>
<td>Session 1. Page 4.</td>
<td>Video and Text</td>
<td>On the last page we discussed how our psychological state can affect our fatigue.</td>
<td>Frame 1. Mary’s Story:</td>
</tr>
<tr>
<td>CRF and quality of life</td>
<td></td>
<td>Click on the video to hear Mary’s story which illustrates a common response to fatigue.</td>
<td>Mary had completed her treatment for cancer 1 year ago, but was still very fatigued. One Saturday afternoon her friends invited her to go shopping with them, followed by dinner. Mary knew that she would be tired and so she declined the invitation. She was afraid that she would only slow her friends down, and that they would worry about her. She did not want to ruin the day out for everyone. On the day of the trip Mary stayed at home. She thought about her friends enjoying themselves and wondered would her fatigue cost her friendships if she could not continue to do things with them. Mary wondered why she got cancer in the first place, and became frustrated at how it had continued to control her life. She feared</td>
</tr>
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</table>
that the fatigue might mean that the cancer had not completely gone away and
began to worry about the future.

Frame 2. In some ways Mary was right to decline the shopping trip on a busy Saturday
afternoon. She knew her limitations and how her fatigue would have made it
difficult for her to manage the day. However, there was no physical reason why
Mary could not have met up with her friends after their shopping trip and joined
them for dinner. Her decision to do that was based on psychological factors, not
physical ones—she was worried about what her friends might think about her, if
they would then pity her and how she might ruin the day for them.

Frame 3. The problem for Mary was how she was thinking. One of the goals of this website
is to help you to recognise and cope with situations where your thoughts and
emotions are getting in the way of your activities. We want to help you to do the
things that you CAN do so that you can live the best life possible despite your
fatigue.

This may mean being creative about how to do things. It may also involve some
compromise and acceptance of your fatigue. In Mary’s case, it could involve
reducing some of her usual activities earlier in the day, getting a taxi or a lift into
town, skipping the shopping but being ready to meet her friends in the restaurant in
the early evening.

Frame 4. This part of session one is now complete. On the next page we will review what
we have covered in this first session. Please hit "NEXT" to progress with the
session.

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<td></td>
<td>Time to recap statements</td>
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#### Session 1. Page 5

**Image and Text**

**Time to Recap**

**Well done!**

Let’s recap and look at what you have learned.

Take some time to read through the statements and if you would like you can print off these 10 key points so that you can refer back to them later.

You will also be able to access these 10 key points in the Session 1 folder of the “My tasks” tab at the top of the screen.

**1.** Cancer-related fatigue is one of the most common symptoms experienced by cancer patients

**2.** Many disease-free survivors of cancer report persistent fatigue, with some experiencing severe persistent fatigue up to 10 years after completing treatment.

**3.** Cancer-related fatigue is very different to “normal” fatigue or tiredness. It is much more severe and distressing and it is not directly related to recent activity.

**4.** Cancer-related fatigue can differ both between people and in the same person over time.

**5.** Many of the symptoms of cancer-related fatigue are also common in depression.

**6.** It is very important that cancer-related fatigue and depression are not confused.

**7.** If you are concerned that your symptoms may be linked to depression or a persistent low mood, it is important to discuss this with your GP or cancer team.

**8.** Cancer-related fatigue can be extremely distressing, frustrating and debilitating.

**9.** Cancer-related fatigue is both a physical and a psychological problem.

**10.** This programme aims to help you to identify and overcome situations where psychological factors are getting in the way of your activities so that you can live the best life possible despite your fatigue.

#### Session Two Content

<table>
<thead>
<tr>
<th>Page Name</th>
<th>Format</th>
<th>Content Written</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 1. Page 6. Stop and think</td>
<td>Questions to be filled in</td>
<td>Before moving forward let’s stop and think for a moment about what you have learned from session 1. Take some time to fill in your answers below.</td>
</tr>
</tbody>
</table>

**Questions**

1. What do we mean by persistent cancer-related fatigue?

2. What in this session was relevant to you?

3. What is important for you to remember?

4. Has it changed any of your beliefs about fatigue? How?

5. How can you use what you have you learned so far to change how you act/behave?

**Content to be filled in**

Participant fills in response to each question.
### Recap of Session 1. And overview of session 2.

- Click on the video to learn more about cancer related fatigue.

---

### Frame 1.

In the first session we gave you a lot of information about what cancer-related fatigue was.

Some of the most important facts to remember were as follows:

1. Cancer-related fatigue is one of the most common symptoms experienced by cancer patients.
2. Many disease-free survivors of cancer report persistent fatigue, with some experiencing severe persistent fatigue up to 10 years after completing treatment.
3. Cancer-related fatigue is very different to “normal” fatigue or tiredness. It is much more severe and distressing and it is not directly related to recent activity.
4. Cancer-related fatigue can differ both between people and in the same person over time.
5. Many of the symptoms of cancer-related fatigue are also common in depression.
6. It is very important that cancer-related fatigue and depression are not confused.
7. If you are concerned about your symptoms may be linked to depression or a persistent low mood, it is important to discuss this with your GP or cancer team.
8. Cancer-related fatigue can be extremely distressing, frustrating, and debilitating.
9. Cancer-related fatigue is both a physical and a psychological problem.
10. This programme aims to help you to identify and overcome situations where psychological factors are getting in the way of your activities so that you can live the best life possible despite your fatigue.

---

### Frame 2.

Now that you have a better understanding of persistent cancer-related fatigue you are ready to start learning how to manage your own fatigue. In this session we will introduce you to Cognitive Behavioural therapy (also called...
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

CBT) in order to develop more helpful ways to manage your fatigue, as well as to reduce the severity of your symptoms.

Frame 3. People with other fatigue conditions such as chronic fatigue have found that CBT can help to reduce tiredness symptoms. We looked at all the previous literature relating to cancer-related fatigue and found that cognitive-behavioral therapies have been previously used in the successful management of cancer related fatigue in cancer survivors.

Frame 4. On the next page we will explain what CBT is and how it can relate to you. Please hit "NEXT" to progress with the session.

<table>
<thead>
<tr>
<th>Page Name</th>
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<tbody>
<tr>
<td>Session 2. Page 2.</td>
<td>Video and Text</td>
<td>On this page we will explain what CBT is, how it works and how this programme will use CBT to help you to manage your fatigue.</td>
<td>Frame 1. Cognitive behavioral therapy is a type of psychological or talking therapy which has been shown to be a very helpful form of self-management for fatigue. The cognitive part refers to our thoughts and the behavioral part refers to our behaviors or our actions. CBT examines the relationship between thoughts and how they influence feelings and behaviors. It may be easier to understand if we think of it in terms of Thoughts and Behaviors Therapy. CBT treatments help you to understand how and why problems develop; what it is that keeps them going and what causes them to worsen. CBT then helps you to make changes in your life- by challenging and replacing unhelpful thoughts and beliefs- so that you begin to feel better. People are not helpless in dealing with fatigue. CBT is aimed at self-management. The goal is to enhance your coping skills and to have a more enjoyable life as a result.</td>
</tr>
<tr>
<td>What is CBT?</td>
<td></td>
<td>Click on the video to learn more about CBT.</td>
<td>Frame 2. CBT is a practical form of psychological therapy. It uses a range of techniques and aims to enhance a person’s coping skills so that they learn to</td>
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self-manage any difficulties which may be contributing to their current problems or hindering recovery.

CBT for cancer-related fatigue involves learning specific skills aimed at reducing limitations in activity and managing symptoms effectively. You have probably already used some strategies that help you cope with other challenges you’ve faced in the past: the aim of CBT is to build on your own strengths and coping abilities. This programme will help you to identify any unhelpful things you do, and offer you new techniques to reduce the effect that fatigue has on your quality of life.

Frame 3. CBT is designed to be tailored to each person’s individual needs and so we will ask you to help us to build up a detailed picture of your own symptoms and experience of fatigue, your pattern of rest, sleep, activity and fatigue, looking at exactly what you can and can’t do on a daily basis.

This programme will focus on developing a plan of graded, consistent activity and planned rest. Other strategies which will be covered include understanding your fatigue symptoms, learning how to identify unhelpful or negative thinking patterns and replacing them with more helpful alternatives, relaxation or sleep control techniques, managing stress, and coping with emotions.

Frame 4. At its simplest level CBT can be best understood through a 5-piece interactive model. The key elements are our thoughts, behaviours (actions), physical (body) feelings and emotions. These are all connected to each other and are in constant interaction. Each piece impacts on the others, feeding into them, potentially creating either vicious (negative) or positive cycles. These can help the person’s symptoms either worsen or improve over time.

All of this happens in the context of a fifth factor- the situation in which we find ourselves, otherwise known as the environment- in other words, the various things that may be going on for us at any one time, including cancer.
This can involve difficulties such as money problems, treatment side effects, relationship difficulties, or family problems. Of course the environment is not usually all bad and it can also include helpful things such as good family or friends or a trusted cancer team.

In session 3 we will examine these potentially vicious cycles in further detail.

Frame 5. It is very important that you regularly login and access the content of this website, in order to ensure that the momentum and consistency of treatment is kept-up. Of course, sometimes things come up, and that’s ok too. However, as far as possible, try to log on at least once a week for the duration of the programme.

Frame 6. CBT sessions are collaborative. This means that we work together as a team. In each session, you will set targets for the week ahead. At the beginning of the session we will review what we have covered to date. If you would like to contact us, you can click on the “Contact us” tab on the bottom of the homepage and we will be happy to discuss any difficulties which may have come up.

During the session you can decide what areas you wish to work on during the coming week, what "homework" tasks you want to try out, and how you will achieve them.

Frame 7. One of the most important aims of CBT is for you to become your own coach, and to continue with a self-directed programme once this online course ends. This is very important, and will enable you to improve on what you’ve achieved, even when this course has ended.

After the course is completed you will be contacted by one of the researchers. We will ask you how much you feel you have benefited from
treatment and how much you have been able to maintain or even improve on what you have learned throughout the programme.

Frame 8. Although this is largely a self-directed treatment, in which you carry out most of the work, many people find it helpful to involve a close friend or relative as a support person. Really all this means is that you have someone available who understands what you are doing and who you can talk things over with. Their main role is supportive, and this can be very important since CBT can require quite a lot of determination.

There may be times when you feel like giving up, or when you feel as though you are making no progress. The presence of someone who can give you encouragement and reinforce your achievements can be invaluable at such times.

Although you may not wish to involve other people in your treatment directly, it can be useful for people close to you to know what it involves, so that they do not worry about whether the treatment is likely to be harmful.

You may choose to show your support person(s) some of this website or print off some of the content to help them understand what you are trying to achieve.

Frame 9. Now that we have covered what CBT is, the first step in tackling your fatigue is to decide:

- what exactly are my current problems
- what are realistic goals for the future

It is very important that your problems are as specific as possible, as this will help you to focus on solutions.
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

GEORGE’S SAMPLE PROBLEMS LIST

<table>
<thead>
<tr>
<th>Problems</th>
<th>(Rating 1-10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I have no energy to do things I used to enjoy (going for walks, swimming)</td>
<td>9</td>
</tr>
<tr>
<td>2. My low energy is stopping me from playing with my children</td>
<td>7</td>
</tr>
<tr>
<td>3. I can't sleep well at night then can't stay awake during the day</td>
<td>8</td>
</tr>
<tr>
<td>4. I am too tired to see my friends</td>
<td>7</td>
</tr>
<tr>
<td>5. I want to go back to work but don't think I'll be up to it</td>
<td>8</td>
</tr>
</tbody>
</table>

In the sample problem list here, George has listed 5 key problems that he associated with his cancer-related fatigue. George rated how severe each problem is on a scale of 0-10 (0= no problem at all and 10= worst possible problem). Notice how George kept his problems very focused. He also rated each of them on the high end of the scale for severity.

Frame 10.

This part of session two is now complete. On the next page we will see how you get on with your own problem list. Remember to stick to problems that are specific and solutions that are possible. Please hit "NEXT" to progress with the session.

<table>
<thead>
<tr>
<th>Page Name</th>
<th>Format</th>
<th>Content Written</th>
<th>Content to be filled in</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 2. Page 3.</td>
<td>Image and Text</td>
<td>My problems List</td>
<td>Participant fills in problems and rate the severity of each problem</td>
</tr>
<tr>
<td>What problems does CRF cause for me?</td>
<td>On this page, please fill in what your key problems related to cancer-related fatigue are right now.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>It is very important that your problems are as specific as possible, as this will help you to focus on solutions. When you have done this, rate how severe each problem is on a scale of 0-10 (0= no problem at all and 10= worst)</td>
<td></td>
</tr>
</tbody>
</table>
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

Of course, you do not have to have 5 problems as George had, you may only have 2 or 3 problems. If you have more than 5 we ask you to focus on the top five problems you have for this exercise.

<table>
<thead>
<tr>
<th>Problems</th>
<th>(Rating 1-10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td></td>
</tr>
</tbody>
</table>

Session 2. Page 4
What are my goals?

Next let’s try to convert these problems into goals. In other words, how would you like to be by the time you finish this online programme. Or if this programme was helpful to you, what would be different in your life?

Frame 1. In order to give yourself the best chance of achieving your goals, it is important to try to make sure that they are ‘SMART’- Specific, Measurable, Achievable, Realistic and Timed appropriately. For example, a goal such “I want to have lots of energy” is quite vague as it doesn’t give you any idea of how low your energy levels are now and what you want to achieve.

Frame 2. Specific

Are your goals specific? It is better to avoid making general goals like “I don’t want to be tired all the time”. Instead choose a specific goal that describes how you want to be, not how you do not want to be. For example, “I want to be able to go back to work full-time” or “I want to go out to lunch with my family”, or “I want to do the grocery shopping”, or “I want to play golf with my friends” or “I
Want to have fun with my children” rather than “I don’t want to sit around on the couch all day.”

Frame 3. **Measurable**

Are your goals measurable? How will you know if you have achieved your goal or if you are making progress on your goal? Put a number on what you would like to achieve. For example: “I would like to go back to work 3 days a week”, “I would like to play 5 holes of golf”. By including measurements we can look back to see progress, which gives great encouragement to continue on.

Frame 4. **Achievable**

Are your goals achievable and within your control? For example, to have a goal that “my cancer will never come back” is not something within your control and whilst it may never come back, that will not have been achieved by cognitive therapy. Goals focusing on “never being tired” or “having lots of energy all the time” are likely to be unachievable as these aspirations are not possible for anyone. Also to have the goal “I want to sleep 8 hours straight through the night” if you have never been a good sleeper is unlikely to be achievable. Similarly to have goals about being able to read a book from cover to cover or to become a successful sportsperson if you have never enjoyed reading or sport are unlikely to be “achievable”! Be careful too about setting goals that are dependent on other people. For example, while you can set the goal to start socializing or working again, to have the goal that no one will mind if you have to leave events early is dependent on other people and is not under your
control. A more achievable goal might be “I will start socialising and will learn to explain my fatigue to my friends so that they are not let down if I leave early”

Frame 5. **Realistic**

Are your goals realistic? If goals are not realistic at the start you are likely to fail no matter how hard you try. Break down bigger goals into small tasks. For example, if you want to run the mini-marathon or start playing soccer or to walk 3 miles daily, start with small steps. A gentle walk building up slowly to bigger more challenging goals may be realistic. It might be useful to divide some goals into short, medium and longer-term aims. Remember that your body has been through a lot. For some people it will not be possible to return to 100% of your previous levels of energy (at least not immediately). Some of the goals you set may fall short of your previous activities but that does not mean that they will not significantly improve your quality of life- so don’t be so hard on yourself. Better start with the small things and work up.

Frame 6. **Timed appropriately**

Set a realistic time frame for where you want to be regarding your fatigue and related issues. Breaking this into steps may be useful. Where do you want to be in 2 months, 3 months, and 6 months? Remember that it takes time to recover both psychologically and physically. Be kind to yourself. Better to exceed your expectation than to put yourself under too much pressure to achieve your goals.

Frame 7. **George’s Goals**

(Participants presented with example of George’s goals Table)
GEORGE’S SAMPLE SMART GOALS LIST

<table>
<thead>
<tr>
<th></th>
<th>Short term (in the next month)</th>
<th>Medium term (4-12 weeks)</th>
<th>Long term (3-6months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Walk 20 mins. 4 days a week</td>
<td>Join a walking and running group. Swim 2 days a week</td>
<td>Start jogging with group. Jog or swim every second day</td>
<td></td>
</tr>
<tr>
<td>2. Plan an activity with my children</td>
<td>Explain to them why I am tired</td>
<td>Learn to prioritise time with my children</td>
<td></td>
</tr>
<tr>
<td>3. Stay awake more during the day</td>
<td>Get better quality sleep (7hours)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Keep in contact with my friends via phone or social networks</td>
<td>Meet up for a drink or a coffee</td>
<td>Go to Jim’s wedding</td>
<td></td>
</tr>
<tr>
<td>5. Start doing some work from home. Talk to boss about going back part-time at first.</td>
<td>Go to work part-time (3 hours per day)</td>
<td>Full-time work</td>
<td></td>
</tr>
</tbody>
</table>

We can see here that George has tried to convert his problem list into a SMART goals list using this table. How do you think he has done? Let’s have a look.

He has made each goal specific and measurable by stating what exactly he wants to do. Goals 1-4 appear achievable and realistic, as they seem to be within his control and are in keeping with what he had done before he got cancer. He has kept his expectations pretty realistic by starting with small short-term goals and building up the difficulty of his goals over a period of months.

Goal 5 may need to be revised as it is very dependent on cooperation from his boss. Before moving onto step 2 or 3, he will have to see how he gets on with his...
George has also done a great job of the “Time Frame” by breaking his goals into short, medium and long-term goals, with rough estimates for when they will happen.

**Frame 8.** This part of session two is now complete. On the next page we will see how you get on with your own problem list. Remember to stick to problems that are specific and solutions that are possible. Please hit "NEXT" to progress with the session.

### My SMART Goals List

<table>
<thead>
<tr>
<th>My SMART Goals List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short term</td>
</tr>
<tr>
<td>(——)</td>
</tr>
<tr>
<td>1.</td>
</tr>
<tr>
<td>2.</td>
</tr>
<tr>
<td>3.</td>
</tr>
<tr>
<td>4.</td>
</tr>
<tr>
<td>5.</td>
</tr>
</tbody>
</table>

This part of session two is now complete. On the next page we will see how you get on with your own problem list. Remember to stick to problems that are specific and solutions that are possible. Please hit "NEXT" to progress with the session.
### Setbacks

Setbacks can happen when you do too much activity because it’s a good day, or if a stressful event happens or if something unexpected comes up. You might have many competing demands on your time, or you may feel unwell.

When things like that happen try not to get too frustrated and aim to do better the next day. Setbacks can be expected. The most important thing is to remind yourself that this is normal and try as far as possible to stick to your goals. Remember that it’s not the occasional few bad days that matter, but it’s the overall trend that is important.

### Where am I now?

The next step in your efforts to overcome cancer related fatigue, therefore, is to turn your attention away from how you got here and focus on exactly where you are right now. 

Click on the video to continue.

Cancer survivors can spend days, weeks, months, and in some cases even years wondering why they got cancer and thinking about how much their lives have changed as a result. For most people there is no clear answer to these questions. If you spend too much time searching for answers, you can miss opportunities to get your life back on track.

The next step in your efforts to cope with your fatigue, therefore, is to turn your attention away from how you got here (and also from the possibility that the future ahead may be bad) and focus on exactly where you are right now.

In order to focus on exactly where you are right now we will ask you to keep a simple diary for 2 weeks.
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

In this diary we would like you to write a brief note on what activity you were doing during each time slot from the time you woke up each morning (remember the time you wake up is not necessarily the time you get out of bed!). So the first activity of the day may be lying in bed. Underneath each activity we would like you to rate your levels of Energy (E) on a scale of 0 (no energy) to 10 (highest level of energy possible). We would also like you to rate your sense of satisfaction (S) (0=no satisfaction and 10= highest level of satisfaction possible). Your satisfaction can related to your sense of enjoyment and achievement with the task. Make sure to record any naps.

Frame 3. Here we see an example of Eileen filling in her diary on Tuesday. She starts off by recording what time she got up at. She rates her fatigue as 1, her satisfaction as 1. While lying in bed her energy level was only 1 out of 10, and her sense of satisfaction was low. She then proceeds to do the same for her other activities that morning. She has breakfast and takes a shower. Her sense of energy increased somewhat to 4 out of 10, and her sense of satisfaction increased to 4. Even if her energy had not increased, she could still experience a better sense of satisfaction because she was doing something that is important to her.

Frame 4. Later Eileen comes back in the afternoon and records that she has watched TV. She rates her energy level as 2, her satisfaction level as 2. She also records that she has eaten lunch, and goes on to rate her energy and satisfaction Eileen will continue to do this for the rest of the week.
**Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices**

Frame 5. Fill in your diary as close to when you do an activity as possible. There is no point in sitting down at the end of the day to try and remember what happened earlier on! It’s just not the same. Remember that there are no right or wrong answers. Just score each activity for energy and task satisfaction as it feels to you. We will show you how use the information from this diary in a later session so it is important that you have it recorded in advance of getting to the end of that session so that you can move on to the next step!

Frame 6. Completing this exercise will require commitment and effort from you. You may be tempted to give up or to only complete some of it. We believe that the effort will be worth it as the information gathered will be very important later in the programme. So try to stick with it!

On the next page you can see your own Fatigue Diary. Please hit "NEXT" to progress with the session.

<table>
<thead>
<tr>
<th>Page Name</th>
<th>Format</th>
<th>Content Written</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 2, Page 8.</td>
<td>Image and Text</td>
<td>You can now print off your own fatigue diary.</td>
</tr>
<tr>
<td>My fatigue diary</td>
<td>In this diary we would like you to write a brief note on what activity you were doing in each time slot from when you woke up.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Underneath each activity we would like you to rate your levels of Energy (E) on a scale of 0 (no energy) to 10 (highest level of energy possible).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>We would also like you to rate your sense of satisfaction (S) (0=no satisfaction and 10= highest level of satisfaction possible).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>We will come back to your diary later in the programme.</td>
<td></td>
</tr>
</tbody>
</table>
Participant prints their fatigue diary.

<table>
<thead>
<tr>
<th>Page Name</th>
<th>Format</th>
<th>Content Written</th>
<th>Time to recap statements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Session 2. Page 9</strong></td>
<td>Image and Text</td>
<td><strong>Well done!</strong> Let’s recap and look at what you have learned. Take some time to read through the statements and if you would like you can print off these 10 key points so that you can refer back to them later. You will also be able to access these 10 key points in the Session 1 folder of the “My tasks” tab at the top of the screen.</td>
<td><strong>1.</strong> Cognitive Behavioural Therapy, or CBT, is a type of psychological therapy. <strong>2.</strong> The word cognitive refers to our thoughts <strong>3.</strong> The word behavioural refers to our behaviours/actions or what we do <strong>4.</strong> CBT has been used to treat a wide range of fatigue and cancer problems, including cancer-related fatigue <strong>5.</strong> CBT looks at problematic interactions between our thoughts, behaviours, physical feelings and emotions. <strong>6.</strong> The first step in CBT is to create a personal problem list. <strong>7.</strong> The next step is to convert your problem list into a goals list <strong>8.</strong> Ideally goals should be SMART. (Specific, Measurable, Achievable, Realistic, Time-framed) <strong>9.</strong> Recording your fatigue, enjoyment and achievement levels in a diary over 2 weeks is a useful way of assessing where you are right now. <strong>10.</strong> Diaries are best completed during the day rather than waiting until the end of the day (or worse still- the end of the week).</td>
</tr>
</tbody>
</table>
### Session 2. Page 10. Stop and think

Before moving forward let’s stop and think for a moment about what you have learned from session 3. Take some time to fill in your answers below.

<table>
<thead>
<tr>
<th>Questions</th>
<th>Content to be filled in</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you understand what your problems with cancer-related fatigue really are?</td>
<td>Participant fills in response to each question</td>
</tr>
<tr>
<td>2. Have you set SMART goals to work towards and motivate you through the rest of this course?</td>
<td></td>
</tr>
<tr>
<td>3. What in this session was relevant to you?</td>
<td></td>
</tr>
<tr>
<td>4. What is important for you to remember?</td>
<td></td>
</tr>
<tr>
<td>5. Has this session changed any of your beliefs about fatigue?</td>
<td></td>
</tr>
<tr>
<td>6. How can you use this session to change how you act/behave?</td>
<td></td>
</tr>
</tbody>
</table>

### Session Three Content

In the first session we gave you a lot of information about what cancer-related fatigue was. Some of the most important facts to remember were as follows:

1. Cognitive Behavioural Therapy, or CBT, is a type of psychological therapy.
2. The word cognitive refers to our thoughts.
3. The word behavioural refers to our behaviours/actions or what we do.
4. CBT has been used to treat a wide range of fatigue and cancer problems, including cancer-related fatigue.
5. CBT looks at problematic interactions between our thoughts, behaviours, physical feelings and emotions.
6. The first step in CBT is to create a personal problem list.
7. The next step is to convert your problem list into a goals list.
8. Ideally goals should be SMART. (Specific, Measurable, Achievable, Realistic, Time-framed)
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

9. Recording your fatigue, enjoyment and achievement levels in a diary over 2 weeks is a useful way of assessing where you are right now.

10. Diaries are best completed during the day rather than waiting till the end of the day (or worse still - the end of the week).

Frame 2. Now that you have a better understanding of persistent cancer-related fatigue and what CBT is you are ready to progress to learning about how your thoughts can influence your cancer-related fatigue.

Frame 3. Our thoughts are extremely powerful. They influence what we feel and what we do. In this session will introduce you to ‘WHY-pie charts’ to help you to examine your thoughts about the causes of your fatigue. We will then look at how accurate and helpful these thoughts might be.

We will then move on to creating a personal model of fatigue that will help you to understand how your thoughts can impact your emotions, behaviours and how you feel physically.

We will finish the session by discussing what you can do to start to tackle unhelpful thought processes.

Frame 4. On the next page we will start to think about how accurate our thoughts are. Please hit "NEXT" to progress with the session.

<table>
<thead>
<tr>
<th>Page Name</th>
<th>Format</th>
<th>Content Written</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 3.</td>
<td>Video and Text</td>
<td>On this page we will explain how we can sometimes have</td>
</tr>
<tr>
<td>Page 2.</td>
<td></td>
<td>The thoughts we have are not always accurate or true. Thoughts are not facts, they are simply the way we see things at a given moment in time. When we have thoughts, they can be influenced by many different things going on in our lives- including how we feel at that moment; the amount of information we have available to us; past experiences and expectations.</td>
</tr>
</tbody>
</table>
Are thoughts always accurate?

Click on the video to learn more.

Thoughts that are not accurate.

It is not the situation that makes us think, feel and act a certain way, but our understanding of and reaction to that situation.

There are many unhelpful thoughts, myths and misconceptions about persistent cancer-related fatigue and what causes it.

Just because we think something is the case, doesn’t make it so!

Sometimes we can believe that our thoughts about a situation are fact, even when the reality is very different.

Often there is more than one possible explanation, and our initial instincts (our “automatic thoughts”) can be very far from the reality of the situation.

Have you ever jumped to conclusions before knowing the facts? Have your emotions and what you planned to do next, ever changed once you realised that you have misinterpreted the situation? Have you ever regretted something you said or had to apologise when you found out that your thoughts (which you had assumed were 100% correct) about a situation were wrong?

It would seem that it is human nature to try to make sense of our surroundings but sometimes our conclusions can be imprecise with unfortunate consequences for our feelings and actions. This is true not only in social interactions but also with regard to thoughts about cancer and persistent cancer-related fatigue. Today’s session will focus on your understanding of the causes of your fatigue symptoms because we know from research that focusing on symptoms and how they came about may impact the experience of fatigue.

On the next page we will start to think about the causes of cancer-related fatigue. Please hit "NEXT" to progress with the session.
Session 3. 
Page 3.

What are your thoughts about the causes of your fatigue?

Fill in

Take some time to think about the following 2 questions and then fill in your answers. This is not an exam, so don’t feel like you need to look up answers or research the topic.

It is important that you get an idea of your views about your fatigue- no matter what they are. The purpose of this section is to explore exactly what your thoughts are about your fatigue. We will be able to use this information later in the chapter to help you tackle your fatigue.

1. What do you think is to blame for causing your cancer-related fatigue?

2. What do you think keeps your fatigue going?

Participant fills in their responses

Session 3. 
Page 4.

Unhelpful thoughts

Video and Text

On this page we will look at unhelpful thoughts

Frame 1.

WELL DONE! Hopefully you have been able to make an attempt at both of the questions. Let’s see if we can explore your answers a little further by taking a look at how much you believe each of these factors contributes to your fatigue on a day-to-day basis. One way to do this is to create a personalised fatigue WHY-pie chart.

Frame 2.

Elaine is a 52 year old receptionist and the mother of two teenage boys. She completed successful treatment for breast cancer 18 months ago, and her assessments have shown that she remains cancer free. However, Elaine experiences severe cancer-related fatigue that she finds extremely limiting. She has not been able to go back to work and feels that she needs to nap every afternoon. She has given up socialising, and in particular she no longer believes that she is able to play golf which has been her favourite hobby for many years. Her constant fatigue has prevented her from enjoying events and she feels that she has lost contact with the other ladies at the golf club as a result. Elaine believes that her fatigue is the price she had to pay for surviving cancer. She describes everyday as a “groundhog day”, merely existing from one day to the next. Her mood and self-esteem are low and she worries that her cancer will come back. She tries to protect herself by resting. On the few occasions where she pushed herself, she was left frightened by her experiences of breathlessness and aches and pains in her muscles. Elaine took these symptoms to mean that she was over-doing things, and now she limits her activities. Despite the fact that she is “cured” of cancer, Elaine’s life is now quite restricted as she spends most of her time in bed or resting.
In Elaine’s case she believes that the cause and maintaining factors of her cancer-related fatigue were the original disease and the side effects of treatment.

Elaine’s WHY-pie chart

Disease
Side-effects of treatment

Elaine was able to show this in her WHY-pie chart. As you can see she felt that the cancer continued to play a small role in her current fatigue. However, she believes that the persistent negative effects of her cancer treatment were the main cause of her current fatigue.

Frame 3. The impact of these thoughts and feelings can be seen her personal model of fatigue.
Mike is a 47 year old father of three and completed his treatment for testicular cancer 8 months ago. His recovery was successful but slow. He is eager to get back to his job as a teacher but is finding it very difficult due to his cancer-related fatigue. He is frustrated and finds it debilitating. He feels that he should have been better by now and is disappointed that he has failed to build up his energy levels. He believes that his failure to beat his fatigue is a sign of mental weakness and is embarrassed by his fatigue. He has begun to spend less time with his friends and family.

Mike's WHY-pie chart

When Mike drew his WHY-pie chart he only felt that treatment only played a small role in his fatigue. For Mike, he attributed most of the blame to his own mental weakness or personality. He believes that if he tried harder or if he was a stronger person he would be able to beat his fatigue.
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

Frame 5. This is Mike’s personal model of how his thoughts about his fatigue relate to his actions, feelings and emotions.

![Diagram](Frame 5)

Frame 9

On the next page we will work towards building a personal model of your fatigue, so that you might see if and how your thoughts impact your actions or behaviours, your emotions and your body or physical feelings. Please hit "NEXT" to progress with the session.

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<tr>
<th>Page Name</th>
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</thead>
<tbody>
<tr>
<td>Session 3. Page 5.</td>
<td>TEXT</td>
<td>Creating your Personal Model of Fatigue</td>
</tr>
<tr>
<td>Creating your</td>
<td></td>
<td>One of the advantages about a personal model such as those we saw in the previous examples is that it allows us to think about the many different factors that contribute to fatigue and can lead to a negative cycle of thoughts, feelings, emotions and behaviours. One of the goals for this programme is to figure out what happens to you when you feel fatigued, how that might fit or relate to this model, and to find new or more helpful ways to manage your fatigue better. Over the course of this session we will develop your own personal model of cancer-related fatigue. To begin, we are going to reflect on how we think about fatigue. Click &quot;NEXT&quot; to get started on making your own personal model.</td>
</tr>
</tbody>
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<th>Tick boxes</th>
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</thead>
<tbody>
<tr>
<td>Session 3. Page 06</td>
<td>Tick boxes</td>
<td>Try and think about your fatigue. Can you describe how it feels physically? Tick up to five physical symptoms that you think are linked to your fatigue.</td>
<td>Tiredness/ absence of energy; Poor sleep; Decreased endurance; Weakness; Poor concentration; Breathless; Exhaustion; Feeling flat; Aches and pains; Headaches/tension; Weariness; Feeling</td>
</tr>
</tbody>
</table>
## Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

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<th>Page Name</th>
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</thead>
<tbody>
<tr>
<td>Session 3, Page 07 Emotions</td>
<td>Tick boxes</td>
<td>Try and think about your fatigue. How does it make you feel? Tick up to five feelings that you think are most strongly linked to your fatigue (Note you can only pick up to 5 feelings)</td>
<td>Sad; Lonely; Upset; Down; Worried; Scare; Angry; Frustrated; Guilty; Embarrassed; Uncertain; Disappointed</td>
</tr>
<tr>
<td>Session 3, Page 08 Thoughts about fatigue</td>
<td>Tick box</td>
<td>Do you notice any changes to the way you think about your fatigue because of the way you feel? We have listed some negative thoughts that are often associated with fatigue and associated negative feelings. Tick up to three that you think most apply to you. If you would like to write down some of your own thoughts, then choose &quot;My own thoughts&quot; and type them in the box below. (Note: You can only select a maximum of three thoughts. If you choose “my own thoughts” this counts towards one of your selections.)</td>
<td>My health is getting worse.; I don't understand what these symptoms mean.; I must see a Doctor; there is nothing I can do to help me feel better.; I still feel ill. My cancer must be back; I can’t seem to predict when I might experience physical symptoms. There’s no pattern. I don’t feel as though there is anything I can do to make my energy levels improve.; Fatigue is inevitable. There is nothing I can do about fatigue; I should be able to do more; I am not coping well enough; Other people who had cancer are doing so much better than me; I am letting people down; I must sleep as much as possible ; My own thoughts (specify here):</td>
</tr>
<tr>
<td>Session 3, Page 09</td>
<td>Tick boxes</td>
<td>Below are some of the common behaviours people do to cope and deal with fatigue. Do any of these apply to you? Please choose up to three</td>
<td>Sleeping more than usual; Taking naps during the day, even if they do not make me feel better; Avoiding social events; Having an irregular sleep pattern; Avoiding activity; Decreasing time</td>
</tr>
</tbody>
</table>
### Behaviours

behaviours. If you would like to add your own behaviours, then choose "My own behaviours" and type them in the box below.

- spent on hobbies or leisure activities;
- Cutting down on work;
- Spending less time with friends and family;
- Doing too much on days where I feel good and feeling worse as a result;
- Procrastinating or putting things off;
- My own thoughts

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<tr>
<th>Page Name</th>
<th>Format</th>
<th>Interactive feedback</th>
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</thead>
<tbody>
<tr>
<td>Session 3. Page 10.</td>
<td>TEXT + option to print</td>
<td>Your Personal Model of Fatigue (based on responses on previous pages, content is filled in and presented to participant)</td>
</tr>
</tbody>
</table>

### Your Personal Model of Fatigue

![My situation](image)

**Thoughts**

**Emotions**

**Actions**

**Physical/Body Feelings**

---

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<th>Page Name</th>
<th>Format</th>
<th>Content Written</th>
<th>Content Spoken/ video</th>
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</thead>
<tbody>
<tr>
<td>Session 3. Page 11</td>
<td>Video and Text</td>
<td>On this page we will discuss some of the potential</td>
<td>Frame 1. Now that you have a better understanding about the beliefs you have about your fatigue, let's see if the following information section changes these beliefs in any way.</td>
</tr>
</tbody>
</table>
Frame 2. **MYTH: THERE IS NOTHING I CAN DO ABOUT MY FATIGUE**

**Multiple causes of fatigue**

Most people underestimate the number of different reasons why someone might have cancer-related fatigue. This might make it more difficult to recognise the various different things that a person can do to cope with their fatigue. This is often the case when we see WHY-pie charts that have very few slices. The belief that cancer-related fatigue is due to only a small number of factors might be unhelpful, especially if these are factors over which you have little control. In turn, this can impact the way in which you act or attempt to cope with your fatigue, and sometimes lead to feelings of helplessness or frustration. What if there were many slices that contribute to your fatigue in your WHY-pie? What if some of these were things that you *could* challenge head on? In order to examine this possibility we will first explore some of the many different causes of fatigue.

Frame 3. **Cancer**

Cancer itself can cause fatigue. For many people fatigue was the first indication that they were unwell

**Surgery**

Following surgery patients can feel tired and uncomfortable. It can take time before energy levels return. This is especially true in cases where surgery means that you are inactive for a long time

**Chemotherapy and Radiotherapy**

It is true that chemotherapy and radiotherapy can have great impact on your energy levels and they are major factors in the development of cancer-related fatigue. Generally the effects of chemotherapy and radiotherapy will wear off over time.

**Hormone therapies**

---

Another slice of the WHY-pie causes of cancer-related fatigue before we look at your responsibility pie chart in further detail.

Click on the video to learn more.
Hormone therapies such as Herceptin and Tamoxifen can affect energy levels directly and they can also cause night sweats, which may interrupt sleep leaving people feeling tired during the daytime.

Frame 4. **Anaemia**
Some patients become anaemic following chemotherapy and radiotherapy treatments. This can lead to fatigue and breathlessness.

**Pain**
Some people develop pain following cancer and cancer surgery that persists over time. This can be very draining. Pain can lead to a reduction in fitness levels (due to inactivity) and to sleep problems, leaving people feeling tired during the daytime.

**Medications**
Fatigue is an unwelcome side effect of some medications.

**Physical Inactivity and Deconditioning**
Treatment for cancer often involves long periods of inactivity either following surgery or during chemotherapy and/or radiotherapy. People can feel very physically ill and may spend most of their time resting. While this is an important part of getting better it can also lead to people becoming very unfit. Unused muscles become weakened and the work of the heart and lungs becomes more difficult as activity decreases dramatically. This can result in a body that tires easily leaving the person breathless with aches and pains even after very little exercise or effort.

**Nutrition**
Some people lose their appetites during treatment and find it difficult to get back into good eating habits when treatment ends. Others might be concerned that their medication has caused or is causing them to put on weight and so may diet or try...
to limit their food intake after cancer. Some may become very concerned about infections or food poisoning during treatment causing them to restrict their diets. These food restrictions can continue even after treatment has ended and any danger periods have passed. Dieting or picky eating can mean that people are not getting enough energy from their food. In turn, this can contribute to feelings of fatigue.

**Sleep Disturbance**

Following cancer many patients experience problems with their sleep. Those people who are not sleeping well at night are more likely to feel very fatigued during the day.

**Frame 5. Distress and Depression**

Low mood and anxiety are quite common after cancer, and both can result in fatigue. One of the most common symptoms of low mood is feeling that you have less energy, motivation and enthusiasm for activities. High levels of anxiety can result in poor sleep at night and relentless tension during the day causing people to feel fatigued.

**Frame 6. Unhelpful Thoughts about Fatigue**

The way we think about a problem can affect how we try to cope with that problem and ultimately whether we overcome it. For example, the person who thinks, “fatigue is the price you pay for cancer, there is nothing I can do about it”, is unlikely to try to tackle their cancer-related fatigue. This type of unhelpful thought is known as a *self-fulfilling prophecy*. In this situation the belief causes the person to act in a way that actually causes the belief to come true.

On the other hand, unrealistic positive expectations or over-optimism can also cause problems. The person who expects to be back to normal too quickly may try to do too much too soon, resulting in exhaustion and frustration that can eventually lead the person to give up trying. Throughout this programme we will often
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

discuss how these and many other unhelpful thoughts can make you more likely to do things that will actually feed your fatigue.

Frame 7. **The Domino Effect and Vicious Circles**

As you can see from the previous examples, there are many causes of fatigue. Each can act alone but they can also have a knock-on effect on other factors. For example, pain will reduce activity, which weakens muscles, which may increase pain, which leads to greater fatigue, which causes daytime napping, which can interfere with sleep, which causes distress, which reduces socialising, which causes low mood, which reduces activity further, which causes greater fatigue. The list can go on and on and on! Each link in the chain causes fatigue to worsen. Finding a way to step in and break these links is likely to be important in managing fatigue.

Frame 8. Having more knowledge about the numerous potential causes of fatigue may change your understanding of what is responsible for your personal fatigue.

On the next page we will take another look at your own fatigue responsibility pie chart. Please hit "NEXT" to progress with the session.

<table>
<thead>
<tr>
<th>Page Name</th>
<th>Format</th>
<th>Content Written</th>
<th>Potential Causes of fatigue</th>
<th>Content to be filled in</th>
</tr>
</thead>
</table>
• surgery  
• chemotherapy and radiotherapy  
• hormone therapies  
• anaemia  
• pain  
• medications  
• deconditioning  
• physical inactivity  
• nutrition | Participant fills ticks contributing factors problems |

New Responsibility Pie Chart

Let’s take a moment to consider your own fatigue responsibility pie chart. Can you make room for other factors or causes? Let’s look at the list of possible causes of your fatigue. Place a tick beside each factor that you think might be a cause of, or a contributing factor to your fatigue and make a guess at how responsible
Now fill those you have ticked into your new responsibility pie chart in your workbook. Remember give the biggest slice of the pie to the factor that is most responsible and so on.

- low mood
- anxiety
- sleep disturbance
- unhelpful thoughts about fatigue
- unrealistic expectations about recovery
- other

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<th>Content Written</th>
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<tbody>
<tr>
<td>Session 3 Page 13</td>
<td>Video and Text</td>
<td>So far in this session we have talked about how thoughts can impact fatigue. Now we are going to see how we can begin to address thoughts that are unhelpful. Click on the video to continue.</td>
<td>Frame 1. So far we have discussed how beliefs about the causes of cancer-related fatigue are often untrue or incomplete. We have also seen how these thoughts can have a negative effect on emotions, body feelings and actions, which can in turn worsen fatigue.</td>
</tr>
<tr>
<td>Unhelpful thoughts</td>
<td></td>
<td></td>
<td>Frame 2. When negative thoughts have been around for a while they can become ‘automatic’. By that we mean that they pop into our heads without us realising. We don’t even consider other ways of thinking – our initial reaction is what we accept to be true. Unhelpful ideas and thoughts can trap us in a cycle where they have negative effects on our feelings and actions.</td>
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<td>Frame 3. The first step in tackling thoughts that are unhelpful or untrue is to start to become aware of them. Think about your personal model and your WHY-pie charts. Did you have any negative automatic thoughts? Do you think that they have an impact on your emotions, action and body feeling? However, you may also have other unhelpful and/or untrue thoughts that we have not yet thought about.</td>
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<td></td>
<td>Frame 4. In your workbook you will find a Fatigue Thought Chart. Over the next couple of weeks we would like you to take note of any thought about your fatigue that pop into your head.</td>
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</tbody>
</table>
Take some time to then examine (and put in the chart) how thoughts made you feel emotionally (for example sad, frustrated, anxious etc.) and physically (for example tired, aches, tense, tearful, etc.) and also what they make you feel like doing (or not doing) (for example, stay in bed, have a nap, don’t meet friends, don’t tidy up). Finally see how you feel from a fatigue point of view after doing (or not doing) these actions. Try rating your emotions and fatigue on a scale of 0-100, where 0=no fatigue and 100= worst possible fatigue (and for emotion…).

Frame 5. By doing this you will be prepared when you get to the later sessions where we will focus on strategies to help you to manage these thoughts. By recognising patterns in your thinking you will be better equipped to deal with them so that they will have much less of a negative impact on your emotions, actions, body feelings and fatigue.

Completing this exercise will require commitment and effort from you. You may be tempted to give up or to only complete some of it. We believe that the effort will be worth it as the information gathered will be very important later in the programme. So try to stick with it!

Please hit "NEXT" to progress with the session.

<table>
<thead>
<tr>
<th>Page Name</th>
<th>Format</th>
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<th>Time to recap statements</th>
</tr>
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<tbody>
<tr>
<td>Session 3. Page 14</td>
<td>Image and Text</td>
<td>Well done! Let’s recap and look at what you have learned. Take some time to read through the statements and if you would like you can print off these 10 key points so that</td>
<td>1. Our thoughts are very powerful and can impact what we feel and how we act. 2. Thoughts are not facts; they are simply how we see things at a given time. 3. Our thoughts can be inaccurate and untrue. 4. There are many unhelpful thoughts and mistaken beliefs about cancer-related fatigue and what causes it. 5. A fatigue WHY-pie chart allows you to draw out the extent to which different factors contribute to your fatigue. 6. People often underestimate the number of different factors than can play a role in their cancer-related fatigue.</td>
</tr>
</tbody>
</table>
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

you can refer back to them later.

You will also be able to access these 10 key points in your Workbook.

7. Believing that fatigue is caused by a small number of factors over which you may have very little control can lead to unhelpful behaviours and feelings of helplessness.
8. If you don’t account for all the potential contributing factors you may underestimate all the things you can do to cope with your cancer-related fatigue.
9. There are many factors and causes of cancer-related fatigue that you can try to address. Other factors may need to be accepted or worked out.
10. The first step in dealing with unhelpful thoughts is to start to become aware of them and their impact.

<table>
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<tr>
<th>Page Name</th>
<th>Format</th>
<th>Content Written</th>
<th>Questions</th>
<th>Content to be filled in</th>
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</thead>
<tbody>
<tr>
<td>Session3. Page 15.</td>
<td>Stop and think</td>
<td>Questions to be filled in</td>
<td>Before moving forward let’s stop and think for a moment about what you have learned from session 3. Take some time to fill in your answers below.</td>
<td>Participant fills in response to each question</td>
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<tr>
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<td>1. What in this session was relevant to you?</td>
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<td>2. What is important for you to remember?</td>
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<td>3. Has this session changed any of thoughts about fatigue?</td>
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<td>4. How might what you learned in this session change how you act/behave?</td>
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<td>5. How might what you learned in this session change how you feel about your fatigue?</td>
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Session Four Content

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<thead>
<tr>
<th>Page Name</th>
<th>Format</th>
<th>Content Written</th>
<th>Content Spoken/ video</th>
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</thead>
<tbody>
<tr>
<td>Session 4. Page 1.</td>
<td>Video and Text</td>
<td>On this page we will review what was</td>
<td>In the previous session we gave you a lot of information about how cancer-related fatigue was related to your thoughts. Some of the most important facts to remember were as follows</td>
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<tr>
<td></td>
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<td></td>
<td>1. Our thoughts are very powerful and can impact what we feel and how we act.</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>2. Thoughts are not facts; they are simply how we see things at a given time.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3. Our thoughts can be inaccurate and untrue.</td>
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</table>
**Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices**

<table>
<thead>
<tr>
<th>Recap of Session 3. And overview of session 4.</th>
<th>4. There are many unhelpful thoughts and mistaken beliefs about cancer-related fatigue and what causes it.</th>
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<tbody>
<tr>
<td></td>
<td>5. A fatigue WHY-pie chart allows you to draw out the extent to which different factors contribute to your fatigue.</td>
</tr>
<tr>
<td></td>
<td>6. People often underestimate the number of different factors that can play a role in their cancer-related fatigue.</td>
</tr>
<tr>
<td></td>
<td>7. Believing that fatigue is caused by a small number of factors over which you have very little control can lead to unhelpful behaviors and feelings of helplessness</td>
</tr>
<tr>
<td>Frame 2.</td>
<td>8. If you don't account for all the potential contributing factors you may underestimate all the things you can do to cope with your cancer-related fatigue.</td>
</tr>
<tr>
<td>Frame 2.</td>
<td>9. There are many factors and causes of cancer-related fatigue that you can try to address. Other factors may need to be accepted or worked out.</td>
</tr>
<tr>
<td>Frame 3.</td>
<td>10. The first step in dealing with unhelpful thoughts is to start to become aware of them and their impact.</td>
</tr>
<tr>
<td>Frame 3.</td>
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</tr>
<tr>
<td>Frame 4.</td>
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</tbody>
</table>

**Page Name** | **Format** | **Content**
---|---|---
Recap of Session 3. And overview of session 4. | Covered in session 3 and give an overview of what to expect from session 4. | Click on the video to get started.

**Frame 2.** Now that you have a better understanding of how you think about fatigue, this session will look at how patterns of rest and activity can affect the body.

**Frame 3.** In this session will introduce you to ‘energy economics’ to help you to think about your activity patterns and how they can influence your fatigue. We will finish the session by discussing what you can do to tackle fatigue by helping you to plan and schedule activity.

**Frame 4.** On the next page we will hear some stories about people’s experiences with fatigue. Please hit "NEXT" to progress with the session.
### Session 4. Page 2.

**Peoples’ experiences with fatigue**

<table>
<thead>
<tr>
<th>Frame 1.</th>
<th>Frank, 63- I had radiotherapy for prostate cancer 3 years ago. You expect to be tired when you’re going through treatment and I took time off to get better. But then as the years go by you start to wonder. I used to swim and walk every day before my cancer. And I’d love to be able to do it again. But I just couldn’t.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frame 2.</td>
<td>Jane, 47- I was diagnosed with Breast cancer 2 years ago and had my treatment. I was always active and expected to bounce back after treatment. But I found no matter what I did, after about an hour I was wrecked. No energy at all. I had to rest and sit down for about 2 or 3 hours and maybe try again in the afternoon. I’ve been that way for a long time.</td>
</tr>
<tr>
<td>Frame 3.</td>
<td>Edith, 52- I was diagnosed with breast cancer nearly 3 years ago. I had chemotherapy and radiotherapy afterward. Since then I’ve had this fatigue that never ends. I can do things, but I get tired very quickly. The wave of tiredness that hits me! I just haven’t the energy to carry on.</td>
</tr>
<tr>
<td>Frame 4.</td>
<td>Paul, 44- I’d testicular cancer four years ago. I’d an operation to remove the tumour and chemotherapy then after that. I spent a couple of weeks resting in bed. Now, I still get tired walking around. I used to do it a good bit of exercise before I got sick, but I don’t have the energy now. And I know that I should be doing it, but I get aches and pains after doing things. My legs would be like lead.</td>
</tr>
<tr>
<td>Frame 5.</td>
<td>Marie, 51- I loved walking and Irish dancing. But almost suddenly then, since the end of my cancer treatment 2 years ago, I haven’t been able to be physically active. I tried to walk, but when I walked the prom once or twice it took me nearly 2 days to recover. I guess I’m not ready for it yet. I will wait until my energy and muscles strength improves.</td>
</tr>
<tr>
<td>Frame 6.</td>
<td>In this session we will look at ways to help you to plan activity and rest in a way that allows you to do the things that you want to do. On the next page we will start to think about the link between energy and fatigue. Please hit &quot;NEXT&quot; to progress with the session.</td>
</tr>
</tbody>
</table>
### Session 4. Page 3.

**The Link between energy and fatigue**

| Frame 1. | During cancer treatments and immediately afterwards patients will often experience a strong need to rest and sleep. This is a normal part of the healing process. People might reduce their usual levels of activity to help them to cope with the energy-draining experience of going through treatment. |
| Frame 2. | There are many reasons why people do not immediately begin to return to previous levels of functioning after cancer treatment. It may be painful after surgery, or people might feel weak after chemotherapy, radiotherapy or bone marrow treatments. Some might feel exhausted by the cancer experience and do not feel up to getting back to normal and returning to their old lives. Some people might decide that they should avoid activity because they feel like their energy levels have decreased. They might try to ‘save up’ their energy for when they really need it. Others might be afraid of over-doing it, or pushing themselves, believing that too much activity after treatment might be bad for them. |
| Frame 3. | When people are tired, they are often advised to rest and to “take it easy”. People are told to take naps and reduce activity. Many people use all of these strategies and they are natural, understandable ways to try and manage fatigue. However although this advice may be well-intended, it can actually worsen fatigue, especially for those long after treatment. |
| Frame 4. | Cancer and its treatment can lead to fatigue which can cause us to rest and be less active. This inactivity makes us less fit. In turn this can result in “deconditioning” which lowers our energy levels. This causes more fatigue and can lead to more avoidance of activity. It is important to try to find a balance between doing too much and not doing enough. |
Generally, we all have a set amount of energy that we use. We use this energy up each day at work, caring for our families and doing various activities. When we have run out of energy we rest until our energy returns and we start again.

However, since having cancer, you may feel that your energy reserves are reduced. It might seem like you have a lot less energy than usual. You may get tired more quickly, and in response to less demands than before cancer. Many cancer survivors have described fatigue as leaving them feeling “empty” or like their “batteries have run out” after treatment.

Frame 6. **Rest is not always best**

People who suffer from prolonged and/ or severe fatigue often try to manage it by either resting more or reducing activity in the hope of feeling better and to prevent the fatigue from getting worse. They sometimes falsely believe that if they rest and ‘mind’ the energy they have, that they can ‘store up’ energy to keep in reserve.

Trying to store up energy in this way is what is known as a ‘safety behaviour’- or something that we do because we think it will make the situation better. Unfortunately it often had the opposite effect.

Frame 7. A lack of activity can lead to a loss of fitness. This will continue and lead to worsening fatigue, reduced stamina and leave people feeling less able to “keep going” when doing everyday activities.
Resting too much means that your body might not be used to a normal cycle or routine of rest and activity. This can make you feel more tired, reduce your motivation and impair the quality of your sleep.

In order to save energy, people might avoid any “unnecessary” activities, which are often those that give us enjoyment or a sense of achievement. Rather than keeping our energy stores, inactivity has the opposite effect and can cause us to have less energy. Evidence now suggests that for many people, gentle to moderate levels of activity and exercising are helpful in improving cancer-related fatigue.

Frame 8. **All or nothing behaviour**

Some people might push themselves to do as much as possible when they can and rest more when their symptoms get worse (all or nothing behaviour).

People with cancer related fatigue often have peaks and troughs of activity depending on their level of energy. When the fatigue is bad they have a lot of rest and do not do much activity around the house or at work. Sometimes an occasion will arise when people with cancer-related fatigue push themselves further than usual. This might be for a wedding or a party, or even just trying to do a particular task at home. While the person
may surprise themselves by being able to complete the task on a ‘good day’, it may come at a cost. In the days that follow, they may have an overwhelming feeling of fatigue that can last for a few days.

It’s ok to do more on some days if you are aware of it. That way you can factor ways to manage it into your plans. So while you might be able to go to a wedding and stay for the night, it is unlikely that you will be able to last the day after as well. It is ok to do this occasionally, but it is unlikely that you will be able to repeatedly push yourself.

It may not be helpful to push yourself really hard for short periods and then collapse for days at a time after. This can make it difficult to regain fitness and get back to how you were before.

This is a vicious cycle of fatigue and it’s not a very effective way of managing it. Such an ‘all or nothing’ approach makes it hard to lead a normal life.

Press NEXT to continue with the session
### Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

#### Session 4. Page 4. How to regain activity and energy levels

<table>
<thead>
<tr>
<th>Frame</th>
<th>Video and Text</th>
<th>Unhelpful thoughts about energy.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frame 1.</td>
<td>So far, we have seen some that thoughts, such as “I must save energy” may not only be incorrect, but may also lead to action that reduces your energy levels. In this part of the session we are going to look at some examples of unhelpful thinking that can affect with what we do, and in turn result in a further decrease in energy.</td>
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</tbody>
</table>
| Frame 2. | **Misinterpreting body symptoms:**  
Some people fear physical activity after treatment. They might worry that aches and pains in their muscles, either during or after any effort, are a sign that there is something wrong. However, these symptoms might just be a sign of a lack of fitness.  
- By reducing activity your physical ability for exercise is reduced resulting in breathlessness and fatigue.  
- Reduced activity increases the feeling of fatigue when you do exercise and with continues rest and reduced activity the body copes with less and less activity over time.  
- Rest can lead to reduced muscle tone. This is called “deconditioning” and relates to reduced energy and physical ability. Also, the cardiovascular system becomes less fit and can result in symptoms including dizziness, palpitations, sweating and nausea. |
| Frame 3. | Before cancer, if you were healthy but somewhat unfit, you might have found it difficult to climb flights of stairs or run for a bus. Such activities may have left you out of breath, with your heart racing or your muscles aching.  
Or sometimes if you started back at some unpractised activity like gardening at the beginning of spring or going for a jog, you might have felt stiff or achy for the day or two that followed. When this happened you are likely to have correctly believed that your symptoms meant that you were out of shape and in need of some regular exercise to build up your fitness.  
The same symptoms after cancer can be unhelpfully misinterpreted as a sign that exercise is doing more harm than good; and that rest and recuperation are needed… or that exercise should be avoided.  
However, in saying that it also important to recognise any severe, unusual or persistent symptoms. Such pains should be checked with your GP or consultant. |
Frame 4. Gerard had avoided strenuous activities since he finished his treatment 9 months ago. He loved gardening with his wife and so, when Spring came they decided to do some work. He was initially enjoying being back in his garden and chatting to his wife, but he became very worried when he suddenly felt very tired. He went back inside to sit down. He began to notice aches and pains in his back and legs, and began to get annoyed at himself for having done too much. The following day he felt very stiff and he was concerned. He began to wonder if his cancer was back and this caused him to become distressed. Later, even when his pains and aches had disappeared, he remembered what had happened and promised to not risk over-doing it anymore. His wife continues to work in the garden, while Gerard now stays indoors doing more restful activities such as watching television.

Gerard, however, was simply not as fit as he had been before his treatment. By doing too much all of a sudden he began to avoid gardening, despite the fact that he had always enjoyed this hobby. This diagram shows an example of how misinterpreting body symptoms can impact actions, emotional and physical states. These actions, thoughts and body feelings can then fuel a vicious cycle of persistent fatigue.
**Fatigue is inevitable**

Some people think that cancer-related fatigue is inevitable and that it is the price you pay for having survived cancer. Such thoughts also lead to ever increasing fatigue and deconditioning. This can lead to sadness or even depression, which can also contribute to more fatigue and worsening quality of life.

It might cause people to slow down or give up completely. They may get even more behind on tasks. People might start to cut out enjoyable or relaxing activities when they experience fatigue. They may miss out on activities that they enjoy in order to do the things that they feel they have to get done. This can lead people to become stressed or anxious. It also can lead people to withdraw from others.

Frame 6.

On the next page we will start setting a plan so that you can balance activities correctly to improve your quality of life.

---

**Now it’s your turn to set a rehabilitation plan so that you can balance activities correctly to improve your quality of life.**
Over the next few pages we will try to identify the activities that you should increase or decrease to improve your quality of life.

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<thead>
<tr>
<th>Page Name</th>
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<th>Fill in</th>
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</thead>
<tbody>
<tr>
<td><strong>Session 4. Page 6.</strong></td>
<td>Image</td>
<td>In session 2 we asked you to keep an activity diary. Let’s look back over what you have filled in over the last two weeks. By now you have a lot of information about what you do each day, and about how different activities make you feel. Do you notice any trends in your diary?</td>
<td>When is your fatigue at its i) best ii) worst? Does your fatigue vary depending on what you are doing? If yes, what activities make it i) better ii) worse? Are there some things that you do that make your fatigue worse but are worth it from an enjoyment or achievement point of view? Are there some activities that make fatigue worse and are not worth it? What are they?</td>
</tr>
</tbody>
</table>
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

It is common to find variation in your levels of fatigue, enjoyment and achievement depending on the activities you are doing, the time of day and how you feel physically. Which activities are linked with high levels of satisfaction? What activities seem to be liked with low levels of satisfaction?

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<td>Session 4. Page 7.</td>
<td></td>
<td>The next step is to increase the amount of activities that add to your quality of life (enjoyment and achievement activities) and decrease those that take away from it.</td>
</tr>
<tr>
<td>Increasing Activities that Add to your Quality of life</td>
<td></td>
<td>1. Increase the number of times you do the things that you rated highly on the enjoyment/achievement scales</td>
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<tr>
<td></td>
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<td>2. Think about activities that you have previously done, from which you got enjoyment or a sense of achievement. You may have done these before you became ill, or at some stage in your past. Maybe you can make adjustments to what you previously enjoyed but can no longer do. For example, you might be able to go to matches, rather than play in them.</td>
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<td>3. What about new activities that you have not done before but you think you might enjoy? (e.g. learning or trying something new) Maybe you can’t do these activities right away but with a little help or preparation you might be able to do.</td>
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<tr>
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<td>4. What tasks do you put off but would like to do? Maybe there is a room to clear out or a garden that needs weeding?</td>
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<td>5. Are there any tasks that you would like to work towards or a goal you would like to achieve?</td>
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<td></td>
<td>6. Decrease the activities that have a negative impact on your quality of life</td>
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<tr>
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<td>Write down the activities that you could increase and decrease.</td>
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<td>Make sure to include a selection of activities that involve gentle exercise. This might include playing golf, swimming or cycling.</td>
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<th>Page Name</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Increase</td>
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<td></td>
<td></td>
<td>• Pleasurable and Enjoyable Activities</td>
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<tr>
<td></td>
<td></td>
<td>• Achievement Activities</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Decrease</td>
</tr>
</tbody>
</table>

145
Frame 1. Now that we have established the patterns of rest and activity in your week from the activity schedules, and the reasons why they may not be very helpful for managing fatigue in the long term, let’s see if we can make activity and rest a more consistent part of your daily routine, rather than it being dependent on your level of fatigue. This means that you may need to work on slowly increasing activity levels, or reducing the amount you do. The key is to pace your activities and to be consistent.

Frame 2.

Pacing involves gradually increasing activity and avoiding extremes of activity.
Healing does not end when the treatment finishes or the scars close but instead there is often a slow return to our old lives. In many ways, the end of active treatment is the start of recovery or rehabilitation.

Sometimes people try to throw themselves back into the life they led before cancer. Such activity is motivated by good intentions and returning to ‘normal’. They go from being very ill and doing very little activity, to expecting to be able to function as they used to. This can be unrealistic and unmanageable for many people. As we saw earlier in the session, repeated cycles of activity bursts followed by exhaustion can be frustrating and demotivating. It can cause people to give up trying to do activities that they had previously enjoyed. This pattern can lead to peaks and troughs of activity levels and is marked in blue.
### Activity Pacing

Activity pacing is seen here in red. In this case, the individual gradually increases their activity slowly but surely. This long, slow process takes patience and can sometimes be a frustrating experience. This is important in order for us to avoid the problem of trying to do too much too soon.

**Frame 3.**

Activity pacing is about being active but not doing too much activity so that it might cause severe fatigue. It means learning to do a little bit more gradually so that your body gets used to it. Over time, your activity level will improve without the long periods of low activity.

Activity pacing is also about planning your activities, making sure that you make time for activities that you enjoy, while reducing those that use a lot of energy but may not be worth it.

Activity pacing is common sense— it simply means pacing activities until you have the ability to do more and more over time. If you want to get fit and decide to take up jogging, it would not be wise to try to run a marathon on your first outing. However, people often overdo it and it can take a lot of self-discipline to stick to an activity schedule. Activity pacing is based on the idea of planning your daily activities and gradually building tolerance.

---

### Consistency

Consistency is achieved by trying to schedule your days so that you do a similar amount every day. You can achieve this by scheduling a balance of work-related activities, activities for other people and also, rest or relaxation periods during the day for yourself.

The next step is to keep a diary again for the next two weeks. If you look on page X of your workbook you will notice that this new diary has an important change. Rather than just recording what you do, plan to include at least one extra enjoyable and one extra achievement activity each day. This usually works better if you plan ahead and decide in advance what you want to achieve, or what activities you will schedule for the day. Make sure to keep recording each activity in the diary.

---

### Exercise

There is strong evidence from research into cancer-related fatigue that gentle exercise following treatment is helpful in regaining your energy levels. It is now believed that a structured exercise programme can help sleep problems, low mood, low self-esteem and depression.

Try to include some gentle exercise in each day. As you find yourself getting fitter you can experiment with gently increasing the speed, distance or effort. If you start off with a 10 minute walk and you find after a few days that this is relatively easy, you might be able to increase your walk to 15
**Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices**

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<th>Frame</th>
<th>Description</th>
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<tr>
<td>6.</td>
<td>You might have to try out a few different things before you figure out what you like and what works best for you. If an activity doesn’t work out, or if it causes you to feel too tired, maybe there is another way or time to do it? If it still doesn’t feel like it’s working for you, or doesn’t provide the satisfaction you expected, maybe try making it easier or replacing it with another activity. Trying out different tasks isn’t about success or failure, but rather an on-going learning experience that will help you to balance your activity and rest patterns better.</td>
</tr>
<tr>
<td>7.</td>
<td>Sometimes people might try to increase their activities dramatically and this can lead to more severe tiredness in the days that follow. Initially, it might be a good idea to schedule less demanding activities for the following days. It is important to strike a balance between doing things that add to your quality of life but don’t exhaust you. It is important that you make changes slowly and steadily over the next few weeks, rather than pushing yourself too hard or trying to change too suddenly or quickly. By sticking to your routine you will start to gain control over your fatigue rather than allowing your fatigue to gain control over you.</td>
</tr>
<tr>
<td>8.</td>
<td>You may need to take a step back if you find that you are over-tired. On the other hand, as your energy improves you may need to up the tempo of your activity. At the beginning starting a new routine can be tiring. Try not to be too hard on yourself. People’s activity patterns have often been developed over a long time and it will take time and effort to change. It is important that you notice and acknowledge any small changes you make.</td>
</tr>
</tbody>
</table>
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

Frame 9. Congratulate yourself when things work out well and recognise that you might have bad days. Some days will be more of a challenge than others. On these days it is important to be kind to yourself. However, some days don’t go according to plan and sometimes activities don’t get done. Don’t be too critical on yourself, or don’t use this as an excuse to give up. Tomorrow is another day, and you can continue on.

Frame 10. When you have completed about 2 weeks’ worth of planning and activities, take the time to have a look over your activity diary. You may have noticed some trends when you first did this exercise. Now you can compare these trends to any new ones. Explore these trends and see whether there has been a change in your quality of life and in your fatigue levels.

If you find that this exercise works for you, you will find extra copies of the Activity Diary at the back of your workbook. These will allow you to plan and review your progress after this programme ends.

Press NEXT to continue.

Page Name | Format | Content Written
--- | --- | ---
Session 4. Page 9. Personal Goals - a step in the right direction | Video and Text | On this page we will start to look at some ways that you can start to address your own personal goal. Click on the video to learn more.

Frame 1. Now that you have started a general rehabilitation plan to increase activities you gain satisfaction from, we will now look at your own personal goals.

In Session 2, we asked you to list some personal goals you had. Today we are going to start breaking these goals into small manageable steps. If you have already divided your goals into short, medium and long-term goals then you are already part of the way there.

Frame 2. George’s sample smart goals list converted into a Goal Step Ladder.

Do you remember George in Session 2? He had 5 key problems, which he turned into short, medium and long-term goals?

**GEORGE’S SAMPLE SMART GOALS LIST**
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

<table>
<thead>
<tr>
<th>Short term (in the next month)</th>
<th>Medium term (4-12 weeks)</th>
<th>Long term (3-6 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walk 20 mins. 4 days a week</td>
<td>Join a walking group. Swim 2 days a week</td>
<td>Start jogging with a local group. Jog or swim every second day</td>
</tr>
<tr>
<td>Plan an activity with my children</td>
<td>Explain to them why I am tired</td>
<td>Learn to prioritise time with my children</td>
</tr>
<tr>
<td>Stay awake more during the day</td>
<td>Get better quality sleep (7 hours)</td>
<td></td>
</tr>
<tr>
<td>Keep in contact with my friends via phone or social networks</td>
<td>Meet up for a drink or a coffee</td>
<td>Go to Jim’s wedding</td>
</tr>
<tr>
<td>Start doing some work from home. Talk to boss about going back part-time at first.</td>
<td>Go to work part-time (3 hours per day)</td>
<td>Full-time work</td>
</tr>
</tbody>
</table>

George then broke each one down into smaller more manageable steps. He tried to make sure that the gap between one step and the next was worthwhile but also manageable. Below is an example of some of these goals.
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices
On the next page you can also create a step-by-step approach to your goals.

Hit NEXT to continue with the session.

<table>
<thead>
<tr>
<th>Page Name</th>
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<tbody>
<tr>
<td><strong>Session 4. Page 11.</strong></td>
<td>Fill in and</td>
<td>My personal step ladder-</td>
</tr>
<tr>
<td><strong>Personal Goals- a step in</strong></td>
<td><strong>Text</strong></td>
<td>On this page we will start to look at some ways that you can start to address your own personal goals. Like George, you can also create a step-by-step approach to your goals.</td>
</tr>
<tr>
<td><strong>the right direction II</strong></td>
<td></td>
<td>For some of your goals you will be able to start right away, while others will have to wait. It is important to consider each attempt a new step, congratulate on each achievement. Sometimes you may have to work out why things have not worked out the way you’ve planned. Remember to set realistic and achievable goals so that you can accomplish them. Occasionally you might find that the jump between one step and another was bigger than you’d anticipated. You might need to go back a step, or build a new half-step. You might also find that you just weren’t up for it on that particular day.</td>
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</table>
Pick 2 goals and break them into 7 individual steps.

<table>
<thead>
<tr>
<th>MY GOAL:</th>
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<tbody>
<tr>
<td>Step 1 in achieving my goal:</td>
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<td>Step 2 in achieving my goal:</td>
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<td>Step 3 in achieving my goal:</td>
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<td>Step 4 in achieving my goal:</td>
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<td>Step 5 in achieving my goal:</td>
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<tr>
<td>Step 6 in achieving my goal:</td>
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<tr>
<td>Step 7 in achieving my goal:</td>
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</tbody>
</table>

It is normal to have setbacks when you start something like this.

Setbacks can happen when you do too much activity because it’s a good day, a stressful event occurs, something unexpected comes up and you have to do lots of other things. Some days you might feel unwell and decide to reduce your activity level and rest more than you planned.

When things happen try not to get too frustrated, and aim to do the same amount of activity as the day before, but no more. Start to increase again when you’re feeling better.

Keep trying in a controlled and gradual way. This will do no harm, but will give you the physical benefits of activity and a reduction of symptoms.

Setbacks can be expected. This is normal; just try as far as possible to stick to your goals. The overall trend over the weeks is important, not the few bad days.
**Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices**

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<td></td>
<td>Let’s recap and look at what you have learned.</td>
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<td>Take some time to read through the statements and if you would like you can print off these 10 key points so that you can refer back to them later.</td>
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<tr>
<td></td>
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<td></td>
<td>1. Lack of activity causes patients to experience a progressive loss of fitness that leads to worsening fatigue, reduced stamina and decreased ability to ‘keep going’ when doing tasks.</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>2. Loss of fitness and low energy due to inactivity after cancer treatment is called deconditioning.</td>
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<tr>
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<td></td>
<td>3. Some people push themselves to do as much as possible when they can and rest more when their symptoms get worse (all or nothing behaviour).</td>
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<td>4. People with fatigue sometimes rest or reduce activity to prevent the fatigue from getting worse, but rest can often make people more tired.</td>
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<td>5. Activity pacing is about being active but not doing too much activity so that it might cause severe fatigue.</td>
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<td></td>
<td>6. It means learning to do a little bit more gradually so that your body gets used to it.</td>
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<td>7. The way you think about your energy and expectations for recovery can feed into vicious cycles of fatigue that can get in the way of recovery.</td>
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<td>8. Recovery from fatigue will be most successful if it happens in small planned steps.</td>
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<td></td>
<td>9. Planning enjoyable activities and those that give a sense of achievement is a good way to improve quality of life and energy levels.</td>
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<td></td>
<td>10. Using a goal step-ladder and breaking down your goals into manageable steps can lead to gradual improvements.</td>
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<thead>
<tr>
<th>Page</th>
<th>Format</th>
<th>Content Written</th>
<th>Time to recap statements</th>
<th>Content to be filled in</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 4. Page 14. Stop and think</td>
<td>Questions to be filled in</td>
<td>Before moving forward let’s stop and think for a moment about what you have learned from session 3. Take some time to fill in your answers below.</td>
<td>1. What in this session was relevant to you?</td>
<td>Participant fills in response to each question</td>
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<tr>
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<td>2. What is important for you to remember?</td>
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<td>3. Has this session changed any of thoughts about fatigue?</td>
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<td>4. How might what you learned in this session change how you act/behave?</td>
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<tr>
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<td></td>
<td>5. How might what you learned in this session change how you feel about your fatigue?</td>
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<tr>
<td>Session Five Content</td>
<td>Video content</td>
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<tr>
<td><strong>Session 5.</strong> <strong>Page 1.</strong> Recap of Session 4. And overview of session 5.</td>
<td><strong>Frame 1.</strong> On this page we will review what was covered in session 4 and give an overview of what to expect from session 5. Click on the video to get started.</td>
<td></td>
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<tr>
<td><strong>Frame 1.</strong></td>
<td><strong>1.</strong> Lack of activity causes patients to experience a progressive loss of fitness that leads to worsening fatigue, reduced stamina and decreased ability to ‘keep going’ when doing tasks. <strong>2.</strong> Loss of fitness and low energy due to inactivity after cancer treatment is called deconditioning. <strong>3.</strong> Some people push themselves to do as much as possible when they can and rest more when their symptoms get worse (all or nothing behaviour). <strong>4.</strong> People with fatigue sometimes rest or reduce activity to prevent the fatigue from getting worse, but rest can often make people more tired. <strong>5.</strong> Activity pacing is about being active but not doing too much activity so that it might cause severe fatigue. <strong>6.</strong> It means learning to do a little bit more gradually so that your body gets used to it. <strong>7.</strong> The way you think about your energy and expectations for recovery can feed into vicious cycles of fatigue that can get in the way of recovery. <strong>8.</strong> Recovery from fatigue will be most successful if it happens in small planned steps. <strong>9.</strong> Planning enjoyable activities and those that give a sense of achievement is a good way to improve quality of life and energy levels. <strong>10.</strong> Using a goal step-ladder and breaking down your goals into manageable steps can lead to gradual improvements</td>
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<tr>
<td><strong>Frame 2.</strong></td>
<td>Now that you have a better understanding of how activity can impact your energy levels, in this session we will look at how sleep can affect fatigue.</td>
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<tr>
<td><strong>Frame 3.</strong></td>
<td>In this session you will learn about insomnia and other sleep problems that people have. We will discuss these with reference to cancer and cancer-related fatigue. We will then identify some of the causes of sleep problems, before looking at what you can do to manage sleep difficulties.</td>
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<tr>
<td><strong>Frame 4.</strong></td>
<td>On the next page we will hear some stories about problems people have with their sleep and learn what sleep disturbances are. Please hit &quot;NEXT&quot; to progress with the session.</td>
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### Peoples’ experiences with fatigue

<table>
<thead>
<tr>
<th>Page Name</th>
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<tbody>
<tr>
<td>Session 5. Page 2.</td>
<td>Video and Text</td>
<td>On this page we will hear stories from people with low energy levels after cancer treatment. Click on the video to learn more.</td>
</tr>
<tr>
<td>Frame 1.</td>
<td></td>
<td>Sleep difficulties are one of the most common problems that people report after cancer treatment. People often report having problems with getting to sleep and staying asleep at night.</td>
</tr>
<tr>
<td>Frame 2.</td>
<td></td>
<td>Even though Owen felt very tired during the day, he felt he was not sleeping as he should be. He would lie awake a lot, thinking about all different things he had to do. Eventually, these thoughts would drift to worrying about his cancer. He would watch as his clock as time passed by during the night. He would worry about waking his wife, and start to get frustrated with himself, knowing he would then be tired again the next day.</td>
</tr>
<tr>
<td>Frame 3.</td>
<td></td>
<td>Following her treatment, Rita found herself very tired during the day. She had a blanket on the living room couch, and she would spend her days resting or napping in the afternoon. She felt she would not get through the day without this nap, but never felt fully restored after her rest. She had trouble getting to sleep at night. When she did sleep, it was a deep heavy sleep that left her feeling un-REFRESHeed when she woke up. This meant that she continued to make up for her poor nights by napping during the day.</td>
</tr>
<tr>
<td>Frame 4.</td>
<td></td>
<td>In this session we will find out more about your sleep patterns and how you can relax. Sleep problems are common in people after cancer treatment and there are many different causes. People who suffer from fatigue find that their sleep patterns can get disrupted, and this can contribute to feeling a lack of energy,</td>
</tr>
<tr>
<td>Frame 5.</td>
<td></td>
<td>On the next page we will examine what sleep disturbances are, before we move on to learning how to manage them. Click next to continue.</td>
</tr>
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</table>
## Session 5. Page 3.
Sleep, cancer and cancer-related fatigue

<table>
<thead>
<tr>
<th>Video and Text</th>
<th>On this page we will examine the different problems people might have with their sleep and how these relate to cancer.</th>
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</thead>
<tbody>
<tr>
<td>Frame 1.</td>
<td>From meeting people and talking with them about their cancer related fatigue, we identified two main problems that people had with their sleep. These were: <strong>1. Problems with getting to sleep</strong>: where people took a long time to fall asleep. <strong>2. Problems staying asleep</strong>: where the person woke up during the night (or earlier than intended) and found it difficult to go back to sleep. Spending more than 30 minutes trying to fall asleep or trying to get back to sleep was common for these individuals. In this session we will consider these problems as ‘sleep disturbances.’</td>
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<tr>
<td>Click on the video to learn more.</td>
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<tr>
<td>Frame 2.</td>
<td>Cancer and its treatment can affect sleep in many people, even if they never had sleep problems before. For those who had difficulty sleeping before they got sick, it can make symptoms worse. This may be due to things such as the stress of having cancer or the type of treatment people had. Physical side effects such as pain, hot flushes, and increased need to use the bathroom might also be consequences of cancer that lead to sleep problems. However, while cancer might initially lead to sleep problems, in many cases there are causes that are linked to things that we can change. Unhelpful thinking patterns can affect sleep. Likewise, emotional factors such as worry or distress can make it difficult to get a good night’s rest. Unhelpful habits and behaviours might also play a role. These changeable factors might keep sleep problems going and contribute to cancer-related fatigue.</td>
</tr>
</tbody>
</table>
Frame 3. Sleep disturbances and cancer-related fatigue are closely linked.

Problems with your sleep can lead to feelings of exhaustion and sleepiness during the day. This is a commonly reported feature of cancer-related fatigue.

Cancer-related fatigue is more common and more severe in people with sleep disturbances.

However sleep disturbances may also be caused by cancer-related fatigue. For example, sometimes fatigued individuals engage in behaviours that are not helpful. These can include things like napping, drinking caffeine and alcohol, as well as spending long periods in bed without sleeping. Each of these behaviours can lead to problems with how much, and how well people sleep at night.

Frame 4. Experts believe that addressing cancer-related fatigue will help with your sleep problems. However, it can work the other way too. In this session we will aim to improve your sleep so that it can have a positive effect on your cancer-related fatigue. If you notice that physical problems are disrupting your sleep, it may be useful to discuss those with your doctor. These might include pain, hot flushes, tingling sensations, and so on. For now we will focus on the behavioural, thought and emotional factors involved.
Frame 5. As we saw previously, we can make a vicious cycle for sleep problems by considering their thoughts, behaviours, emotions and physical symptoms.

Using techniques from cognitive-behavioural therapy can help sleep disturbances. Many studies have found that this treatment can improve the quality and quantity of sleep in people, and also lead to a decrease in levels of cancer-related fatigue.

Let’s consider some of the changes we could make to our thoughts, behaviours, and emotions in order to help us manage sleep difficulties.

Frame 6. We will look at each of these potential solutions to managing sleep disturbances in this session. Click next to continue.

Page Name | Format | Content Written | Video
--- | --- | --- | ---
**Session 5. Page 4. Sleep well** | Video and Text | Learning to sleep well: Introducing Sleep Hygiene | Frame 1. Sleep Hygiene is a term that refers to the things we can do in our daily lives to prepare for a good night’s sleep. This is an important first step as it sets the scene for the other changes we hope to make. In this part of the session we are going to consider things such as your bedroom, products that interfere with sleep and activities that impact sleep.

Frame 2. It is important to have the right sleep environment. This can help lead to good quality and quantity of sleep. Your bedroom should ideally be associated with sleep rather than wakefulness.
Simple things like a quiet darkened room can facilitate sleep. Ear plugs or eye shade can help if you can’t get the environment the way you would like it.

It might be a good idea to remove the clock from your bedroom. A clock reminds us that time is ticking away and this can be very frustrating during the night. Hearing or watching a ticking clock might make you feel anxious and it is less likely that you will sleep.

Aim for comfortable temperature in the bedroom. It is believed that around 18C is ideal. This can reduce the amount of tossing and turning. If you find that you are often too warm, a fan might be useful. You can also add layers of bed-sheets and blankets that can easily be added or removed as needed.

Comfort is very important, and especially so if you suffer with pain at night. Your body may have changed after cancer, so it is worthwhile trying out different types of mattresses and pillows to find out what suits you best now.

Avoid stimulants such as caffeine, cigarettes, spices and alcohol at least 4 hours before you go to bed. These might disrupt sleep.

- Caffeine keeps us awake. Although it is often used during the day to fight tiredness, it can lead to problems in going to sleep later. It might be useful to reduce or eliminate your caffeine intake- or even just limit it- to early in the day.
- Spicy foods and large meals should also be avoided before bed. A light snack might be better to reduce hunger during the night.
- While it is important to stay hydrated, drinking too much before you go to bed can lead to regular trips to the bathroom in the middle of the night. It might be best to limit the amount you drink before bedtime.
- Some people believe that having a drink at night helps them to relax and get to sleep. While it may help you to fall asleep, it causes waking later in the night. During the night, alcohol can lead to lighter sleep, anxiety, restlessness and dehydration. It is better to avoid alcohol 4-6 hours or so before bedtime.
### Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

<table>
<thead>
<tr>
<th>Page Name</th>
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</table>
| Session 5. Page 5. Sleep well Plan | Print off and text | Take a few minutes to think about the changes that you could make. How would you go about achieving these changes? You might also want to take note of things you need to do in order to make these changes (do you need new curtains? Or pillows? Do you need to learn about suitable exercises or talk to your GP about smoking?).

---

**MY PERSONAL SLEEP HYGIENE PROGRAMME**

<table>
<thead>
<tr>
<th>Frame 4.</th>
<th>Some activities promote sleep.</th>
<th>You may find that some of these pieces of advice are more relevant to you than others. On the next page you can plan the changes you might want to make. Hit NEXT to continue.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If you are a smoker, the best advice is to eliminate or reduce your smoking before going to bed. If you wake during the night, it is better not to have a cigarette. However, quitting smoking is not easy and quit attempts can lead to problems sleeping as well. Your local HSE smoking cessation programme might be able to help you with this (link to <a href="http://www.quit.ie">www.quit.ie</a>)</td>
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<td></td>
<td>Relaxing by reading a book, listening to music or doing relaxation exercises can help you unwind before going to sleep.</td>
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<td></td>
<td>An evening bath before bed can influence your body temperature and have a positive impact on sleep.</td>
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<td></td>
<td>Exercise is also linked to sleep quality. By exercising for 20-30mins each day, 4-8 hours before bedtime you can improve your sleep. Vigorous exercise just before going to bed can make it difficult to sleep.</td>
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</tr>
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</table>
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

<table>
<thead>
<tr>
<th>What changes can I make?</th>
<th>What do I need to do before making this change?</th>
<th>How successful was I in making this change?</th>
<th>Further changes to be made</th>
</tr>
</thead>
<tbody>
<tr>
<td>BEDROOM ENVIRONMENT (LIGHTING, COMFORT, CLOCK, ETC.)</td>
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<tr>
<td>PRODUCTS THAT INTERFERE WITH SLEEP (STIMULANTS, ALCOHOL, NICOTINE, SPICES ETC.)</td>
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<tr>
<td>ACTIVITIES THAT PROMOTE SLEEP (E.G. EXERCISE, BATHS, RELAXATION ETC.)</td>
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Try out your changes for a few weeks and then review them. Make any changes that you feel would help improve your sleep. Remember sleep hygiene is the first step in managing your sleep difficulties. We will begin to look at other cognitive behavioural factors in the next part of the session.

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<th>Content</th>
<th>Video</th>
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<tr>
<td>Session 5. Page 6. Managing the problem of where and when you sleep</td>
<td>Video and Text</td>
<td>Managing the problem of where and when you sleep</td>
<td>Frame 1. 1. One way to help to improve sleep disturbances is to teach your mind and body to fall asleep quickly by making sure that your bedroom is associated with sleep rather than wakefulness. This will be one aim of this part of the session. 2. A second aim is to help you to deal with erratic sleep patterns that vary from day-to-day. Having a sleep-wake cycle that is “out of sync” with our internal body clock or natural bodily rhythm can worsen fatigue, increasing the likelihood of naps and also keep us awake at night. Frame 2. Sometimes in people who have had cancer, the link between bed and sleep is weakened. During illness, individuals spend long periods of time in bed engaging activities that are not sleeping. They may have visitors, chat on the phone, read books, play on their iPads, watch</td>
</tr>
</tbody>
</table>
TV, and listen to the radio and so on. Beds and bedrooms became associated with activity rather than sleep.

The first thought that comes to mind when we think of our bed should be sleep. Getting to sleep is easier if we strengthen the association between our bed and bedrooms and sleep.

When we lie on our bed, our bodies should automatically relax and prepare to rest. Our aim is to strengthen this bed-sleep connection.

Frame 3. In order to weaken the association between your bed and any activities that interfere with sleep, you can make some simple changes to your bedroom routine. With the exception of sex, try to avoid doing all other forms of activity in the bedroom such as watching TV, using your laptop, working or eating.

Frame 4. Other activities that can interfere with our sleep include worry and stressing about things. During the day we might be distracted from those things that concern us. Often at night in a dark quiet room, unhelpful thoughts can come to the surface and cause us to associate our beds with negative feelings. Rather than strengthening the bed-sleep link, this causes us to strengthen a link between bed and worry.

Frame 5. During the recovery period people might have spent a lot of time resting on the couch in the living room, or in a comfortable chair in the conservatory. This can lead to daytime napping and an erratic sleep-pattern which can make it difficult to sleep at night.

Sleeping in places that are not your bed can weaken the association that you have between bed and sleep.

Therefore WHERE you sleep is very important.

Frame 6. Only sleep in your bed and do not use the bed for any activity other than sleep.

This might initially seem like quite a difficult challenge if you are used to reading, working or chatting on the phone in bed. Or maybe you like to save all your mental activities such as planning, worry and reviewing your day until bedtime. All these activities can still be done, but they should be done in a different room before bed. While you may prefer to do these
habits in your bed, they may be getting in the way of your good night’s sleep. The only exception to the ‘bed is only for sleep’ are sexual activity (if you feel comfortable and ready to do so) and relaxation exercises.

Frame 7. Only go to bed when you are ready to sleep. This is to help you to strengthen the connection between being sleepiness and sleep.

If you try and fall asleep before your body is ready you might lie in bed thinking about things that are not helpful, or you might start to worry about not being able to sleep.

Sometimes when you have cancer-related fatigue, it can be difficult to distinguish between being tired and being sleepy. When you have fatigue you have low energy which might make you want to rest. This might not cause you to sleep however. When you are sleepy, you struggle to stay awake or keep your eyes open.

Frame 8. Here, you can see an example of Annette’s “Symptoms Chart”. You will notice that she cites rubbing her eyes, deep breaths and head dropping with being sleepy.

However, tiredness is linked to feelings of heaviness, difficulties concentrating and feeling weak after activity. Take some time over the next few days to pay attention to how you feel and what you do when you are sleepy in comparison to when you are tired.

Annette’s Symptoms Records

<table>
<thead>
<tr>
<th>Unique Symptoms or Signals</th>
<th>Tiredness/ Fatigue</th>
<th>Sleepiness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Heaviness</td>
<td>rubbing eyes</td>
</tr>
<tr>
<td></td>
<td>Difficulty concentrating</td>
<td>deep breaths</td>
</tr>
<tr>
<td></td>
<td>Feel weak after activity.</td>
<td>head dropping</td>
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</tbody>
</table>

Frame 9. Sometimes, even when you think you’re sleepy, you might get into bed and not feel ready to sleep anymore.
### Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

| Frame 10. | In order to keep our body clock in sync with our sleep-wake cycle, we should try to develop a consistent sleep routine.  
If you’ve ever experienced jetlag you will be aware of the symptoms that occur due to erratic sleep patterns.  
Symptoms can include waves of extreme tiredness, difficulty concentrating and difficulties getting to sleep. If you sleep at different times during the day similar symptoms can arise.  
Go to bed at more or less the same time and wake up at the same time each day.  
Try to stick with this routine even if you have really bad night’s sleep. |
|---|---|
| Frame 11. | Avoid daytime napping.  
You may have gotten into a habit of taking naps during the day as you rehabilitated after cancer. Rest and sleeping can be very important after treatment.  
Daytime sleep may have helped in the short term, but if you are still doing it many months or years after treatment it may cause problems by interfering with your sleep pattern. |
Napping during the day is often responsible for sleep difficulties at night.

Cutting out naps (if possible) should lead to better-quality, longer sleep at night.

- If naps are a regular part of your routine you might start by taking shorter naps.
- Alternatively, at naptime you could try replacing your nap with a different activity. This time could be spent doing some relaxation exercises or going for a short walk.
- Sometimes you might still feel sleepy, and chose to have a nap. That’s ok too. If you feel that you are very sleepy and cannot do without a nap then make sure that you only nap in your bed.
- Try to limit these naps to 30 minutes - set your alarm.
- Having the nap early in the day might reduce its impact on night-time sleep.

Hopefully you will then feel tired at bedtime.

Trying out different things will help you to discover how you can better cope with your sleep disturbance. This may be difficult at first and you may feel more tired initially. Experimenting with different times and lengths of naps or with replacing naps with something else can help you to sleep better at night.

As with any change, with perseverance the situation improves and you will start to experience the benefits.

If you are unwell or receiving treatment that can affect sleep, you should talk to your doctor before making changes to your sleep and nap schedule.

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In some cases, due to work or family commitments you may not get to sleep at regular times each night. In these cases, it is recommended that you still try to have a set sleep and wake up time as far as possible.

- If you are getting woken up every night, try and schedule a relatively consistent time every day to have a daytime nap.
- If you do shift work, when you are on night duty try and have the same sleep wake times during daylight hours.
Some people may find that they are sleeping too much. They might take it as a sign that their body needs a lot of sleep if they sleep for over 12 hours. However, sleeping this amount every night is actually going to make you feel more tired.

You will not wake up feeling REFRESHeed.

Sometimes having an extra-long sleep when sleep deprived can be restorative, but it should not become a habit.

If you are sleeping too much (9+) hours a night try going to bed a little later each night and continue to get up at the same time each morning. Start off gradually, for example staying up for an extra 15 minutes and building this up over time.

If you go to bed at a reasonable hour but tend to sleep late, try and wake up each day a little earlier than the day before with the aim of reducing your sleep to around 8 hours.

Once again the key here is to do this gradually, waking up 15 minutes earlier at first and increasing it by 5 minutes each day.

In the next part of this session we will discuss how our thoughts can impact sleep. There are many common myths about sleep. These can create unrealistic expectations about sleep. In turn, this can lead to feelings of frustration, anxiety and tension when you cannot sleep and actually, make it more difficult to get a good night’s sleep.
Myth 1: "I lay awake for hours before nodding off just in time to have to get up!"
Sometimes a person's beliefs about the quantity of sleep they have are quite far from reality. If we have a night where we feel like we “haven’t slept”, it might be the case that we managed to sleep at some stage, but for some unknown reason we don’t always remember.

Myth 2: "I have to have a long deep sleep for 8 hours or more each night"
The average adult sleeps about 7-8.5 per night. However, sleep patterns can vary greatly and still be considered "normal". There are natural variations in the amount of time people need to sleep. As long as there are no negative physical, mental or emotional consequences to sleeping less than average then it would seem that for some people short sleeping is sufficient.

The need to sleep varies hugely with age. As we get older the quantity and quality of sleep we need reduces. Sleep in older adults may be lighter and much more broken than in younger people.

Myth 3: "I need a nap or I can’t cope"
We have previously discussed ways that can help people to reduce day-time napping. This can have very positive effects on quantity and quality of sleep. Moving the time and length of the nap can also limit the impact it has on night-time sleep.

Myth 4: "My sleep is useless. I wake for about 5 minutes 5 or 6 times a night"
Waking during the night for short periods of time is very common. This is especially true if there were physical side-effects of treatment. Even with these short bursts of sleep, you can still achieve the many physical and psychological benefits of sleep. As we mentioned earlier, the most important thing is avoid associating your bed with being awake by getting up if you do not go back to sleep after 15 minutes.

Myth 5: "I know I had an awful night’s sleep because I feel muggy and weak when I have woken up"
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

| Frame | Myth 6: "If I was a stronger person I would be able to sleep"
Sleep disturbances are extremely common both during and after cancer. Most studies show that between 1 in 4 and 1 in 2 people who have had cancer will experience sleep difficulties. Focusing on the fact that you slept poorly can have a negative impact on emotional and physical wellbeing and quality of life. It can also make it more difficult for you to sleep.
|
| Frame 9 | Many of the negative thoughts which interfere with falling asleep are either untrue, unhelpful or both.  
*Caroline lay in bed going over her day. She had met a friend who told her that a mutual acquaintance had passed away from cancer. They had both been diagnosed at the same time. Caroline started thinking about her own cancer and if it would come back. She began to feel guilty about surviving and worried about her family would cope without her. This made her very anxious. Her heart started to race and she became tense. She began to wonder if there was something wrong with her. She could not get back to sleep and she began to get frustrated. She had been tired that day and started to fret about how tired she would be the next day as a result.* |
Caroline was trying harder and harder to go to sleep, but this was making it more difficult for her. Many of the negative thoughts which come to mind when falling asleep can be untrue, unhelpful or both. Finding more realistic or helpful thoughts may have a positive influence on your feelings. It is important to critically think about your thoughts so that you can find more realistic helpful ways to think. This will help you sleep better.

*One way to do this is to use a tackling thoughts record.*

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<tbody>
<tr>
<td>Session 5</td>
<td>Image and Text</td>
<td>Here are some tips on how to “Tackle Thoughts”. Follow the steps below to evaluate your thoughts</td>
</tr>
<tr>
<td>Page 8</td>
<td>Image and Text</td>
<td>how to “Tackle Thoughts”</td>
</tr>
</tbody>
</table>
Questions that may help when developing a new more accurate or helpful way to think include:

- Is there an alternative explanation?
- What would be a more helpful way to think?
- What is the worst that could happen?
- What have I learned from this type of situation in the past?
- What would I tell a friend if he/she was in the same position?
- How would someone I think of as good at coping think in this situation?
- What is the best that could happen?
- What would be a more compassionate way to think?
- Are my expectations realistic?
- What is a more realistic view?
### Session 5. Page 9.

**Tackling Untrue or unhelpful thoughts that keep us from our sleep**

| Frame | Following treatment for cancer many people can have anxious and sad thoughts. We will look more closely at these in another session. Often these thoughts relate to fears about the cancer coming back, regret about what they and their families have gone through and frustrations at the side effect of treatment (fatigue, scarring, work, money, or loss of function). You may also find yourself worrying about not sleeping and your fatigue. Sometimes at night fears and concerns can be exaggerated out of control. These types of thoughts can be very strong and can have an impact on emotions, actions and body feelings. 
This mental, emotional and physical response is known as hyper-arousal and is an important factor in disrupting sleep. Such hyper arousal can cause muscles to tense, the heart to race and blood pressure to rise. It can cause an increase of adrenaline in your body and make you alert even when you are very tired. This is clearly not helpful getting you to sleep or for your psychological wellbeing. |
<table>
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<tr>
<td>Frame 1.</td>
<td>Following treatment for cancer many people can have anxious and sad thoughts. We will look more closely at these in another session. Often these thoughts relate to fears about the cancer coming back, regret about what they and their families have gone through and frustrations at the side effect of treatment (fatigue, scarring, work, money, or loss of function). You may also find yourself worrying about not sleeping and your fatigue. Sometimes at night fears and concerns can be exaggerated out of control. These types of thoughts can be very strong and can have an impact on emotions, actions and body feelings. This mental, emotional and physical response is known as hyper-arousal and is an important factor in disrupting sleep. Such hyper arousal can cause muscles to tense, the heart to race and blood pressure to rise. It can cause an increase of adrenaline in your body and make you alert even when you are very tired. This is clearly not helpful getting you to sleep or for your psychological wellbeing.</td>
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<tr>
<td>Frame 2.</td>
<td>As we mentioned previously, it might be a good idea to limit your problem thinking to places outside of the bedroom. To do this, you can set aside some time in the evening in order to review your day. During this time you can go over what has happened, and plan what you have to do tomorrow. It might even be useful to write down some ideas to get them out of your head. It can be helpful to gain control over the day and assess how you got on before you go to bed.</td>
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</table>
| Frame 3. | It might be helpful to think of the mind as a computer screen with many different pages open. The mind, like the computer, hums as it busily tries to manage all the different things that are running at once. At the end of the day, by writing down your thoughts you can save what you need to remember, while closing down the rest of the things that are going on. This process of “shutting down” your overactive mind can help you to sleep better later. If you can deal with an
| Frame 4. | Sometimes overactive minds can focus on a wide range of issues that extend beyond today or tomorrow. In these cases it can be helpful to plan some designated “worry time” into your day. This can be done instead of, or in tandem with, the “shutting down” exercise.  
- Worry time involves setting aside 15-30 minutes each day to worry. During this time you can worry as much as you want. This is the time to focus on all the repetitive unwanted concerns that race around your head when you are lying in bed and trying to sleep.  
- Once the time is up, try to avoid worrying or thinking about these concerns until the next day.  
- It is completely natural to expect that worries might still pop into your head when you lie in bed. Rather than getting frustrated with yourself, kindly acknowledge the topics and again, write them down so that they can be dealt with in tomorrow’s worry session. |
| Frame 5. | Another way to tackle the overactive mind is known as thought stopping. Some people try to push thoughts out of their minds and suppress their unhelpful thoughts. This can often have the opposite effect however, sometimes making the thought or image even more vivid. To illustrate this, you can try this simple exercise:  
*Close your eyes and think about anything you wish for the next 20 seconds. Think about anything at all. Anything. Except for one thing. For the next 20 seconds do not think about an orange elephant playing football. Don’t think about how this large orange elephant uses his trunk to hit the ball.*  
What did you think about?! |
It’s important not to try too hard to fall asleep. Sometimes focusing in sleep can actually keep us awake by making us anxious. This is called paradoxical intention.

It might be a good idea to actually give up on unsuccessful sleep strategies and replace them with the intention to lie quietly awake. Try to keep your eyes open for as long as possible. It is important that you don’t try to compete with your sleep, and try to avoid thinking about whether your paradoxical intention is working or not.

Just focus on relaxing and keeping your eyes open, but let yourself eventually surrender and close your eyes to fall asleep.

Session 5. Page 10.

Relaxation techniques

Links and Text

3 separate videos that will be linked here but available to participants on the homepage, so that they can access them outside of sessions.

Relaxation

Click on one of the options to try out one of these types of Relaxation techniques.
Dealing with setbacks

- Your sleep problem may get worse before it gets better. This can make it difficult to stick to your goals.
- Try not to get discouraged as the long term benefits of sticking to a good sleep plan can make a substantial difference to how you feel and cope in your daily life.
- Remember you are retraining your body about sleep and it may take a few weeks before you start to feel the difference.
- If you have any concerns or are in any way worries, talk to your GP or feel free to contact us (link to contact details). It is also important that you recognise how far you have come by starting on the path to address the difficulties you have had.

Time to recap statements

1. Sleep difficulties refer to problems related to getting to sleep or staying asleep.
2. Cancer and cancer treatment can cause problems in those who have never had trouble with their sleep. It can worsen those who had previously suffered with sleep problems.
3. Cancer-related fatigue is closely linked to sleep disturbance.
4. Cognitive behavioural therapy aimed at sleep problems after cancer might help to decrease levels of cancer-related fatigue.
5. It might be useful to talk to your GP about physical problems that might be contributing to your sleep problems before trying cognitive behavioural methods.
6. Sleep hygiene and relaxation are behavioural techniques that can help with sleep disturbances.
7. Setting time and place rules; thought challenging; and paradoxical intentions can help also.
8. Making changes in your sleep pattern is difficult and will take time and effort to be effective.
9. It is important to commit to these efforts so that you will eventually see the benefits.
10. Setbacks are normal. Try to learn from them and do not be disheartened by them.

Participant fills in response to each question
moment about what you have learned from session 3. Take some time to fill in your answers below.

3. Has this session changed any of thoughts about fatigue?
4. How might what you learned in this session change how you act/behave?
5. How might what you learned in this session change how you feel about your fatigue?

Session Six Content

<table>
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<tr>
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<tbody>
<tr>
<td>Recap of Session 5. And overview of session 6.</td>
<td>Video and Text</td>
<td>On this page we will review what was covered in Session 5. And give an overview of what to expect from session 6.</td>
</tr>
</tbody>
</table>

Click on the video to get started.

1. Sleep difficulties refer to problems related to getting to sleep or staying asleep.
2. Cancer and cancer treatment can cause problems in those who have never had trouble with their sleep. It can worsen those who had previously suffered with sleep problems.
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Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

10. Setbacks are normal. Try to learn from them and do not be disheartened by them.

Frame 2. Now that you have a better understand how sleeping and activity patterns can affect your fatigue, we are now going to move on and look at how low mood and negative thinking could be linked to fatigue. Before we begin, if you are concerned that your mood is very low, or that you might be depressed it is important that you talk to your oncologist or your GP about it.

Frame 3. In this session we will discuss how feelings can be a result of how we think about situations. In particular, we will try to help you to understand the role of thoughts and feelings in relation to fatigue. We will then identify some ways that can help you to challenge negative thoughts and cope with difficulties you are faced with.

Frame 4. On the next page we will explore the link between low-mood and its impact on your life… and how this relates to persistent fatigue after cancer. Please hit "NEXT" to progress with the session.

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<th>Page Name</th>
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<th>Content Written</th>
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<tbody>
<tr>
<td>Session 6. Page 2. Mood, quality of life and life with fatigue after cancer.</td>
<td>Video and Text</td>
<td>On this page we will look at the link between low mood, quality of life and life with fatigue after cancer. Frame 1. After cancer, many people feel like their lives are not as good as they could be, or that their life is not as good as it was before cancer. Sometimes this can be linked to low mood and negative feelings associated with a sense of loss or regret after cancer and its treatments. These feelings might be maintained due to negative or unhelpful thinking, beliefs or attitudes. Low mood can also lead to feeling demotivated or having less interest in things you used to enjoy.</td>
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Click on the video to learn more.

People can start to focus on things that they can no longer do, rather than looking at what they can do. All of these thought processes can feed into fatigue.

Frame 2.

Most of our actions are a result of what we think and feel about a situation. Our thoughts and feelings motivate and influence us. Likewise, how we feel fatigue and how we respond to it is influence by our thoughts, feelings and behaviours.

Negative thoughts about fatigue (for example, “this fatigue will never end”) can make us feel bad (e.g. sad) and both that thoughts and feelings can influence how we behave (e.g. avoid exercise).

Negative thoughts can make the fatigue experience worse whereas positive thoughts can help us to cope with fatigue better.
Frame 3. In session 3 we explored how thoughts were not facts, and yet they can have a huge impact on our emotions. Sometimes it is not the event or situation that makes us feel a certain way, but rather it is our interpretations of the event and how we make sense of it.

There is a link between what we feel (or their reaction) and what we think (our perception, judgement or evaluation of that situation). When we feel bad, it is often because our thoughts have lead us to these reactions.
| Frame 4. | Our own personal understanding of, or the meaning we attach to a situation can lead to different emotions.  
Sometimes we are unaware of the thoughts we have and the impact they can have on us.  
The first step in managing your thoughts is to identify negative thoughts so that you can begin to examine and evaluate them.  
This will allow you to look for more helpful ways of thinking. Helpful alternatives might not necessarily be positive thoughts. Often they may just be more realistic and compassionate ways of viewing the situation. |
|---|---|
| Frame 5. | Our thinking not only affects our emotions but also our behaviours and our bodily or physical sensations too. Each of these factors can interact to create vicious or positive cycles.  
These interactions can affect how you think and behave, which can in turn affect your fatigue. |
Frame 5. **Here we have an example of an “Environmental trigger”**

*Derek had been fatigued for a few months after his cancer treatment. Eventually, he was motivated to go for a walk as a way of coping. Just as he was planning his new activity, he read an article in the newspaper about a group of fellow cancer survivors who had taken up jogging and were about to compete in a local 10k. Derek began to get annoyed, thinking “I’m too fatigued, and why has this happened to me and not to other people? I wish my life were different”. As we see in this example, the newspaper article lowered Derek’s mood (emotion). This low mood may lead to some bodily symptom such as feeling tearful or tense. He might decide to take the action of staying in and watching TV rather than getting out for the walk he had been planning.*
Later on he might start to think "now I've wasted the day, I'll never get my energy back" (thought) which can make you feel even worse (emotion), more fatigued (body feeling).

**Frame 6**
**Thought trigger**

*On day, Avril was looking at the calendar and noticed, “it is over a year now since my treatment has ended and I still have no energy. I will never get my life back.”*

This thought can lead to a sudden drop in mood (emotion), a sense of nausea (bodily symptom). Avril might decide that she doesn’t want to be around your family because of her low mood, so she goes to bed for a nap (behaviour). This can lead to further negative thoughts, leading to a further drop in mood. Napping or resting too much can also affect your physical strength and ability to exercise.

**Frame 7**
**Emotion trigger**

*Waking up in the morning James feels down, and he begins to wonder why he feels sad. He begins to regret his cancer experience and think “why did I have to get cancer, my life will never be the same again, I am just so tired all the time, I will never get back to work” (thought).*

This thinking can cause James to feel even worse (emotion), to have a sensation of heaviness in his chest (bodily symptom). Feeling like this might make James feel like he'd prefer to stay in bed rather than getting up out of bed to face the day (behaviours).

**Frame 8**
**Bodily sensation trigger**

*Janette notices aches and pains in her muscles after doing some light exercise the day before. She begins to think “oh no, I have caused myself harm by trying to do too much. I should never have gone for that walk. If I am going to get better I need to get as much rest as possible. What if these pains are a sign that my cancer had come back?” (Thoughts).*

This can lead to worry and fear (emotions). In turn Janette might become more inactive, avoid exercise and start noticing every little body sensation (behaviours). As time goes on she becomes more unfit and more likely to notice and misinterpret normal aches pains, tingles and other feelings. Again, the cycle continues leading to more worrying thoughts and a further drop in mood.
**Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices**

**Frame 9. Behavioural trigger**

*Tom decides that rest is the best thing that you can do to manage your fatigue after cancer. In turn, he starts to avoid any activity that might use up the little energy he have Rather than protecting or storing his energy, Tom becomes less and less fit. He finds that he is less and less motivated, has less energy.*

As we have pointed out before this can ultimately lead Tom to become more tired. This can make Tom feel down and anxious (emotions). He might think, "I am still doing too much" (thought) and reduce your activities even further (behaviour). This results in a further drop in energy and mood, and an increase in anxiety and worrying thoughts.

**Frame 10. Cognitive behavioural therapy**

Cognitive behavioural therapy focuses on the roles that our thoughts and behaviours play in examples like these. By changing the way you think and/or act in any stressful situation, you may be able to change how you feel- both emotionally and physically. Click next to continue.

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**Session 6. Page 3. Thinking Myths Image and Text**

There are many myths about cancer related fatigue. These can contribute to low mood and distress. You can print of this list of examples to remind you of some of the most common myths that were discussed by people we spoke to about cancer related fatigue.
Myth 1: "I must be positive all the time if I am going to beat fatigue after cancer"
Some people believe that the more positive and optimistic they are, the more likely they will feel better. They may also believe that feeling sad, angry or afraid is unacceptable. These beliefs are very unhelpful. They damage psychological wellbeing as they can cause people to feel guilty for not coping or thinking the so-called "right" way. This can increase worry, fear and sadness about fatigue. The reality is there is no one correct way to deal with fatigue. Everyone will experience "low times" and "bad days". It is not possible to be positive all the time.

Myth 2: "Talking to my partner or family about my feelings will only upset them."
People with fatigue after cancer often try to protect their family or friends by "putting on a brave face". This can place a great burden on them. It may also prevent them from getting help. Friends and family (even children) are often aware that the person is trying to hide their concerns. Not communicating your worries can put strains on relationships and increase psychological distress for both you and your family and friends.

Myth 3: "Only "failures" or "mad" people struggle with their mood"
Cancer is one of the most stressful events a person can face. While many will manage with the support of friends, family and the medical/nursing staff, a significant number will develop severe psychological distress. Fear about what cancer and what happens after treatment can affect even the strongest individuals. Even those who have been excellent in managing stress in the past can be so overwhelmed by uncertainty about the future that they are unable to manage basic daily activities. This is not something to be ashamed of. It is not a sign that you are "a failure", "crazy", "weak", or "mad". Psychological support will help you to make sense of your specific difficulties and help you to deal with them. Being able to seek psychological help is a sign of strength.
Sometimes our thoughts can lead to vicious cycles of negative thoughts and feelings. The way we interpret events plays a huge part in how we feel about them. The way we evaluate or appraise a situation is often based on the thoughts we have.

When we are upset our thinking can become distorted. We might have thoughts that are not true, or only half-true. We might see problems where there are none, or blow difficulties out of proportion. This can happen if we overestimate the threat we face and underestimate our ability to cope. These can be considered as thinking mistakes.

We often do not even realise we are making these thinking mistakes, but everyone makes them from time to time. We are more likely to make these mistakes when our mind is racing, or when we find ourselves in a stressful situation. Negative thinking can cause us to feel down, anxious, and angry. It can also lead us to behave in ways that make more difficult to manage the situation at hand.

Over the next part of the session we will consider examples of thinking mistakes that might be made by people with fatigue after cancer. Simply being aware of unrealistic or negative automatic thoughts can help you to recognise them. You can then learn to question the truth or helpfulness of the thought. Replacing these thoughts with more helpful or realistic thoughts will have a positive effect on your emotions, behaviours and body feelings. In turn you can create a positive cycle rather than a vicious one.

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<tr>
<td><strong>Session 6. Page 5.</strong></td>
<td>Video and Text</td>
<td>On this page we will look at an example of a thinking mistake known as “All or Nothing thinking”</td>
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<tr>
<td><strong>“All or Nothing thinking”</strong></td>
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<td>Click on the video to learn more.</td>
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<td></td>
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<td>Frame 1. Sometimes when we are upset or stressed we can start to think in “black and white.” We begin to consider things to be in rigid categories, with no grey area in between. These thoughts often contain an always or never statement. People might start to think of their fatigue in terms of “always having it” or “never managing my symptoms.” All-or-nothing thinking is unrealistic because life is often not so clear.</td>
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<td>Frame 2. All-or-nothing thinking forms the basis for perfectionism. You might start to fear any mistakes. Any performance that is not</td>
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perfect can be considered to be a complete failure or waste of time. If it is not 100%, a performance might be considered useless. An example of such thinking can be seen in Veronica’s story.

Frame 3. Veronica loved playing golf before she got cancer. But since the end of her treatment she has noticed that her energy levels are still very low. Despite being invited to play a few holes with her friends, Veronica prefers to avoid activity and stays at home. She says “There is no point in doing anything. I have no energy to do anything. I won’t enjoy it like I used to. So I do nothing.” Veronica has become more and more down. She feels isolated from her friends. She does less activity and has become more fatigued.

Frame 4. However, there are alternative ways for Veronica to consider her situation. If she realised that even if she only enjoyed her round of golf half as much as she did before, it would still be more enjoyable than sitting at home alone. She could play fewer rounds and may not perform at 100% but she would still meet up with her friends and have a day out. Being able to do some things partially is often far better than doing nothing at all.

Frame 5. On the next page you can consider occasions where you might have been doing some all or nothing thinking. Click next to continue.

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<th>Page Name</th>
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<th>Content Written</th>
<th>Questions</th>
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<tbody>
<tr>
<td>Session 6. Page 6.</td>
<td>Participant fills in responses</td>
<td>Can you think of a recent example or your own “All or Nothing thinking”?</td>
<td>Recent personal example of all or nothing/ black or white thinking:</td>
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<tr>
<td>“All or Nothing thinking”</td>
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<td>Questions to help challenge your all or nothing/black or white thinking:</td>
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<td>1. Is there a way that I can view this situation that is not all or nothing?</td>
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<td>2. Is there any evidence against my all or nothing belief?</td>
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### Session 6. Page 7.

Catastrophizing

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<tr>
<th>Page Name</th>
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<tbody>
<tr>
<td>Written</td>
<td>Video and Text</td>
<td>Another example of a thinking mistake is known as “Catastrophizing”</td>
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</table>

**Frame 1.** Catastrophizing or Fortune Telling is part of a group of thinking mistakes that lead people to jump to conclusions about a situation. People can do this in situations where they have no definite facts to support their conclusions.

People can jump to “thinking the worst”. Sometimes you might predict or assume that "things will turn out badly, I will be unable to cope, and this will be a disaster". You are unable to think of other, more positive outcomes.

**Frame 2.** People who catastrophize often feel like their predictions are facts.

The prediction that something bad will happen might be unrealistic or highly unlikely. Yet it can still cause stress and anxiety to think about. An example of this type of thinking can be seen in the following story by Denis.

**Frame 3.** “I’ve never missed a checkup or a scan... and go to see my doctor quite often. I’m bound to have a recurrence. It’s just a matter of time. Especially when I feel so fatigued all the time. The results of my next scan are going to be bad, I just know it. I wouldn’t be able to cope with another bout of cancer.”

**Frame 4.** Denis does not have any evidence for his fears. He is focusing on the worst possible outcome. There might be more helpful and realistic...
alternative ways of thinking. Denis frequently visits his doctor and although he has worried in the past that his scan results would be bad, he was proved wrong each time.

**Frame 5.** On the next page you can consider occasions where you might have been catastrophizing. Click NEXT to continue.

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<th>Page Name</th>
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<th>Questions</th>
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<tbody>
<tr>
<td><strong>Session 6. Page 8.</strong></td>
<td>Participant fills in responses</td>
<td>Can you think of a recent example or your own “Catastrophizing”? Answer the following questions in the space provided.</td>
<td><em>Recent personal example of catastrophizing or fortune telling?</em></td>
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<td><strong>Catastrophizing</strong></td>
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<td><em>Questions to help challenge my catastrophizing or fortune-telling</em></td>
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<td>1. What other possible outcomes might there be?</td>
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<td>2. Is there any evidence against my belief?</td>
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<td>3. Have I ever been wrong when expecting my worst fear to come true before?</td>
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<td>4. What are the costs of thinking this way?</td>
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<td>5. What are the benefits of thinking this way?</td>
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<td>6. What would I say to a friend who was thinking in this extreme way?</td>
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<td>7. What would be an alternative more balanced way of thinking about this situation?</td>
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<th>Page Name</th>
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<th>Video</th>
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<tbody>
<tr>
<td><strong>Session 6. Page 9.</strong></td>
<td>Video and Text</td>
<td>The next thinking mistake that we will address is</td>
<td>People who overgeneralise assume that a single negative event will develop into a never-ending pattern. You might conclude that something that happened once will happen over and over again.</td>
</tr>
<tr>
<td><strong>Overgeneralisation</strong></td>
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<td><strong>Frame 1.</strong></td>
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**“Overgeneralisation”**

**Frame 3.**

*Jim was always a very particular person. One day, Jim left his keys in the door of his house while he was rushing for an appointment. When he returned home he was very annoyed with himself, despite the fact that nothing had happened. While in the past he would have said “I was worried and distracted, this could happen to anyone” now he thinks: “the cancer and fatigue have affected my memory. I am no longer an intelligent capable person. I can’t trust myself anymore.”*

**Frame 4.**

*Jim could have thought in an alternative, more balanced way. Everyone makes mistakes. Especially when stressed. It does not help to be critical of himself when he has a moment of forgetfulness. He is forgetting all the things he has remembered in the last few weeks. He is also forgetting that he might have made similar mistakes long before he ever got cancer. Even if his fatigue and stress is interfering with his concentration, it does not mean that he is not intelligent or trustworthy. In future he can try to slow down.*

**Frame 5.**

*On the next page you can consider occasions where you might have been overgeneralizing. Click next to continue.*

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<th>Questions</th>
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<tbody>
<tr>
<td><strong>Session 6. Page 10.</strong></td>
<td>Participant fills in</td>
<td>Can you think of a recent example or your own “overgeneralization”?</td>
<td><strong>Recent personal example of overgeneralization?</strong></td>
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<td><strong>overgeneralization</strong></td>
<td>responses</td>
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<td><strong>Questions to help challenge my overgeneralization</strong></td>
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<td>Answer the following questions in the space provided.</td>
<td><strong>1. Is it reasonable to judge myself or the future on the basis of a single event or even two or three examples of an event?</strong></td>
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<td><strong>2. Is there evidence of recent situations which support the opposite view?</strong></td>
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<td><strong>3. What are the costs of overgeneralising?</strong></td>
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<td><strong>4. What are the benefits of overgeneralising?</strong></td>
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<td><strong>5. What would I say to a friend who was thinking in this extreme way?</strong></td>
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## Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

### Session 6. Page 11.

<table>
<thead>
<tr>
<th>Frame</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Frame 1.</strong></td>
<td>People who jump to conclusions often negatively interpret events even though they have no definite facts to support those conclusions. When we are upset we can make negative assumptions. We can believe that certain bad things are likely to happen, without considering other (often more likely) possibilities.</td>
</tr>
</tbody>
</table>
| **Frame 2.** | Sometimes people can magnify a situation and exaggerate the importance of the event.  
Janette assumes that “Now that I’m not as fit as I used to be I will be useless. I won’t ever be ready to return to work and won’t be able to support my family”.  
However magnifying this event will not help Janette to slowly work up her energy levels and gradually prepare herself for returning to work. |
| **Frame 3.** | People who minimize a situation downplay the relevance of certain factors.  
Anne managed to go for a walk in spite of her fatigue but later began to think “I’m useless; I used to be able to do so much more when I was well.”  
This caused Anne to be less motivated to do any activity, and her fatigued worsened. However, Anne was down-playing or minimizing the importance of her success. Her fatigue is a big problem, yet she is managing to do more now than she could a few months before. Anne is gradually improving all the time and |

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6. What would be an alternative more balanced way of thinking about this situation?
can achieve realistic goals. She might not be able to do everything but that doesn’t mean that Anne can’t enjoy and succeed in the activities that she can do.

Frame 4. On the next page you can consider occasions where you might have been Jumping to conclusions. Click next to continue.

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<th>Page Name</th>
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<th>Questions</th>
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<tbody>
<tr>
<td><strong>Session 6. Page 12.</strong></td>
<td>Participant fills in responses</td>
<td>Can you think of a recent example or your own “Jumping to conclusions”?</td>
<td><em>Recent personal example of Jumping to conclusions?</em></td>
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<tr>
<td><strong>Jumping to conclusions</strong></td>
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<td>Answer the following questions in the space provided.</td>
<td><em>Questions to help challenge my Jumping to conclusions</em></td>
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<td>1. Am I confusing a thought with a fear or a fact?</td>
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<td>2. Do I have any good evidence for my conclusion or do I need more facts?</td>
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<td>3. Am I ignoring some evidence that would disprove this conclusion?</td>
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<td>4. What other likely possibilities exist?</td>
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<td>5. Am I blowing this problem out of proportion?</td>
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<td>6. What abilities or positives am I discounting or downplaying</td>
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<td>7. Is there evidence of recent situations which support the opposite view?</td>
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<td>8. What are the costs of thinking this way?</td>
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<td>9. What are the benefits of thinking this way?</td>
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<td>10. What would I say to a friend who was thinking in this extreme way?</td>
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<td>11. What would be an alternative more balanced way of thinking about this situation?</td>
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</table>
### Session 6. Page 13.

**Selective attention**

<table>
<thead>
<tr>
<th>Video and Text</th>
<th>The next thinking mistake that we will address is mental filtering or Selective attention</th>
<th>Frame 1. Sometimes when we are stressed, we focus in on the negative aspects of our lives. We might start to selectively filter out and ignore the positives. This can prevent us from enjoying life.</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Click on the video to learn more.</td>
<td>Frame 2. Dismissing, or failing to appreciate positive events allow you to maintain a negative belief. This can happen even when it is contradicted by your everyday experiences.</td>
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<td>Disqualifying the positive can be a very destructive way of thinking, because it reduces the importance of the positive aspects of your life.</td>
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<td>Frame 3. Mary was worried about her fatigue. Her doctor runs a series of tests and says that he is very happy with Mary's progress. With a little time and patience, Mary can expect a 90% chance of returning to normal in the next year. Rather than feel pleased that her fatigue is not a symptom of a physical problem, Mary cannot think of anything other than the fact that there is a 10% chance that something might go wrong. She is disappointed to think that her recovery might take a whole year.</td>
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<td>Frame 4. An alternative way of thinking could be for Mary to pay attention to the positives in her conversation with her doctor. There is no point in focusing on the negative as there is nothing she can do about it. Getting down about the situation is not going to help. Mary could start to recognise that we can’t be 100% certain about most things in life, and that recovery takes time. Her doctor is happy with her progress and has confidence in her returning to good health.</td>
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<td>Frame 5. On the next page you can consider occasions where you might have been selectively attending to situations. Click next to continue.</td>
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### Session 6. Page 14
**Selective attention**
- Participant fills in responses
- Can you think of a recent example or your own “Selective attention”? Answer the following questions in the space provided.

**Questions**

<table>
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<tr>
<th>Questions</th>
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<tbody>
<tr>
<td><strong>Recent personal example of Mental Filter or Selective Attention?</strong></td>
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<tr>
<td><strong>Questions to help challenge my Mental Filter or Selective Attention</strong></td>
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<tr>
<td>1. What positives am I ignoring in this situation?</td>
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<tr>
<td>2. What are the costs and benefits of thinking this way?</td>
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<tr>
<td>3. What would I say to a friend who was thinking in this extreme way?</td>
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<tr>
<td>4. What would be an alternative more balanced way of thinking about this situation?</td>
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### Session 6. Page 15
**Mind-reading**
- Video and Text
- The final thinking mistake that we will address in this session is Mind-reading

**Frame 1.** Mind-readers might conclude that someone is reacting negatively to them, but may not take the time to find out if this is true or not.

**Frame 2.** Sometimes we assume that we know what others think about us. Rather than taking to the person or considering alternatives we jump to conclusions about them.

**Frame 3.** Frank’s niece was getting married. When Frank received the invitation, his niece had written a little note saying that she had heard he was still tired since his cancer treatment and so, she understood if he could not make it. Frank immediately concluded that his niece did not want her sick old uncle ruining her day and decided that he did not want to be a burden on her.

**Frame 4.** Frank did not know what his niece was thinking. He did not know if she wanted him there or not. He did not know if her gesture was a genuine act of thoughtfulness and concern for his energy levels or not. Frank could have contacted his niece asking her what she
thought about his fatigue. He could have explained that he appreciated the invitation and that although he was still quite tired, he might be able to make it to some of the day rather than miss the wedding.

Frame 5. On the next page you can consider occasions where you might have been mind-reading. Click next to continue.

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<tr>
<th>Page Name</th>
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<th>Questions</th>
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<tbody>
<tr>
<td><strong>Session 6. Page 16</strong> Mind-reading</td>
<td>Participant fills in responses</td>
<td>Can you think of a recent example or your own “Mind Reading”? Answer the following questions in the space provided.</td>
<td>Recent personal example of Mind Reading?</td>
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<td>Questions to help challenge my Mind Reading</td>
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<td>1. Am I confusing a thought or fear with a fact</td>
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<td>2. What evidence do I have for thinking this way</td>
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<td></td>
<td>3. Are there alternative possibilities to explain this &quot;evidence&quot;?</td>
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<td>4. Is there evidence against this conclusion?</td>
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<td>5. What are the costs and benefits of thinking this way?</td>
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<td>6. What would I say to a friend who was thinking in this extreme way?</td>
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<td>7. <strong>What would be an alternative more balanced way of thinking about this situation?</strong></td>
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There often more realistic ways of looking at the situation when we acknowledge Negative Myths and Thinking mistakes. By challenging negative thought when they occur we can break the vicious cycle, creating a positive cycle.

However, in this section we will ask:

**What do we do when the thoughts that are making us sad are realistic?**
Not all of the thoughts that make us feel upset or stressed are unrealistic thinking mistakes or myths. People often have to live with some very difficult realities. Focusing on such thoughts can be very unhelpful and might prevent you from living your life.

Liam is afraid that his fatigue might be a sign that his cancer could come back and that he might die. He has 3 young children and was 46 when diagnosed with cancer. His treatment was successful, but his doctor would give him no guarantees that his cancer would not come back. He began to dwell on this fact all the time. He thought “After everything I’ve been through, I still have no guarantee.” He began to worry about going through treatment again and how it would probably be worse because of how fatigued he was. He was preoccupied by thoughts of his death and the impact that would have on his family.
This is a cognitive behavioral model of Liam’s situation. See if you can fill in the empty sections of the model. The questions below might help you

**Behaviours or actions**
What impact might constantly thinking about the possibility of cancer recurrence, future treatment have on Liam's behaviours at home? How might it affect his relationship with others, including his wife and children? Do you think he would be as eager to go to the pub or go out with his wife and friends? Will he feel motivated to try new things, or do activities that he had enjoyed before treatment? Do you think he might withdraw or avoid certain activities? What actions might he be more likely to take because of these thoughts?

**Physical Symptoms or body sensations**
Do you think that Liam might experience some physical response to his thoughts? Might he feel drained, or stressed or tearful? Could he experience headaches, tightness in his chest or tension at the thought of his death? Might he feel sick, or could his heart start to race?

**Emotions**
What impact might these thoughts have on Liam’s mood or emotions?

Now that you have completed the diagram do you see how the vicious cycle might work? Liam’s thoughts can influence his behaviours, thoughts and body feelings in a way that worsen negative thoughts in an ongoing cycle.

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<tbody>
<tr>
<td>Session 6. Page 18. Costs and benefits of thoughts</td>
<td>Video and Text</td>
<td>Sometimes it can be helpful to consider the advantages</td>
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<td></td>
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<td>Frame 1. Liam shows us how realistic negative thoughts can harmfully affect people’s lives. Thoughts can have an effect on behaviours, mood and body feelings.</td>
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<td>Frame 2. If we were to challenge these thoughts we might find out that they were supported by evidence. In Liam’s example, evidence cannot completely rule</td>
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Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

**Frame 3.** Now we will look at the possible advantages (benefits) and disadvantages (costs) that Liam’s thoughts bring.

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<thead>
<tr>
<th><strong>Disadvantages (costs)</strong></th>
<th><strong>Advantages (benefits)</strong></th>
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<tbody>
<tr>
<td>It makes me feel sad and upset</td>
<td>It causes me to spend more time with my children</td>
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<td>It causes me to act and feel like I’m already dying</td>
<td>I can prove my wife wrong if I am rediagnosed</td>
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<tr>
<td>I can’t enjoy myself, or my time with my family</td>
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<tr>
<td>I have withdrawn from my wife and my friends</td>
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<tr>
<td>I want to spend time with my children, but I’m distracted by sad thoughts</td>
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<tr>
<td>I can’t sleep at night and my fatigue makes it difficult to do anything during the day</td>
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Typically when people do a cost and benefits analysis they come to see that there is little or no benefit to dwelling on possible yet unhelpful thoughts. Often, any benefits that are gained are greatly outweighed by the costs.
Frame 4. The next step is to use the information from this costs and benefits exercise, to try and find more useful or helpful ways of thinking about your situation. Liam might focus on the thought “Nobody knows what is going to happen in the future so why waste my time thinking about what might never happen? Instead I am going to do what I can to live the best quality life I can”

Frame 5. By thinking this way, Liam has the power to change his vicious cycle into a positive one

Frame 6. Can you think of any possible realistic thoughts that you have which do not help your mood?
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1. Pick a thought
2. Try to draw out your own vicious cycle model for that thought.
3. Work out the costs and benefits for that thought.
4. See if you can come up with a more helpful or useful thought
5. Test whether this thought can change your vicious cycle into a positive one.

On the next page you can will introduce you to some techniques that will help you to deal with unhelpful thoughts Click next to continue.

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<tr>
<td><strong>Session 6. Page 19. Introducing mindfulness</strong></td>
<td>Video and Text</td>
<td>Frame 1. We can all get distracted and lost in our thoughts or day-dreams. Sometimes we work on autopilot. You might have times where you get to the end of the page but can't remember a word we've read; or when you walk into a room but forget what you were looking for. Even though we are going through the motions, our thoughts and minds are elsewhere. Sometimes when we are stressed we might spend a lot of time thinking about the past (<em>I wish I hadn't gotten sick in the first place</em>) or worrying about the future (<em>what will I say to people if they ask how I am</em>). The more we do this, the more likely we are to become distressed, and the less likely we are to enjoy our lives right now.</td>
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<td>Frame 2. Sometimes we can go over the same unanswerable questions and negative feelings over and over again without ever getting anywhere. This is called <strong>ruminating</strong>. It can lead to us feeling upset and we lose interest in doing useful, productive activities.</td>
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<td>Frame 3. Other times we want to <strong>wait until the time is right</strong>. We can always find reasons why right now is not the right time to do something or change something that has been negatively impacting our mood. Sometimes there is never a good time. We can always find another good reason to wait and put things off.</td>
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One way to get as much as possible out of each day is to be mindful.

Being mindful encourages us to live our lives fully in each moment and reminds us that all we have is this moment right now.

Frame 4. Mindfulness has been the subject of growing interest in recent years. Evidence demonstrates that it can be helpful for many mental and physical health problems, as well as for improving well-being more generally.

Mindfulness aims to help people change the way they think and feel about their experiences, especially stressful experiences such as fatigue after cancer.

By paying attention to thoughts and feelings, we can become more aware of them, less caught up in them, and more able to cope with them. Rather than struggling with our thoughts and feelings, or reacting impulsively to them, we can just notice them in a compassionate and interested way. This allows us to make more thought-out decisions about how to respond to events in our lives.

Frame 5. There are many benefits associated with being more mindful including:

- greater awareness, understanding and acceptance of emotions,
- Recovering from bad moods more quickly.
- Having less frequent negative thoughts and being better able to let them go when they arise.
- Enjoying more satisfying relationships.
- Better communication, good social skills, ability to cooperate and ability to see another person’s perspective.
- Being less likely to react defensively or aggressively.

Mindfulness is associated with greater vitality.
People who are mindful feel more in control of their behaviour and are more able to recognise and respond to thoughts and feelings rather than acting on impulse.

Frame 6. Modern day mindfulness is based on a combination of Western science and ancient Eastern practices.

Mindfulness is a way of experiencing things “as they are”. By paying careful attention to how things are in a non-judgmental way, we can see what is happening more accurately and respond more effectively in all areas of our lives. In this way, it enhances our quality of life and well-being.

A key idea is to accept our lives and ourselves fully, no matter how far from the ideal they are. Despite any challenges we can commit ourselves to the best quality of life possible.

Frame 7. Mindfulness helps us to train our attention so that we can focus on the present moment and become distracted by the future or the past.

When you are fatigued after cancer it is extremely common (and indeed "normal") to experience moments of frustration and fear, negative thoughts and physical reminders of what your cancer experience. To hope or to expect not to experience such things is often an unrealistic, unachievable goal. However, it is our reaction to these experiences that will decide how they impact our lives.

Frame 8. Mindfulness is an ABC skill.
Frame 9.

If you want to learn mindfulness skills you can complete an 8 week Mindfulness-Based Cognitive Therapy course or an 8-week Mindfulness-Based Stress Reduction course. There are also many books that you can buy.

As a brief introduction to some of these techniques, on the next page you can we will introduce you to some simple strategies based on Mindfulness, which you may find useful.

Click next to continue.
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<tr>
<td>Mindfulness in everyday life: tips for dealing with negative thoughts</td>
<td>We will now look at some ways you can use mindfulness techniques in your life to help you deal with negative thinking.</td>
<td>Some studies suggest that mindfulness techniques may be useful in the management of cancer-related problems including low mood, anxiety, insomnia and fatigue. Although more research needs to be done on the subject, initial findings are very promising.</td>
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<td>Click on the video to learn more.</td>
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Frame 2. It is normal to experience negative thoughts but it is getting caught-up in them that causes trouble.

By taking a step back from our thoughts and feelings we can gain some distance from the situation. We can do this by simply stopping and taking a deep breath. We can think about what is going through our mind in that moment. We can name the thought, before returning our attention to whatever we had been doing before it came to mind (e.g. playing with children, watching the match, doing chores).

Taking a step back allows you to get some perspective. This can help you to return your focus to whatever it was that you had intended to do before the negative thought or feeling interrupted.

Frame 3. Sometimes the thoughts aren't all that clear initially and it may be a strong emotion (e.g. unhappiness, irritation, fear, and frustration) that reminds you that you are not coping. If this happens, take a moment to check in.

Pay attention to what is going on in your emotions (e.g. "I am frustrated"), your body feelings (e.g. I feel tense) and your thoughts (E.g. I am sick of being tired all the time) right here and now.

Through this checking in you may be in a better position to decide what to do next rather than just getting more and more annoyed or upset.

Frame 4. One way to cope with negative thoughts is to imagine that you are giving advice to a good friend.
Sometimes we are more understanding of our friend's problems than we are of our own. We can be much quicker to forgive a friend’s mistake than our own. Being more compassionate towards ourselves, our thoughts, our bodies and our behaviours can also help us to react in more psychologically helpful ways. Being kind to ourselves stops us from becoming self-critical.

Some people believe that being hard on yourself is a good way to motivate yourself. Being kind or understanding might be seen as being weak. However, judgement and self-criticism are just more types of thinking to distract us. Rather than focusing on now, we start to focus on the past or the future.

Frame 5. **Tackling Negative thoughts with thought records**

One way to try to manage negative thoughts is to use the Tackling Thoughts Record just as you did in Session 6. This tool allows you to apply many of the strategies described in this session. If you have been using the Fatigue Thought Chart from session 3 you will already know some of the thoughts that negatively impact your mood and you will be familiar with how to fill in some of the columns.

**Helpful Questions that may help when developing a new more accurate or helpful way to think include:**

1. Is there an alternative explanation?
2. What would be a more helpful way to think?
3. What is the worst that could happen?
4. What have I learned from this type of situation in the past?
5. What would I tell a friend if they were in the same position?
6. How would someone I think of as good at coping think in this situation?
7. What is the best that could happen?
8. What would be a more compassionate way to think?
9. Are my expectations realistic?
### Session 6. Page 21

**Time to Recap**

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<tr>
<th>Page Name</th>
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<tr>
<td>Time to Recap</td>
<td>Image and Text</td>
<td>Well done! Let’s recap and look at what you have learned.&lt;br&gt;Take some time to read through the statements and if you would like you can print off these 10 key points so that you can refer back to them later.&lt;br&gt;&lt;br&gt;You will also be able to access these 10 key points.</td>
</tr>
<tr>
<td>1.</td>
<td></td>
<td>Negative thinking and low mood are common after cancer and cancer treatment</td>
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<tr>
<th>Page Name</th>
<th>Content Written</th>
<th>Time to recap statements</th>
<th>Content to be filled in</th>
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<tbody>
<tr>
<td>Session 6. Page 22. Stop and think</td>
<td>Before moving forward let’s stop and think for a moment about what you have learned from session 3. Take some time to fill in your answers below.</td>
<td>1. What in this session was relevant to you? 2. What is important for you to remember? 3. Has this session changed any of thoughts about fatigue? 4. How might what you learned in this session change how you act/behave? 5. How might what you learned in this session change how you feel about your fatigue?</td>
<td>Participant fills in response to each question</td>
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Session Seven Content

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<tr>
<td>Session 7. Page 1. Recap of Session 6. And overview of session 7.</td>
<td>Video and Text</td>
<td>On this page we will review what was covered in session 6 and give an overview of what to expect from session 7.</td>
<td>Frame 1. 1. Negative thinking and low mood are common after cancer and cancer treatment 2. Low mood and negative thinking can worsen cancer-related fatigue making it difficult to have a good quality of life. 3. By changing how we think in a difficult situation we can change how we feel—both emotionally and physically. 4. Myths and thinking mistakes can negatively affect how you feel and how you manage 5. By recognising and questioning thinking mistakes when they occur we can break vicious cycles, creating more positive cycles 6. Some thoughts that make us upset are realistic, or at least somewhat possible. Dwelling on these thoughts can be unhelpful when we are trying to live our lives.</td>
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Click on the video to get started.

7. Ruminating refers to thinking about the same unanswerable questions and negative feelings over and over and over again without ever getting anywhere
8. When we ruminate we lose interest in doing useful productive activities and we miss out on many positive experiences
9. By finding more helpful ways of thinking, mood, quality of life and fatigue can improve
10. Cost-benefit analysis self-compassion, mindfulness and tackling thought records can help in the management of unhelpful negative thoughts

Frame 2. We have seen how thought processes can lead to low mood and behaviours that can worsen your fatigue. Now, we are going to look at how worry and stress could be linked to fatigue.

Frame 3. In this session we will focus on the influence of stress on fatigue. Stress is the physical, mental or emotional tension caused by an event. Being tired can make you feel more stressed and less able to cope. Feeling stressed can cause physical fatigue, and can also make you feel more fatigued as a result of a constant mental overload. We will discuss how worry and anxieties are common among survivors of cancer. In particular, we will try to help you to understand the cause of these worries. We will then identify some ways that can help you to cope with and manage your stress.

Frame 4. On the next page we will explore what worry is, and what it means for those with fatigue after cancer.

Please hit "NEXT" to progress with the session.

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<tr>
<td>Session 7. Page 2.</td>
<td>Video and Text</td>
<td>On this page we will discuss what worry is and how it can</td>
<td>Everyone worries from time to time. Worry and anxiety arise when we are faced with challenges such as an exam, a job interview, or walking alone down a dark, isolated street. We get anxious or stressed when we think or feel that we are not able to cope with a situation. Usually, once the situation passes, the anxiety goes away.</td>
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Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

negatively affect peoples’ lives.

Click on the video to get started.

Frame 2. In many instances, worry is an expected, reasonable and even sensible reaction to a difficult situation. Worry and anxiety can motivate us and help us to prepare or to problem-solve. The right amount of worry in the right circumstances can protect, prepare and prompt us to action.

Frame 3. Sometimes stress and worry can also be overwhelming and unhelpful. It becomes a problem for us when it occurs in the wrong places, at the wrong time and/or the wrong extent. Stress and anxiety can also be a problem if they continue even after the problem situation has been dealt with. Examples of problematic worry and anxiety include:

- Being so anxious about your energy levels that you refuse to try any activities;
- Being so worried about other peoples' opinions that you avoid all social gatherings;
- Being so worried about all the bad things that might happen that you stop enjoying and participating in your social, work and family life.

Frame 4. **What is worry?**

To worry is to have upsetting "what if?" type thoughts. Worry can be prompted by things that happen around you, or by particular thoughts that pop into your head. Worry can also be triggered by physical sensations such as tiredness.
Frame 5. When worry is unhelpful or when worry lasts too long, the triggers lead to a cycle of "what if" type questions and answers. This causes a chain of worry rather than a solution and immediate action plan.

Each new link on the worry chain is deepens a sense of uncertainty and worsening levels of anxiety. Unhelpful worry might focus on questions that cannot be answered in the immediate future. People often worry about things such as "what if my cancer comes back?", "what if my energy levels never improve?", "what if i can’t concentrate on my job the way i used to?"

This is problematic worry and is often the result of thinking mistakes. In the absence of information, the person begins to look to the worst possible outcome, leading to more and more questions, uncertainty and anxiety.

Frame 5. People who have had cancer, are more likely to experience problematic anxiety about their health, their lives and their future. The table below shows some of the most common worries that cancer survivors experience.

**Common worries of cancer survivors with fatigue**

- Worry about whether fatigue means their cancer will come back
- Worry about whether treatment was completely successful
- Worry about general health
- Worry about fatigue and low energy
- Worry about sexual relationships
- Worry about going back to work
- Worry about social life
- Worry about family members
- Worry about money
- Worry about what people will think of them
- Worry about mood
- Worry about sleep
- Worry about worry
### Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

Frame 4. People with fatigue after cancer have to cope with many different worries and stressors. This can affect your sleep, and make you feel more fatigued. It may also mean that because there are times you have less energy, you try and do things for others but have not much time left for yourself.

Frame 5. On the next page we will explore what it is about the experience of cancer and fatigue that makes people likely to have long-lasting, unhelpful worry and anxiety.

Please hit "NEXT" to progress with the session.

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<tbody>
<tr>
<td>Session 7. Page 3. Why cancer survivors worry</td>
<td>Video and Text</td>
<td>On this page we look at some of the reasons why cancer survivors said they worried.</td>
<td>Cancer survivors might worry because cancer and fatigue can rock core beliefs</td>
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<td><strong>Frame 1.</strong></td>
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<td><strong>Cancer survivors might worry because cancer and fatigue can rock core beliefs</strong></td>
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<td>Many of us have a strong sense of who we are and the types of relationships we</td>
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<td>have with other people. These beliefs are a central part of our identity and are</td>
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<td>often called our core beliefs.</td>
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<td>We frequently use these beliefs to ground ourselves or to form simple rules for</td>
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<td>living. Core beliefs can help to guide us through life and help us to make sense</td>
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<td>of the world around us.</td>
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<td>Being sick can challenge these core beliefs. If we want to imagine ourselves as a</td>
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<td>strong survivor, cancer fatigue can hinder our progress. Fatigue can cause us to</td>
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<td>question our core beliefs, and in turn can cause us to worry about who we are and</td>
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<td>who we want to be.</td>
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<td><strong>Frame 2.</strong></td>
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<td>It can take some time to adjust to your life after treatment, especially when</td>
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<td>coping with fatigue. However, with time, support and if necessary, help from a</td>
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<td>mental health care professional, you might be able to adjust to your new situation.</td>
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<td>In some cases it might involve revising your core beliefs and changing some rules</td>
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<td>so that they can fit with your current situation. You might have to accept that</td>
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<td>some of the core beliefs you hold now.</td>
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your past rules are now unhelpful. Creating new rules or goals for life can enable you to worry less and have a better quality of life.

Frame 3. It is important to make sure Thinking Mistakes are not driving your worry.

Few people are able to start with perfectly positive beliefs about themselves when faced with such a difficult challenge. For people who struggled through cancer, the experience of persistent fatigue might strengthen already negative beliefs about other people, the future and ourselves.

These kinds of beliefs can lead to low moods and negative thought processes. They make it more difficult to reclaim life after treatment has ended. Sometimes it might be worthwhile to seek advice and support from a mental health professional.

Frame 4. **Cancer survivors worry because cancer takes away strategies that help manage worry**

Before cancer, people might consider themselves as being good at coping. They may have a selection of effective coping strategies to use in times of stress.

However, during and after cancer many of these may be no longer be effective.

- You might not be able to distract yourself from your worries by throwing yourself into work or exercise due to fatigue.
- You may not seek support from your friends and family because you do not want to be a burden to them, which would only add to your own worries.

After cancer, you may have a lot more free time on your hands. Unfortunately, this can provide fertile ground for worry. Because of your fatigue, you might abandon activities that would previously have distracted you from niggling thoughts and worries stopping worry chains before they got started.

Frame 5. **Cancer survivors worry because of Damocles syndrome**

The persistent uncertainty associated with cancer survival has been called the “Damocles syndrome.” In Greek mythology, Damocles was invited to the king’s
banquet for dinner. Once there, he found himself sitting beneath a sword suspended over his head by a single horsehair. Damocles was happy to be at the king’s feast, but any movement he made while reaching for food or drink might knock the sword loose and lead to a quick death. He immediately asked the king to remove it, but the king told him that part of being a king was to live with this sword at all times. The king had managed to live with this fear, but for Damocles, to have it suddenly thrust upon him was overwhelming.

Frame 6. For cancer survivors, fears of recurrence can result in persistent anxiety and difficulties in planning for the future. However, constant worry does not always help us. If we were to worry and alter our behaviour on the basis of all the bad things that might possibly happen, we might never leave our houses at all.

The experience of having cancer and fatigue often robs many people of their positive perspectives on life. Cancer forces people to face up to their own mortality. The treatment process makes people aware of how vulnerable they are and how bad things can, and do, happen.

People might feel helpless and have a sense of uncertainty that continues after treatment. For some people, this uncertainty continues to dominate thoughts and dictate actions. Being fatigued is likely to add to this uncertainty.

Frame 7 It is easy in situations like this to become preoccupied with cancer and the possibility that it might return or progress. Returning to life as you knew it before cancer might seem more difficult if you are worried all the time about cancer either progressing or returning.

Worries about recurrence are probably the most frequently reported worry that we hear from people with fatigue. One of the key features of this worry is an inability to cope with uncertainty.
Uncontrollable stressors are those aspects of your life that you don’t have control over. Trying too hard to gain control over uncontrollable aspects of your life can lead to fatigue.

It is very difficult to predict how you fatigue will progress or if your cancer will recur.

Cancer survivors worry because of an inability to tolerate uncertainty

Uncertainty is very difficult to deal with. For some people who worry a lot, uncertainty or "not knowing" can be unbearable.

Cancer survivors worry because it lets them feel like they can control what might happen

Some worriers wrongly believe that worry is a can somehow reduce uncertainty. Trying to prepare for all possibilities, helps them to feel that they can gain some control and make it less likely that something bad will happen.

This can be exhausting and distressing, especially when they are trying to gain certainty about problems or questions that have no answers. Worry typically makes uncertainty worse. Not knowing, uncertainty and feelings of loss of control are very relevant to people who have cancer related fatigue.

Questions about "why me?", "does this mean my cancer back?", "why have I not heard about fatigue before?", "what can I do to ensure the cancer never comes back?" are asked by many people.

Unfortunately, no one will be able to give us the answers we want to these questions, because we do not know for certain how events might unfold.
Is it possible to eliminate uncertainty and control the future?

In much the same way that the king had learned to live with the sword of Damocles, you may need to look at how you manage your worry and uncertainty.

Uncontrollable stressors are best managed with strategies such as getting social and emotional support from people around you. It can be useful to talk with close family and friends about your concerns, to accept that this is an uncontrollable worry, and to express your fears and other feelings. It is ok to sometimes let people know that you are concerned about something. It is also ok to ask for support when you need it.

The other thing that you can do is to identify whether you are thinking in a realistic and helpful manner. Are you making a thinking mistake? You can revise your thought records to see if there is a more helpful way to think about a situation.

You can also consider the following questions:

- What aspects of the situation do you experience as uncontrollable?
- Could it actually reduce uncertainty and did it result in any sense of control?

Can you think of some ways you can manage this in a more helpful manner?

On the next page we will consider the question “How useful is your worry?” Please hit "NEXT" to progress with the session.

Complete this cost-and-benefit analysis of worrying by filling in the spaces provided

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<tr>
<th>Disadvantages (costs)</th>
<th>Advantages (benefits)</th>
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These questions might help you to consider the pros and cons of constant worrying.
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

| Does it influence our ability to control the future. | • Does worrying more mean that you are more or less likely to have a recurrence of cancer?  
• Does worrying more mean that you are more or less likely to have a recurrence of cancer?  
• Does worrying more mean that you have a better quality of life?  
• Does worrying more mean that you have better relationships?  
• Does worrying more mean that you are more responsible for what happens?  
• Does worrying more mean that you are happier?  
• Does worrying more mean that you are more likely to fall apart?  
• What would you have time to think about if you worried less?  
• What would you have more time to do if you worried less?  
• How would you feel if you worried less? |

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<tr>
<td>Session 7. Page 5.</td>
<td>Video and Text</td>
<td>On this page we look at safety behaviour and how they impact cancer fatigue</td>
<td>Frame 1. A safety behaviour is something that we do because we think it will stop bad things from happening. However, safety behaviours can often make the situation worse. Cancer survivors often use safety behaviours to try to achieve certainty. These safety behaviours often have the effect of increasing anxiety and fatigue. In this section we will look at commonly used safety behaviours after cancer treatment.</td>
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<tr>
<td>Safety Behaviours</td>
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<td>Frame 2. Reassurance seeking</td>
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<td>Click on the video to get started.</td>
<td>When we not sure about something, one of the first things we often do is to ask someone about it. This is a very helpful strategy when a) there is an answer to the question being asked and b) you then believe the answer. Reassurance-seeking becomes a problem when you continue to seek it again and again. The problem with this type of repeated reassurance seeking is that it only offers short term comfort. For some reason, the person finds another reason to doubt the reassurance, and so must seek reassurance again. For example, you might feel that you didn’t explain exactly how your fatigue felt. Did you remember to give all the details? Could the doctor have mixed up your</td>
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details with that of someone else? Why didn't he send you for a scan? Was he really listening to you?

You might feel better temporarily due to a reduction in worry and anxiety, but this kind of problematic, repeated reassurance-seeking can have a negative impact on our relationships with our friends, family and doctors.

It is important to recognise the difference between unhelpful repeated reassurance-seeking and the need to go to your doctor when there is a very real change in your physical experience.

Frame 3. **Checking and Hypervigilance**

Sometimes if we are worried about a symptom like fatigue, we might start to actively check our bodies for any signs of change or illness.

Although this may be a useful and indeed an important behaviour post treatment, it can become a problem when it is excessive.

Hypervigilance refers to the constant scanning of your body for anything that seems unusual. People do this because they think that it will help to identify threats quickly so that immediate action can be taken if necessary.

It is important to go for arranged scans and follow up appointments are useful, productive and important things to do. It is reasonable to check for lumps, bumps and skin changes.

However, this becomes problematic when people start to check on a daily basis, to the degree that they leave become sore and actually cause skin changes and swelling. These changes (caused by checking) will only cause anxiety to increase, as well as checking for symptoms with no logical or medical basis. Too much checking also creates the additional problem of keeping thoughts about cancer and fatigue at the centre of your thoughts.
We might start to become aware of normal bodily actions and changes that would otherwise go unnoticed. These might be misinterpreted as something dangerous in turn; we are left with increased worry and anxiety and more checking.

Your doctors will be able to give you advice about how much checking is useful and what type of checking you should do and what a sensible amount of vigilance is for you. Any new or persistent symptom should be discussed with your doctor before being dismissed.

**Thought suppression**

Many people try to push their worries about cancer and fatigue to the back of their mind, so that they don't have to think about it. Often, the harder we try to force a thought out of our mind, the stronger the thought becomes.

Sometimes a better approach is to just notice the thoughts and try not to get into debate with them. It can be helpful to try and distract yourself with an activity from your activity menu that you made in session 4.

Worrying thoughts will still pop into your head but the if you learn to recognise them and accept that they are there, you can gain control by not wasting so much time and mental energy trying to keep these thoughts at bay.

**Information gathering**

Sometimes, constantly seeking out more and more information results in a feeling of less, rather than more, control and certainty.

Many people we have spoken to said that they have looked up all sorts of books and websites in search of comfort or answers about their fatigue. However people rarely find answers they trust, and often do not feel any better having done so. The internet is a source of much misinformation and distress while some newspapers and magazines typically have a negative bias in their reporting.
It is important that the information source you use is not biased and is based on scientific evidence and theory.

**Avoidance**
People who are fatigued often try to avoid physical exertion, which can lead to a loss of physical fitness and muscle strength.

Frame 5. On the next page we will explore some other strategies to help manage worry, anxiety and uncertainty.
Please hit "NEXT" to progress with the session.

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<tr>
<td>Session 7. Page 6.</td>
<td>Video and Text</td>
<td>On this page we look at different things that you can do to help manage worry, anxiety and uncertainty.</td>
<td>Frame 1. There are many different things that you can do to help manage worry, anxiety and uncertainty. In this part of the session we will give you some examples of things that you can do to reduce the impact of stressors and worries on your life.</td>
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| New strategies to manage worry | Video and Text       | Click on the video to get started.                                                                 | Frame 2. **Reframing**
Our daily activities are often influenced by negative thoughts and feelings. These are sometimes unhelpful and can add to the stressful impact of the event. Sometimes simply changing how you think about an event can help you manage your stress. |
|                 |                      |                                                                                  | Frame 3. Pádraig finds that by taking an hour each day to go for a walk on the beach he feels much better. He can relax and feel better about his fatigue. However, he often feels guilty for taking this time out of his busy schedule. He feels that he is letting his family down by not spending this time with them. Pádraig learns to think differently about this. He tells himself that he will have more energy for the people and things in his life if he takes this time out to relax and do |
some exercise. He replaces the idea of letting his family down with the new thought of ‘self-care’.

Can you think of something that you could reframe in your life? Can you give something a new meaning?

Frame 4. "worry time"

Given the unpredictable nature of fatigue, fear and anxiety are common emotions. If you find that worry and anxiety are invading too much of your time and are having a negative consequence on your quality of life you may find it useful to build some "worry time" into your routine.

You can set aside a time and a place to worry each day.

- Try 30 minutes in the morning or early evening in a quiet place, where you are unlikely to be disturbed. If it is too late in the evening and it might interfere with falling asleep.
- Take this time to sit down, write out and examine your worries as they occur to you. Don't get up until your worry time is over.
- If, after a week, you notice that 30 minutes is too long, try reducing the worry time down to 20 minutes.
- During the rest of your day, if you catch yourself worrying, write down the thoughts in a notebook. You can then deal with them during your worry time.

This allows you to gain a sense of control over worries.

You don't have to worry every minute of the day and you can use your "worry-free" time for more useful or enjoyable activities.

You might also start to recognise patterns in your worries and see how repetitive your worries are. Sometimes we might think that we have hundreds of worries. But in reality, we might only have four or five worries that keep repeating.

Frame 5 Mindfulness techniques
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

Some of the mindfulness techniques we described in session 6 are ideal for catching and slowing the development of worry chains. Try to take a step back, examine all the information available and then decide on the best course of action.

On the next page we will explore some other strategies to help manage worry, anxiety and uncertainty. Please hit "NEXT" to progress with the session.

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<th>Time to recap statements</th>
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<tr>
<td>Session 7, Page 7</td>
<td>Image and Text</td>
<td>Well done! Let's recap and look at what you have learned. Take some time to read through the statements and if you would like you can print off these 10 key points so that you can refer back to them later. You will also be able to access these 10 key points in your Workbook.</td>
<td>1. In many instances worry or anxiety is a normal, reasonable and even sensible reaction to an unpleasant situation. 2. Worries can be problematic if they occur in the wrong situations, at the wrong time, or if you worry too much. 3. People who have faced a stressful health-threat such as cancer are more likely to be anxious about their future health and well-being, than if they had never been sick. 4. Cancer survivors worry because cancer and fatigue can rock their core beliefs. 5. Cancer survivors worry because strategies that helped them to cope with stressors before cancer might not work as well for them anymore. 6. Cancer survivors worry because of a worry that cancer will return. 7. Cancer survivors worry because it is difficulty to live with uncertainty and with lingering symptoms such as fatigue. 8. Worry might help cancer survivors to feel that they can control what might happen. 9. Many people use safety behaviours to try to achieve certainty. 10. There are many things that you can do to effectively manage uncertainty. Cognitive and behavioural strategies include cost benefit analyses of the situation, worry time and mindfulness.</td>
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### Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

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| **Session 7.**  
**Page 8. Stop and think** | Question s to be filled in | Before moving forward let’s stop and think for a moment about what you have learned from session 3. Take some time to fill in your answers below. | 1. What in this session was relevant to you?  
2. What is important for you to remember?  
3. Has this session changed any of thoughts about fatigue?  
4. How might what you learned in this session change how you act/behave?  
5. How might what you learned in this session change how you feel about your fatigue? | Participant fills in response to each question |

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### Session Eight Content

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<th>Video content</th>
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| **Session 8.**  
**Page 1.**  
Recap of Session 7.  
And overview of session 8. | Video and Text | On this page we will review what was covered in session 7 and give an overview of what to expect from session 8. | Frame 1.  
1. In many instances worry or anxiety is a normal, reasonable and even sensible reaction to an unpleasant situation  
2. Worries can be problematic is they occur in the wrong situations, at the wrong time, or if you worry too much.  
3. People who have faced a stressful health-threat such as cancer are more likely to be anxious about their future health and well-being, than if they had never been sick.  
4. Cancer survivors worry because caner and fatigue can rock their core beliefs.  
5. Cancer survivors worry because strategies that helped them to cope with stressors before cancer might not work as well for them anymore.  
6. Cancer survivors worry because of a worry that cancer will return.  
7. Cancer survivors worry because it is difficulty to live with uncertainty and with lingering symptoms such as fatigue.  
8. Worry might help cancer survivors to feel that they can control what might happen.  
9. Many people use safety behaviours to try to achieve certainty. | Click on the video to get started. |
There are many things that you can do to effectively manage uncertainty. Cognitive and behavioural strategies include cost benefit analyses of the situation, worry time and mindfulness.

This is the final session in the REFRESH programme. Now that you have worked through the modules, you should have a good grasp of how fatigue after cancer can be affected by how we think and feel about it.

In this session we will focus on looking forward to life after this programme. We will plan how you can apply what you have been learning to your everyday life. Also we will look at how you can work towards building a life after cancer that you are happy with.

On the next page we will look at how your life might have changed because of your cancer experience.

Please hit "NEXT" to progress with the session.

Life can change very dramatically after a cancer diagnosis and treatment. You might be less active and fatigued for some time after. However, over time you can begin to recover physically and emotionally from the challenge you have faced. This can be difficult, as you can now decide what the next part of your life will look like.

Many of the cancer survivors that we met told us that life is never quite the same after cancer. They consider cancer to be a life changing experience. However, these changes are not necessarily always negative. Some people describe how the experience of going through cancer can be both a not just a burden, but also a benefit. It can force people to take a step back and change how they spend their time, as they take less for granted and try to live life to the full.

Reaching this stage is not always easy. And everyone can have bad days. It can be especially difficult to recognise the benefits for those who have struggled with fatigue.
Those who have fallen into the traps of inactivity, negative thinking, anxiety and low mood can also find it really difficult to get back into a fulfilling routine.

Frame 2.

Frame 3. **Reclaiming your life**

Life can be rewarding: full of quality and activity. However sometimes it can feel somewhat empty, and people can experience regrets and worry. What would you like your life to look like? How would you like to pass the time?

The first thing we will do in this session is to take a look at what your life is like right now. You can then compare that to what it was life before you were diagnosed. From there we will look to the future. We will take into account your cancer experience and any physical limitations or obstacles, and from there you can plan what you would like your future to be like.

Frame 4. If we take the example of Pamela, a 53 year old teacher who has 3 children aged 10, 15 and 19. She was always a very active member of the local school board and trained the camogie team. She enjoyed horse-racing and would attend meets with her husband whenever she had a day to spare. Since her radiotherapy ended 2 years ago, she finds that she simply has no energy. She spends her evenings on the couch watching TV. She tries to keep on top of the housework, but has little energy for anything else.
Now let’s have a look at how much time Pamela thinks she spends on activities each day.

**Time spent on activities now (since cancer)**

Frame 5. Now let’s compare that to a pie chart showing how much time Pamela was spending her time before cancer.
Frame 6. Finally, comparing “Life Now” and “Life Before Cancer” pie charts, Pamela was asked to consider what her ideal future like could be like. She looked at what she liked from her life now, and what she would like to keep. She looked at what she had been doing before and whether she would like to do any of those again. She then thought about any new activities that she would like to include in her life from now on. Here is her new pie chart showing how much time she would allocate different activities. She was sure to think about the physical restrictions that were placed on her due to fatigue and other issues. This helped to ensure that Pamela’s goals were realistic and achievable.
Frame 7. And so Pamela was able to start thinking about how to spend her time the way she wanted to. She focused on increasing the time that she spent on activities that increased her quality of life. After a few weeks doing this, she noticed that activities that had previously had a negative impact on her quality of life were reduced. They had been replaced by her more positive activities.

Pamela even began to realise that her relationships with her family and friends began to improve. Although she would not like to go through cancer again, it had been a blessing in disguise for her in many ways.

It is not unusual for many people to make very positive life changes to their life after cancer. People might begin to appreciate relationships and life more than they had before. For many, cancer allowed them to change their life goals and priorities in a way that improved their lives.

Frame 7. On the next page we will have a look at your own life now, before cancer and what it might be like in the future. Press NEXT to continue with the session.
# Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

### Activities now

<table>
<thead>
<tr>
<th>Time spent on activities now</th>
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<tbody>
<tr>
<td>Daytime sleep</td>
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<td>Religion</td>
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Just as you saw Pamela do on the last page, give a rough estimate of what percentage of your day (during an average week) that you spend doing each activity.

### TIME SPENT ON ACTIVITIES BEFORE CANCER

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<th>Life before cancer</th>
<th>Fills in percent of each activity</th>
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<td>Daytime sleep</td>
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Now estimate how much time you spent doing these or other activities before your diagnosis.

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<td>Image and Text</td>
<td>Now estimate how much time you spent doing these or other activities before your diagnosis</td>
<td>TIME SPENT ON ACTIVITIES BEFORE CANCER</td>
<td>Fills in per cent of each activity</td>
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</table>
**Session 8. Image and Text**

Using the information from "LIFE NOW" and "LIFE BEFORE CANCER", begin to consider what your ideal life could be like now.

1. Which, if any of the activities in those pie charts are good for your quality of life and are worth putting into your *Future Life pie chart*.  
2. Then look at those activities which you don’t enjoy so much, but are necessary in your life. Perhaps reduce the amount of time you give to them, and increase the time for positive activities.  
3. Can you drop some of the negative activities that are not essential for the future?  
4. Are there any new activities that you would like to include in your future life? (take into consideration any physical or practical limitations)

### HOW I WOULD LIKE TO SPEND MY TIME

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Reclaiming life after cancer can be hindered by a number of obstacles. Over the next few pages we will discuss some of these, including:

1. Avoiding others
2. Giving up
3. Waiting for something to change
4. Procrastination.

It can be difficult for people to get back into the swing of things after the completion of cancer treatment. This can be made even more difficult when you are fatigued. People often report that it can be challenging to start re-engaging with people around them. The people we spoke to described feeling that others often did not understand their fatigue and that they felt under pressure to be “back to normal” once they finished their treatment.
Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices

meeting up with people after cancer find in socialising and meeting up with people after cancer.

Frame 2. Some people maintain social interactions during their treatment; and so, those around them might be better tuned into how they are feeling. For others, being sick might have required them to withdraw somewhat. They might not have seen work colleagues, or some friends and family in some time. It can be difficult to reconnect. Sometimes it can be awkward to bump into friends and acquaintances that have not been seen for some time. Such difficult situations may even cause some people to avoid social situations. This can stop you from returning to everyday life.

When we began preparing this online programme, we met with a group of people with cancer related fatigue to get a sense of their experience. In this section we will discuss some reasons why some people might find social interactions difficult.

Frame 3. Some people that we spoke to described interactions where people had been quite insensitive about their experience. These cancer survivors described how people told them stories that they did not wish to hear, about a friend or relative of theirs who had also “fought” cancer.

Hearing about someone who has died as a consequence of their cancer can understandably affect your mood.

Individuals told us about feelings of guilt they experienced, wondering why they had survived when another person did not.

People also described how these conversations triggered worry about their future. This sort of thinking can be very unhelpful as it can lead to people feeling even more vulnerable. These are natural and understandable responses to hearing such stories. However, it is important to remember that these stories are nothing to do with you and your own recovery and future.

Frame 4. Cancer survivors also told us how they found it difficult to be identified as a sick person, when they were trying to get back to a sense of normality.
They described experiences where they were not invited to events because it was assumed that they could not go. Many people we spoke to described how people told them they were “looking well”, but this only led to frustration. They felt that others had no understanding of the fact that they were fatigued and were unable to manage the same level of activity as before.

Others described how misguided (though well meaning) comments and actions sometimes only reminded them of the fact that they had been ill, rather than helping them move on with their lives after cancer.

**Frame 5.** Many people reported receiving unhelpful advice and recommendations about their fatigue. While advice is often given with the best of intentions, this was difficult to tolerate and could be quite confusing, as everyone’s experience of cancer is different. People felt that their fatigue was unlikely to be understood and appreciated by those who had not been through it.

**Frame 6.** Some people described how their fatigue made it difficult for them to maintain interest in a conversation. They felt that others often did not appreciate the extent of their fatigue. They found it difficult to concentrate and focus when they were tired, or often their mind would wander. Social events were also difficult, with individuals finding it difficult to explain why they had to leave early and could not manage late nights.

**Frame 7.** On the other hand, some people described how some friends were not very interested or seemed to ignore what they had been through. This is particularly the case if the person was considered a close friend. People reported that they sometimes felt that they would be whining if they brought up the fact that they had been ill, or that they would be perceived as playing it up in order to get attention. This led people to be reluctant to begin a conversation about their cancer and fatigue. It made returning to work difficult when there was no allowance or understanding for low energy or fatigue.
**Development of an online intervention for cancer survivors with cancer-related fatigue: Appendices**

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<td><strong>Session 8. Page 9</strong></td>
<td>Video and Text</td>
<td><strong>How to overcome these difficult situations</strong></td>
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**Frame 1.**
On this page we look at the ways that you can overcome difficult social situations. Click on the video to get started.

**Frame 2.**
- **Don't avoid**
  Most of these difficult social situations become more manageable once you have worked your way through them a couple of times. It can be helpful to approach problem situations in a stepped way; starting with the easiest situation first then working your way up to more difficult situations.

**Frame 3.**
- **Don't personalise**
  It can be difficult to remember sometimes, but most people are not trying to be unhelpful, or insensitive. Often, people just do not know what to say when someone they know has been very ill. It is often through their own awkwardness that they say the "wrong thing".

**Frame 4.**
- **Individual difference**

Frame 8.  On the next page we will have a look some things you can do to help you to prepare for and manage these social situations. Press NEXT to continue with the session.
People respond to cancer and treatment in very individual ways. It can be quite a personal experience. Sometimes, questions or statements that you find overly intrusive or upsetting may not have the same effect on another person.

Frame 5.

- **Take control**
  It can be helpful to take control over the conversation and steer the topic in the direction you choose. By being assertive in conversation, you do not become a passive participant at the mercy of whatever question is thrown at you.

Frame 6.

- **Be prepared**
  One of the best ways to take control of conversations is to prepare before the encounter ever happens.

  Being unprepared can sometimes lead to feeling uncomfortable after the conversation, due to fears that you come across badly or that you said too much or too little.

  There are three key steps to preparing yourself for social interactions and conversations. These are:

  1. deciding on different levels of social closeness;
  2. consider the amount of information you are comfortable sharing depending on how close the person is to you
  3. Plan some sentences that you can use to redirect the conversation.

Frame 7.

**Deciding on the different levels of closeness:**

*Sometimes it can be useful to consider people in terms of your “Relationship circles of closeness”.*

If you imagine that you are at the centre of a series of circles
Not every person can offer you the same support, and you might not be willing to share some information with some people.

In advance, think about the amount of information (if any) you want to give people on each circle should you meet them. **Consider the amount of information you are comfortable sharing.** The amount of personal information you share will most likely decrease the further out the circles you move.

You might also consider what support people can offer.

Some people might be better when it comes to finding practical solutions, whereas if you wanted to talk about how you were feeling someone else might offer better support. You might like to think about those you have in your life and what type of support they are good at giving. These can include

- emotional support (people who you can talk to about your feelings);
- practical support (people who can do jobs or tasks to help you out);
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- Informational support (people you know you might give you information about your symptoms or illness).

Frame 9. Plan sentences to redirect conversations

Sometimes you simply might not want to talk about cancer and fatigue and the recovery experience. It can be handy to prepare some things to say in advance, so that you can redirect conversations if you wish. This might include giving a small amount of information and then diverting the conversation. Redirection usually works best if you change the conversation to a topic of interest to the other person. You might even like to build up a variety of responses. You can try them out in different situations and learn what works best for you.

1. redirect to their family
   “I’m doing well now thanks, how is your daughter getting on with the exams?”

2. redirect to the other person
   “I haven’t decided about getting back to work yet. How are you all getting on at work? You must be busy this time of year?”

3. redirect to popular news
   “Yeah, I’m still tired but I’m hoping I’ll be grand again soon. Were you watching the match at the weekend?”

Sometimes people might not get the hint, or might persist even after redirection. In a situation like that, you can firmly but politely redirect once more, but this time emphasise that you are purposely changing the subject:

“Oh let’s not talk about cancer now, I’m sick of talking about it. Have you planned anything for the holidays?”

Or

“If you don’t mind, I’d rather not talk about it now. How is Mary getting on?”
For people who are very close, you might be comfortable telling them that you do not feel like talking about your illness today. Open and honest communication can prevent loved ones from trying to second guess how you feel.

You could say:

“Would you mind if we talked about something else. You don’t have to ask me about my energy every day. I appreciate it, but will let you know when and if I need help.”

Clarification of your feelings reduces the likelihood of unnecessary hurt, disappointment, or frustration.

On the next page you can do an exercise to help you to prepare for social situations. Press “NEXT” to continue.

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<thead>
<tr>
<th>Page Name</th>
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<th>Content Written</th>
<th>Questions</th>
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<tbody>
<tr>
<td>Session 8. Page 10</td>
<td>Question s to fill in and Text</td>
<td>It can be useful to try and prepare yourself by creating a social planner. To do this, think of various responses that you could say in these situations. Consider the amount of information you would give and how you would redirect. This will probably vary</td>
<td>You meet someone who asks you about how you are recovering from cancer and whether you have to go back to the hospital.</td>
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<tr>
<td>Social planner</td>
<td></td>
<td>You meet someone who asks you about how you are recovering from cancer and whether you have to go back to the hospital.</td>
<td>What would you say to…?</td>
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<td>A close friend?</td>
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<td>A work colleague/neighbor?</td>
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<td>An acquaintance?</td>
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<td>You are at a party and someone asks you about your fatigue.</td>
<td>What would you say to…?</td>
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<td></td>
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<td>A close friend?</td>
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depending on how close you are to the person.
Each time you encounter a difficult social situation think about what worked well and what did not work so well.
In order to avoid unnecessary awkwardness it can be useful in some situations to ask someone close to you to give others a heads up about what to say and what not to say.

A work colleague/neighbour?_____________________
An acquaintance? __________________________

You bump into someone when you are out shopping. They start to tell you about someone who had the same cancer as you. You would rather not hear the story.

What would you say to…?

A close friend? __________________________
A work colleague/neighbour?_____________________
An acquaintance? __________________________

You are out with a small group of people when someone asks you about why you are not back at work.

What would you say to…?

A close friend? __________________________
A work colleague/neighbour?_____________________
An acquaintance? __________________________

Write down any other social situations that you might find difficult or that you have found difficult in the past and try to create a list of possible responses.

Social situation 1.

What would you say to…?

A close friend? __________________________
A work colleague/neighbour?_____________________

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Waiting for something to change

Some people *put off starting their lives again because they are waiting for something to happen first.*

This may be physical, like waiting for their hair to grow long again or waiting until their energy levels return to how they were before cancer. Or it can be health, like waiting until they are 2 years post treatment or waiting until they have their review meeting or scan results.

Of course during this time when they are waiting, *life and time are continuing to tick by.* The longer you avoid getting back into life the harder the return becomes.
Although you may not be 100% ready, it might be better to try something rather than not doing it at all. Even reaching 80% of your previous level is better than 0%.

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<tr>
<th>Session 8. Page 12</th>
<th>Fill in and Text</th>
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<td><strong>What have you lost vs.</strong></td>
<td>Surviving cancer can sometimes come at a cost. Some of the costs are temporary but unfortunately some will be permanent. Perhaps you have lost some of your energy and your physical fitness. Hopefully with time and some of our suggestions that will improve.</td>
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In his book "The Worry Cure", the Psychologist Robert Leahy refers to the "Restaurant Solution" in managing situations where you have failed at something. We think this solution may also apply in situations where something significant has been lost. In the "Restaurant Solution", Leahy asks us to imagine our favourite restaurant. He then gets us to imagine that we ask for our favourite main course only to be told that there is none left.

Leahy then asks the following questions:
what can you still do?

"What do you do? Do you refuse to eat because there is no beef? Do you demand to speak to the owner to complain? Do you sit and dwell on how lucky all the other people who ordered beef earlier are?" Leahy suggests that you do none of those things. Instead, you look at the menu and "select something else". (Leahy 2005, pp 193).

The most helpful thing to do when something goes wrong in life is to ask ourselves what we can still do. Rather than focus and dwell on the thing that has gone wrong, we should turn to our life's menu where there are still many things we can still do.

Complete the exercise below…

1. What were the costs of cancer for you? What can you not do now that you could before?
2. Make a list (perhaps enlist some help from family or a good friend) or all the things that you can still do. It may be useful to group these under the headings of:
   - Relationships/friendships
   - Family
   - Partner
   - Work
   - Leisure
   - Chores
   - Exercise
   - Other

3. Are you losing the enjoyment of many of the things you can still do because of the loss of something else?
4. Is there a different or more helpful way of thinking about or dealing with your loss so that it will have less of an impact on these areas of your life?
5. If you had a friend who had experience the same loss what would you recommend him/her to do?

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<tbody>
<tr>
<td>Session 8. Page 13.</td>
<td>Video and Text</td>
<td>On this page we look at the Frame 1.</td>
<td>Cancer can strip people of a sense of control and certainty. For some it can become difficult to make plans for events that seem a long way off for fear that they will get sick again and won't be able to follow through.</td>
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</table>
| Putting things off or putting things on hold | Frame 2. Frank had always been an active member of a community group. He enjoyed being busy and planning local events, but also he loved the social element of frequent meetings with people from his locality. He had not done much work for the group since his diagnosis and treatment for prostate cancer. Despite the fact that his treatment had finished 9 months ago, he was reluctant to go to any of the group’s meetings. Whenever people contacted him to tell him about the next meeting he would say that he was planning on attending and then cancel at the last minute. Those in the group were all close friends and neighbours, but were becoming increasingly frustrated with him, as they were eager to re-involve him in the group.

Eventually Frank admitted that he was afraid to return to the group in case he was not able to keep up to speed with the activities, as he had found it difficult to concentrate since his treatment ended. |
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<tbody>
<tr>
<td>Putting things off or putting things on hold</td>
<td>Click on the video to get started.</td>
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</table>
| Frame 3. Frank was using a safety behaviour. He thought that by not attending the meetings, he would avoid letting himself and others down. Of course, the very act of not making a decision about staying in the group was what caused others to get annoyed.

Sometimes, the longer we avoid doing something (e.g. making a decision, going back to work etc.) the harder doing that activity becomes.

It is often the case- as with Frank- that we put things off for fear that something negative will happen. We wonder, what is the point in trying only to be let down? What do you think Frank’s friends said to him when he reveals his reasons for not attending the meeting? Do you think the advantages of going to the meeting outweigh the disadvantages? |
| Frame 4. Frank’s community group admitted that they had no idea that he had been avoiding due to fears about his concentration and energy levels. However, to Frank’s surprise they told him that they were aware that he might not be ready to take on all his previous duties since his illness.

They assured him that if he needed to take a break or leave a meeting early that they would get by, but that they had missed his valued input and the sense of humour he always brought to the meetings. They had hoped that he could ease his way back into the group. They |
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pointed out that people often skip meetings and that the group was primarily a reason to bring the community together rather than to put people under pressure.

Frame 5. We do not have to wait for a major event like going back to work or starting to socialise again to see evidence of how putting things off stops us from reclaiming our lives. Some people we spoke to described doing this on a daily basis in what is often known as procrastination (putting things off to a later time).

Frame 6. Sometimes it is better to do something than to do nothing. On the next page we will give you some tips for beating procrastination.

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<tr>
<td>Session 8.</td>
<td>Image</td>
<td>8 hints to beating procrastination</td>
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<tr>
<td>Page 14.</td>
<td></td>
<td>1. Make a list of all the things you have been putting off.</td>
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<td>2. Put the tasks in order of importance. If you can't decide which ones are most important, put them in order of difficulty (easiest first) or simply put them in alphabetical order</td>
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<td>3. Break down your first task into small steps, listing exactly what it is you need to do</td>
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<td>4. Consider any obstacles that might arise in completing each step and devise ways to overcome these obstacles (get help of you need it)</td>
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<td>5. Roughly decide on how long you will spend on each task. Don't stop in the middle of a step, keep going until either a step or the entire task (if small enough) is finished.</td>
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<td>6. Focus on what you have achieved not what you have left to do.</td>
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<td>7. Be flexible. Don't allow obstacles or circumstances outside your control to become a convenient excuse for a break. You may need to go back or step or even create some new steps.</td>
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<td>8. Review how well you got on at the end of each day.</td>
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Remember to take a very compassionate stance with yourself and your efforts. Slow and steady wins the race!
Note what you can learn from any problems you encountered. Explore possibilities that may exist for improvement.

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### Session 8. Page 15.

**Video and Text**

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<tr>
<th>Frame</th>
<th>Content</th>
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<tbody>
<tr>
<td>1.</td>
<td>As we come to the end of the programme this may be a good time to review your problems and goals list from session 2. Have any of your problems reduced in severity? Have you have achieved (or are closer to achieving) any of your goals? This may also be a good time to review your Fatigue Score by retaking the questionnaire in session 1.</td>
</tr>
<tr>
<td>2.</td>
<td>Eight sessions is a relatively short time to make major changes in your behaviour or the way you think or feel. Don't be disheartened if you still have a way to go in achieving your goals. Managing persistent cancer-related fatigue so that you can reclaim a life you are happy with is a big challenge. It is not something that will occur overnight and it requires ongoing commitment and effort on your part. Remember, positive actions may seem small right now, but your efforts will hopefully help you along the road to recovery.</td>
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<tr>
<td>3.</td>
<td><strong>Dealing with setbacks</strong> One of the most important things to successfully making changes is not to get too disheartened when setbacks occur (and they will occur). There are specific circumstances which may increase the risk of a setback in fatigue. These might include illness or stressful life events. These type of events can increase fatigue and limit the opportunities to continue regular, planned activity. Going through these events does not mean that you will automatically have a setback; it simply means that these are times when you are more at risk. Remember to congratulate yourself on what you have achieved and try to remember that setbacks are a normal part of recovery and improvement.</td>
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<tr>
<th>Frame 4.</th>
<th>It is often helpful to judge your efforts as you would judge the efforts of a good friend. Typically, we are much kinder, compassionate when we give our friends advice than when evaluating ourselves.</th>
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</thead>
</table>
| Frame 5. | It is a good idea to look after yourself by making sure that you use your stress management techniques. It might be worth keeping up a small programmed of planned activity and rest as a preventative measure. Having a routine can help to minimise setbacks in how you manage your fatigue.  
Remember that it is best to stick to being moderate and consistent in your efforts. Now that you have completed the programme, do not be tempted to try bursts of activity or to slip back into inactivity. |
| Frame 6. | See each challenging situation as an opportunity to try something new. As such, there should be no sense of failure. Even those attempts that do not go well can be learned from. From this learning you can tweak action plans and strategies to be tried the next time. If you are overly self-critical it is likely that you will give up before you get started and will miss many opportunities to learn. |
| Frame 7. | Even though you may sometimes feel you are back at square one and your SMART goals are unattainable, this is rarely the case. You will find that once you get back into the programme again you will quickly regain lost ground. |
| Frame 8. | In order to maintain the gains you have made, it is important to ensure that the steps you have taken are now part of your daily life. Many activities that were practices during the day should be starting to happen automatically. It is very important to try and make sure that they remain part of your daily life.  
- Make sure that you maintain a balance between activity and relaxation  
- Use goal sheets and thought records to work on areas of your life that you find challenging  
- Set yourself targets, broken down into manageable chunks which are practiced regularly  
- Try to keep working on goals and tasks until you can achieve them consistently and regularly, without feeling tired.  
- Think about how you would like to continue to build upon the progress you have made in regards to your fatigue. |

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<tr>
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<th>Time to recap statements</th>
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**Session 8. Page 16**

Time to Recap

Well done!

Let’s recap and look at what you have learned.

Take some time to read through the statements and if you would like you can print off these 10 key points so that you can refer back to them later.

You will also be able to access these 10 key points in your Workbook.

---

1. Persistent fatigue after cancer can make it difficult to stay motivated and move on with your life.
2. How you spend your time can change dramatically after cancer.
3. Cancer is not only a life-threatening, but also a life-changing experience.
4. The first step to reclaiming your life is to take a close look at how it is right now, compare that to how it had been before becoming ill. Then take into account your cancer experience and any physical limitations or obstacles. Finally, decide how you would like your future to look.
5. It is not unusual for people to report making very positive changes to their life after cancer.
6. Many cancer survivors report that they have a greater appreciation for relationships and life in general after cancer.
7. Common obstacles which hinder returning to a satisfying life after cancer include: the desire to avoid people, giving up on things, waiting for things to change, and procrastination.
8. Through preparation, reframing, focusing on possibilities and tackling procrastination it is possible to overcome these obstacles.
9. Reviewing your problem and goal lists will help you to examine your progress.
10. Remember not to get too disheartened when setbacks occur. These are a normal part of recovery and improvement. You have taken a great first step by completing this programme!

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**Session 8. Page 17.**

**Video and Text**

THANK YOU FOR COMPLETING THE PROGRAMME!

We will contact you soon with some follow-up questions about the sessions that you have taken part in.

Thank you very much for participating in this research project and good luck for the future!