Evaluating the Redesigning Daily Occupations (ReDO-10®) programme for women with stress in Ireland

A feasibility study and process evaluation

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Declaration

I certify that the work presented in this thesis is my own and that I have not obtained a degree in the University of Galway, or elsewhere, on the basis of the work described here.

Abstract

Mental health interventions are in high demand in primary care in Ireland where psychological distress is commonly seen as a reason for presenting to general practice. Women present more frequently with stress and anxiety. Occupational therapists have the potential to meet the needs of this population with programmes such as Redesigning Daily Occupations (ReDO®-10). The objectives of this research were to (1) explore the feasibility, acceptability and potential effectiveness of the ReDO®-10 programme as it was implemented for the first time in an Irish primary care setting and (2) to analyse the mechanisms of action of this programme to understand the process of change for participants. Women were recruited from general practice sites and through self-referral over two phases in 2018 and 2019. In total, 31 women expressed interest and 15 were recruited. ReDO®-10 group sessions were delivered by primary care occupational therapists who had received training and certification. Outcomes measured at three time points included; functioning, psychological distress, mastery, occupational value and perceived health. Qualitative interviews with participants, general practitioners and occupational therapists were analysed to understand the feasibility and acceptability of the intervention. A separate analysis of participant narratives informed a directed content analysis based on the Behaviour Change Wheel to understand mechanisms of action.

ReDO®-10 was found to be acceptable and feasible in this small study. However, it required considerable resources of time from occupational therapists and general practitioners. The group support was highly valued and women reported changes in their patterns of occupations, choosing more occupations for health and restoration and finding greater autonomy in home settings. The analysis informed by the Behaviour Change Wheel showed that the practice of occupations between sessions and the occupational self-analysis aspects of the programme were particularly influential in changes that occurred. This study informs future research on the ReDO®-10 and other programmes by providing information on aspects of feasibility, outcome measurement, recruitment challenges and data analysis. It also provides important data to understand how occupation-focused interventions may work to bring about changes for those who take part in them.

Acknowledgements

The completion of this PhD study would not have been possible without the help and support of many individuals over the past 6 years and earlier.

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To the participants of the ReDO®-10 groups – without your voices, I would not have been able to understand what it was like to sit in the groups, try the exercises, hear from each other and contend with barriers to making health changes. I thank you for your eloquence and support for each other during the process.

To the University of Galway – I am sincerely thankful for the support of the Further Education Policy and the Millennium Fund during my studies. I am deeply privileged.

To my parents, Michael and Cathy Fox – you never doubted that I would get here. But I would not have gone on this journey without the love for learning that you instilled in me early. I want to thank you particularly for the practical support in the last few years when sometimes writing had to come before making dinner or doing the school run!.

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Chapter 1 - Introduction

"What I am about to say probably sounds far-fetched, but here it is. The health problems of the majority of patients I see – yes, the majority – are driven entirely by their lifestyle. It's not cuts or bruises or bacteria or a fungus or a virus or some tumour or hereditary disorder that's the source of their pain, but the way they're choosing to live. Their conditions are often very exacerbated by the fact that they're super busy. They wake up fully stressed, rush to get the kids ready, do the school run, come back, try to juggle their jobs and their home life. On top of that, they might have other family members who require care and attention. From the moment they open their eyes, it's all go, go, go. Then, when their kids are finally in bed, they're straight into their emails or social media. At no point in the day are they just chilling out, or even alone. Everything they do is for someone else. When I mention this in surgery, they roll their eyes, telling me, 'But I just don't have time for me'. To which I reply, 'Well that, right there, is your problem'"

Dr Rangan Chatterjee, General Practitioner and Author (2018 p.14)

Rationale for the study

Mental health is a large and growing concern in primary care, with rates rising from one in six patients in 2011-2013 (O'Doherty *et al.* 2020) to one in five in 2020 (Kelly 2020). However, not all who consult their General Practitioner (GP) with mental health concerns meet the threshold for a mental health condition and it is estimated that up to one in three patients present with some form of non-specified psychological distress (Hughes *et al.* 2010). Lifestyle factors, including poor sleep patterns and overwork (Baxter *et al.* 2014) as well as many social determinants such as housing, financial pressures and inequality all contribute to this (Alcántara *et al.* 2020). Characteristics of modern everyday life, such as excessive technology use (Small and Vorgan 2008), a decline in number and quality of social relationships (Kovacs *et al.* 2021; McPherson *et al.* 2006), lack of nature connectedness (Capaldi *et al.* 2014) and sedentary behaviour (Teychenne *et al.* 2015) have all been linked with poor psychological and physical wellbeing. Despite this, much mental health research and treatment focuses on "*matching the 'right' diagnosis with the 'right' medication*" (Gardner and Kleinman 2019, p.1697).

In Ireland, primary care teams were set up to meet the holistic (mental and physical) needs of populations (DOHC 2001), but teams either lack multidisciplinary staff with mental health expertise (Agyapong *et al.* 2012) or, in the case of occupational therapists, are not staffed sufficiently to be able to treat any but the most severe and urgent cases, as reported by one West of Ireland GP; "*Occupational therapy is a cloud service….we pray to her for intervention….You could say you need to see an occupational therapist but it could be a year before you see her – the woman [the patient] could be dead and buried in that year*" (Mackenzie and Clifford 2018, p.528). Gaps in this primary care mental health treatment provision are met by the community, voluntary and private sector in the main – apart from the recent provision of the Counselling in Primary Care service by the HSE (Health Service Executive 2019). Prevention of serious mental illness in those presenting to primary care has potential to save money, lives, and general practice workload, according to the Royal College of General Practitioners (Thomas *et al.* 2016). Promotion of mental health for all – an enabling process of achieving positive mental health, flourishing and quality of life (Keyes 2002) and enhancing the strengths, competencies and resources of individuals and communities could have even greater impact, particularly through changing the modern lifestyle risk factors previously described (World Health Organization 2004; Walsh 2011). Therefore, exploring mental health interventions within the primary care team/service setting is important. The vision of the Sláintecare strategy is to restructure and expand primary care services in Ireland and includes increased funding for mental health and a review of the workforce (Committee on the Future of Healthcare, 2017). Occupational therapy, "*the most underused profession in primary care*" has potential to offer interventions focused on daily life to a people and communities with a variety of needs, but requires greater evidence for health and cost-effectiveness (De Maeseneer 2017, cited in Bolt *et al.* 2019, p.6).

Women experience higher rates of mental health issues, particularly depression and anxiety than men do (Plaisier *et al.* 2008). There is evidence that women are more exposed to the risk factors for mental health e.g. being in unstable employment or experiencing single parenthood (World Health Organisation 2001). They are also more vulnerable to stress related to their roles in relationships, parenting, caring and in their social network (Drapeau *et al.* 2012). There are gender differences in some protective factors for mental health e.g. working full-time is associated with good mental health for fathers, but not for mothers (Plaisier *et al*. 2008). In trauma-informed care particularly, there are strong preferences among women for women-only group support programmes (Pebole *et al*. 2021). The

acknowledgement of gender differences in mental health presentation and treatment preference has led to a number of different programmes being developed specifically for women in primary care with psychological distress (Chapter 2), in a move toward a more gender-sensitive approach (Tedstone Doherty and Kartalova-O'Doherty 2010).

Interventions within the core skill-set of occupational therapists, such as therapeutic group support and facilitated self-help are recommended for psychological distress for all patients in primary care (NICE 2011). Other programmes within the scope of practice such as approaches incorporating mindfulness (Burnett-Zeigler *et al.* 2016), positive psychology (Chaves *et al.* 2017), or physical movement (Mailey and McAuley 2014) show some emerging evidence for effectiveness with female-only populations, although studies are small and heterogeneous in nature. Occupational therapy-designed and led programmes such as OPTIMAL (Garvey *et al.* 2015) and RENEW (Connolly *et al.* 2019), have been developed in Ireland for a primary care population recently but are still being explored for effectiveness. A comprehensive literature review (Chapter 2) and a systematic review (Appendix I) were carried out to identify an intervention that could be explored for feasibility for women with psychological distress within the Irish primary care context. The primary care version of the Redesigning Daily Occupations programme (ReDO®-10), designed and evaluated in Sweden, was identified as an appropriate approach to explore in a feasibility study. The research evidence and programme content of the ReDO®-10 are described in detail in Chapters 2 and 4 of this thesis and in a published paper (Appendix II).

ReDO®-10 was felt to be potentially relevant in the Irish primary care context for a number of reasons. Firstly, there are few publicly-funded treatment options for people with psychological distress or stress-related issues in primary care (O'Doherty *et al*. 2020). There are charitable organisations (for example, Jigsaw, Aware or Pieta House), employee assistance programmes in some workplaces or online self-help, but in the main people are helped solely by their GP. As they are part of Irish primary care teams and are trained to support people with physical and mental health challenges, occupational therapists in Ireland could meet some of this unmet need, as part of a growing call for a more health-promoting focus in the profession (Jordan 2019). Secondly, ReDO®-10 is not a diagnosis-specific intervention. It was designed to help people redesign their daily activity patterns to improve their health and has been previously used with populations with a range of diagnoses and with those at risk of burnout (Eklund and Erlandsson 2011; Olsson *et al.* 2019). It can potentially meet the needs of a primary care population that may have co-occuring mental

and physical health complaints or be experiencing sub-threshold (but nonetheless distressing) symptoms of stress, depression or anxiety (Ford *et al*. 2016). It has shown promising results in a small trial in a Swedish primary care context (Olsson *et al*. 2019). Training Irish primary care occupational therapists in the ReDO® approach means they can use this intervention in the future with a wide range of people (such as carers or people with chronic conditions) experiencing overload, imbalance and burnout (Alves *et al*. 2019; Matuska and Bass 2016).

Finally, some primary care occupational therapists in Ireland perceive themselves as having become stuck in a role as "*equipment providers and that's all we are*" (Mackenzie and Clifford 2018, p.529) and referrals to the service can be compromised by fragmentation and lack of team meetings in practice. However there is a strong call for a diversification of the primary care OT role (Bolt, Ikking, Baaijen and Saenger 2019; Halle, Mroz, Fogelberg and Leland 2018) and an intervention grounded in occupational therapy theoretical perspectives like ReDO®-10 would allow OTs to use and articulate their disciplinary skill-set and theory-base more strongly. This also comes at a time of increased focus on primary care funding and service provision in Ireland (Committee on the Future of Healthcare 2017). A new model of mental health primary care is being piloted in some areas of Ireland and in this new approach, community, group-based programmes such as ReDO®-10 are being delivered by primary care staff as part of a stepped-care approach (Kierans and Byrne 2010). It is vital to pilot ReDO®-10 using a process evaluation methodology to understand how/whether the programme could be a feasible and potentially effective intervention as health services are realigned in Ireland in the coming years.

There are challenges to implementing occupational therapy interventions that have been designed and evaluated in clinical trials in one country in other countries with cultural differences. A project evaluating the Lifestyle Redesign programme (Jackson *et al*. 1998) in a Danish context (Løkken and Overgaard 2009) was criticised for calling for the mainstreaming of the programme into Danish occupational therapy services despite having a weak study design (Glasdam *et al.* 2021). There is emerging evidence for the effectiveness of ReDO®-10, but results have yet to be published from any trial outside of Sweden (Olsson *et al.* 2019). Taking a feasibility study approach is important to explore the key areas of uncertainty of an intervention such as acceptability, demand, cultural perceptions and the possible need for adaptations from multiple stakeholder perspectives (Bowen *et al.* 2009). In addition to this, current thinking in intervention development and evaluation requires researchers and clinicians to be systematic and methodical in the evaluation of programmes,

including describing the mechanisms by which they are expected to work (Moore and Evans 2017; Treweek 2005). A feasibility study and process evaluation were used to explore the implementation of ReDO®-10 on a pilot basis in the new context of Irish primary care focusing on acceptability, feasibility, stakeholder perspectives and potential mechanisms of action.

Purpose statement

The background and rationale for the research questions for this PhD study are presented in detail in Chapter 3. In summary, the project had three aims: (1) to determine the evidence-base for occupational therapy-led interventions for women with anxiety and stress-related conditions and identify an intervention with potential to be piloted in Ireland (2) to carry out a feasibility study of such an intervention in the local primary care context and (3) to carry out a process evaluation of this intervention to understand the mechanisms of action for women in this new context.

Ethical considerations

Full ethical approval for this study was received from the Irish College of General Practitioners in March 2017. The main ethical considerations were; (a) informed consent, (b) data management, processing and retention and (c) the management of distress and clinical reporting. To ensure fully informed consent, there was a two-step process for recruitment. Participants were told about the study by their GP or self-referred and, if interested, were followed-up with a phone call to receive more information. Separate consent was sought from all stakeholders to allow recording and use of qualitative interview data. After hearing more about the study, they were still free to decline participation both then and at any stage of the study. All written data gathered in hard copy for this study, such as consent forms, were stored in a locked cabinet to which only the researcher had access. Any digital data was stored in encrypted cloud storage. A key to link participants' demographic data with their assessments was held securely only for long enough to link the pre, post and follow-up data. All personal data, including any email trails, phone numbers and names were deleted after the linking of data and after participants had been given a chance to review their interview transcripts.

Finally, a comprehensive distress protocol was developed with reference to previous research with individuals with mental health difficulties (Draucker *et al.* 2009) that included a plan for reporting to the GP any issues of serious clinical concern. GPs were informed that their patients were taking part in the study, were provided with a synopsis of the overall results and the contents of the group sessions following GP feedback that they would like to understand the intervention their patients were receiving. The occupational therapists were CORU-accredited occupational therapists, competent in responding empathically to participant distress. The distress protocol was only implemented once in the case of a patient who expressed a high degree of depressive symptoms in her qualitative interview. The researcher paused the interview to probe more closely, using Mental Health First Aid principles (MHFA Australia 2021), about any risk. No such risk was determined. The ethical approval letter from the Irish College of General Practitioners (ICGP) is Appendix IV and the distress protocol is Appendix V.

Ethical amendments

Over the course of the study, the researcher sought ethical permission from the ICGP on a number of occasions when amendments to the study were necessary. An example of this was seeking permission to ask the occupational therapists to complete a short reflection after each group and to use these data to understand their perceptions of the ReDO®-10 programme better. Details of the amendments sought from the ICGP Research Committee and their responses are presented in Appendix VI.

Contribution to the published papers

This section will highlight the three papers arising out of this PhD study to date that have been published or accepted for publication. It will clarify the respective contributions of the PhD student Jackie Fox (JF), the two academic supervisors, Prof. Agnes Shiel (AS) and Prof. Lena-Karin Erlandsson (LKE) and other authors.

Paper 1: Systematic review (Published)

Citation: Fox, J., Erlandsson, L-K. and Shiel, A. (2019) 'A systematic review and narrative synthesis of occupational therapy-led interventions for individuals with anxiety and stress-related disorders', *Occupational Therapy in Mental Health*, 35(2), 179-204, doi: 10.1080/0164212X.2018.1516172 (Appendix I)

The review search terms and inclusion/exclusion criteria were drawn up by JF in conjunction with the academic supervisors and the University of Galway librarian. Initial searches and exclusion of results at the title/abstract stage was done by JF. All included papers were agreed on by all authors. Papers that partially met the inclusion criteria were reviewed independently by two different authors before inclusion/exclusion. The first draft of the published paper was written by JF. AS and LKE provided advice on content and editing. The paper was reviewed after the journal's editorial process by JF, approved by all authors and finished for publication by JF.

Paper 2: Feasibility study (Published)

Citation: Fox, J., Erlandsson, L-K. and Shiel, A. (2021) 'A feasibility study of the Redesigning Daily Occupations (ReDO®-10) programme in an Irish context', *Scandinavian Journal of Occupational Therapy*. Published online Feb 2021 doi: 10.1080/11038128.2021.1882561 (Appendix II)

The implementation of the ReDO®-10 groups in 2018 and 2019 was carried out by JF, including; recruitment, data collection over three time-points with all stakeholders and support for the ReDO®-10 facilitators. The data analysis was completed by JF. The first draft of the paper was written by JF and AS and LKE provided advice on content and editing. The paper was reviewed after the journal's editorial process by all authors and finished for publication by JF.

Paper 3: Mechanisms of change (Published)

Citation: Fox, J., Erlandsson, L-K., McSharry, J. and Shiel, A. (2021) 'How does ReDO®-10 work? Understanding the mechanisms of action of an intervention focused on daily activities and health from the perspective of participants**',** *Journal of Evaluation and Program Planning*, 102092, doi: 10/1016/j.evalprogplan.2022.102092 (Appendix III)

This paper gives an overview of a qualitative analysis of the data from the ReDO®-10 groups in 2018 and 2019, gathered and analysed by JF. In addition, this paper includes data from a small project carried out by Aideen McKiernan, an occupational therapy student, under the supervision of Dr Sinead Hynes in the University of Galway. This project, co-designed by JF, included another pilot ReDO®-10 group, followed by qualitative interviews with participants (See Chapter 4). The full data set was completely re-analysed by JF with expertise in behaviour change theory provided by Dr Jenny McSharry (JMS) at the University of Galway. The first draft of the paper was drafted by JF and AS, LKE and JMS provided advice on content and editing. The paper was reviewed after the journal's editorial process by JF, approved by all authors and finished for publication by JF.

Structure of the thesis

The thesis will begin with a review of the literature (Chapter 2) followed by an explanation of the research questions that guided the study (Chapter 3). An extensive methodology chapter is then presented (Chapter 4). Chapter 5 outlines the three published journal articles that have come from this study to date and gives an overarching summary of the results. Finally, Chapter 6 will discuss these findings further and outline possible future application and development of this work.

Chapter 2 - Literature Review

This chapter will provide a critical overview of the literature that forms the background to this research. Although a systematic review was published at the beginning of this PhD project, it only covered one aspect of the literature i.e. the effectiveness of occupational therapy-led interventions for individuals with anxiety and stress-related issues (Appendix I). It is acknowledged that the bodies of literature in relation to treatments for stress, primary care healthcare provision and occupational therapy programmes are all very broad and extensive. A comprehensive literature review of all of these areas would not be possible within the limits of this chapter. Because of the higher rates of help-seeking in primary care among women with psychological distress (Tedstone Doherty and Kartalova-O'Doherty 2010) and the acknowledgement of gender differences in the risk factors and treatment preferences for mental health issues (Pebole *et al*. 2021; World Health Organisation 2001), it was decided to focus this literature review and study on the experiences of women only. Therefore, this chapter will focus on the most up-to-date literature on the delivery of group-based mental health interventions at a primary care level for women with anxiety, depression, stress and/or psychological distress.

Search strategy

The following PICO search strategy was used:

P = women with psychological distress, stress, anxiety or depression in a primary care setting

I = group-based programmes, programmes that are predominantly discussion-based

C = any

O = improved mental health, other psychological health-related outcomes, functional outcomes e.g., return-to-work. Qualitative studies were included where they included a qualitative evaluation e.g., exploring satisfaction, acceptability or perceptions of change.

A number of exclusion criteria were applied to the literature (Table 1). A large number of abstracts were identified and reviewed. At the full-text review stage, it was evident that there was a large body of literature regarding women's groups in relation to

specific issues such as breast cancer, intimate partner violence and antenatal support/health. Although the groups in these studies addressed psychological distress, they were excluded in the final, detailed analysis as the populations were felt to have particular specialist health needs that would influence the theoretical mechanisms of the programme e.g. breast cancer support groups often address complex issues about fear of reoccurrence or communication with healthcare providers (For example Weis *et al.* 2019).

Table 1. Excluded literature with rationale

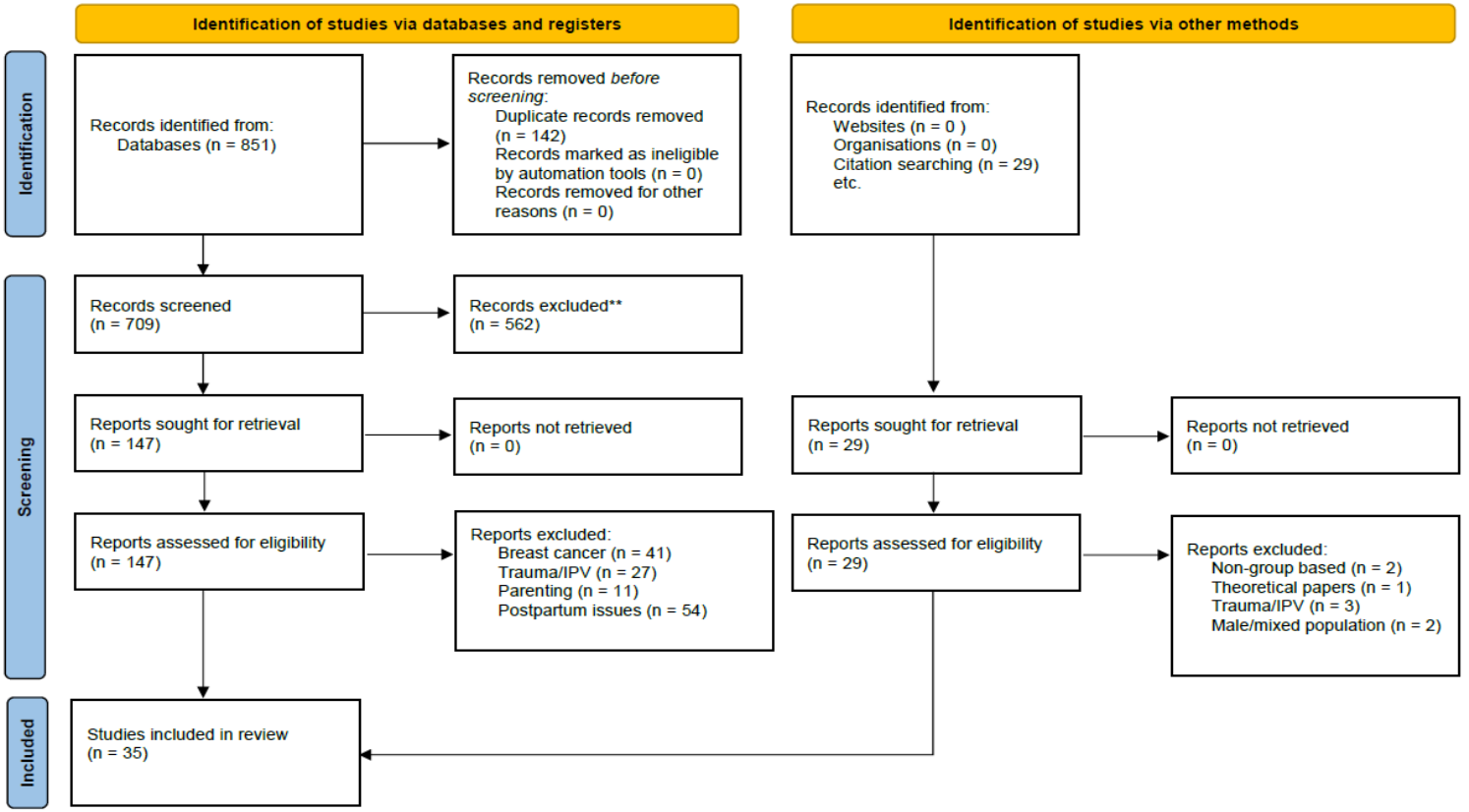
Excluded Literature	**Rationale**
Population = children or adolescents	This review is concerned with the experiences of adult women only
Population = men or mixed-gender	Groups designed for men, or for mixed-gender populations will not have a female gender-specific theoretical framework
Research studies that used cross-sectional methodologies	This review was concerned with the evaluation of group-based programmes, rather than studies exploring the association between variables e.g., the association between stress and age.
Setting = inpatient, forensic or other institutional settings	Programmes in institutional settings will not be comparable to those in primary/community settings – given the presumed severity of health/social issues in those settings.
Programmes/interventions delivered on an individual basis	Group-based interventions include social/group dynamics as part of the therapeutic process
Programmes/interventions that were purely physical exercise or medication-based. Also excluded were programmes that were concerned with physical health outcomes e.g. blood sugar levels, urinary continence.	This review was concerned with comparing groups that had (primarily) a talk/discussion-based framework. Purely physical exercise-based groups e.g., pelvic floor exercise or yoga, would be concerned with physiological mechanisms of change
Literature describing study protocols, theoretical perspectives or unrelated systematic reviews	This review was concerned with outcomes of group-based programmes that have been evaluated (qualitatively or quantitatively)
Literature published earlier than 2011	This exclusion criteria was applied after the initial literature search (see Prisma diagram). This was to limit the review to a manageable number of papers and the most up-to-date research. This is acknowledged as a limitation of this review
Programmes/interventions for women with issues relating to breast cancer, trauma, domestic violence or antenatal/post-natal health.	This exclusion criteria was applied after the initial literature search (see Prisma diagram and rationale given above).

A systematic literature search was completed in the SCOPUS, CINAHL and MEDLINE databases in February 2021. Table 2 outlines the search terms, Boolean logic and limiters applied in each database, as well as the number of papers found. The results were exported to the EndNote® software programme where they were sorted and reviewed. The reference lists of all studies included were checked for other relevant papers. Google Scholar was used to check for other citing papers in order to completely review the literature.

Table 2. Search terms and Boolean logic applied

Database and results found	**Search terms**	**Limiters applied**
SCOPUS (n=578) MEDLINE (n=198) CINAHL (n=75)	"psychological distress" OR stress OR anxiety OR depression" AND "primary care" OR community OR outpatient OR public AND "group-based" OR "group format" OR "group therapy" OR "group delivery" OR "psychotherapeutic group" OR "therapeutic group" OR "psychoeducational group" AND Female OR women OR woman OR "gender-specific" OR gender OR "single-gender"	Title, Abstract and Keyword only Limit to keywords "woman" OR "women" and exclude keyword "male" Limited to publication dates 2000-2021

Figure 1: PRISMA diagram representation of the literature search



Page et al. (2021) The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. International Journal of Surgery, 88, p.105918 https://doi.org/10.1016/j.ijsu.2021.105906

*562 Records were excluded during title/abstract screening. The reasons for exclusion are as follows; Pre-2011 (n = 197), non-adult population (n = 22), protocols/theoretical papers (n = 37), inpatient/prison population (n = 11), unrelated outcomes (n = 55), unrelated diagnoses (n = 73), non-group based programmes (n = 4), pharmacological treatments (n = 2), male/mixed populations (n = 33), cross-sectional studies (n = 124) and assessment development (n = 4

Literature Review

The final review included 35 papers, describing 18 studies. There was a very high degree of heterogeneity between all the group-based interventions for women with psychological distress described in these papers, despite the application of the strict inclusion/exclusion criteria above. For clarity, the studies are described, critiqued and synthesised in this chapter in theoretical categories in order to compare similar programmes. The details of all studies included are presented in table form under each theme of this review.

Interventions based on Cognitive-behavioural theory/approaches

Interventions using cognitive-behavioural (CBT) principles have been evaluated extensively to date and are recommended for primary care mental health interventions (NICE 2011). However, only five studies (seven papers) evaluating primary care, female-only groups based on CBT were found for this review. CBT is considered to modify and replace persistent negative thoughts and using behavioural experiments (desensitisation) to reduce avoidance (Beck and Beck 1995). The five programmes using this theoretical approach were evaluated using quasi-experimental approaches in five different countries (Table 3) (; Bernhardsdottir *et al.* 2013; Bernhardsdottir *et al.* 2014; Bernhardsdottir *et al.* 2018; Chetty and Hoque 2013; Cramer *et al.* 2011; Doornbos *et al.* 2018; Sahranavard *et al.* 2019).

Three papers reported on the design, qualitative and quantitative evaluation of a four-session group programme with female University students with psychological distress in Iceland (Bernhardsdottir *et al.* 2013; Bernhardsdottir *et al.* 2014; Bernhardsdottir *et al.* 2018). The programme included cognitive restructuring, affirmations and activity scheduling and was held on campus. Scores on the Beck Depression Inventory (BDI) and Beck Anxiety Inventory (BAI) measures showed a statistically significant improvement in the treatment group (n=19) compared to a no-therapy control (n=11) ($p<0.01$). Female university students in Iran were also evaluated in a study by Sahranavard *et al.* (2019). Thirty medical students were randomly assigned to a CBT-based treatment group, held in a campus environment and/or to a waiting list control group. The programme included material on study skills and some culturally-specific elements e.g. “cultivating honour”. Post-test evaluation showed a

significant improvement in anxiety, self-efficacy and hardiness ($p<0.001$) as measured on the BAI, Schwarzer's General Self-Efficacy Scale and the Ahvaz Hardiness Inventory respectively.

The longest programme in this category, delivered to women with depression in a community clinic in South Africa, consisted of 15 sessions based on cognitive therapy as outlined by the "Women's workbook" (Chetty and Hoque 2013; Gordon and Tobin 2002). Thirty women with depression were randomised to the treatment and control (usual care) arms and there was a statistically significant improvement in depression (measured on the BDI) in the treatment group at 12-week follow-up ($p<001$). A 12-session programme, delivered by community-recruited facilitators who were given CBT training, delivered non-significant improvements in depression symptoms for women (measured on the Patient Health Questionnaire (PHQ-9)) in a disadvantaged area of the UK (Cramer *et al.* 2011). Interestingly, this study explored the proposed mechanism of change, but a negative thoughts questionnaire used as a secondary outcome measure showed no differences between the treatment/control arms, despite the participants reporting perceived differences in qualitative interviews. Doornbos *et al.* (2018) also evaluated a programme for women in a disadvantaged area (in the US). Their four-session intervention was based on a nursing theory (the theory of self-care (Orem 2001)) but incorporated CBT content and used some community-based research approaches to explore acceptability with the population. The programme was delivered to 72 women by nursing students under supervision as part of their undergraduate training and participants showed statistically significant improvements in self-care knowledge, anxiety and depression from pre-test to 6-month follow-up ($p<001$). The authors used the Generalised Anxiety Disorder Assessment (GAD-7), the PHQ-9 (depression) and a researcher-constructed instrument for self-care knowledge, which was analysed for reliability during the study.

All studies in this category, despite using CBT principles, had different amounts of sessions and different session content making direct comparison difficult. However, trends towards effectiveness of this approach were shown, especially in studies that had a longer follow-up. A number of methodological issues were noted in these studies. Chetty and Hoque (2013, p.31) did not justify their recruitment of only Indian women living in South Africa for their study, or for "selecting" their 30 participants out of a possible 117 women meeting the inclusion criteria. There was no discussion of the cultural or socioeconomic appropriateness of a programme developed in the US (Gordon and Tobin 2002) being

applied in this context. The paper by Sahranavard *et al.* (2019), describing a programme for female Iranian medical students, had inconsistencies. The programme is described differently in text (ten sessions) and in a table (six sessions). One of their exclusion criteria was "unsatisfied students" (p.2) creating a high potential for bias in both participant outcomes and compliance. Two of the studies showed some methodological strengths in the process of intervention optimisation to a particular population. Doornbos *et al.* (2018) and Bernhardsdottir *et al.* (2018) carried out qualitative research with participants to understand the acceptability of their programmes and revised them accordingly. Doornbos *et al.* (2018) in particular held multiple rounds of focus groups with the local community and factors such as having ethnically-congruent groups and providing transport and childcare expenses were considered following community engagement. In summary, programmes based on cognitive-behavioural approaches show some effectiveness but need to be optimised to include other topics that are highlighted as meaningful to the target population.

Table 3. Interventions based on cognitive-behavioural theory/approaches

Article(s)	Participants	Site	Methodology	Intervention/Programme	Outcomes
(Bernhardsdottir *et al.* 2013; Bernhardsdottir *et al.* 2014; Bernhardsdottir *et al.* 2018)	N=30 (Female university students, aged 22-45, with psychological distress)	University setting, Iceland	Quasi-experimental design. Random allocation to intervention (n=19) and no-treatment control (n=11). Included qualitative evaluation.	Facilitated by psychiatric nurses. Followed brief CBT group therapy principles, including some activity scheduling. Four weekly group sessions	Significant improvements in depression (BDI) and anxiety (BAI) in intervention group compared to control ($p<0.01$). Qualitative findings showed acceptability and recommended increasing the number of sessions
(Chetty and Hoque 2013)	N=30 (Indian women, aged 25-66, diagnosed with mild-moderate depression	Community clinic, KwaZulu-Natal, South Africa	Quasi-experimental design, random allocation to intervention (n=15) and usual treatment control (n=15).	Nurse-facilitated. Followed CBT group therapy principles based on a workbook. Fifteen weekly group sessions	12 weeks post-intervention, treatment group showed significant improvements in depression (BDI) compared to control group ($t=8.34$, $p<0.001$)
(Cramer *et al.* 2011)	N=75 (Women aged 30-55, diagnosed with depression)	Disadvantaged area of the UK (Bristol)	Pilot RCT. Random allocation 2:1 in favour of the intervention arm (n=49) vs usual care (n=26).	Facilitated by non-specialists trained with a five-day CBT course. Followed cognitive therapy principles. Ten weekly group sessions followed by two booster sessions.	Non-significant improvements in depression (PHQ-9) in intervention group compared to control. Qualitative findings showed acceptability but issues with attendance reported.
(Doornbos *et al.* 2018)	N=72 (Women, aged over 18, self-identifying at risk for anxiety/depression)	Urban, low-income area of the US	Quasi-experimental design, non-equivalent comparison group.	Facilitated by community health workers/nursing students. Followed principles of the nursing theory of self-care – coping strategies and CBT	Significant improvements in anxiety (GAD-7) and depression (PHQ-9) reported ($p<0.01$). Improvements in self-care knowledge also

			Programme was part of undergraduate nursing student training.	techniques. Six group sessions over four months.	reported (author-created instrument).
(Sahranavard *et al.* 2019)	N=30 (Female medical students, aged 20-24, Beck Depression Inventory score >16).	University of Medical Sciences, Iran.	Quasi-experimental design, non-random assignment to treatment (n=15) and no treatment (n=15)	Facilitated by CBT-trained therapists. Followed CBT principles with some cultural variation. Ten weekly group sessions.	Significant improvements in anxiety (BAI), self-efficacy (Schwarzer's General Self-Efficacy Scale) and hardiness (Ahvaz Hardiness Inventory) reported ($p<0.001$)

Interventions based on Mindfulness theory/approaches

Similar to cognitive-behavioural approaches, mindfulness approaches to the treatment of anxiety, depression and psychological distress have been explored extensively in recent years (Strauss *et al.* 2014) and are a recommended form of treatment (Kuyken *et al.* 2012). Mindfulness involves "intentionally paying sustained attention to ongoing sensory, cognitive and emotional experiences without elaborating or judging any part of that experience" (Kabat-Zinn 2005, cited in Burnett-Zeigler *et al.* 2016, p.60). However, only one study evaluating a mindfulness-based programme for women with mild-moderate depression or distress specifically in the last 10 years was found. A study carried out using a pre-test, post-test design (Burnett-Zeigler *et al.* 2016) and a qualitative evaluation (Burnett-Zeigler *et al.* 2019) explored an eight-session programme called M-Body in a disadvantaged urban area of the US. Participants were 31 African-American women diagnosed with depression or self-referred with psychological distress. This programme incorporated practical mindfulness exercises such as meditation and yoga, as well as psychoeducation around topics such as self-compassion and mindful communication. Participants were asked to do some daily mindfulness-based homework, but the qualitative data showed that personal and contextual barriers meant that only a small minority of women practiced mindfulness in between sessions. At the 16-week follow-up, participants demonstrated a statistically significant improvement in depression ($p=0.04$), stress levels ($p<0.01$) and mindfulness ($p<0.01$) on the Inventory of Depressive Symptoms, the Perceived Stress Scale and the Five Facet Mindfulness Questionnaire respectively. However, there were no significant changes in overall well-being (Ryff Scale of Psychological Wellbeing) or functioning (WHODAS 2.0) (Burnett-Zeigler *et al.* 2016). A limitation of this study is the lack of a control group and the lack of formal monitoring of the mindfulness homework. The authors also highlight that this population were exposed to many environmental and interpersonal stressors that may have impacted their participation and the degree to which depression could have been mitigated. This study shows the potential difficulty of asking women, who are experiencing many stressors already to include unfamiliar mindfulness activities in a daily practice, which was also identified as linked to outcomes of other mindfulness-based programmes (Vettese *et al.* 2009).

Table 4. Interventions based on Mindfulness theory/approaches

Article(s)	Participants	Site	Methodology	Intervention/Programme	Outcomes
(Burnett-Zeigler *et al.* 2016; Burnett-Zeigler *et al.* 2019)	N=31 (African-American women, aged 18-65, diagnosed with depression or self-referred with psychological distress	Community clinic in an urban, disadvantaged area of the US (Chicago)	Pre-test, post-test design with follow-up (16 weeks). Also qualitative focus groups to explore feasibility	Facilitated by clinical psychologist with training in mindfulness. Programme called "M-Body" – including mindfulness practices and psychoeducation. Eight weekly sessions including daily mindfulness homework.	Significant improvements in depression (IDS-SR), mindfulness (FFMQ) and stress levels (PSS) ($p=0.04$), but no significant improvement in functioning (WHODAS 2.0) or overall wellbeing (RYFF).

Interventions based on Positive Psychology theory/approaches

An emerging body of research evaluates positive psychology interventions (PPI) for mental health (Bolier *et al.* 2013). Five papers from the same group of authors evaluating a group-based PPI intervention for women with depression were found (Blanco *et al.* 2020; Chaves *et al.* 2017; Lopez-Gomez *et al.* 2017a; Lopez-Gomez *et al.* 2017b; Lopez-Gomez *et al.* 2019;). PPI interventions focus on positive aspects of human flourishing, such as developing gratitude, resilience, self-compassion and cultivating positive emotions and relationships (Chaves *et al.* 2017). A controlled clinical trial to compare a PPI programme called IPPI-D (n=62) with CBT (n=66) for women with depression/dysthymia was carried out in Spain (Chaves *et al.* 2017; Lopez-Gomez *et al.* 2017a). Mental health symptom scores (BDI-II) decreased and positive functioning scores (Global Assessment of Functioning) increased for participants in both conditions ($P \leq 0.01$). The effect sizes were large for both groups for depression outcomes, but favoured the IPPI-D. IPPI-D participants were significantly more satisfied with their treatment than the CBT participants (p=0.004) (Lopez-Gomez *et al.* 2017b). A network analysis, based on the same data, was carried out to explore patterns of changes in the network of symptoms of depression following IPPI-D and CBT (Blanco *et al.* 2020). The authors found that IPPI-D was more successful than CBT in changing well-being by strengthening both negative (i.e. reduction of symptoms on the BDI-II) and positive (Pemberton Happiness Index) psychological variables. An evaluation of the pattern of improvements for participants in both groups found that depression and wellbeing improved at the same rate across four measured time points (Lopez-Gomez *et al.* 2017b).

This study had a number of methodological strengths: the use of an active control group, an intention-to-treat analysis and the detailed breakdown of drop-out/baseline characteristics, confounders (e.g. medication) and numbers of sessions attended, which allowed for more nuanced analysis of acceptability and reaction to the different treatments. For example, it was found that people with more negative thoughts at baseline (on the Automatic Thoughts Questionnaire) were more satisfied with the PPI treatment (Lopez-Gomez *et al.* 2017b) and responded better to that treatment (Lopez-Gomez *et al.* 2019) suggesting that for some individuals with depression, drawing attention to negative thinking (as in CBT) may actually be counterproductive (Castonguay *et al.* 2004). However, the fact that the IPPI-D programme was developed for this study (without a process evaluation of the content) and the sample size, which does not allow for full statistical power to be confirmed are limitations of this study. Nearly half of the participants in both groups still met the

criteria for a depressive/dysthymic diagnosis following the interventions. Nevertheless, this body of research suggests that considering person-specific factors (such as level of negative thoughts) when choosing psychotherapeutic interventions may be important to achieve optimum outcomes.

Table 5. Interventions based on positive psychology theory/approaches

Article(s)	**Participants**	**Site**	**Methodology**	**Intervention/Programme**	**Results**
(Blanco *et al.* 2020; Chaves *et al.* 2017; Lopez-Gomez *et al.* 2017a; Lopez-Gomez *et al.* 2017b; Lopez-Gomez *et al.* 2019;)	N=128 (Women aged over 18, diagnosed with depression or dysthymia)	Women's health centre, Spain.	Controlled clinical trial. Participants randomised to treatment (n=62) and active comparison (n=66) (CBT). Satisfaction, acceptability, longitudinal and network analyses also completed.	Both programmes delivered by therapists. IPPI-D included; optimism, gratitude, self-compassion, identifying personal strengths and resilience. CBT delivered as per an established manual (Lewinsohn *et al.* 1984). 10 weekly sessions (each arm).	Mental health symptoms (BDI-II) and positive functioning (GAF) significantly improved in both conditions ($p \leq 0.01$).

Interventions based on theory/approaches relating to racism or designed for people of specific ethnicities

Two programmes that evaluated outcomes for women of specific ethnicities were found. Both 8-week group programmes were designed based on race-specific experiences and delivered by ethnically-congruent therapists. RISE, (Resilience, Stress and Ethnicity) was evaluated in a small randomised controlled trial (Saban *et al.* 2021) and using qualitative methods (Conway-Phillips *et al.* 2020) with African-American women in an urban US context. This programme is underpinned by allostatic load theory (McEwen 1998) which posits that cumulative life stress places wear and tear on the body systems and predisposes some individuals, particularly those experiencing structural inequality and stressors such as racism, at greater risk for cardiovascular disease and poor health outcomes (Geronimus *et al.* 2006). The 8-week group programme includes psychoeducation with an emphasis on recognising and validating responses to racism, re-shaping beliefs such as self-stigma and shame, acknowledging past trauma and identifying strategies for resilience and coping (Conway-Phillips *et al.* 2020). Compared to a no-treatment control group (n=34), the intervention group (n=40) had lower levels of avoidance coping ($p \leq 0.01$) (on the Ways of Coping Questionnaire) and a non-significant decline in stress-related inflammatory markers following the intervention (Saban *et al.* 2021). There was no association between the intervention and decline in depression, stress or anxiety symptoms (on the Depression, Anxiety and Stress Scale (DASS-21)), although these levels were already low at baseline. Qualitative data showed that participants identified an increase in stress during some sessions, as their attention was drawn to racism-related issues, but reported feeling more empowered after the whole programme (Conway-Phillips *et al.* 2020).

A programme called AWARE (Asian Women's Action for Resilience and Empowerment) was evaluated with Asian-American female students in a US university campus context (Hahm *et al.* 2020a). AWARE was also evaluated specifically for women with experience of intimate partner violence (Hahm *et al.* 2019; Rivera *et al.* 2019) and is the subject of a theoretical paper (Hahm *et al.* 2020b), but these papers did not meet the inclusion criteria for this review. As with RISE, AWARE targeted race-related stress, but used theory specifically relating to "empowerment traps" that Asian-American women face, including family-level expectations, race-expectations of Asians as a "model minority" and a self-critical inner voice (Hahm *et al.* 2017). Eight weekly group sessions are supplemented by daily supportive text messages and the group content includes psychoeducation about

family structures and developing boundaries, identifying self-critical thoughts, recognising and coping with racist micro-aggressions and destigmatising seeking support. In an uncontrolled feasibility study, 37 female students with depression, anxiety or PTSD were enrolled in three AWARE groups. Authors report statistically significant improvements in depression (CESD-R), anxiety (HADS-A) and PTSD symptoms (PCL-C) post-intervention ($p<0.001$) with a large effect size (Cohen's $d = 0.92$).

There was some lack of clarity in the reporting of the RISE study reducing the transparency. The Index of Race-Related Stress was used to measure perceived racism-related stress at baseline, but was not measured post-intervention (Saban *et al.* 2021). This would have been an important outcome to measure, since high levels of race-related stress in this population was the rationale for developing this intervention. There was also no explanation why only women specifically in the age bracket 50-75 were invited to the qualitative focus groups (Conway-Phillips *et al.* 2020). The lack of a control group is a limitation in the evaluation of the AWARE programme, as is the lack of any follow-up measurement of outcomes (Hahm *et al.* 2020a).

Table 6. Interventions based on theory/approaches relating to racism or designed for people of specific ethnicities

Article(s)	Participants	Site	Methodology	Intervention/Programme	Results
(Conway-Phillips *et al.* 2020; Saban *et al.* 2021)	N=74 (Black women aged >21, with psychological distress and risk factors for cardiovascular disease	University campus, Chicago, US. Women recruited from Chicagoland area.	RCT feasibility study with qualitative evaluation. Women randomised to RISE (n=40) or no treatment control (n=34). 22 participants provided qualitative data following the programme	Resilience, Stress & Ethnicity (RISE). Delivered by Black clinical psychologists. Programme included; understanding racism, addressing trauma and coping. 8 weekly sessions plus daily home exercises	No significant differences in depression, stress or anxiety (DASS-21). RISE participants showed reduction in avoidance coping (WCQ). Non-significant reductions in inflammatory markers in RISE participants. Participants qualitatively reported increased awareness of race-based stress and empowerment.
(Hahm *et al.* 2020a)	N=48 (Asian-American women, unmarried, aged 18-35, diagnosed with depression, anxiety or trauma.	University campus locations in the US.	Feasibility study. 5 pilot groups with pre/post evaluation.	AWARE (Asian Women's Action for Resilience and Empowerment). Delivered by Asian-American therapists. 8 weekly sessions. Programme included; understanding "disempowerment traps" on individual, family, community and system levels.	High retention and intervention fidelity rates. Statistically significant improvement ($p<0.001$) in depression (CESD-R), anxiety (HADS-A) and PTSD (PCL-C).

Interventions based on Body Awareness theory/approaches or including some physical activity

Although studies describing purely physical exercise-based programmes were excluded from this literature review (see inclusion/exclusion criteria), some papers describing programmes where physical movement was incorporated within group sessions to improve mental health augmenting and being supported by group psychotherapy were found. Two interventions in this category were developed from the perspective of psychiatric physiotherapy, which focuses on how physical motion and emotions are connected and helps people develop ways to stay with uncomfortable physical sensations of stress and/or express/release them through movement (Danielsson 2015). Ölund *et al.* (2020) describe a physiotherapeutic group treatment that incorporated basic body awareness therapy and acceptance and commitment approaches in a manualised programme called "Anxiety Management in Movement and Rest (AMMR)". This group programme is offered as part of usual care in the study site which was an outpatient mental health clinic in Sweden. Qualitative interviews were completed with 11 women who completed AMMR as part of their treatment and participants indicated that the supportive group environment and the body awareness exercises, particularly those related to physical grounding, were valued. The authors acknowledged some participants, with more complex psychiatric backgrounds including issues with attachment, had difficulty contributing in a group setting and reported less benefit from the intervention.

A series of groups developed by Strömbäck and colleagues (2013; 2016) combined mind-body physiotherapy with a feminist perspective. The authors theorise that stressors for young women are situated in social constructions and expectations of their gender which they describe as being "a normative and constrained femininity" (Strömbäck *et al.* 2013, p.4). This can lead to a woman's body itself being seen as "both the expression and object of distress" (McLaughlin, 2005, cited in Strömbäck *et al.* 2016, p.21). Body awareness activities to improve grounding, breathing, balance and verbal expression of body experiences were combined with discussion about gender and stress for young women. Fifty-four young women (≤ 25 years) completed the programme in a youth health centre in Sweden, but complete pre-post data were only available for 32 participants. The authors report statistically significant improvements in symptoms of anxiety/depression on the Adult Self-Report scale ($p<0.01$) and self-image using Structural Analysis of Social Behaviour ($p<0.01$) (Strömbäck *et al.* 2016).

Qualitative interviews showed that the participants saw the groups as a safe space, an oasis to challenge gender expectations and that non-judgemental acceptance had been important in changes that occurred reflecting the fact that young women can feel in competition with each other socially in other contexts (Strömbäck *et al.* 2013). While these physiotherapeutic studies indicate potential for mind-body interventions, the programmes should be evaluated using more robust methodologies in order to clearly show effectiveness. Issues such as having a large amount of missing data (Strömbäck *et al.* 2016), lack of clarity about how participants were recruited/selected for qualitative interviews and evaluation interviews being completed by the treatment providers (Strömbäck *et al.* 2013; Ölund *et al.* 2020) mean that it is likely that only participants moderately satisfied with the intervention provided evaluation data in these studies.

One other intervention in this category aimed to bring physical exercise and psychoeducation together, with the rationale that both treatments have an evidence-base in the treatment of anxiety and depression (Cuijpers *et al.* 2009; Conn, 2010). The "Exercise Without Worries" (EWW) programme was developed in the Netherlands for low-SES women with depressive or stress-related concerns and combined a standard "Coping with Depression" course with low-intensity exercise in 8 weekly sessions based on themes (e.g. a group discussion on emotional strength was augmented with physical strength-based exercise). This paper was included in this systematic review as the purpose of the physical movement in the sessions was to underpin the discussion-based content as in Strömbäck *et al.* (2016). An RCT compared EWW (n=55) with an exercise only condition (n=46) and a waiting list control group (n=48) (Van der Waerden *et al.* 2013). Only the participants in the exercise-only arm of the trial showed statistically significant improvements in depression (CES-D) and perceived stress scores (PSS) at 6- and 12-month follow-up ($p<0.01$) although participants across all three arms of the trial showed some improvements. A process evaluation was carried out with 15 cohorts of women completing the EWW course (n=135). This included some who had participated in the RCT previously described. There was considerable drop-out from the EWW programme across the process evaluation time period. Of 135 recruited, 36 did not attend any EWW sessions and only 66 completed the evaluation questionnaire. Of those, mean satisfaction rates with the intervention content was 8.71 (out of 10). The authors of the EWW programme acknowledge that they shortened the number of sessions normally given in similar psychoeducation interventions and that the exercise component did not reach the amount or intensity for therapeutic benefit (Van der Waerden *et al.* 2013). It is therefore possible that neither component had a sufficient "dose" to be effective.

Table 7. Interventions based on body awareness theory/approaches or including some physical activity

Article(s)	**Participants**	**Site**	**Methodology**	**Intervention/Programme**	**Results**
(Ölund *et al.* 2020)	N=11 (Women aged 23-43 years, with an anxiety diagnosis).	Mental health outpatient clinic.	Qualitative, descriptive, retrospective design. Interviews were carried out 1-2 months after participation in the programme.	"Anxiety Management in Movement and Rest" (AMMR) Delivered by physiotherapists. Programme included: meditation, psychoeducation, acceptance of anxious sensations and 15-min daily homework. 10 weekly sessions.	Qualitative outcomes reported were; becoming more grounded in the body, identification with other group members and becoming more self-compassionate.
(Strömbäck *et al.* 2013; Strömbäck *et al.* 2016)	N=54 (Young women aged ≤ 25 years, who sought help for stress-related issues).	A youth health centre in Sweden	Pre-post design, including a qualitative evaluation (interviews). Seven cohorts of participants were evaluated pre-post the intervention and 32 were interviewed.	Gender-sensitive stress management programme. Delivered by physiotherapists and psychologists. Programme included; psychoeducation about stress, thematic discussions on gender expectations and a body-awareness exercise. 8 weekly sessions.	Full pre-post data available for n=32. Statistically significant improvements reported in self-image (SASB) ($p<0.01$), anxiety/depression symptoms (ASR) ($p<0.01$) and body perception (BPQ) ($p<0.05$). In qualitative interviews, participants reported change in how they viewed their body and felt empowered as a group of young women.

(Van der Waerden *et al.* 2011)	N=135 (Women aged 20-55, from low-SES backgrounds, with depressive or stress-related complaints).	Primary care setting (community centres) in the Netherlands	Process evaluation of attendance, fidelity, reach, levels of satisfaction (scored 1-5) and appreciation of the intervention content (scored 1-10) for each session.	"Exercise without Worries" (EWW). Delivered by a mental health practitioner and an exercise professional. Programme included; psychoeducation based on the Coping with Depression course (Cuijpers *et al.* 2009) plus 60 minutes low-moderate intensity exercise. 8 x 2-hour weekly sessions.	Overall satisfaction with intervention content was 8.71 (range 6.5-10) (n=66 questionnaires completed)
(Van der Waerden *et al.* 2013)	N=149 (Women aged 20-55, from low-SES backgrounds, with depressive or stress-related complaints).	Primary care setting (community centres) in the Netherlands	RCT. Participants were randomised to the EWW intervention (n=55), an exercise-only condition (E) (n=46) and waiting-list control condition (C) (n=48). Data collection at baseline, post-intervention and at 2, 6 and 12 months follow-up.	"Exercise without Worries" (EWW). Delivered by a mental health practitioner and an exercise professional. Programme included; psychoeducation based on the Coping with Depression course (Cuijpers *et al.* 2009) plus 60 minutes low-moderate intensity exercise. 8 x 2-hour weekly sessions.	Participants in the exercise-only condition showed statistically significant improvement in depression (CES-D) ($p<0.01$) and perceived stress (PSS) ($p<0.01$) by 6 and 12-month follow-up. Participants in all conditions showed improvement over the study period.

Interventions designed for low-resource settings and non-specialist delivery

Two papers describing programmes for women living in low-income settings were found, although a number of very similar papers (such as Khan *et al.* 2019) were excluded as they recruited women living with trauma or in conflict zones specifically. These two studies describe attempts to intensify treatments for common mental health difficulties in low-resource settings, such as training non-specialist group facilitators and using informal settings such as rural village centres. Petersen *et al.* (2012) describe a pilot study, including both process and outcome evaluation, in which a version of group-based Interpersonal Therapy was evaluated with women with moderate/severe depression in a low-income, South African context. The 12-week group programme was evaluated with 30 women and a further 30 women received enhanced usual care. Community health workers received training and supervision from psychologists and delivered sessions focused on coping with the interpersonal and contextual causes of depression e.g. grief (particularly around HIV-related bereavement), interpersonal conflict, life transitions and financial stress (Petersen *et al.* 2012). Over the three timepoints (baseline, post-intervention and 24-week follow-up), mean Beck Depression Inventory scores were 34.85-17.85-12.90 (Intervention group) and 32.45-31.23-26.86 (Control group) ($p < 0.0001$). The authors also report a significant improvement in psychological functioning on the HSCL-25 in the intervention group, compared to the control group (2.99-1.60 vs 2.64-2.26, respectively, $p < 0.0001$).

The second study in this category was a cluster randomised control trial of the WHO Problem-Management Plus (PM+) programme adapted for group delivery in rural Pakistan (Rahman *et al.* 2019). This programme has been evaluated in other studies with mixed populations (Jordans *et al.* 2021) and with women living with post-conflict trauma (Khan *et al.* 2019), but these papers fell outside the scope of this chapter. PM+ was developed to be a brief, transdiagnostic programme that can be rolled out rapidly in low-resource settings and includes topics such as problem solving, behavioural activation and group-supported problem-solving (Dawson *et al.* 2015). The intervention was delivered by local women with bachelor degrees who received training and supervision from psychologists. Recruitment and assessment were carried out by local, female research assistants and there was close collaboration with existing "lady health workers" to ensure sensitivity with the community. The group facilitators used locally relevant pictorial materials and narrative (story-telling) methods in a non-clinical setting (a local house). Using cluster randomisation at the level of the community (approximately 150 households), 306 women aged 18-60 scoring above the

cut-off for psychological distress on the GHQ-12 were randomised to the PM+ programme and 306 received enhanced usual care. Those receiving the programme had significantly lower mean scores on the HADS three months post-intervention (10.01 vs 14.75, p=0.0007).

There was little description of individual intervention sessions or how interpersonal therapy (IP) was adapted to the South African setting in the paper by Petersen *et al.* (2012), particularly as the authors note that IP was specifically developed in a Western context. Because participants were assigned to the comparison group based on the basis of whether they were available, it is likely that the intervention participants had greater need or availability to participate which may explain their greater improvement over the study period. Results are only reported for 20 participants who completed all assessments, indicating a 33% loss of follow-up data. The cRCT by Rahman *et al.* (2019) had a high degree of rigor, including blinded randomisation and assessment, measures to ensure ethical consent and participation for non-literate participants, close supervision of group facilitators and an assessment of treatment fidelity. However, as in many studies with a treatment-as-usual control group, usual care differed widely between individuals. No follow-up data were collected after 3 months. Longer-term evaluation of effectiveness of mental health interventions in low-income countries is often lacking in RCTs (Barbui *et al.* 2020). In both studies, although the causes of mental distress are described as contextual (being related to poverty, gender-based abuse or role restriction or the after-effects of war and conflict), the emphasis in the programmes is on individual "behavioural strategies" (Rahman *et al.* 2019, p.1734) or "personal agency, resilience and coping" (Petersen *et al.* 2012, p.340). There is an increasing debate among critical theorists about how interventions that place responsibility for coping with unequal life circumstances on the person themselves reduces the responsibility of government and society to ameliorate such conditions and are unlikely to lead to long-term health improvements, as arguably they do not address the real causes of the distress (see Kaplan (2019) for an overview of this debate).

Table 8. Interventions designed for low resource settings and non-specialist delivery

Article(s)	Participants	Site	Methodology	Intervention/Programme	Results
(Petersen *et al.* 2012)	N=60 (Women aged >18, with moderate depression, living in poor socio-economic conditions)	Community clinic, rural KwaZulu-Natal, South Africa.	Outcome and process evaluation (n=30) with a non-randomised comparison group (n=30) receiving enhanced normal care. Pre, post and 24-week follow-up.	South-African adapted, group-delivered Interpersonal Therapy. Delivered by community health workers who received training and supervision from psychologists. Programme included; coping with grief, interpersonal conflicts, life transitions and financial stress. 12 weekly sessions.	Mean scores on the BDI reduced from 34.85 to 12.90 at follow-up (I) compared to a reduction of 32.45 to 26.86 (C) ($p<0.0001$). Global psychological functioning (HSCL-25) also improved significantly. Group support was reported as particularly important in qualitative interviews.
(Rahman *et al.* 2019)	N=611 (Women aged 18-60, with clinically significant distress (on the GHQ-12))	In the homes of lady health workers (LHWs) in Swat district, rural Pakistan.	Single-blind, cluster RCT. Community clusters (approx. 150 households) were randomised to the intervention (n=306) and enhanced usual care (n=306).	A group-based version of the WHO Problem Management Plus (PM+) intervention. Delivered by local women who had a bachelor degree but no mental health experience, with training and supervision. Programme included; motivational interviewing, behavioural activation, stress management, problem solving and strengthening social support. 5 x 2-hour sessions.	At 3-month follow-up, mean HADS scores were significantly lower in the intervention group compared to the control group ($p=0.0007$). Improvements in functioning (WHODAS 2.0) were also greater for the intervention group (*ns*). Significant post-intervention improvements in PTSD were not maintained at follow-up.

Interventions based on Occupational Therapy theory/approaches, including the Redesigning Daily Occupations (ReDO®) programme

In this final category eleven papers describing interventions based specifically on occupational therapy theories were identified. These all included women experiencing stress-related issues and had an emphasis on returning to work following sick leave. This category included nine papers describing the quantitative, qualitative and long-term follow-up evaluation of a quasi-experimental trial of the Redesigning Daily Occupations (ReDO®) programme for women on stress-related sick leave in Sweden. A theoretical paper outlining the content of the programme (Erlandsson 2013) was not included in this literature review, but provided background to the evaluative papers. The programme was developed based on research on the relationship between occupational patterns, stress and health for women (See Chapter 3 for further detail on the theoretical underpinning of ReDO®). The programme consisted of twice-weekly group sessions over 10 weeks, followed by a 6-week return-to-work placement supported by three follow-up sessions. Sessions focused on self-analysis of occupational patterns and occupational balance, identifying stressful or uplifting daily activities and group support to problem-solve making changes to daily life (Erlandsson 2013). Women were referred by Social Insurance Officers in one Swedish district (n=42) and a comparison group was selected and matched in a neighbouring district (n=42). This comparison group received care as usual, which consisted of individualised work rehabilitation such as CBT, physical therapy or work training (Eklund and Erlandsson 2011).

A wide range of outcomes were evaluated over the nine papers. ReDO® participants showed slower return-to-work rates and higher sick leave rates immediately after the programme, but at 12 months, the return-to-work rates were 59% (ReDO®) and 37% (CAU) respectively (Eklund and Erlandsson 2011). Both ReDO® and CAU participants showed significant improvements in occupational value (measured on the OVal-pd instrument), with ReDO® participants improving more on satisfaction and participation in everyday occupations (Satisfaction with Daily Occupations (SDO) assessment) (Eklund and Erlandsson 2014). There were no significant differences in quality of life (MANSA) or mastery (Pearlin Mastery Scale), although the ReDO® participants showed more improvement over time (Eklund and Erlandsson 2013). A mixed methods follow-up study three years after the initial trial showed that both ReDO® and CAU participants had similar work and sick leave rates. However, ReDO® participants reported higher rates of satisfaction with daily occupations (SDO) and occupational value (OVal-pd) (Eklund 2017). Qualitative

interviews with participants showed that the programme was well-accepted, particularly the group support and occupational self-analysis, but return-to-work following sick leave remained a stressful process (Wästberg *et al.* 2013).

A methodological issue with the ReDO® trial was the non-random allocation of the comparison group. Almost all baseline measures showed that women in the comparison group were significantly different to those in the ReDO® group. For example, CAU participants had more previous rehabilitation, better self-esteem and lower rates of anxiety and depression than ReDO® participants to begin with (Eklund and Erlandsson 2011; Eklund 2013). A reform process in the Swedish Social Insurance system also forced women in the CAU group back to work at a greater rate (Eklund and Erlandsson 2011). It is likely that these factors may have led to underestimation and/or overestimation of the effect of the ReDO® programme, as the results may have been due to contextual factors e.g. being required to return to work by an employer.

Agosti *et al.* (2019) describe an intervention with a similar therapeutic focus to the ReDO®, but delivered to women still in employment with a focus on preventing stress-related sick leave. The Balance in Everyday Life Empowerment (BELE) programme was developed following consultation with the author of the ReDO® (Personal communication, Erlandsson 2017) but was developed as a multidisciplinary intervention and thus contains some similar session topics including; occupational balance, occupational value, goal-setting and occupational patterns (Agosti *et al.* 2019). In contrast to ReDO®, the BELE programme also included sessions on health competence and workplace health promotion and was evaluated with female employees of one single organisation (n=55). All participants contributed to focus groups after the 10-week programme. Eight participants were also interviewed in-depth. The value of bringing awareness to one's own time use together with the importance of making empowered decisions about occupational choices was recognised by participants. The complexity of making daily life changes within the context of the family unit was acknowledged as a gender-based barrier. A strength of this study was the inclusion of all participants in the focus groups, giving a range of perspectives. However, the focus groups were facilitated by the leaders who had delivered the programme, leading to a risk of response bias.

Finally, one paper in this category described a therapeutic gardening intervention to improve outcomes for women in vocational rehabilitation for stress or burnout. Lidén *et al.* (2016) describe a programme attempting to bring together therapeutic gardening with a return-to-work focus – the Four Leaf Clover project. This programme was a combination of therapeutic horticulture (gardening and handicrafts in a natural environment), group-based discussion and the one-to-one input of a job coach to support the participant back to work or into new employment. There was a strong emphasis on the importance of the natural environment (the Alnarp Rehabilitation Garden) as a therapeutic mechanism in this intervention. Of 129 participants who began the programme, pre, post and follow-up data were only available for 52. Health-related quality of life scores (measured on the SF-36) were compared to a matched comparison dataset (n=1370) drawn randomly from a national Swedish database. There were statistically significant improvements on some SF-36 subscales between baseline and follow-up, such as social functioning ($p<0.001$) and mental health ($p<0.01$). However, scores on all subscales remained substantially lower than the reference group scores. Lidén *et al.* (2016) acknowledge the difficulties completing research within an already established clinical programme, including a heterogeneous client group experiencing multiple social stressors, but the loss of data from baseline to follow-up means that results may be skewed. One issue identified was that those who dropped out were more likely to be on long-term unemployment benefit.

Article(s)	Participants	Site	Methodology	Intervention/Programme	Results
(Eklund and Erlandsson 2011; Eklund 2013; Eklund and Erlandsson 2013; Eklund *et al.* 2013; Wastberg *et al.* 2013; Eklund and Erlandsson 2014; Eklund *et al.* 2015; Wästberg *et al.* 2016; Eklund 2017)	N=84 (Women aged >18, on sick leave for stress-related diagnoses)	Work rehabilitation setting, Sweden.	Quasi-experimental trial including qualitative evaluation and 3-year follow-up. Women recruited to ReDO® (n=42) and a matched comparison group (n=42)	The Redesigning Daily Occupations (ReDO®) programme. Delivered by occupational therapists with ReDO® training. Programme included occupational self-analysis, goal-setting and strategies for making changes to patterns of everyday activities. Twice-weekly sessions for 16 weeks. The final 6 weeks includes return-to-work placement.	Return-to-work rate at 12 months was 59% (ReDO®) vs 37% (comparison) but this difference was not maintained at 3-year follow-up. Non-significant improvements in anxiety and depression (HADS) also seen.
(Agosti *et al.* 2019)	N=55 (women aged 23-64, with stress-related health problems or with an interest in preventing health problems).	A local authority workplace in Sweden	Qualitative evaluation using focus groups (n=55) and interviews with a selection of participants (n=8).	Balance in Everyday Life (BELE) programme. Delivered by a health educator and two occupational therapists. Programme included; work-life balance, occupational patterns, occupational value and goal-setting. 10 weekly sessions and one follow-up (3 months).	Qualitative data indicate that the programme helped women to analyse their everyday life and strengthen inner resources.
(Lidén *et al.* 2016)	N=129 (Women aged >18, with reduced working capacity due to illness).	Alnarp Rehabilitation Garden, Sweden	Cohort study. Data collection at baseline, post-intervention and after a period of job coaching (n=52). Data was compared to an age/gender-matched reference group (n=1370)	"The Four Leaf Clover" programme. Delivered by physiotherapists, occupational therapists, social workers and counsellors. Programme combined horticultural therapy and supported employment. 14 weeks of group sessions.	Complete dataset was n=52. Health-related quality of life (SF-36) improved for some subscales (such as social functioning) but remained lower than controls.

Table 9. Interventions based on Occupational Therapy theory/approaches

Limitations of the literature review

Because of the strict inclusion/exclusion criteria for this literature review, a number of papers that could have some relevance were excluded. For example, the study by Olsson *et al.* (2019), reporting on an evaluation of the ReDO®-10 programme and a number of studies involving nature-based programmes (Eriksson *et al.* 2011; Hellman *et al.* 2013) were excluded because, even though the papers reported only outcomes for female participants, the interventions had a mixed population. Many studies with a strong emphasis on the female experience with trauma, cancer or interpersonal violence (for example; Sayin *et al.* 2013; Rizo *et al.* 2018; Weis *et al.* 2019) were also excluded, even though female-specific group support was a crucial therapeutic mechanism cited in these programmes. Interventions designed to support women with female-specific health concerns such as pregnancy and with the transition to specific roles, such as parenting were also excluded.

Of the papers that were included, many had small sample sizes or only used qualitative methods to evaluate programmes. However, qualitative research can provide important insights into how complex interventions might work and the psychological reactions of participants to them (O'Cathain *et al.* 2014), so these papers were deemed relevant. The breadth and range of research into programmes for women with, or at risk for, psychological distress is wide and growing. A date range from 2011-present was set for this literature review, which also restricted the results. This date range was selected to include the most up-to-date research and to make this review feasible within a thesis chapter. A more comprehensive literature review covering interventions for all possible health/social causes of stress for women requires greater resources than those available in the current study.

Conclusion

It is evident from this literature review that no particular intervention programme is clearly more effective than any other for women with psychological distress. All the authors give reasoned arguments for the theoretical approach they take to programme development, but it is striking how the reasons for psychological distress are conceptualised as being quite different in each study. For example; stress for African-American women is attributed to the attitudes of society towards Black women by Conway-Phillips *et al.* (2020) but is linked to mistrustfulness of conventional treatments among Black women in another study promoting

mindfulness (Burnett-Zeigler *et al.* 2019). Similarly, psychology-based programmes use approaches which are sometimes contradictory to reducing distress. Cognitive-behavioural approaches (such as in Sahranavard *et al.* (2019)) require an individual to focus on their negative thoughts in order to change them, while acceptance-based approaches (as in Ölund *et al.* (2020)) advocate accepting any thoughts that occur, without trying to change them. There is evidence that patients themselves can have strong preferences for particular ways of conceptualising mental health. In a study of the psychotherapy preferences of 315 men, strong preferences were shown for a positive psychology approach as opposed to a cognitive behavioural approach for example (Cole *et al.* 2019).

This review has also demonstrated that all interventions produce at least some positive outcomes when compared to no-treatment controls, although not all studies reviewed included a control group. In general, as stated by Winter and Barber (2013) "*in most cases, active treatments (whether it be medication compared with other medication, psychotherapy compared with other psychotherapy, or medication compared with psychotherapy) are more or less equivalent*" (p.1048) in the treatment of depression at least. Predicting those who are more likely to benefit from a particular approach will be an important future research direction. For example, Lopez-Gomez *et al.* (2019) found that those who had more negative thoughts and who had previously been on anti-depressants actually showed worse outcomes in a CBT programme which contradicts the theorised mechanism of change of CBT. This highlights the importance of plurality i.e. that a range of different approaches is likely to be needed, as participants are likely to benefit from different interventions based on a range of interpersonal and contextual factors (Leichsenring and Steinert 2017).

As was discussed in Chapter 1 and in the second paper published as part of this PhD (Appendix II), sub-threshold and mild/moderate anxiety, depression and psychological distress have been linked to lifestyle factors inherent in modern life such as poor sleep, more sedentary time spent, longer working hours, complex role multi-tasking, more consumption of social media/digital content and a reduction in protective factors such as spiritual activity, social connections and time spent in nature (Walsh 2011). The ReDO® programme (Eklund and Erlandsson 2011) was the only intervention found in the review directly targeting these everyday life activities as a potential therapeutic mechanism of change for women to improve their mental health. The intervention in Agosti *et al*. (2019) was based on the same theoretical frameworks but was only evaluated qualitatively. Nevertheless, the value of

bringing awareness to one's own time use and the importance of making empowered decisions about occupational choices was recognised by participants in both interventions. Occupation-focused interventions that explore different ways to use your time for health can offer a very different perspective to interventions focused on symptom reduction. Research with people in mental health recovery indicates that an occupational perspective is vital as it develops routines, a feeling of competence and productivity, and the acquisition of skills, meaningful routines and pleasure in life. Qualitatively, patients indicate how vital this occupational time-use perspective is in their recovery; *"the only thing that really makes us well …is when you become active", "the good habits that we need to develop to get well", "you're asked to do things that you may not have done for a long time*" (Kelly, Lamont and Brunero 2010, p.133). Feeling imbalanced in one's daily time use and having low participation in activities that give meaning is associated with low perceived health among those experiencing psychological distress (Karlsson, Ivarsson and Erlandsson, 2021).

Outside of, but highly relevant to occupational therapy, the Behavioral Activation (BA) approach has been rigorously evaluated. Designed to systematically increase people's engagement in pleasurable, meaningful and valued activities, BA now has a strong evidence-base for improving outcomes for people with depression particularly. BA may be more acceptable to participants than traditional "talk therapy" because the strategies are individualised, realistic, result in positive reinforcement and resemble their own natural coping strategies (Malik *et al.* 2021). Interventions such as ReDO®-10 offer another added "ingredient" to the BA perspective in that the programme includes practice of occupations within the sessions, allowing for exploration of new possible occupational choices (Erlandsson 2013). Occupational therapists in Ireland could offer this valuable perspective to the plurality of approaches to management of psychological distress. But as this is an emerging occupational therapy direction, in the Irish primary care context at least (Tinelly and Byrne 2016), the feasibility and acceptability of an occupation-focused intervention requires exploration. Chapter 3 will discuss the development of the research questions for this study – exploring the feasibility of the ReDO®-10 programme in Irish primary care.

Chapter 3 - Explanation of the Research Questions

Introduction

In addition to the background literature reviewed in chapters 1 and 2, the development of the research questions for this study were influenced by guidance on appropriate research questions for a feasibility study, frameworks for conducting a process evaluation and literature on understanding the mechanisms of change of complex interventions, such as the ReDO®. This chapter outlines how the research questions were developed based on these considerations.

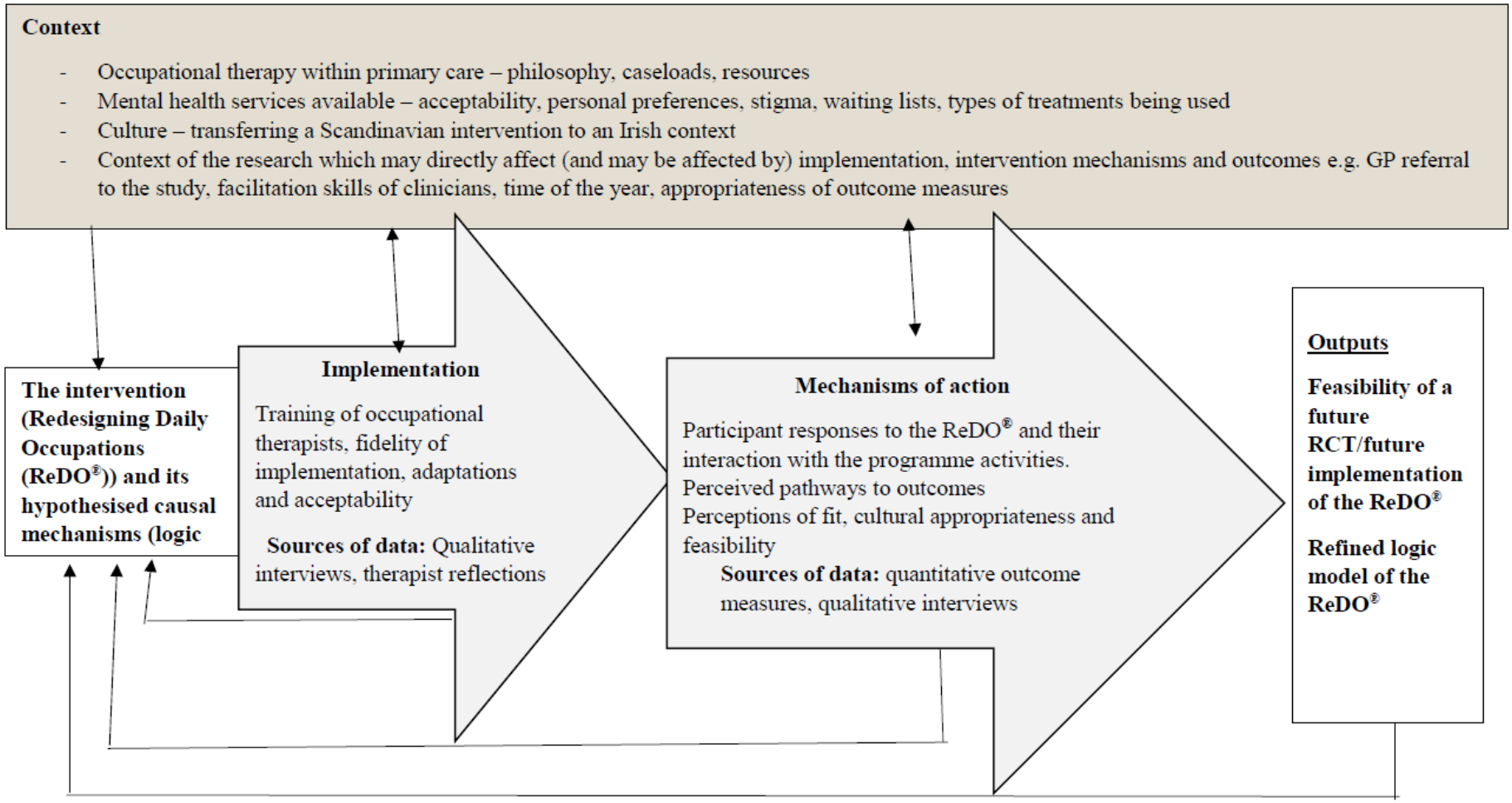
Feasibility studies and process evaluations

A feasibility study is used to determine important considerations when implementing an intervention in a new context, particularly when future randomised controlled trials may be planned (Bowen *et al.* 2009). It is recommended that such studies have eight main areas of focus relating to an intervention. These are acceptability, demand, implementation, practicality, adaptation, integration, expansion and limited-efficacy testing (Bowen *et al.* 2009). Researchers consider whether the intervention fits within current infrastructure, the resources needed to implement it, the satisfaction of stakeholders and make some inferences about the potential for the intervention to show trends towards effectiveness in important outcomes in this context.

When conducted alongside a trial or a feasibility study, a process evaluation can be used to assess the fidelity and quality of implementation of a complex intervention, clarify causal mechanisms and identify contextual factors associated with variation in outcomes (Craig *et al.* 2008; Moore *et al.* 2014). While process evaluations and feasibility studies are focused on some of the same areas e.g. the acceptability of an intervention to participants (Bowen *et al.* 2009; Moore *et al.* 2014), a process evaluation is more thorough and often includes both qualitative and quantitative methods. Advocates of "realist" feasibility studies believe that feasibility studies and process evaluations can be combined effectively to answer questions such as those proposed by the current study i.e. exploring the causal mechanisms of interventions, the perspectives of stakeholders and understanding the delivery of the intervention in a particular context (Fletcher *et al.* 2016).

The ultimate goal of a process evaluation is to "illuminate the pathways" between an intervention, the hypothesised theoretical assumptions and the context into which it is being introduced (Moore *et al.* 2014, p.24). The following diagram (Figure 2) shows the areas covered by this research and the types of data generated to illuminate these areas of uncertainty. In the diagram, it can be seen that context influences and is influenced by, the intervention and the outcomes. These are not linear steps; rather, they depict the whole area under investigation visually. The diagram is adapted from the framework developed by Moore et al. in their Medical Research Council guidance on conducting process evaluations (Moore *et al.* 2014).

Figure 2. Visual representation of the process evaluation in this study



Based on these guidance documents and after developing the model above for conducting the study, the following research questions were proposed to "illuminate pathways" and key uncertainties about the feasibility of the ReDO®-10 in Ireland:

- How successful were the research processes of recruitment, randomization, blinded allocation, retention, data collection and analysis?
- How well was the ReDO®-10 implemented (fidelity) in this context and how acceptable was this new intervention to the occupational therapy facilitators?
- How did this intervention fit in the new context of Irish primary care and what were the contextual factors influencing implementation and perhaps, outcomes?
- How satisfied were stakeholders with the research process? Did they find randomisation acceptable? How did the referral procedure work for GPs?
- Did the ReDO®-10 programme show some trends towards effectiveness in improving outcomes for women with anxiety and stress-related conditions?
- What factors would need to be considered for a future trial to be implemented successfully for example resources, supports needed or other logistical issues?

Understanding the theoretical mechanisms of the Redesigning Daily Occupations (ReDO®) programme

Pawson and Tilley (1997) stated that all interventions are "theories incarnate" since they have assumptions about the cause of the problem at hand and the actions needed to solve it. A clear statement of the underlying theories of how an intervention is hypothesised to bring about change is a vital starting point for a process evaluation as it helps researchers to identify key uncertainties to be explored (Moore *et al.* 2014). The researcher began by eliciting and documenting the implicit causal assumptions of ReDO®-10: the mechanisms through which change is assumed to occur. This was done by collaborating with the intervention developers, reviewing the literature, considering other relevant theories (e.g. health behaviour change theories), close examination of the manual and reflecting on clinical experience as an occupational therapist and group facilitator (Pawson and Tilley 1997; Rogers *et al.* 2000). Only the content included in the ReDO®-10 and not the full 16-week version (ReDO®-16) that includes a work placement was examined. A series of ten theoretical assumptions linking a theory, a target of change and an outcome were developed

by the researcher. For example, "*Imbalance in the occupations of daily life may cause stress and ill-health THEREFORE improving balance in daily life occupations SHOULD IMPROVE health and REDUCE stress*". This was the proposed logic model for how the ReDO®-10 programme was expected to bring about change developed as part of this study and is presented in full in Table 10.

Table 10. Theoretical assumptions of the Redesigning Daily Occupations programme (ReDO®-10)

In the table below, the theoretical assumptions can be read as a series of connected statements that link a theory, a target of change and an outcome. For example: "Imbalance in the occupations of daily life may cause stress and ill-health THEREFORE improving balance in daily life occupations SHOULD IMPROVE health and REDUCE stress".

Theoretical statement		Target of change in the ReDO® programme	Desired outcome	Key proponents of this theory and sources (based on a review of the ReDO® literature).
Imbalance in the occupations of daily life may cause stress and ill-health	*Therefore*	Improving balance in daily life occupations	Should improve health and reduce stress	Occupational balance was defined by Wilcock as "*a balance of engagement in occupation that leads to well-being. For example, the balance may be between physical, mental and social occupations; between chosen and obligatory occupations; between strenuous and restful occupations, or between doing and being*" (Wilcock 2006, p.343). Addressing life balance has long been part of stress management programmes (Schafer 1996) and occupational therapy interventions (Edgelow and Krupa 2011; Pekçetin and Günal 2021).
The ability to manage work for women with stress may depend on the ability to adapt daily routines and manage daily life as a whole	*Therefore*	Improving the ability to adapt daily routines and examining daily life as a whole (rather than just managing stress at work)	Should improve work functioning and overall life functioning	The Strength model posits that people have a limited reserve of self-control and that if people's reserve is depleted (as by a stressful day at work), they will become exhausted and less well-able to have control over other aspects of their life (Baumeister, Bratslavsky, Muraven and Tice 1998). This exhaustion can be counteracted by interspersing other forms of activity and/or rest during the day (Tyler and Burns 2008). Studies with women experiencing work-related stress have supported this theory (Jansson and Björklund 2007; Holmgren *et al.* 2009; Johansson *et al.* 2012)
Lifestyle changes may be hard for women to make on their own. The	*Therefore*	Adjusting the social environment to be more supportive of	Should improve women's ability to make lifestyle changes	Several theories emphasise the importance of considering the social environments that contextualise human behaviour in effective

social environment can constrain her ability to find balance, cause hassles and increase complexity		lifestyle changes, have less complexity and fewer hassles		interventions. The Social-Ecological Model of Behaviour Change (Panter-Brick *et al.* 2006) states that the social environment can have enabling factors for health behaviour change (such as social support) or constraints on behaviour (such as social expectations). Erlandsson and Eklund (2004) found that many hassles for women were located in their social context and this constrained their ability to find balance in daily life.
Recognition of the need for change needs to come from the person themselves for effective lifestyle change	*Therefore*	Providing tools for self-analysis, individualised goal-setting and problem-solving	Should make lifestyle changes more sustained, individualised and meaningful	Social Cognitive Theory (Bandura 1986) outlines how the capability of humans for self-reflection, self-regulation and learning through observation are dynamically integrated in behaviour change. The Integrated Theory of Health Behaviour Change (Ryan 2009), also holds that motivation to change is a necessary precursor to behaviour change.
An increase in complexity (such as constant interruptions and unexpected tasks) in daily life may increase stress	*Therefore*	Practicing occupations in unbroken action sequences	Should reduce stress	An extensive concept analysis of the idea of "interruption" was carried out by Brixey *et al*. (2007) and their Model of Interruption outlines how interruptions disrupt task performance, particularly in a work environment. Being frequently interrupted during occupations is linked to poorer self-rated health for women (Erlandsson and Eklund 2006), but the relationship between complex daily lives and wellbeing was not established in that study.
A high level of hassles has a negative impact on wellbeing and subjective health	*Therefore*	Reducing hassles, changing the circumstances to make the hassles an uplift or increasing the number of uplifts in the day	Should improve wellbeing and subjective health	In a cross-sectional study, DeLongis *et al*. (1982) showed that more frequent and intense daily hassles were related to poorer health. More frequent uplifts are associated with wellbeing for women (Kanner *et al*. 1981), but the important issue would appear to be how the hassle/uplift is appraised by the person. Erlandsson (2008) confirmed the relationship between daily hassles,

				frequent uplifts and subjective health in the more contemporary context of women with both work and home responsibilities.
It is important to have a variety of (meaningful) occupational value experiences in everyday life for wellbeing	*Therefore*	Performing a range of occupations of different value and meaning	Should increase experiences of occupational value and wellbeing	Meaning-making as an important driver of human action has been explored by authors from occupational therapy (Persson *et al.* 2001) and other fields (Bruner 1990). Persson *et al.* (2001) devised the Values and Meaning in Occupations (ValMO) model and posit that humans experience value in occupations in three ways, depending on what is gained by the experience. Occupations may have concrete value (a tangible outcome), socio-symbolic value (is significant personally/culturally/universally) or self-reward value (an experience of enjoyment, pleasure or flow). It is hypothesised that performing occupations of different values day-to-day are prerequisites for discovering meaning in the person's life as a whole (Persson *et al*. 2001).
Group dynamics have therapeutic benefits for participants	*Therefore*	A group-based intervention will develop supportive group dynamics	Should increase perceived social support and improve outcomes generally	Eleven therapeutic factors, such as the instillation of hope, catharsis and imparting information, were identified by Yalom (1995) and have been confirmed as continuing to be important in group-based interventions (Kivlighan and Holmes 2003).
Providing knowledge and understanding of how the person's unique patterns of occupations are developed and how they affect health empowers participants and increases motivation for change.	*Therefore*	Providing information and tools for analysing one's occupational patterns	Should improve the sense of empowerment (mastery) and result in improved self-management of daily life stressors	The Transtheoretical Model of Behaviour Change (Prochaska and DiClemente 1982) outlines the importance of processes such as consciousness-raising and self-re-evaluation in the decision-making of a person considering a health behaviour change. Having sufficient self-efficacy to make and maintain a change is important for long-term changes in behaviour, according to the Health Action Process Approach (Schwarzer 2008). Many client-centred occupational therapy interventions try to increase self-efficacy and empowerment by

				providing opportunities to practice new patterns of occupations (Erlandsson 2013)
Including the practice of occupations within occupational therapy programmes is an important mechanism of change.	*Therefore*	Including occupational experiences (practicing occupations) in the group sessions	Should improve mastery of occupations and carry-over of change into daily life – rather than providing knowledge/theoretical information alone	Participating in occupations gives an experience of occupational value which may be self-reward, concrete or socio-symbolic in nature (Persson *et al.* 2001). The act of "doing" an occupation can provide a sense of restoration, relieve stress, shape identity and achieve mastery, among other outcomes identified in a recent meta-analysis (Roberts and Bannigan 2018). Including the practice of a new/desired behaviour in a health intervention is an important behaviour change technique to help people learn new skills/habits (Michie *et al.* 2013).

In order to understand whether these theoretical mechanisms of change were perceived as important to the participants in this study and whether they reflect how change happened for them accurately, an additional research question was proposed:

- How does the ReDO®-10 programme bring about change, if positive outcomes are seen? Are the hypothesized causal/theoretical mechanisms confirmed in this context?

Chapter 4 - Methodology

Introduction

This study combined a mixed-methods feasibility study and a process evaluation to answer the research questions outlined in the previous chapter. This chapter will describe the methods used to conduct the study, gather and analyse the data, the research partnership process and measures taken to improve rigor. Considerable detail on the study methodology is presented in the published papers (Appendix II and III).

Research Philosophy

The worldview that shapes this study is that of pragmatism. Pragmatic studies involve topics that have arisen out of real-world situations, use pluralistic approaches to derive knowledge about the problems and try to find solutions to problems (Patton 1990). This pluralistic approach involves the collection, analysis and integration of both qualitative and quantitative data to provide the most complete analysis of problems (Johnson and Onwuegbuzie 2006). Pragmatist philosophy sees all experiences as being located in a historical and cultural context and having an emotional embodied element, meaning that researchers cannot make assumptions about how a new intervention will work in a new context (Dewey 1922/2008). It is problem-centred and real-world practice oriented (Mackenzie and Knipe 2006)

Pragmatism was the appropriate philosophical lens for this study for several reasons. Firstly, the feasibility of a future randomised controlled trial needed to be determined through a practical research strategy and embedded in a real-world context (Creswell and Clark, 2011). Implementing a multi-session healthcare intervention like ReDO®-10 in this new context meant intervening in already complex systems; the participant and their social context, the occupational therapists in their work context, even the general medical practice, disrupting prior ways of working and introducing new ones (Moore *et al.* 2017). Secondly, both objective and subjective knowledge was required to answer the research questions, meaning that post-positivist or constructivist standpoints alone would not be adequate. Health outcomes and rates of recruitment could be measured quantitatively, but the nuanced

perspectives of stakeholders and causal mechanisms of the intervention required qualitative methods. Thirdly, there can be in pragmatic studies, as Morgan states, an "active process of inquiry that creates a continual back-and-forth movement between beliefs and actions" (2014, p.1048), where qualitative and quantitative methods are each used for their respective research strengths. This is recognised as being necessary in feasibility studies where there may be changes to methodology or data collection methods during the lifetime of the project as the research team make ongoing decisions (Eldridge *et al.* 2016). Studies informed by pragmatism apply practical theory to inform future clinical or research practices (Robson and McCartan 2016). Process evaluations are inherently pragmatic and researchers should combine methods in these studies to explore how an intervention was delivered in context, how it produces change and whether the underlying mechanisms of impact are as expected (Moore *et al.* 2014).

Critical realism is an alternate philosophical approach that could have been taken in this study. McEvoy and Richards describe the main features of the critical realist philosophy as focusing on "generative mechanisms, the stratified character of the real world, the dialectical interplay between social structures and human agency and a critique of the prevailing social order" (2003, p.412). In their guide to how tenants of critical realism should be used to guide mixed method evaluations, Mukumbang (2021) states clearly that any critical realist-informed research should select and use methods informed by these philosophical assumptions (Allana and Clark 2018, cited in Mukumbang 2021). Because critical realism holds that there can be multiple explanations for phenomena, it is recommended that there are multiple investigators, multiple analytical and methodological techniques and a variety of data sources and types. It also requires thick descriptions of case stories, exploration of structural entities (e.g. health services) and the relationship between entities and analysis of all possible proposed mechanisms linking the structures and context to events (Mukumbang 2021). To carry out a study fully informed by these principles would have required greater resources than that of a single researcher-led PhD study.

There are similarities between pragmatism and critical realism as approaches to research and critical realists have drawn on the work of early pragmatists as this more modern approach developed. Both approaches see knowledge as being relative and having the potential to be based on assumptions, for example. However, one difference is that pragmatist research tends to focus less on social structures than critical realism (Elder-Vass 2022). In places, critical realism has been criticised as being "*rich in philosophical*

explanation but fail(ing) to translate this into a practical methodology for gathering empirical data" (Stutchbury 2022, p.114). However, realist perspectives have been increasingly recognised in more recent updates to the Medical Research Council guidance on Developing and Evaluating Complex Interventions (Skivington et al. 2021). The current study took context and mechanisms into account and gathered data to understand these influences on outcomes, albeit on a small scale (for example, reflecting on the impact of OT staffing levels on the sustainability of this intervention – see Chapter 6). The current study also included exploration of participant's understanding of mechanisms of change and attempted in the coding to link dyads (e.g. linking a particular homework activity to a perceived change for the woman) (Jackson and Kolla 2012), even if this analysis did not extend to the triad of Context-Mechanism-Outcome analysis recommended by critical realist advocates Pawson and Tilley (1997) (See Published Paper 3).

Study design and timeline

This was a multi-phase, explanatory, sequential mixed-methods study. In this design, quantitative data collection is followed by qualitative data collection and the qualitative data assist in the interpretation of the results (Creswell and Clark 2011). Authors in the field of mixed-methods do not recommend a particular qualitative methodology for use, as mixed-methods are seen as a methodology in their own right (Bazeley 2009). However, the study was influenced by the pragmatic principles of Interpretive Description as (i) being influenced by questions of clinical interest, (ii) being explicit about theoretical frameworks guiding the analysis and (iii) producing outcomes that can guide clinical practice and/or clinical research (Thorne *et al.* 1997).

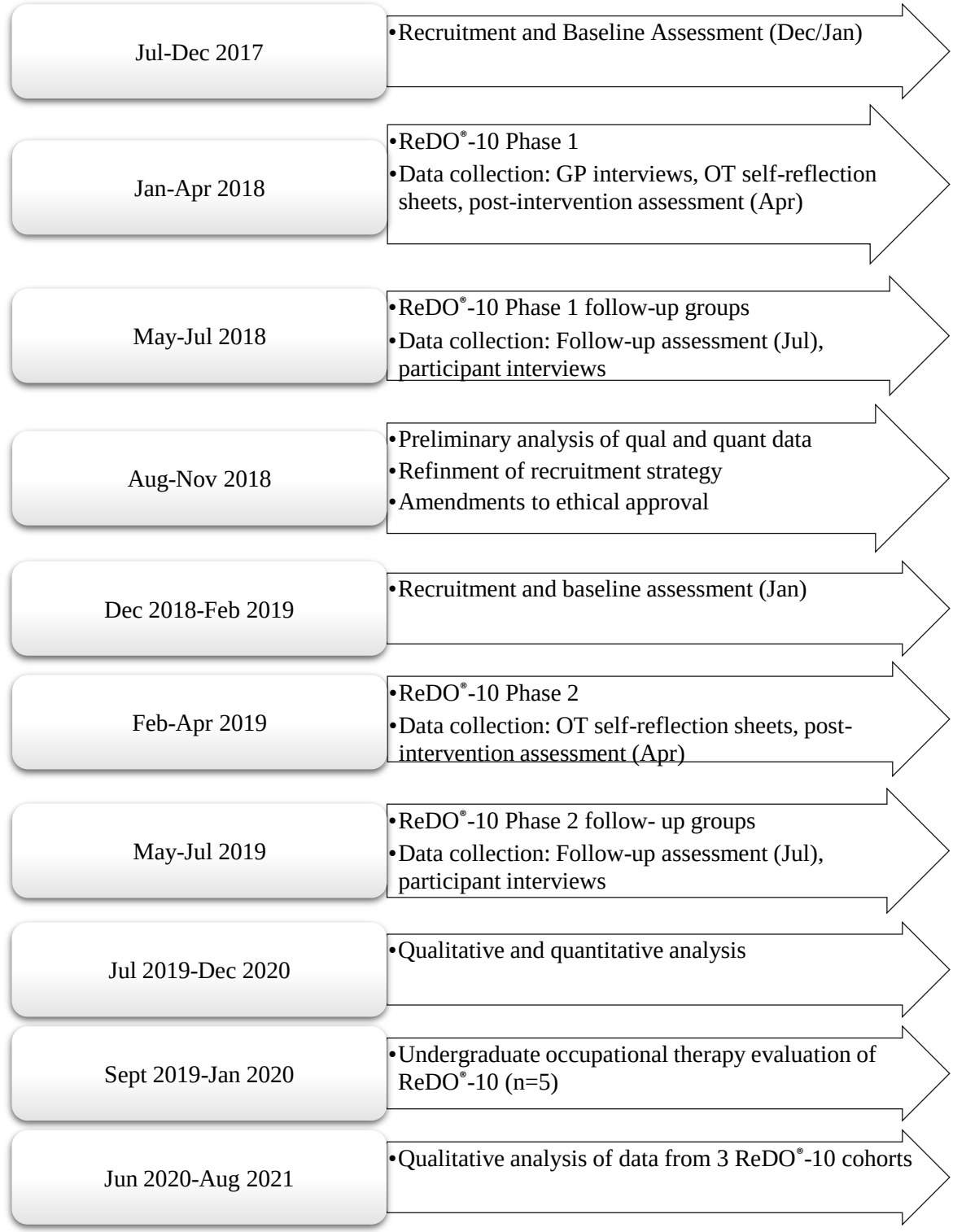
The main study was carried out in two phases. ReDO®-10 was delivered twice (in 2018 and 2019), using a pre-test, post-test design. Slow recruitment in the first six months led to the pragmatic decision to begin the programmes without a control group as intended, rather than lose those participants who had expressed interest. Some, but not all feasibility studies need to include a pilot randomised-controlled trial (Eldridge *et al.* 2016).

Quantitative data were collected from each participant at three time points and qualitative data with all stakeholders informed an iterative approach to the study throughout. For example, stakeholder feedback following phase 1 informed a change to the inclusion criteria for phase 2. See Figure 3 for the timeline of data collection phases and analysis in this study.

Addendum to the study – undergraduate project

Between September 2019 and April 2020, an undergraduate student in the Discipline of Occupational Therapy, University of Galway (Ms Aideen McKiernan) completed a research project that included a further pilot ReDO®-10 programme, under the supervision of Dr Sinéad Hynes and co-designed by Jackie Fox. Women aged 18-66 with psychological distress self-referred for the study and the ReDO®-10 was facilitated in 10 weekly evening sessions on the University of Galway campus. The group sessions were co-facilitated by Jackie Fox and a ReDO®-trained primary care occupational therapist. Levels of psychological distress and occupational balance were measured pre-intervention, post-intervention and after the 2-month follow-up groups and qualitative interviews were completed. Data collection and analysis were completed by Aideen McKiernan under the supervision of Dr Hynes (McKiernan 2020). Before beginning the programme, the participants gave fully informed consent for their anonymous data to be retained for a period of up to five years, combined with that of other ReDO®-10 participants and analysed for academic study. In June 2020, Jackie Fox sought permission to analyse the anonymised qualitative transcripts. The qualitative data from these three ReDO®-10 cohorts were therefore included in the third published paper for this PhD (Appendix III).

Figure 3. Data collection phases and analysis



Ethical Approval, Trial Registration and Research Collaboration

Ethical approval for this study was granted by the Irish College of General Practitioners (ICGP) in March 2017 (see Chapter 1). Because this study was originally planned as an RCT, it was registered with the ISRCTN registrar in November 2016 as good research practice (Lancaster 2015; Fox *et al.* 2016) and this record was updated regularly.

Having the support of a core group of occupational therapists was vital to the feasibility of both this study and to any future implementation of the ReDO®-10. Occupational therapists in the HSE PCCC Occupational Therapy Department in Galway were offered training in the ReDO® method free-of-charge, support during the research process and collaboration with publicising results. The service offered venues for the ReDO®-10 groups and the vital input of facilitating the intervention.

Three research groups based within the University of Galway provided support to this project. Firstly, the Health Research Board (HRB) Primary Care Clinical Trials Network Ireland (HRB Primary Care CTNI 2017) provided informal guidance in the development of the research questions. This collaboration was formalised in October 2016 and the study was registered as one of the trials being supported by the CTNI. The CTNI contacted primary care GPs to recruit them for the study. They made a small financial contribution to the practices that recruited participants and they facilitated access to a public/patient involvement group.

Secondly, the Health Research Board Trials Methodology Research Network (HRB-TMRN 2017) made methodological training available to the researcher via webinars and face-to-face teaching events. They also provided ongoing informal support and guidance around recruitment issues. Finally, the Health Behaviour Change Research Group at NUI Galway provided methodological training e.g. in the evaluation of complex interventions and qualitative data analysis (HBCRG 2020).

The involvement of the public and healthcare patients as partners in the research process is considered vital (Health Research Board 2016) and the process aims to make the research more relevant, more acceptable to potential participants and more ethical (Bagley *et*

al. 2016). The researcher met the Public and Patient Involvement Panel convened by the HRB Primary Care CTNI in Galway to explore the acceptability of this study and the information materials. This PPI group felt strongly that recruitment through the GP practices was the most appropriate route but raised a concern that people may refuse participation because of fear of meeting someone they know at the group. This latter issue was debated at the meeting and the researcher agreed to mention this risk to participants during recruitment, but that this was an unavoidable aspect of healthcare in a small community.

Training of ReDO® facilitators

The Redesigning Daily Occupations programme is a manualised intervention that requires training from a certified trainer before being implemented. Dr. Lena-Karin Erlandsson and Ms. Suzanne Bohs from Lund, Sweden visited the University of Galway in June 2017 and delivered training to eight primary care occupational therapists who had agreed to support the study. This training included: principles of occupational science and the ValMO theory (Persson *et al*. 2001), the research background for ReDO®, occupational self-analysis using tools such as time-use diaries and homework similar to that expected by ReDO®-10 participants. The therapists attended 2 ½ days of training and were then asked to run one session of the ReDO® for a group of their choice. Therapists ran these practice sessions with colleagues or with students on placement in their service, wrote a reflective assignment which was sent to Dr. Erlandsson and received their certification.

Context

Moore et al. (2014) recommend reflecting on some key aspects of context during the design phase of a process evaluation. Three questions are given in the MRC guidance document to guide reflection on important uncertainties and plan for how they may be considered in the data collection process. In the design phase for this study, the researcher used these three questions to hypothesise some contextual factors and designed aspects of the data collection/analysis in order to gather relevant data. The following table presents this process.

Table 11. Key contextual uncertainties

MRC Process Evaluation Guidance questions (Moore *et al.* 2014, p11)	**Hypothisised mechanisms in this context**	**Consideration in the research process**
What are the causal mechanisms in the context acting to maintain the status quo or potentiate effects?	Mechanisms which could be maintaining the status quo (psychological distress for women in primary care in Ireland) - Current lack of primary care mental health services and waiting lists. Modern life pressures and stressors. Mechanisms which could act to potentiate the effects of the intervention in this context - Occupational therapy manager and staff enthusiasm for research and new training. ReDO® being supported by GPs (patient/doctor trust).	Qualitative interview questions were designed to gather relevant data e.g. - Where would you normally refer women meeting these criteria in your practice? (GPs) - Do you see a continuing place for ReDO® in your work? (OTs) Preliminary meetings were held between the researcher and the occupational therapy staff and with the HRB Primary Care Clinical Trials Network to understand the clinical context prior to the study
What are the contextual factors that affect (and may be affected by) implementation, intervention mechanisms and outcomes?	Factors such as GP time, OT support, ReDO® facilitator group-work skills, time of year and level of ReDO® group cohesion could affect implementation, intervention mechanisms and outcomes. Implementation, intervention mechanisms and outcomes could be affected by factors like the life-stage, social support or co-occuring conditions for participants, ReDO® group cohesion or environmental issues like traffic/choice of venue	Qualitative interview questions were designed to gather relevant data e.g. - Did you work by the manual or make changes? What (if any) changes did you make? (OTs) - What supported or hindered your participation in this study? (Participants) Occupational therapists were asked to reflect on contextual factors after each group session
What are the contextual factors that shape theories of how the intervention works?	The theoretical background to the ReDO®-10 was presented in Chapter 3. However, some contextual factors may interact with/shape these theories in a new context. Some examples are; - Therapeutic factors of group-work could be affected by the level of experience of group facilitators	Qualitative interview questions were designed to gather relevant data e.g. - How did you feel about the group format? How well did the group facilitation work? (participants) - What supported or hindered your ability

	- The ability of women to make changes to daily life could be affected by their life stage or level of support from others in the home - Developing occupational balance could be affected by personal/cultural values	to make changes during the programme? (participants)

Recruitment and consent

Participants were recruited through primary care medical practices in urban and rural areas of Co. Galway with a wide spread of socioeconomic representation, or (in Phase 2) through advertisements in public libraries, family resource centres and other venues (Appendix VII). When women meeting the inclusion criteria (See published paper Appendix II) visited their GP, they were informed about the study (Appendix VIII) and asked if they would be interested in hearing more details. They signed a consent form to indicate that they were willing to be contacted, but this did not imply consent to take part in the study (Appendix IX). This form was posted to the researcher using stamped addressed envelopes provided. The researcher contacted these women and gave them information about the study.

During recruitment, the researcher kept in touch by text message with interested participants to improve retention. When a sufficient number of participants had been recruited (between 6-10 in each phase), the researcher met each woman individually and they completed a consent form (Appendix X) and the baseline outcome measures. After the follow-up period (two months), the researcher invited participants to a recorded interview to discuss their experiences. Again, women signed a consent form to take part in this phase (Appendix XI). General practitioners and occupational therapists also signed consent to provide data for the study.

Sample size

Authors suggest that the sample size in a feasibility study should be based on the pragmatics of recruitment and be adequate to explore all the aspects of feasibility being explored (Arain *et al.* 2010). It was originally planned to recruit 32 participants: 16 in a

treatment arm and 16 in a control arm, with participants randomised to each group. However, due to the change in methodology, the final sample size was based on the practicalities of running a group intervention. Between 6 and 10 women were sought for the groups in 2018 and 2019.

Participants

Three groups of people provided data for this research study; the women who attended ReDO®-10, the general practitioners and the occupational therapists. The general practitioners and occupational therapists who took part were both research participants and research partners in the process. The general practitioners were the gatekeepers for referrals to the study and the occupational therapists delivered the intervention. Both professional groups were part of decision-making about study logistics e.g. deciding on group venues, offering insights into the local context and disseminating study details more widely. Details about the inclusion and exclusion criteria for the ReDO®-10 participants, the general practitioners and occupational therapists are given in a published paper (Appendix II).

Outcome measures

ReDO®-10 is an occupational time-use intervention. However, assessments chosen for this study measure a range of factors; perceived health, mental health symptoms, occupational value, functioning and mastery. Changes to patterns of daily occupations may be found using measures of functioning (see subsequent sections). However there is clear evidence that occupational imbalance (being overburdened, experiencing burnout or being under-occupied) is predictive of stress-related disorders (Håkansson and Ahlborg Jnr 2018) and is related to a lower perceived level of health (Karlsson *et al.* 2021). An important focus of ReDO®-10 is to help participants make changes to their occupational balance/time-use to improve their health. Therefore it was important to also gather data relating to levels of psychological distress and perceived health in this population experiencing imbalance. Gathering these data will help to refine the theoretical model of the intervention and explore whether the intervention is working as intended. Measuring and publishing mental health outcomes of ReDO®-10 participation will also allow future interdisciplinary researchers to compare the potential effectiveness of the intervention to other group interventions in addressing psychological distress at a primary care level. Finally, using both occupation-focused outcome measures (such as the OVal-pd) and symptom-focused outcome measures

(such as the DASS) will provide important data about whether an intervention with an occupational perspective can influence both functioning and mental health outcomes. Further rationale for the outcomes measured and the psychometric properties of the tools used are given in the following sections. For reasons of copyright, the standardised assessments are not reproduced in this thesis.

Demographic data

Some straightforward demographic data were collected (Appendix XII). Since the sample was too small for sub-group analysis, the purpose of this data was descriptive. Demographic data collected were; (i) age, (ii) number of children if any, (iii) married/single/cohabiting, (iv) working full/part time/unemployed/working in the home/other and (v) GP. The latter information was collected for clinical reasons if concerns arose in the group.

Impact of health condition on daily life (disability)

The WHO International Classification of Functioning, Disability and Health (World Health Organisation 2002) takes a broad view of health, viewing it as relating to functioning in everyday life. Taking the ICF view of health, that "every human being can experience a decrement in health and thereby experience some disability" (World Health Organisation 2002, p.3), using an ICF-based instrument such as the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0) was appropriate for research being carried out in primary care, where individuals may or may not have a diagnosis. The WHODAS 2.0 is also one of the tools recommended for measuring outcomes for people with anxiety (ICHOM 2017).

The WHODAS 2.0 was developed by an international collaborative team including the WHO, the National Institute of Health (US) and the National Institute of Mental Health (US), as an instrument that could assess health status and disability in many different cultures and settings around the world (Ustun *et al.* 2010). It assesses health and disability across six domains; cognition, mobility, self-care, getting along (with others), life activities and participation (which takes into account environmental factors affecting health). It is available in 36-item or 12-item formats that can be self-administered or completed as part of

an interview. The 36-item, self-administered format was used in this study as it is the most detailed and allows an overall functioning score to be calculated. In this version, the respondent is asked to think back over the past 30 days and rate the level of difficulty they had in various activities due to their health condition on a 5-point Likert scale from "none" to "extreme or cannot do". Sample items assessed are "Taking care of your household responsibilities" and "getting along with people who are close to you" (Üstün *et al.* 2010).

The psychometric properties of the WHODAS 2.0 have been evaluated extensively. It was aligned with the ICF framework, checked for cultural acceptability and redundant items were removed (Üstün 2001; Üstün *et al.* 2010). WHODAS 2.0 has very good test-retest reliability (Cronbach's alpha 0.98) and it is more responsive to change in functioning in people receiving treatment than some similar measures (Üstün *et al.* 2010). The World Mental Health Surveys were carried out with 51,344 people in 22 low, medium and high-income countries worldwide (Alonso *et al.* 2013). The mean score on the WHODAS 2.0 in high-income countries including Ireland was 3.6 with a standard error of 0.08 (Alonso *et al.* 2013). The mean score on the WHODAS 2.0 for individuals in high-income countries who have had depression in the last 30 days is 15.3 with a standard deviation of 8.9 (Bromet *et al.* 2011).

Experience of value in daily occupations

ReDO® is grounded in the Values and Meaning in Occupations (ValMO) model (Persson *et al.* 2001). As part of exploring the hypothesised theory of change of the intervention, it was important to use an outcome measure designed to measure the targeted outcomes of the programme. The ValMO model was developed in Sweden by occupational therapy researchers who argue that how we experience occupations in daily life is important for meaning, health and well-being (Erlandsson *et al.* 2011). According to the model, three dimensions of occupational value are present when doing occupations - the dimension of value depending on how the experience is perceived. Occupations may have concrete value (something is achieved), socio-symbolic value (what the occupation signifies to the person's identity or culture) and/or self-reward value (the "flow" value of the occupation and how much the experience is enjoyed) (Erlandsson and Persson 2020; Persson *et al.* 2001).

The Occupational Value instrument with predefined items (OVal-pd) was developed as a 26-item, self-rated questionnaire, but it was refined during psychometric testing to 18 items (Eklund *et al.* 2003). Respondents state how frequently on a 4-point scale (not at all, rather seldom, rather often and very often) they have participated in occupations that gave them different experiences during the past month. The questionnaire requires respondents to consider, "during the past month I have been doing things…." and sample statements are "where I learned something new" and "that helped me relax". A higher score on the OVal-pd indicates a higher level of occupational value in everyday life (Eklund *et al.* 2009). The tool provides separate scores for each of the three dimensions of occupational value in the ValMO (concrete/socio-symbolic/self-reward). The 18-item version had a reliability score of 0.91 (Index of person separation) and "good overall and individual item level fit" (Eklund *et al.* 2009) (p.123). Although developed in Swedish originally, an English language version was tested for consistency and reliability (Eakman and Eklund 2011). A test of internal consistency of the OVal-pd resulted in a Cronbach's alpha coefficient of 0.80 for the Swedish version (Eklund *et al.* 2003) and 0.90 for the English language version (Eakman and Eklund 2011). It showed good test-retest reliability (r (116) = 0.77 (95% CI 0.67-0.84)) (Eakman and Eklund 2011).

Severity of psychological distress

The Depression, Anxiety and Stress Scale (DASS) (Lovibond and Lovibond 1995) was used to measure trends towards improvement in symptoms of psychological distress. This scale was developed because there was growing awareness that anxiety and depressive symptoms often overlap clinically and existing scales such as the Beck Depression Inventory and the Beck Anxiety Inventory correlate in the region of 0.50 (Costello and Comrey 1967). It was also apparent that a third group of symptoms such as irritability, agitation and difficulty relaxing, rather than classic symptoms of depression and anxiety were more related to stressful life events (Lovibond and Lovibond 1995). The DASS was then developed as a measure of general negative affect or psychological distress and, while it is not used to allocate people to diagnostic categories, it can discriminate between those who are experiencing more symptoms of depression, anxiety or stress (Lovibond and Lovibond 1995). There are recommended cut-offs for severity (normal, mild, moderate, severe and extremely severe).

The DASS assesses symptoms of depression (dysphoria, hopelessness, devaluation of life, self-depreciation, lack of interest/involvement, anhedonia and inertia), anxiety (autonomic arousal, skeletal muscle effects, situational anxiety and subjective experience of anxious affect) and stress (difficulty relaxing, nervous arousal, being easily upset/agitated, irritable/over-reactive and being impatient). Respondents examine 42 statements like "I felt scared without any good reason" and rate the extent to which they have experienced each state over the past week on a 4-point scale (Lovibond and Lovibond 1995). The norms were developed with a non-clinical sample of psychology students and more recent norms for the general adult population are 5.55 (SD=7.48) for depression, 3.56 (SD=5.39) and stress 9.27 (SD=8.04) (Crawford and Henry 2003). The reliability of all three subscales and the total scale is excellent and it has adequate convergent and discriminant validity (Crawford and Henry 2003).

Feelings of self-mastery

Mastery was measured using the Pearlin-Schooler Mastery Scale (PMS) (Pearlin and Schooler 1978). Mastery is "the extent to which one regards one's life-chances as being under one's own control, in contrast to being fatalistically ruled" (p.5) and is a significant psychological resource for protecting oneself from stress. Having low mastery has also been shown to be associated with higher utilisation of general practitioner consultations, especially when combined with an anxiety diagnosis (Smits *et al.* 2014). Therefore, it was an important outcome to consider in this study. This measure was also used in previous studies evaluating ReDO® programmes, allowing for outcomes to potentially be compared (Eklund and Erlandsson 2013).

On the PMS, the respondents rate on a 5-point Likert scale whether they agree or disagree with 7 statements such as "what happens to me in the future mostly depends on me" and "there is really no way I can solve some of the problems of life". Overall scores range from 7-35, with higher scores reflecting higher mastery (Krokavcova *et al.* 2008). The PMS is a valid scale (r = 0.73) (Airlie *et al.* 2001) and has good internal consistency (Cronbach's alpha = 0.75) (Krokavcova *et al.* 2008).

Overall perception of health

The EQ-5D-5L is a widely-used instrument in which respondents self-rate their health on 5 dimensions: Mobility, Self-Care, Usual Activities, Pain/Discomfort and Anxiety/Depression (Herdman *et al.* 2011). It also includes a visual analogue scale (EQ-VAS) on which respondents mark their overall health on the day of the assessment on a scale from 0-100 with a score of 100 representing perfect perceived health. Only the EQ-VAS aspect was used in this study. This avoided duplication for respondents as the WHODAS 2.0 also included questions regarding their ability to complete usual activities and the DASS assessed psychological distress. In addition, some dimensions of the EQ-5D-5L like "Mobility" might not be sensitive to change for people with anxiety (Konnopka and Koenig 2017).

The EQ-5D-5L has been used in trials of psychosocial interventions (Visser *et al.* 2016; Collado-Mateo *et al.* 2017), including with patients in primary care (Hewett *et al.* 2016; Kendrick *et al.* 2017). Some research has explored the minimally important difference to be shown on the EQ-5D-5L following healthcare interventions (McClure *et al.* 2017) but none, to the researcher's knowledge, for the visual analogue scale (EQ-VAS). International studies with the general population show an EQ-VAS mean score between 81-85.1 (Alonso *et al.* 2013; Huber *et al.* 2017). People with depression or anxiety respectively show scores 8 points or 5 points lower than this on average (Alonso *et al.* 2013).

Data Collection

Quantitative data collection

An initial meeting was arranged at the participants' convenience once they had heard the study details and given verbal consent. At this meeting, they signed consent forms and completed all five outcome measures. The WHODAS 2.0 requires that the researcher introduce the questions using a specific script so this was followed (Üstün *et al.* 2010). The other questionnaires were explained to the participants more informally and the person filled them in independently. Participants were given another copy of the outcome measures to complete on their last day of the main 10-week part of the ReDO®-10 programme and again

at their 2-month follow-up meeting. They posted these assessments back to the researcher in stamped addressed envelopes provided. Any participants who had not returned outcome measures were followed-up with up to two reminder text messages. The hard copy outcome measures were marked only with a participant code and were stored securely in a locked filing cabinet.

Qualitative data collection

To gather the qualitative data, interview schedules were developed with reference to key papers offering guidance on the appropriate areas of uncertainty that a feasibility study should address (Bowen *et al.* 2009; Leon *et al.* 2011; Eldridge *et al.* 2016) and the Medical Research Council guidance on process evaluations (Moore *et al.* 2014). All stakeholders were interviewed on each topic in slightly different ways to take account of their perspectives on the study. For example, the research question, "How satisfied were stakeholders with the research processes?" was answered by asking slightly different questions of the GPs, occupational therapists and participants. An example of an interview guides is given in Appendix XIII.

The interview guides were piloted and/or discussed with individuals who met the inclusion criteria e.g. the GP interview was piloted with a GP colleague. After piloting, some jargon was removed from the interview (for example, the term "intervention" was changed to "group") and additional questions about current treatments for stress in primary care were added to understand contextual factors.

The study had multiple periods of qualitative data collection and the data were analysed in an iterative way informing later decision-making. The general practitioners were interviewed on a single occasion following Phase 1 (April-May 2018). Occupational therapists were interviewed twice, after each time they facilitated the programme. The therapists were also asked to complete reflection sheets at the end of each ReDO®-10 session (Appendix XIV). This was to explore and monitor issues relating to fidelity (see Table 11). Finally, all ReDO®-10 participants were invited to participate in an interview after the final follow-up session. Data collection was arranged for participant convenience and so took place in individuals' homes, places of work (in the case of therapists and GPs) and in the

University of Galway. All interviews were transcribed in full, either by the researcher, or by the NVIVO transcription service.

Evaluation of fidelity

It is recognised that when an evidence-based programme is delivered in a new context, real-world factors such as service delivery constraints, facilitator characteristics or programme location can mean that the programme is not delivered exactly as intended, with possible implications for outcomes (Chen 1990). Therefore, evaluating implementation and fidelity was important for this study. Monitoring and evaluating fidelity has five elements (Bellg *et al.* 2004); study design, training providers, delivery of treatment, receipt of treatment and enactment of treatment skills. Not all of these elements could be evaluated, (Spillane *et al.* 2007), given the lack of resources for this project. However, Table 12 gives an outline of how these elements were monitored and/or evaluated in this study.

Table 12. Monitoring and evaluating fidelity

Fidelity element	**Method of monitoring/evaluation in this study**
Study design	Clear guidelines to GPs for referrals. Plan for standardised data collection at set time-points with validated tools and interviews guided by the research questions
Training providers	Standardised training and certification provided to occupational therapists
Delivery of treatment	Use of the ReDO® manual, standardised webinar materials and handouts for groups Post-session reflections completed by occupational therapists detailing any adaptations made to session plans (Appendix XIX).
Receipt of treatment	Qualitative exploration of participants' experience of ReDO®-10 and their understanding of the content and group exercises
Enactment of treatment skills	Qualitative exploration of the occupational therapists' experiences facilitating the ReDO®-10

The Redesigning Daily Occupations programme (ReDO®-10)

This section outlines the detail of ReDO®-10 as delivered to the participants in this study and the adaptations made while implementing it in this new context. In both phases (2018 and 2019), two occupational therapists delivered one weekly 2-2.5 hour session for ten weeks, followed by two follow-up sessions spaced one month apart. The timing of the programmes meant that some sessions were rescheduled due to national weather warnings or

holidays (Easter). Because of the normal working hours of primary care occupational therapists, sessions were scheduled for late mornings, midweek. Groups took place in an urban Primary Care centre that had good transport links and parking. Following the manual, each session began with general discussion on the homework, progress and any issues from the week and included a half-way tea/coffee break. Details of the ReDO®-10 programme that was delivered is given in Table 13. The therapists made some adaptations e.g. including some homework material in the sessions, using their clinical reasoning.

Table 13. The ReDO®-10 programme

(Prior to programme) - Individual meeting with the occupational therapist			
1.	**Introduction.** Getting to know each other and the programme. Setting group rules. Discussing participant expectations. Distribution of binders and worksheets.	**Homework:** Reflect on a goal	
2.	**Occupational history.** Reflection on previous week. Discussion of occupations important to participants at different stages of their lives. Occupational time-line worksheet. Discussion on occupations that have been lost or changed.	**Homework:** Reflect on a goal	**Adaptation:** Therapists completed occupational balance circles (how occupations were balanced in the past, now and what they would like in the future) in the session, rather than for homework
3.	**Occupational balance.** Reflection on emerging goals. Seminar on occupational balance. Discussion on the occupational balance circles.	**Homework:** Write a goal related to the activity. Keep a time-use diary for a day	
4.	**Patterns of daily occupations and time (1).** Seminar on complexity in patterns of daily occupations. Explore time-use diaries. What are my daily patterns like?	**Homework:** Write a goal related to the activity. Go for a walk without a watch or distractions	**Adaptation:** Some participants chose to do a different kind of uninterrupted occupation e.g. gardening
5.	**Patterns of daily occupations and time (2).** Follow-up on doing an uninterrupted occupation. Discussion on interruptions in daily life. Participation in an	**Homework:** Write a goal related to the activity.	**Adaptation:** In phases 1 and 2, the uninterrupted occupation in this session was eating some fruit in the group. In phase 3, participants took some time on their own with a

	occupation with full attention. Discussion of areas for change in daily time-use		hot drink. In this session, therapists also included a short seminar about the stress response.
6.	**Hassles and uplifts in daily life.** Discussion of daily hassles and uplifts. Fill out the Hassles and Uplifts scale. Pleasant (uplifting) occupation as a group. Problem-solving to reduce hassles and increase uplifts.	**Homework:** Do an uplifting occupation	**Adaptation:** In phases 1 and 2, the pleasant occupation was tasting herbal teas. In phase 3, it was chocolate tasting.
7.	**Goal-setting.** Discussion about uplifting occupations. Seminar about setting goals. Brainstorm about resources and strengths e.g. social or material resources.	**Homework:** Think about all the goals you wrote so far. Discuss goals with friends/family	
8.	**Occupational value.** Follow-up on goals. In smaller groups, participants break their goals into smaller steps and prioritise. Seminar on occupational value. Creative occupation as a group. Fill out the Oval-9 assessment to describe the occupational experience	**Homework:** Do an uninterrupted occupation. Do an uplifting occupation	**Adaptation:** In phases 1 and 2, the creative occupation was card-making. In phase 3 it was clay modelling.
Additional	**Evening seminar for partners, friends, employers or other supporters.** Give supporters information about all the programme content.		**Adaptation:** Participants did not wish to hold this seminar in any of the three phases of the project. See published paper 2 (Appendix II).
9.	**Goals and strategies.** Follow-up on goals. Draw new occupational balance circles. Discussion of any changes or areas needing change.	**Homework:** Work on goals. Do some more uninterrupted occupations.	
10.	**Conclusion.** Discussion of the occupation-based homework. Enjoy a meal together. Follow-up on goals and plan for ending the group.		**Adaptation:** This session was due to have some discussion about preparing to return to work following stress leave. However, this was not a priority issue for these participants.

Follow-up	**One month later.** Reflection and discussion on progress. Use occupational balance circles. Revising goals and problem-solving.		
Follow-up	**One month later.** Reflection and discussion on progress. Reflection on occupational balance and patterns now.		**Adaptation:** The manual states that OTs should write a note on participants' progress in the group to share with health professionals. However, no ethical approval was obtained to keep records such as this for this project.

Data Analysis

Quantitative data analysis

The sample size of this study was not adequate to detect a clinically meaningful difference accurately (Leon *et al.* 2011). Descriptive statistics such as the median and spread of scores, were used to describe the data (Pallant 2013) and non-parametric statistical tests were used. To investigate within-group differences over the three time-points, the non-parametric Friedman test was used (Field 2013). The sample size was too small to run any sub-group analysis e.g. to compare outcomes for women working full or part-time.

Qualitative data analysis

Qualitative studies influenced by Interpretive Description (Thorne 1997) often use an analytic framework that locates the interpretive analysis within existing theories or knowledge (Caelli *et al.* 2003). Two such phases of qualitative data analysis were carried out to meet the two areas of interest outlined in the research questions and they are described in more detail in the two published papers (Appendix II and Appendix III).

Phase 1: Framework Method

The Framework Method (Ritchie *et al.* 2013) was used to analyse the qualitative data from participants, GPs and occupational therapists to determine the feasibility of the ReDO®-10 programme in an Irish context. This method allows for views on a topic to be compared across different stakeholders, while keeping each person's words closely connected to their other statements. The researcher had no a priori codes, but was influenced by guidance documents on appropriate areas of focus for feasibility studies (Bowen *et al.* 2009). This method helped the researcher to connect context to participant views, especially where there were differing or divergent views. The following steps were taken:

- Interviews were transcribed in full
- The researcher familiarised herself with the interviews by listening to the audio and reading the transcripts repeatedly.
- Inductive line-by-line coding was carried out
- The codes were defined and reduced (by removing duplication or collapsing codes) and then clustered into categories. These categories were influenced by the research objectives and relevant literature (Bowen *et al.* 2009)
- The coded transcript sections were inserted into the framework. Quotes were shortened or synopsized if necessary.
- Connections between the categories were explored, interpreted and conclusions were developed.

The analysis was also guided by the detailed outline of the Framework Method as applied to health research given by Gale *et al.* (2013). Appendix XV gives an example of how the framework was arranged to allow for cross-participant and within-participant comparison of views of stakeholders in three areas (codes); (1) how the study was introduced during the GP consultation, (2) what reasons women gave for declining participation and (3) how GPs decided who to invite to the study. These codes were later clustered with other relevant codes into the category; "Recruitment – understanding who was invited, how and why".

Phase 2: Deductive and Inductive Framework Analysis

In order to understand how the mechanisms of how change occurred (if they did) for the women who attended ReDO®-10, a second phase of data analysis was completed. A number of studies have used a theoretical framework to identify and explore mechanisms in complex healthcare interventions (Cassidy *et al.*, 2019; Fancourt, Wee and Lorencatto 2020). The most commonly-used theoretical frameworks are the Behaviour Change Wheel (Michie *et al.*, 2011) and the Theoretical Domains Framework (Michie *et al*. 2005). An extensive description of this data analysis process is presented in Paper 3 (Appendix III).

Chapter 5 - Summary of Findings from Published Papers

The purpose of this chapter is to summarise the findings of this project and the three papers that have been published from this work to date. Each paper will be summarised very briefly and there will be discussion on how each stage of the project built on the previous, to build up an interrelated and overarching thesis. Two papers are published and available Open Access. The three papers are presented in full in Appendices I, II and III.

Paper 1: Systematic review (Published)

Citation: Fox, J., Erlandsson, L-K. and Shiel, A. (2019) 'A systematic review and narrative synthesis of occupational therapy-led interventions for individuals with anxiety and stress-related disorders', *Occupational Therapy in Mental Health*, 35(2), 179-204, doi: 10.1080/0164212X.2018.1516172 (Appendix I)

A systematic review was carried out to address the research questions (i) "What is the evidence for the effectiveness of occupational therapy interventions in improving functioning and mental health outcomes for individuals with anxiety and stress-related disorders?" and (ii) "What are the characteristics of the occupational therapy interventions that have been evaluated as effective in improving outcomes?" The literature search identified 19 articles describing 13 individual studies where occupational therapy-led interventions were evaluated for people with anxiety or stress-related diagnoses; four controlled trials and nine non-controlled studies. Because of the heterogeneity of the interventions found, it was not possible to directly compare studies. The results were presented in this paper as a narrative synthesis – clustering the interventions according to their theoretical underpinning. Five theoretical categories were identified; cognitive-behavioural interventions, health behaviour change interventions, skill-building interventions, occupational science/therapy theory-based interventions and neurological/sensory interventions.

In summary, it was not possible to make an overall conclusion about the effectiveness of occupational therapy for this population. However, some individual studies with high quality methodologies demonstrated potential effectiveness. A randomised

controlled trial showed that a health behaviour change intervention, delivered by occupational therapists, significantly reduced panic disorder symptoms and was a cost-effective, primary care-based treatment option (Lambert *et al.* 2007). Skill-building interventions, focused on driving (Classen *et al.* 2014), surfing (Rogers *et al.* 2014) or life skills (Helfrich and Fogg 2007) also demonstrated positive outcomes for people with PTSD, albeit in small, individual studies. Using an occupational science/occupational therapy theoretical framework, the Redesigning Daily Occupations (ReDO®) programme was identified as an intervention with emerging evidence for effectiveness for women with anxiety, depression and psychological stress in a primary care setting (Eklund and Erlandsson 2011).

Update to systematic review

Since the publication of this systematic review (Appendix I) the number of occupational therapy interventions being evaluated with individuals with anxiety and stress-related conditions has increased slightly. In August 2021, a search for any new studies published from 2018-2021 was completed. The same inclusion/exclusion criteria were applied: Over 50% of participants should have an anxiety diagnosis or be in that diagnostic category on an outcome measure, the intervention should be led, designed or facilitated by an occupational therapist and mental health and/or daily functioning should be measured as an outcome. The search terms, databases and results are presented in Table 14. Four studies - two randomised controlled trials and two mixed-methods pilot studies - were found.

Table 14. Updated systematic review 2018-August 2021

Search terms and limiters used	**Results found and screened**	**Imported to Endnote**	**Results after duplicates removed (Full-texts screened in Endnote)**	**Papers excluded with reasons**	**Full-texts**
anxiety OR *"anxiety disorder"* OR *panic* OR *phobia* OR *"obsessive-compulsive disorder"* OR *OCD* OR *"post-traumatic stress"* OR *PTSD* OR *"adjustment disorder"* OR *"acute stress"* AND *"occupational therapy"* OR *"occupational therapist"* Limited to 2018-August 2021 Limited to Title, Abstract or Keyword Limited to English Language	Scopus 253	27	43	No anxiety diagnosis (n=25) No/little occupational therapy involvement (n=4) Theoretical/opinion paper/review (n=7) Population under 18 (n=1) Qualitative methodology (n=1) Service delivery (n=1)	4
	Medline 89	46			
	CINAHL 85	19			

As in the first systematic review, the interventions found used different theoretical approaches and were too heterogeneous to directly compare results. The main features and results of the studies are given in Table 15.

Table 15. Studies published 2018-August 2020

Article(s)	Participants	Site	Methodology	Intervention/Programme	Results
Connolly *et al.* (2019)	(n=12) Adults >18. Self-referred or referred with stress issues. Median score of 13 on the HADS indicates "caseness" levels of anxiety disorder.	Primary healthcare site in Ireland	Mixed methods convergent parallel pilot study. Assessments pre, post and at 3-month follow-up. Qualitative data gathered in a focus group and follow-up interviews	RENEW 6-week programme. Based on Cotton's integrated approach to stress management (Cotton, 1990) including psychoeducation about physiological responses to stress, relaxation, lifestyle and stress, CBT principles and goal-setting. Nutritionist, social worker and physiotherapists involved as guest speakers, but programme led and facilitated by OT.	Significant improvement for anxiety (not depression) on the HADS (p=0.011). Significant improvements for occupational performance and satisfaction on the COPM. Qualitative feedback indicated group support, the programme content and psychoeducation were valued.
Danielsson *et al.* (2020)	(n=42) Working adults >18 years. Depression/anxiety.	Primary healthcare site in Sweden.	Pilot randomised controlled trial. Randomised to work-directed rehabilitation (n=21) or physical activity (n=21)	Individual sessions, depending on client goals (between 4-16) with an OT or PT focused on activity analysis, ReDO® principles, body awareness therapy and guided exercise). Control group did gym/home exercise recommended by a PT.	Statistically significant improvements in work ability (WAI), depression (MADRS), anxiety (BAI) and functioning (GAF) in both groups ($p<0.05$). No between-group difference.
Fontaine *et al.* (2018)	(n=68, from 104 referred) Aged >18 years. Mood/anxiety disorder	Outpatient Mood Disorders Department, Canada (transitional programme between acute and community)	Mixed methods. Pre-post analysis of outcomes plus qualitative interviews with healthcare staff.	Mood Disorders Occupational Therapy Rehabilitation and Education (MORE) service. 9-week programme. Twice weekly groups (Life management and mindfulness) plus individual sessions (behaviour activation and goal-setting, informed by CBT).	Significant pre vs post improvement in depression (mean BDI-II score 26.21 vs 16.97, p=.000). Sig. improvement in anxiety (mean BAI score 20.16 vs 9.17, p=.000). Sig. improvement in quality of life (QOLI) although scores remained low.

Gunnarsson *et al.* (2018)	(n=118) Aged >18. Depression/anxiety diagnoses	Primary and outpatient mental health context, Sweden.	Randomised controlled trial. Participants randomised to TTM (n=62) and OT as usual (n=56).	5 sessions of the Tree Theme Method® (TTM). Based on art therapy (painting a tree representing different life stages). Control group received individualised OT (varied between participants)	Significant differences in occupational performance/engagement (COPM), occupational balance (OBQ) and anxiety/depression (HADS) in both treatment conditions but no between-group differences.

In summary, the participants in these four studies experienced benefits in mental health symptoms and functioning following participation in OT-led programmes or interventions. The interventions all used different theoretical perspectives, but common to all was a focus on problem-solving about engagement in activities of daily life. When control conditions also included individualised support (Gunnarsson *et al.* 2018; Danielsson *et al.* 2020), both arms of the trials showed improvements, giving more evidence for this approach. Two studies showed potential for occupational therapy programmes to have preventative benefits for people with emerging issues with anxiety (Connolly *et al.* 2019) and to prevent re-hospitalisation (Fontaine *et al.* 2018), albeit in studies without a control condition. In two studies, the intervention programme lacked a description of the mechanism by which it was expected to work or the underlying evidence for the approach (the RENEW programme (Connolly *et al.* 2019) and the TTM method (Gunnarsson *et al.* 2018). In general, as discussed in Chapter 2 (Literature Review), it is difficult to identify which programme/intervention is most effective for people with anxiety because the reasons for psychological distress are conceptualised as being quite different in each study. Acceptance of participants for the approach is likely to influence how efficacious it is (Cole *et al.* 2019). For practitioners to be able to choose between different occupational therapy approaches/programmes for people with different interpersonal and contextual factors influencing their mental health, authors and researchers should describe the intervention, the underpinning theory, the context and the characteristics of the participants thoroughly.

Paper 2: Feasibility study (Published)

Citation: Fox, J., Erlandsson, L-K. and Shiel, A. (2021) 'A feasibility study of the Redesigning Daily Occupations (ReDO®-10) programme in an Irish context', *Scandinavian Journal of Occupational Therapy*. Published online Feb 2021 doi: 10.1080/11038128.2021.1882561 (Appendix II)

The second paper published as part of this project focused on answering the research questions outlined in Chapter 3 relating to the feasibility of either a future RCT of ReDO® in Ireland and/or the feasibility of its future implementation more generally. A mixed-method feasibility study was carried out with two cohorts of women with psychological distress, recruited either via their GP or through self-referral. The ReDO®-10 programme was facilitated by two primary care therapists trained in the method. Qualitative perspectives

were gathered from the ReDO®-10 participants (n=10), the occupational therapists (n=2) and the GPs (n=9) and quantitative outcomes were measured at three time points (Pre-intervention, post-intervention and 2-month follow-up).

The quantitative outcomes showed trends towards effectiveness in terms of psychological distress, occupational value, mastery, perceived health and overall functioning. However, the small sample size and lack of control group means this should be interpreted cautiously. Qualitative perspectives from participants indicated that the group support was very important to any changes that occurred for them. The general practitioners welcomed the opportunity to refer to a new programme in primary care, although the numbers actually recruited through direct GP referral were low. The occupational therapists enjoyed the change in their usual practice and the experience of delivering an occupation-focused intervention, but were challenged to keep up with their existing waiting lists. In summary, a future trial of ReDO®-10 is feasible and could deliver positive outcomes for women with stress, but significant support would be required for both recruiters and facilitators (See Chapter 6 for discussion of future research implications).

Paper 3: Mechanisms of change (Published)

Citation: Fox, J., Erlandsson, L-K., McSharry, J. and Shiel, A. (2021) 'How does ReDO®-10 work? Understanding the mechanisms of action of an intervention focused on daily activities and health from the perspective of participants**',** *Journal of Evaluation and Program Planning,* 102092, doi: 10/1016/j.evalprogplan.2022.102092 (Appendix III)

The third paper focused in detail on exploring the changes experienced (or not) by participants and attempting to understand the mechanisms by which ReDO®-10 brought about those changes. It outlines the results from a qualitative analysis of participants' perspectives based on the Behaviour Change Wheel (BCW) and the Theoretical Domains Framework (TDF) (Michie *et al.* 2005; Michie *et al.* 2011; Michie *et al.* 2013). This paper included qualitative data from fourteen participants – the ten participants included in Paper 2 above and a further four participants who were part of a ReDO®-10 programme facilitated by Jackie Fox and a primary care occupational therapist in 2019-2020. A fourth-year occupational therapy student gathered this latter set of data as part of a separate research

study. Participants gave full written consent for their data to be combined with that of other ReDO®-10 participants and to be published in this PhD and related papers (See Chapter 4).

The TDF provided a coding frame for analysing participants' narratives about what changes they perceived during and following participation in the ReDO®-10 (if any). Participants described changes in their psychological capability (Knowledge, Memory Attention and Decision Processes, Cognitive and Interpersonal Skills and Behavioural Regulation), Automatic motivation (Emotions and Reinforcement), Reflective Motivation (Beliefs about Capabilities, Beliefs about Consequences, Intentions, Social Role and Identity and Goals) and their social opportunities. Changes to occupational choices, patterns and balance were described by some participants, while others simply noticed a raising of awareness or intention to make lifestyle changes. The BCW was used as a coding framework to understand how ReDO®-10 might have brought about these changes. A large number of behaviour change techniques (BCTs) including those directly facilitated by the occupational therapists as set out in the ReDO®-10 manual (e.g. goal-setting (BCT 1.1)) or occurring more naturally during group discussions (e.g. social comparison (BCT 6.2)) were perceived by participants . In summary, ReDO®-10 appears to influence behaviour change through four intervention functions of the BCW; (1) Education, (2) Persuasion, (3) Modelling and (4) Enablement. Self-awareness, raised by education and occupational self-analysis and practice of occupations as homework and in sessions were particularly highlighted as important mechanisms of change.

Synthesis of published papers and overarching thesis

The systematic review identified a number of issues that guided the opening stages of this research study. Firstly, almost all of the interventions were evaluated only once, in small studies, in a particular context. This lack of replication means that even interventions demonstrating positive outcomes (such as the life skills programme described by Helfrich and Fogg 2007) are not being evaluated further with randomised controlled trials. There are multiple barriers to replication research, including the emphasis on originality among research funders and publishers and the lack of clear descriptions of interventions (Vachon *et al.* 2021). Single studies of occupational therapy interventions are not likely to change practice, policy or evidence-based guidelines (Schmidt 2016). Secondly, both this systematic review and the literature review in Chapter 2 highlighted the lack of occupational therapy-led programmes for women in primary care settings with psychological distress. While many

of the interventions in Chapter 2 are within the scope of practice and skill-set of an occupational therapist, only the ReDO® programme was identified as an intervention with sufficient evidence to explore for feasibility in the Irish context.

Finally, description about how the interventions intended to bring about change was missing from many of the papers reviewed (Appendix I). Some interventions were a mixture of multiple different theories (for example, one intervention is described as "*motivational interviewing, cognitive-behavioural therapy, relaxation strategies, skills training and interpersonal therapy*" (Kohn *et al.* 2012, p.439)). Inadequate understanding of the "black box" of interventions can lead to poor evaluations, running the risk of "*trying to change behaviour that was not related to the problem, trying to change determinants for behaviour that were not relevant to the behaviour…..trying to apply change methods that were never shown to be effective*" (Kok and Mesters 2011, p.176). Based on this systematic review, it was decided to carry out a feasibility study and process evaluation (including exploration of mechanisms of action) of the ReDO®-10 programme in primary care in Ireland for women with psychological distress.

The various phases of the feasibility study resulted in important information about recruitment, randomisation and data collection for future research. In total, 31 women expressed interest or were referred to the two pilot ReDO®-10 groups in 2018-2019. However, it is unknown how many were approached by their GP or saw information posters/leaflets and declined participation. Self-referral was an additional method of recruitment in 2019 and this resulted in faster recruitment and better retention of participants. Because of slow recruitment in 2018, randomisation and blinded allocation to a treatment-as-usual control group was not possible. Baseline and post-intervention data collection was successful with those who completed the programme, but three of 12 participants did not submit follow-up data. The outcome measures (See Chapter 4) were broadly acceptable, although some WHODAS 2.0 items were found to be difficult to answer accurately from a mental health perspective.

The qualitative data from the occupational therapists showed that the ReDO®-10 had been carried out with fidelity in this new context and that the concept of fidelity to a manual in the context of trial-like conditions was well-understood. The only adaptations made were to bring some material from the original 16-week version back into the ReDO®-10, as

clinical reasoning on the part of the therapists was that the flow of content was interrupted without this addition. The occupational therapists welcomed what they perceived as a change from their usual type of clinical work in primary care and noted some personal changes in their own lives from using the ReDO®-10 principles.

The qualitative findings also indicate the importance of considering the context into which this new intervention was being trialled. High demand for mental health treatment options in primary care was noted by GPs who reported that "*every second consultation has an element of anxiety and stress*" (GP2). Despite being aware of occupational therapy in primary care, GPs would not usually make direct referrals to the service, other than for home modifications for older adults. The pilot ReDO®-10 groups had the support of the Occupational Therapy service, but placed some pressure on already high waiting lists. Contextual factors, such as relationship difficulties, university/work concerns and co-morbidities (e.g. fibromyalgia) were evident in both causing and maintaining psychological distress for the participants of ReDO®-10 but could not be controlled for in this small-scale study.

The analysis for Paper 2 indicated that there were trends towards effectiveness on the various outcome measures for the women who participated in the ReDO®-10. However, there were considerable individual differences in scores and in qualitative experiences. Women described idiosyncratic changes to their daily lives, such as prioritising restorative occupations or saying no to multiple demands. Completing a further stage of data analysis using the BCW (Michie *et al.* 2011) (Paper 3) allowed for a more nuanced understanding of the psychological processes, knowledge or behaviours that changed (if they did) and the specific ReDO®-10 activities influencing that change. Facilitating opportunities for women to analyse their own occupational time-use, levels of hassles/uplifts and occupational balance provided important information about the relationship between activities and their health. Seeing this information visually represented, using colour-coded diaries or pie-charts was effective in raising awareness of issues of imbalance. Starting to make changes in time-use or activity choices was often a result of persuasion, consisting of encouragement by other women that they were entitled or deserving of taking breaks or making empowered choices about their activities. Seeing how other women dealt with problems or made changes was effective, as was hearing directly from women who had previously been in similar situations.

ReDO®-10 enabled women through a number of behaviour change techniques. Goal setting, especially formulating manageable, realistic, meaningful goals was important, as was the encouragement of other women in making changes. The practice of occupations in sessions and as homework was an emotional experience that was not always comfortable. However, finding ways of individualising the occupational homework (e.g. going for a horse ride instead of a walk), helped women to embed changes into daily life. Not all women made this connection however. For some, poor interpersonal relationships in the home, having young or disabled children, or having a strict and demanding workplace made it difficult to choose autonomous occupations or change occupational patterns. A seminar to educate family members/colleagues about ReDO®-10 in order to help make family/workplace changes was offered to participants but was not welcomed by a majority. Therefore, any family-level changes were made by women in areas over which they had control e.g. delegating chores to children. In general, the emotional social support of other women in the sessions was highly valued. Group dynamics, the establishment of trust, clear ground rules and sensitive therapist facilitation were all vital in any changes that occurred for the participants. These findings illuminate the mechanisms by which ReDO®-10 may bring about change, highlight some particularly important activities and techniques used and have implications for the training of occupational therapists who may facilitate this programme in the future.

Chapter 6 – Discussion

This chapter will discuss the findings of the study under the headings of the diagram given in Figure 2. Discussion of context is integrated into each section as contextual issues arose at many stages across the project. The following themes will be discussed;

- Primary care in Ireland: Opportunities and challenges for the implementation of ReDO®-10 in a new context
- Refining understanding about how ReDO®-10 works, proposed mechanisms and a refined logic model
- Feasibility of a future trial and future research considerations
- Generalisability of the findings

The chapter also includes a discussion of some post-Covid-19 pandemic considerations, an extensive reflexivity statement and an outline of the strengths and limitations of this research study.

Primary care in Ireland: Opportunities and challenges for the implementation of ReDO®-10 in a new context

There is high demand for mental health services in primary care (Agyapong *et al.* 2012). A counselling service in Irish primary care has been implemented in recent years (Health Service Executive 2019), but the GPs in the current project indicated that there can be a long waiting list for this service (See Paper 2, Appendix II). Pharmacological treatment may not be appropriate for patients who do not meet the criteria for an anxiety or depressive disorder fully (Moncrieff 2009). A qualitative study of people with psychological distress in primary care identified that community interventions that de-medicalise symptoms and use self-management strategies would meet the needs of this population more appropriately (Geraghty et al. 2017). In the current project, ReDO®-10 showed promising outcomes for women of different ages, work roles and family commitments. There were also promising indications that ReDO®-10 met the needs of women who were both over- and under-occupied in their daily patterns of activity (See Paper 2, Appendix II). Olsson *et al.* (2019) found that ReDO®-10 participation was associated with significant improvements in occupational balance, perceived health and work ability in a primary care population ($p<0.005$). ReDO®-10 could potentially be provided to a wide and heterogeneous primary

care patient group as an alternative or complement to other community-based treatment options.

However, ReDO®-10 required considerable time and resources to facilitate. The therapists in this project acknowledged that future implementation of this programme would be difficult within current staffing (See Paper 2, Appendix II). A vision of the 2001 strategy, "Primary Care: A New Direction", was that a network of almost 1000 interdisciplinary primary care teams, including medical, nursing, therapies and welfare professionals, would provide interventions to manage people's health close to home (Oireachtas 2001). However, it is estimated that, due the global financial crisis in 2008 and a culture of poor implementation of health policy generally, less than half of the planned primary care teams were established (Kelly *et al.* 2016). Those that were, reported that the teams functioned poorly and often did not include all disciplinary perspectives (O'Sullivan et al. 2015).

The implementation of "Sláintecare", the new strategic plan for primary care services, could provide an opportunity for increased primary care occupational therapy provision in Ireland (Committee on the Future of Healthcare 2017). This strategy has a focus on localised, multidisciplinary, free health-care delivery, with an emphasis on health promotion and streamlined care between primary and secondary services. The combination of the Covid-19 pandemic, a highly disruptive cyberattack on the Irish health services and political controversy has stalled the implementation of Sláintecare recently (Clarke 2021). Nevertheless, the prioritisation of primary care service provision in the coming years offers an opportunity for occupational therapists to broaden their role in that setting. The development and evaluation of manualised programmes like ReDO® (Eklund and Erlandsson 2011), Lifestyle Redesign® (Jackson *et al.* 1998) or OPTIMAL® (O'Toole *et al.* 2021) can provide an evidence-base from which to advocate for an increase in staff numbers to allow implementation of these programmes. Cost-effectiveness evaluations, (such as that of Lambert *et al.* (2010) who evaluated the economic impact of occupational therapy for people with panic disorder in primary care), can demonstrate the impact of the intervention on measurable outcomes such as hospitalisations, people returning to work, or improved quality adjusted life years (QALYs). Such studies are needed to argue for the prioritisation of occupational therapy, particularly in times of health system transformation (Rexe *et al.* 2013).

In addition to the need to increase occupational therapy staff numbers in primary care, it is also necessary to broaden the typical scope of practice in this setting to include programmes such as those described above. The therapists in the current study spoke of their frustration in their perceived "equipment provider" role (See Paper 2, Appendix II). At present, equipment provision and advice on home modifications forms a large part of Irish primary care occupational therapy practice (Fitzgibbon and Chockalingam 2010) and a survey of therapists in Ireland identified that only 18% felt they had the skills to provide intervention for people with depression. That survey also indicated that the management of physical health conditions is perceived as more straightforward (Gallagher *et al.* 2016). Burnout is a risk among occupational therapists when they feel a lack of accomplishment in their professional role or feel undervalued (Edwards and Dirette 2010). There is evidence, albeit from the United States, that both primary care staff and patients identify considerable unmet occupational needs in current service provision. While complex medical needs may be met, issues relating to managing one's own health, problem-solving around daily tasks (like managing money), community mobility or developing healthy habits were identified as being unmet needs (Winship *et al*. 2019). The WHO has called for a more progressive approach to primary health care, one which views the person holistically: "*their physical, emotional and social concerns, their past and their future and the realities of the world in which they live*" (World Health Organisation 2008, p.46). Programmes such as the ReDO®-10 offer primary care occupational therapists tools to take this broader perspective.

Refining understanding about how ReDO®-10 works, proposed mechanisms and a refined logic model

"The place to start evaluation is with the well-travelled programme theory that underpins it" (Pawson 2013, p.8). A logic model for how ReDO®-10 is expected to work was proposed (see Chapter 3). This model outlined the implicit causal assumptions of the intervention i.e. the mechanisms through which change is assumed to occur. A series of ten theoretical assumptions were developed. For example, "*Imbalance in the occupations of daily life may cause stress and ill-health. Therefore improving balance in daily life occupations should improve health and reduce stress*". By using directed content analysis and the Behaviour Change Wheel (Michie *et al.* 2011) as a coding framework, these statements can now be refined further. A mechanism by which the change should occur i.e. how balance in daily life could be improved can now be considered. The use of the Theoretical Domains Framework (Michie *et al.* 2005) allowed for some key mechanisms such as changes to social opportunity, beliefs about capabilities or the triggering of emotions

to be identified. The following sections will review the logic model in light of the new understanding of mechanisms discussed in Paper 3 (Appendix III) and outcomes presented in Paper 2 (Appendix II).

From the data in this study (Appendix III), it was evident that some women did make changes to life balance during the ReDO®-10 programme. Some examples were taking more breaks during a workday, reducing time spent in bed or delegating chores to others in the home to allow for more rest. For those with small children, being able to justify self-care or restorative occupations without guilt was very important. The prevalence of maternal guilt among mothers in Western societies is very high and other studies have found that group contexts can allow women to examine myths, unrealistic standards and pressures critically in order to reduce stress (Seagram and Daniluk 2002). Helping people who have withdrawn from normal daily activities to schedule and experience a sense of achievement and mastery in daily tasks again gradually is an accepted and effective mechanism in occupational therapy (Eklund *et al.* 2017) and behavioural activation (Martell *et al.* 2001) programmes and was discussed by one participant in particular in this study (See Paper 2). Overall, perceived health improved over the three data collection points for the women in this study (55.67 - 72.92 - 70, p=0.078). There is also some evidence that the programme improved overall life functioning, as mean WHODAS 2.0 scores fell from 31.49 (pre) to 17.24 (follow-up) (p=0.013). This indicates an improvement in the overall ability to participate in life activities. For those who were working or in fulltime education, identifying ways to have a productive morning routine, take breaks, take time off when needed or to have a more restful evening routine were all described as helpful. Consideration for personal preferences around goal setting was important. For example, one participant valued drawing up a very detailed, structured morning plan (See Paper 2).

Many women in this study discussed stressful life circumstances and daily hassles, including marital communication difficulties, differing opinions on parenting or pressure from extended family. As discussed in Paper 3 (Appendix III) most women were trying to change occupational patterns in a partnership or family context where time-use and occupations had to be negotiated and shared. Other women had to consider elderly parents, co-workers, employers, friends and adult children in making decisions about occupations. The ReDO®-10 programme includes a seminar for partners, family, friends or employers, so that these individuals can also receive information about the importance of occupational balance, reducing complexity in daily life and other aspects of the programme (Erlandsson 2013). In this study however, married women in particular felt that the group space was

private so the seminars were cancelled. Because these ReDO®-10 programmes were offered to women with stress, anxiety or depression, it is possible that they were fearful about strangers (outside of the closed group circle) seeing them in this vulnerable position. Qualitative evidence from Irish people with mental health issues shows that many use "face management" strategies to "wilfully project an image of a competent, emotionally regulated individual" and that many do not discuss the extent of their psychological distress even with family members for fear of it changing the dynamic in the relationship (Lakeman *et al.* 2012, p.277). If ReDO® programmes are provided in Ireland in future, this response can be anticipated. Presenting the evening seminar as an opportunity for friends, partners or other family members to learn new occupational patterns themselves, as opposed to helping or supporting the woman, might help the participant to save face. Alternatively, the information from the programme could be developed into a video or other materials that the participant can show their family in their own time.

In addition, the qualitative data suggest that the social environment might not have been addressed sufficiently in the programme. One participant felt that the information presented in ReDO®-10 about the biological mechanisms of stress places the "blame" for the stress within the woman, rather than her social environment (See Paper 3, Appendix III). This is an argument which was also presented by some authors critical of individual-level interventions for stress (Kaplan 2019). As ReDO®-10 is not intended as a mental health intervention, but as one that focuses on occupational balance and patterns, empowering families/households/groups to analyse co-occupations and family-level occupational patterns and then make changes together would reduce the pressure and problematizing of one individual (Orban *et al*. 2012; Pickens and Pizur-Barnekow 2009,). In the current study, some women improved wellbeing by delegating chores to children or doing restorative occupations as a family. An unmarried participant reconnected with a female friend in leisure activities, improving the occupational patterns of both. Having specific worksheets and homework tasks related to setting family/social group goals could be considered. Families create their own culture so facilitating understanding of "how we do things" (Alegria *et al.* 2010, p.50) could be used as a mechanism of change to improve the occupational patterns of more than just the participant in the ReDO® programme.

The qualitative data from this study emphasise the importance of the occupational self-analysis tools used in ReDO®-10 for drawing attention to areas of imbalance in the participants' occupational patterns (Paper 2). As described in Paper 3 (Appendix III), these

activities improved knowledge and intentions to make occupational changes. Therefore, it is evident that Social Cognitive Theory (Bandura 1986) and the Integrated Theory of Health Behaviour Change (Ryan 2009) are both appropriate theories underpinning the programme (See logic model, Chapter 4). However, moving from intention to action was a slower process for some participants. Following the occupational self-analysis with occupation-based homework enabled some participants to try new behaviours and patterns and led to more sustained behaviour change (See Paper 3), albeit with considerable individual variation for the women over the three phases of ReDO®-10. The occupation-based activities in some group sessions triggered an emotional response for participants, which again led to some participants trying new occupational experiences outside of group sessions. This emotional response was not always positive initially, particularly when women did not expect activities within what they perceived as a discussion-based group (See Paper 3). While the ReDO®-10 manual specifies the type of occupation to be used in the sessions (e.g. eating a fruit with full attention), scope needs to be given to group facilitators to choose group-relevant occupations or adapt the occupations for the needs of their group/context.

Finally, the group dynamics created within each ReDO®-10 group was highly influential of change as would be predicted by the logic model and in group-delivered interventions generally (Yalom and Leszcz 2005). The group environment allowed for many behaviour change techniques to be used to good effect e.g. social comparison (BCT. 6.2), verbal persuasion about capability (BCT. 15.1) and social support (BCT. 3.3) (Michie *et al.* 2013) (See Paper 3). Treatment outcomes in groups arise from a complex interaction between the therapist, the group and the individual member (Roback 2000). Many participants gave direct examples (See Paper 3) of times when they learned from one another, were persuaded to try a new course of action by group members or felt emotionally supported after sharing information in the group. Given the importance placed on the group environment by members, it is unlikely that the ReDO®-10 activities or materials would have similar impacts if facilitated in individual sessions.

Most participants in this project described a highly supportive group environment, even for those who self-identified as being quiet (See Paper 2). However, participants bring their own individual personality factors to a group-based intervention and their expectations and reactions to that environment can be "emblematic of their approach to the world" (Mohr 1995, p.13). For a participant who valued order and boundaries for example, incidents where other women arrived late were perceived as highly disruptive (See Paper 3). There were individual differences in whether the ReDO®-10 was perceived as a group-delivered

"course" or "therapy" (See Paper 2), possibly reflecting differences in levels of distress and/or how participants approached the task and homework elements of the programme. ReDO® programmes are designed as a "course" and the emphasis is on education, occupational self-analysis and goal-setting, rather than general psychotherapeutic support, although sensitive group facilitation is needed at all times (Erlandsson 2013). Careful attention may need to be paid to the expectations of participants prior to starting a ReDO® programme as a mismatch of expectations is linked to increased drop-out rates in group-delivered interventions (Egan and Kenny 2005). Because of the wide range of topics that could arise in discussions about daily life activities, careful group facilitation skills are required to keep the group focused on the topics and to maintain cohesiveness (See Paper 2).

Feasibility of a future trial and future research considerations

Both qualitative (perspectives of GPs, OTs and participants) and quantitative (outcomes, recruitment and retention) data were gathered during this project in order to determine the feasibility of a future trial of ReDO®-10 in Ireland and the future implementation of the programme more generally. These data were presented in Paper 2 (Appendix II). The following section expands on these findings and outlines considerations for how future research on this programme could be approached in the Irish context.

Economic evaluation

The inclusion of economic evaluation in trials of occupational therapy interventions is strongly recommended (Weatherly and Davies 2021). The economic benefit of including occupational therapy is evident for family carers of people with Parkinson's disease (Sturkenboom *et al.* 2015). However, such benefits are not as clear-cut in, for example, community-dwelling older adults (Flood *et al.* 2004) or stroke recovery (Sampson *et al*. 2014). From a mental health point of view, an occupational therapy intervention for work-related depression (Schene *et al*. 2007) and a lifestyle intervention for panic disorder (Lambert *et al*. 2010) have been evaluated economically and, while more expensive than routine care, show reasonable cost-effectiveness. Any future trials of ReDO® programmes in Ireland should consider gathering data which could inform an economic evaluation, such as numbers of GP consultations, days of stress-related sick leave, use of other services (such as counselling), cost and/or dosage of medications and the occupational therapy hours required. The occupational therapists in this study were released from their normal work duties for the

hours required to prepare and facilitate ReDO®-10. However, their waiting lists grew during this period and potentially put pressure on other areas of the primary care service (Paper 2, Appendix II). At present, current staffing levels do not allow for multiple therapists to participate in a research trial in addition to their normal workload. Therefore, a future trial would require at least one funded occupational therapy position. Including funding for therapy provision in a future trial would provide important economic information for future workforce planning in primary care, particularly with the emphasis in Sláintecare on more health promotion/prevention services being provided in the community (Committee on the Future of Healthcare 2017).

Recruitment considerations

This study was welcomed by GPs who saw ReDO®-10 as a positive "treatment option" (see Paper 2). However, despite the large number of women meeting the inclusion criteria, not enough participants were recruited to complete a randomised pilot as intended. A number of barriers to recruitment to trials have been identified in general practice settings and were also identified by the GPs in the current study. Such barriers include the difficulty of fitting research recruitment into daily practice or the culture or acceptance of research within the practice (Foster *et al.* 2015). Recruiting to mental health research within routine clinical practice in primary care can be especially difficult. GPs value the doctor-patient relationship so will avoid bringing up research participation in a consultation with a patient experiencing distress. There can also be a degree of gatekeeping, where a GP will decide subjectively who to tell about a research study, rather than offering it to everyone meeting the inclusion criteria (Mason *et al.* 2007). A combination of self-referral and GP referral led to faster recruitment in the current project. However, as GPs are the main and often the central hub of service provision in primary care in Ireland, any future research trial of ReDO®-10 will require their support for recruitment. Facilitators to support the involvement of small primary care practices in research recruitment were described by Cuthel *et al.* (2020). These measures include aligning the study with existing practice priorities carefully, developing long-standing relationships with the practices and providing monetary incentives. The promotion of this project through the Primary Care Clinical Trials Network (HRB Primary Care CTNI 2017) (including financial incentives to recruit patients) and the identification of study "champions" worked well. These "champions" were GPs who were already interested in this clinical area and who consistently told their patients about the study. Other recruitment strategies that have been recommended for primary care/general

practice research trials are to have multiple avenues of recruitment using different stakeholders (e.g. practice nurse, practice manager) and to collaborate early and often to identify recruitment challenges (Fernald *et al.* 2018).

Some social barriers may present a challenge to the successful future implementation of ReDO®-10 and similar programmes. As described in Paper 2 (Appendix II), a number of women declined participation in the programme. Lack of time and personal preference for individual therapy or medication were mentioned as reasons for declining. Self-management interventions such as ReDO®-10 require capacity, responsibility and motivation from participants. Individuals need to have sufficient physical and emotional capacity to focus on making changes, time to do so, a belief that they have some agency over their own health (as opposed to relying on medical treatment), an expectation that such programmes will bring about improvements and a sufficiently positive mood to hope for change (Coventry *et al.* 2014). Although only mentioned by one participant and one GP, an internal barrier that was present (in this Irish context at least) was the feeling that taking time for a self-improvement programme would be "self-indulgent" (See Paper 2). There can be a misinterpretation that to have compassion for oneself and one's situation is "self-indulgent" (Neff 2004). As described above, presenting ReDO®-10 as an educational course, rather than therapy, may reduce numbers of women declining to participate for this reason.

Although detailed demographic data were not collected about all the participants in the current study, it was evident that they were all White and the majority were university-educated, employed (or retired) and living in their own homes. Women from poorer socio-economic backgrounds may participate less in mental health interventions because of the financial cost, transport constraints or lack of time (Beeber *et al*. 2007). There is also evidence that cognitive-oriented programmes, requiring a high degree of verbal skill, can be daunting for women with lower educational attainment (Van der Waerden *et al*. 2013). The energy required for a self-management intervention can also be affected negatively by socioeconomic deprivation (Coventry *et al.* 2014). To recruit a wider diversity of women into future Irish ReDO® programmes, particular care should be taken to address the needs of women who face social, economic or racial barriers to participation directly. There are some aspects of the ReDO® perspective that could resonate with people experiencing such barriers which could be emphasised. Socio-economically vulnerable people may be focused on day-to-day life (rather than aspirational future goals such as retirement, for example (Clark *et al*. 2008) and are likely to be spending a lot of energy on coping with life in general (Shippee *et*

al. 2012). The emphasis in ReDO® on problem-solving daily stressors, finding realistic and uplifting daily occupations and managing patterns of activity so as not to be overwhelmed could offer a useful mental health-promoting perspective to this population in Ireland. To enrol individuals facing socioeconomic challenges to preventative primary care interventions, a number of strategies have been suggested. Using telephone screening, focusing on GP practices in disadvantaged areas, doing outreach activities to local community services, reimbursing public transport/childcare costs and presenting a programme as a course, rather than therapy, have all been found to increase both the recruitment and retention of low-SES women to a community-based depression intervention successfully (Van Der Waerden *et al.* 2010).

Randomisation and control group considerations

Comparison of ReDO®-10 participation with a control condition using random allocation is an important direction in future research. Previous studies of ReDO®-16 using a non-randomised control group found that differences between the two groups at baseline contributed to the non-significance of some results (Eklund 2013; Eklund and Erlandsson 2011). Waiting list controls are often used in healthcare trials but there is some evidence that being assigned to a waiting list control condition can worsen mental health outcomes for research participants, in comparison to those receiving usual care (Furukawa *et al*. 2014, Patterson *et al.* 2016). Some GPs in the current study felt uncomfortable randomising people to wait for what was perceived to be an effective intervention (See Paper 2). An active control condition such as a weekly non-specific support group could be used, since group dynamics was one important mechanism of action in ReDO®-10.

Training of occupational therapists

The findings of this study suggest two important considerations for the training of occupational therapists to deliver ReDO®-10 programmes in the future. These have relevance for the Irish context and more broadly. Firstly, as discussed, ReDO®-10 participants identified the strong potential for group dynamics to be supportive of or a barrier to change (Papers 1 and 2, Appendices II and III). At present, the importance of peer modelling and group dynamics and the potential for strong emotions to arise in the group is not covered in the ReDO® training. Secondly, the therapists in the current study used clinical

reasoning to adapt the manualised programme in places e.g. to include some material from the 16-week programme (Phases 1 and 2) or to change the type of creative/mindful occupation used (Phase 3). These adaptations are examples of changing the "form" of the intervention, but not the "function", since they do not change the underlying proposed mechanism of action of the activity (Hawe *et al*. 2009). Again, ReDO® training could include information for potential facilitators about where they can use clinical reasoning and make adaptations while retaining fidelity. This would allow the programme to be tailored to different populations e.g. to younger adults or to a male-only group or to different cultures/countries.

Outcome measurement

The outcomes measured as part of this project were; psychological distress, occupational value, mastery, perceived health and disability/functioning. Some of these outcomes (mastery and occupational value) were measured using the same instruments as in previous evaluations of ReDO® (see below), allowing for some comparison.

Mastery

Eklund and Erlandsson (2013) found no significant differences in mastery (as measured on the Pearlin Schooler Mastery Scale (Pearlin and Schooler 1978)) between women who received ReDO®-16 and a comparison group, although the CAU cohort had significantly higher mastery scores at baseline (p=0.001). Participants in the current study demonstrated a significant increase in mastery (means over the three timepoints were 17.33-20.58-20.89, p=0.009). There was dropout between the intervention (n=15) and follow-up (n=9) and there was no control group (See Paper 2). The sense of mastery can have intercultural differences (O'Connor and Shimizu 2002) and is likely to be dependent on external circumstances such as living in poverty. However, it would continue to be an important variable to measure in future studies of ReDO® programmes since a recent study exploring older people's mental health during the Covid-19 pandemic (n=1068) found an unexpected increase in mastery over the period, which the authors hypothesise was due to the participants being able to reflect on and choose the activities they most enjoyed (van den Besselaar *et al.* 2021).

Occupational Value

The participants in this study experienced an increase in their perceived occupational value as measured on the OVal-pd instrument (Eklund *et al.* 2009) (mean scores over the three time points were 38.78-48.67-47.11, p=0.016). Wästberg *et al*. (2016) found that improved occupational value was associated with an improvement in the perception of the work environment for women who attended ReDO®-16. This supports one of the theoretical pillars of the programme which is that the everyday life as a whole needs to be in balance for work to feel manageable (see Chapter 3). Work (or return to work) was not the primary concern of the participants in the current study. The qualitative data (Paper 3) support the idea that, for these women, an increase in occupational value was associated with choosing more varied occupations, restorative occupations and doing occupations with more awareness to reduce stress.

Perceived Health

Perceived health was measured in this study on the visual analogue scale part of the EQ-5D-5L (Herdman *et al.* 2011), the EQ-VAS. International studies show an EQ-VAS mean score between 81-85.1 out of 100 among the general population (Alonso *et al.* 2013; Huber *et al.* 2017) with scores for people with mental health difficulties between 5-8 points lower (Alonso *et al.* 2013). Participants in the current study had a baseline mean score of 55.67 (n=15), which is significantly lower than this international average. While this information was not formally gathered, the qualitative data indicated that participants were also experiencing a range of health challenges, common in a mixed primary care population such as fibromyalgia, chronic pain and menopause (Wittchen *et al*. 1999). While perceived health increased post-ReDO®-10 (to a mean of 72.92, n=12), the fact that this is still much lower than the average shows that, while ReDO®-10 participation may have increased some perceived emotional health, physical health was less affected. Scores on this VAS-type measure could be skewed by short-term health complaints, so future ReDO® studies could incorporate a measure such as the Health Locus of Control scale (Wallston *et al*. 1976). Since ReDO® programmes will explore issues such as taking control over sleep, time spent on relaxation or saying no to excessive demands, a construct like perceived control would be more likely to be sensitive to the intervention effects.

Disability/Functioning

The internationally validated WHODAS 2.0 was used to measure overall functioning in everyday life in this study (Ustun *et al.* 2010). The average score on the WHODAS 2.0 in high-income countries including Ireland is 3.6, or 15.3 for people with a diagnosis of depression (Alonso *et al.* 2013; Bromet *et al.* 2011), with a lower score indicating poorer functionning. Again, participants in the current study scored much lower than these averages (baseline mean 31.49, n=15). While functioning scores improved post-intervention (mean 22.04, n=12) and at follow-up (mean 17.24, n=9), participants were still experiencing a significant degree of disability in everyday life. Despite the WHODAS 2.0 being a recommended outcome measure in trials for people with anxiety (Obbarius et al., 2017), it is likely that it identifies some issues not likely to be addressed in a psychosocial intervention, similar to the EQ-VAS. Some participants reported difficulty completing the WHODAS 2.0, identifying that there can be a difference between being "unable" to do an activity and feeling unmotivated to do so, or functioning with a lower quality of performance (e.g. in work) (See Paper 2). Ambiguities like this have led some authors to recommend supplementing the WHODAS 2.0 with an interview-type assessment to explore daily functioning so as to achieve a more accurate assessment of disability (Konecky *et al*. 2014).

Psychological distress

The Depression, Anxiety and Stress Scales (DASS) were used to measure overall psychological distress and to distinguish levels of depression, anxiety and stress-type symptoms in the participants in this study (Lovibond and Lovibond 1995). The full scores for these outcomes are given in Paper 2 (Table 3), but participants showed significant improvements on all three domains, with three women improving from the "extremely severe depression" category to "normal mood" over the timeframe of the project. In a larger study of ReDO®-16, participants also showed reduced "caseness" levels of anxiety and depression at a 12-month follow-up after the programme (Eklund 2013). Because ReDO-10 did not specifically address mental health topics in the programme (apart from discussing stress), these reductions in psychological distress levels indicate that, nevertheless, the programme addressed at least part of the women's concerns in this area. Group therapeutic factors are likely to have been influential in the psychological improvements seen (Yalom and Leszcz 2005). Ogrodniczuk, John and Piper (2004) found that women experienced better mental health outcomes than men in group-based interventions because of these factors.

In conclusion, the outcome measures used in this trial were found to be broadly acceptable to the participants in this study, apart from some confusion about items in the WHODAS 2.0 instrument (Paper 2). It is likely that an outcome measure measuring feelings of overwhelm and toxic stress (Moreno *et al.* 2021) could be a useful one for a future trial. The DASS (Lovibond and Lovibond, 1995) was a useful instrument for this population and was sensitive as a baseline measure, differentiating between people who had more anxiety or depression symptoms and qualitatively was described as relevant by participants. Alternative and more nuanced demographic data that could have been collected would include whether children were living in the home, educational status and type of employment, as these factors were related to outcomes in previous studies of ReDO® programmes (Eklund *et al.* 2013).

Barriers and enablers to occupational therapists doing research in practice

A consideration for future research studies of ReDO® programmes in an Irish context is the feasibility of occupational therapists being involved in research in their current roles. As in a previous exploration of research participation with occupational therapists delivering an occupation-focused programme as part of a trial (Di Bona *et al.* 2017), the therapists in the current study valued the opportunity to refresh their practice, explore a new intervention and get certification in a new area (Paper 2, Appendix II). Di Bona *et al*. (2017) found that supportive management, protected time for research, peer support and valuing research highly are all enablers to occupational therapists being able to manage facilitating a complex intervention as part of a trial. The management of the practice-research relationship is crucial in the success of healthcare trials because the two groups may hold different worldviews. Clinicians may feel frustrated by the pace of research, particularly the analysis and dissemination of findings for example (Laustsen *et al.* 2021). To counter this, Eriksson *et al*. (2017) recommend bridging the knowledge-to-practice translation gap by developing close, mutually respectful relationships between clinicians and researchers. Research involvement has the potential to raise professional pride, self-esteem and value for the profession of occupational therapy (Eriksson *et al*. 2017). However, securing adequate funding to support occupational therapy trials is vital to support both the clinical and research partners (Adams and Bancroft 2013).

Generalisability of findings to other populations and contexts

Bonell et al. (2006) suggest two questions to consider when generalising the findings of a health intervention evaluation to a new population. Firstly, they ask whether the intervention can practically be delivered elsewhere. The findings of the current study indicate that the Irish primary care occupational therapists felt that their services were not currently staffed sufficiently to run ReDO®-10 on a regular basis. However, in Irish mental health services, occupational therapists would have greater capacity to run group-based interventions for people experiencing psychological distress. Considering that ReDO®-10 appeared to show both mental health and occupational participation benefits for participants in the current study, training therapists and evaluating ReDO® programmes within an Irish mental health setting could result in greater coverage for the intervention. In other words, it could be delivered to a larger potential pool of participants (Bonell *et al*. 2006).

Secondly, it should be considered whether ReDO®-10 would meet the needs of a population different to that studied in the current project. The focus of ReDO® programmes is on analysis of occupational patterns, reflection on the potential relationship between time-use and a person's health and goal-setting and problem-solving around making changes to occupational patterns (Erlandsson 2013). This makes ReDO® programmes potentially applicable to a wide variety of individuals and groups experiencing dissatisfaction with their current occupational lifestyles. For example, people living with obesity, carers, those facing burnout or those experiencing significant transitions (such as retirement) have all been identified as populations where life balance is linked to health (Alves *et al.* 2019; Håkansson and Ahlborg Jnr 2018; Matuska and Bass 2016). Process evaluations should be built into all future studies, especially where ReDO® is explored with new populations, to ensure that the intervention's mechanisms continue to be relevant and beneficial (Bonell et al. 2006).

However, there are some limitations to generalisability that must be considered prior to implementing ReDO®-10 with a new population. Even within similar populations, people may experience wellbeing in very different ways and have different viewpoints on the value and costs associated with making health behaviour changes (Birch and Gafni 2003). The women in the current study may have had a particular perspective on their own health that is not generalizable to other populations, even within Ireland. In addition, factors that are contributing to an underlying problem can also vary widely between different populations (Bonell *et al.* 2006). For example, in an affluent, employed population, burnout and lack of

occupational balance could be related to overwork or juggling multiple roles, whereas in a more socially deprived population, lack of occupational balance could be related to lack of choice, control and opportunity for occupations (Murthi and Hammell 2021).

Apart from considering ReDO® for different healthcare populations, it is also relevant to consider the implementation of this approach in different countries. Having been developed in Sweden, ReDO®-10 was found to be feasible and acceptable in an Irish primary care context, but it is not known if this would be the case in other countries. The ADAPT guidance document (Moore *et al*. 2022), although more concerned with the transferability of population-level health interventions, provides some guidance for this process. One key step is to map similarities and differences between the original and new contexts. While there may be strong similarities between the Irish healthcare context and that of a country like New Zealand for example, there would also be key differences such as the experience of First Nations populations or the social welfare systems. Considering ReDO® for countries such as India or South Africa would require much critical interrogation of the concept of colonialization in healthcare. Many critical occupational therapy authors are questioning the appropriateness of transplanting interventions developed in WEIRD (Western, Educated, Industrial, Rich, Democratic) countries to countries with more collectivist, religious or traditional cultures (Hammell 2011; Hunter and Pride 2021). Measures that could minimise colonial practices if ReDO® were to be evaluated in other countries would be to (1) involve a diverse group of stakeholders in the evaluation team from the start, (2) carry out some background research to really understand the experience of occupational time-use from the specific cultural perspective (3) critically interrogate the theoretical underpinnings of the intervention and challenging any dominant belief systems in them (4) use the ADAPT guidance when planning any changes to structure or delivery of the intervention and (5) consider language, culture, representation and access in all programme materials and arrangements.

Post-Covid-19 pandemic considerations

During the recent Covid-19 pandemic, occupational time-use, balance and experiences were discussed in many areas of healthcare, in the general population and media. Occupational deprivation (Fristedt *et al*. 2021), overload and imbalance (Buomprisco *et al.* 2021) were all experienced by different sections of society at different times during 2020-2021. As yet, no research has been published exploring outcomes of ReDO®

programmes during the pandemic, although some researchers developed their own online occupational time-use programmes (Pekçetin and Günal 2021). Occupational therapists, as with all healthcare providers in the community/primary care sector, had to change quickly to delivering interventions via telehealth and digital means. Online-based interventions for mental health (Sánchez-Guarnido *et al.* 2021), paediatric (Camden and Silva 2021) and home-bound populations (Zahoransky and Lape 2020) were provided successfully during the pandemic and there is a body of literature confirming that telehealth is a valuable addition to healthcare provision, especially where there may be geographical or time barriers (Snoswell *et al.* 2021).

While pandemic restrictions have been lifted (at time of writing) restoring occupational routines for many, telehealth will remain as an option for future healthcare delivery. The potential for ReDO® programmes to be delivered online warrants consideration. During lockdown, even highly sensitive psychotherapeutic interventions such as dialectical-behaviour therapy for suicidality (Landes *et al*. 2021) were facilitated successfully and were well-accepted by patients. Therapeutic relationships and outcomes have been shown to be similar when face-to-face and online interventions are compared (Flückiger *et al*. 2018, Castro *et al.* 2020). Thorpe (2016) has provided some recommendations for online group facilitators that could be included in training for ReDO® facilitators. For example, misunderstanding or miscommunication, verbally or non-verbally, is more likely in online groups (Thorpe 2016), so facilitators may need to be more explicit about the group purpose, group rules and expectations and carefully consider closure at the end of a group session. Participants would require a safe and confidential space in the home in order to participate fully in ReDO® (Barker and Barker 2021). The importance of being able to speak confidentially about one's home life in a trusting group setting was emphasised in the qualitative accounts of the participants in this study. Helping participants to learn how to use the technology and overcome connection difficulties would add to the workload required for the group facilitators (Thorpe 2016). It is also likely that adapting ReDO® programmes for telehealth would require a revision of the manual and materials.

Aspects of the ReDO® group sessions would need to be considered if the programme was delivered online. Adapting the occupation-based sessions would require careful consideration. However, many activities were shared by friends, families, groups, educational settings and workplaces during the Covid-19 pandemic and was associated with greater wellbeing (Brown and Greenfield 2021). Where the "function" of these occupation-

based activities is to take part in a pleasant occupation as part of a group, stimulate conversation about possible restorative occupations and practice doing an occupation with full awareness with no distractions, then this "function" could also be met by doing an occupation at home, but connected to others via the screen (Hawe *et al*. 2009). The length of the sessions may need to be adapted with movement or comfort breaks.

In addition, there is some evidence that, rather than improving access to healthcare, the widespread use of telehealth widened already-existing health inequalities (Cantor *et al.* 2021). Many potential participants may lack high-speed broadband access (Clare 2021), have out-dated devices, be sharing devices with others in the home or find it difficult to find privacy (Rahiem 2020). ReDO® facilitators would need to consider improving access to the programme to socially excluded populations and recognising that choice and autonomy in daily occupations is not equally distributed (Whalley Hammell 2021), so the ability of particular populations to make changes to occupational patterns may be constrained.

Reflexivity Statement

Reflexivity is one of the "big tent" criteria for rigor in qualitative research, according to Tracy's influential paper (2010). It is a way for qualitative researchers to be transparent about how subjectivity shapes their enquiry and involves reflecting on personal, interpersonal, methodological and contextual dimensions (Olmos-Vega, Stalmeijer, Varpio and Kahlke 2022). On a personal level, I am an occupational therapist experienced in working in mental health settings and using group-based interventions with individuals with stress and anxiety. My interest in this topic came from frustration in clinical practice with a lack of manualised programmes available to me to use at the time with people with mental health concerns. While individualised practice is (I believe rightly) valued by occupational therapists, I also feel there is a place for manualised programmes that can be replicated, used by therapists across different settings, used in programme/service planning and evaluated in large-scale research studies. It is difficult to argue for the distinct value of occupational therapy without this kind of research. This worldview influenced my decision to design a study with practical applicability to occupational therapy and to choose a methodology (process evaluation) that would provide usable findings for future implementation and research. In the data interpretation phase, this focus on evaluation of ReDO®-10 meant that data not relating to the research questions were not given as much weight in the final results. Examples of this were one participant's discussion of perceiving stigma towards mental

health concerns in Ireland or another participant's discussion about social welfare entitlements to return to work. However, I hope to do further analysis of this data in a post-doctoral publication.

I was privileged to be able to complete my own training in ReDO® alongside the occupational therapists involved in this research. While I had read thoroughly about ReDO®, spending three days immersed in the activities, theories and discussions about this time-use focused intervention was very powerful. As occupational therapists, we spoke about how we had lost some confidence in using occupation-focused interventions, or in the case of the primary care therapists, had become "stuck" in a narrowly focused role. I delivered the ReDO®-10 myself in the third phase of this research study, alongside one of the other trained primary care occupational therapists. This was personally very meaningful to me. As a clinician, running therapeutic groups was one of the aspects of my work I particularly enjoyed, and missed when I became an academic. I felt it was an important way for me to keep my research grounded in practice, to keep closely in touch with those who use occupational therapy services and to see "from the inside" some of the processes involved in how/whether this intervention was helpful. I feel delivering the ReDO®-10 myself immediately sharpened my critical skills about this intervention. I could immediately see which activities were responded to by participants, where the sessions seemed to be constructed well and where there could be more time given. I and the other therapist reflected extensively after/before each session. We made adaptations based on our clinical reasoning (as had the other therapists) e.g. changing some of the occupations used in the sessions. It was evident to us that ReDO® has a clear structure and theoretical background, but that there was room for individual therapists to bring in some of their own reasoning or other relevant training in aligned perspectives. One example of this was using some questions from the Acceptance and Commitment Therapy approach to encourage reflection on valued occupations. This in no way changed the focus or fidelity of the delivery of ReDO®, but I think should be seen as a natural consequence of experienced therapists bringing their own reasoning to a manualised intervention.

In a process evaluation, researchers need to have good working relationships with intervention developers but also maintain sufficient independence to be critical in the analysis of any problems with the intervention (Moore *et al*. 2015). In this study, Dr Lena-Karin Erlandsson was a co-supervisor and also the original developer of the ReDO® method. Dr Erlandsson continues to train occupational therapists in the use of ReDO®, is responsible

for adaptations/translations and works with other researchers/clinicians who are using or evaluating this intervention. We had open discussions about how to maintain the independence of my evaluation of ReDO®-10 in the Irish context. Early in the research study, it was agreed that Dr Erlandsson would (i) advise on methodology, (ii) make me aware of published, unpublished and ongoing work around ReDO®, (iii) be responsible for the training/certification of the Irish occupational therapists, (iv) read and help revise written work and (v) help me understand the Swedish context in which the intervention was originally developed and evaluated. However, we agreed that she would not actively analyse the qualitative/quantitative data as she could have a potential conflict of interest in the results. In the published papers, Dr Erlandsson did not comment on/review the results sections, but focused her co-writing on aspects of background, methodology or drawing contextual conclusions. An example of how this relationship was managed came when the Irish ReDO®-10 participants did not all welcome the evening seminar session and provided critical comments about it. Dr Erlandsson was able to provide some contextual information about Sweden which was useful in understanding why the Irish results were different (the course being presented as a work-place health intervention, rather than a "mental health" intervention, for example). The Irish results were presented transparently but this information was helpful in understanding why that difference might have occurred and how this aspect of messaging might need to be different in an Irish setting. A further example of the good, but open working relationship between myself and Dr Erlandsson was in how the occupational therapists perspectives were used in a further adaptation of the ReDO® manual. The perspectives of the Irish therapists were combined with that of those in Sweden and elsewhere to adapt and make changes to the manual to be used in future training/implementation.

Finally, it is impossible to disentangle subjectivity from qualitative research, but it is possible to be transparent about how that subjectivity was managed (Olmos-Vega *et al.* 2022). In this study, in keeping with the pragmatist approach, data were gathered about "potential effectiveness", "acceptability" and "feasibility" from different stakeholders, at different times and using different (mixed) methods and then combined to provide an overall conclusion. While the potential impact of the intervention was explored qualitatively with participants, they were also asked to complete standardised, validated and robust outcome measures at three timepoints. These measures were completed either by the person alone (and returned by post) or with the researcher who was not involved in delivering the intervention, in order to mitigate potential influence. This was especially important in the third ReDO® phase, where I delivered the intervention myself. In this case, the interviews

were completed, transcribed and anonymised by an occupational therapy student. Recognising that qualitative results are constructed and interpreted by the researcher (rather than emerging as truth that is uncovered) (Varpio et al. 2017), I was very transparent about all stages of the data analysis, presented examples of how data were coded, acknowledged and described the frameworks used, carefully described divergent voices and discussed how the findings were representative across the data set (Olmos-Vega et al. 2022).

Limitations of this study

This study has a number of limitations associated with the methodology, the sample and the researcher. Using a pre-test, post-test design without a control group may have meant that the post-test outcomes were influenced by response shift bias, where participants have a change in perspective unrelated to the programme content (Kaushal 2016). The lack of a control group means that changes that occurred may have been due to factors such as maturation, the Hawthorne effect or be due to uncontrolled confounders such as medication (Akobeng 2005; Knapp 2016). Those who dropped out may have differed substantially from those who received the full programme (Groenwold 2021). This study had a small sample size, consisting primarily of women who self-referred and GPs/occupational therapists with an interest in the topic. ReDO®-10 participants were not representative of the general primary care population in terms of diversity and no record was kept of how many women declined participation or why. It is likely that women from disadvantaged populations or those who lacked access to childcare, transport or social support declined participation. Finally, the student completed the majority of the data analysis for this study. Researcher bias is a risk where one person completes all the data analysis (Pope *et al*. 2000). While transcripts were returned to participants for them to edit if they wished, also allowing participants to view or comment on emerging findings could have ensured that the final themes reflected people's experiences accurately (Fade 2003). It is also a limitation that public and patient opinions were not sought at the planning stage of the research. Seeking these viewpoints after ethical approval has been sought and granted could be seen as tokenism and is seen as a less meaningful collaboration (Brett *et al*. 2014).

Strengths of this study

While acknowledging these limitations, this study has a number of strengths that enhance the rigor of the work. Exploring the theoretical underpinning of ReDO®-10 and

evaluating whether the programme worked as intended required taking a critical and analytical perspective. The involvement of one of the ReDO® authors as a co-supervisor in this project could have been a threat to this criticality. Some measures taken to mitigate this threat were discussed in the Reflexivity Statement above. In addition, a second data analyst from the Health Behaviour Change Research Group at NUI Galway was approached. Dr Jenny McSharry provided a viewpoint from outside the occupational therapy discipline and gave guidance on the application of the TDF and Behaviour Change Wheel (Michie et al., 2005, Michie et al., 2011). This reduced potential conflicts of interest in the analysis and dissemination of the qualitative data.

Although the author is an occupational therapist, she undertook training during the PhD process in transdisciplinary intervention development and evaluation methods. This allowed for a critical and broad approach to be taken to the analysis and design of the project. The project received the support of local occupational therapy staff who facilitated the project with enthusiasm and care. Their work on this project meant that participants received a quality intervention, outside of their normal care. The qualitative data analysis (both for Paper 2 and Paper 3) were carried out with rigor and reflexivity, including the use of reflective notes during coding and having sections of transcript independently coded by a second researcher (Paper 3) (Tracy 2010). Finally, the input of stakeholders before and during the feasibility study (from occupational therapists, GPs, participants and a public/patient involvement committee) meant that triangulation of data could occur and allowed for a deep and wide-ranging understanding of the acceptability and feasibility of ReDO®-10 in this context.

Contribution of this PhD

This study makes a contribution to (i) the field of occupational therapy research, (ii) evaluation and future development of ReDO® programmes and (iii) to research and practice potential for future occupational therapy research at NUI Galway. Firstly, as noted by Tickle-Degnen (2013, p.171), "*feasibility studies are rare in our field*" and many pilot studies in occupational therapy do not contain enough information about intervention implementation to guide future trials. The current project provides a clear, published example of an occupational therapy feasibility study and process evaluation which can guide other researchers or clinicians who wish to carry out similar studies. The data gathered and analysed for this project provide important information about research design, recruitment,

data collection, resource implications and other factors that will be of interest to research funders prior to making any future investment in a ReDO® clinical trial.

Secondly, Redesigning Daily Occupations programmes are evolving and being evaluated in a number of contexts (Erlandsson 2019; Olsson *et al*. 2019). However, previous studies of ReDO® have not presented extensive qualitative perspectives from the participants who took part in the programme. The views of key stakeholders, particularly GP referrers and the occupational therapy facilitators about the intervention had also not been explored to date.

Apart from a small number of Dublin-based trials (Connolly *et al.* 2019, Garvey *et al*. 2015), this project was one of the first to research an occupational therapy intervention with a health promotion/self-management focus for primary care service users in Ireland. Because of the study, six occupational therapists were trained to deliver ReDO® programmes, enhancing the diversity of interventions that can be delivered to primary care patients in the Galway region. The study was the first occupational therapy study to be supported by the HRB Primary Care Clinical Trials Network at NUI Galway, laying a foundation for possible future research collaboration.

Conclusion

In conclusion, this project encompassed several phases of mixed method data collection and analysis to understand both the feasibility of the Redesigning Daily Occupations (ReDO®-10) in an Irish context and the perceived mechanisms of action of this programme as experienced by participants. The qualitative views of occupational therapists (n=2), general practitioners (n=9) and ReDO®-10 participants (n=14, out of 21 recruited) showed that the programme was feasible, well-accepted and of potential benefit within the Irish context. However, barriers to feasibility include current resources for primary care occupational therapy services and potential recruitment issues. The participants described changes to their occupational patterns and balance, although there were considerable individual differences, with the social context being a particular enabler or barrier to change. The trusting and well-facilitated group environment was essential to changes that took place. In terms of mechanisms, it was evident that activities that stimulated occupational self-analysis were highly motivating. Occupation-focused activities and homework were emotive

and important for embedding any occupational changes in real life. This project was guided by process evaluation theory and corresponding guidance from the Medical Research Council (Moore *et al.* 2014), behaviour change theories and occupational therapy theory and these complimentary perspectives allowed the researcher to develop a deep understanding of the theoretical underpinning of the ReDO® intervention as it was implemented in this new context of Irish primary care.

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Appendices

Appendix I: Published Paper 1.

Published in the Occupational Therapy in Mental Health journal using the APA referencing style. The following is the Accepted Manuscript without journal type facing.

A systematic review and narrative synthesis of occupational therapy-led interventions for individuals with anxiety and stress-related disorders

ABSTRACT

Anxiety and stress-related disorders are highly prevalent and impede participation in life activities. Occupational therapists work extensively with this population but the effectiveness of their interventions is unclear. A systematic search strategy identified 19 papers describing 13 studies. Studies varied in methodology, intervention type and theory-base. The results show the potential for lifestyle approaches, occupational science-based programmes and skill-building to improve mental health. The variety of interventions and methodology of many studies means that the effectiveness of occupational therapy interventions for this population is not yet determined. High quality research is required to replicate interventions with emerging potential for effectiveness.

KEYWORDS

Occupational therapy, anxiety disorders, psychological stress, psychosocial rehabilitation, systematic review

Introduction

Anxiety and stress-related disorders are the seventh highest cause of disability globally, as measured in years lived with a disability in the Global Burden of Disease Study 2013 (Vos et al., 2015). Some authors suggest this may be an underestimate (Vigo, Thornicroft, & Atun, 2016). Anxiety disorders are highly persistent over the lifetime (Kessler et al., 2007, 2009) and are associated with significant levels of disability, poor functioning and reduced quality of life. Many domains of daily life functioning are affected in those with anxiety, including work and household functioning (Iancu et al., 2014), social functioning

(Rodriguez, Bruce, Pagano, & Keller, 2005) and community participation (Buist-Bouwman et al., 2006).

Interventions for anxiety and stress-related disorders have been the focus of several systematic reviews in the fields of pharmacology, psychology and alternative therapies. Cognitive-behavioral therapy has demonstrated evidence for effectiveness (Hendriks, Oude Voshaar, Keijsers, Hoogduin, & van Balkom, 2008; Richardson, Stallard, & Velleman, 2010), as have mindfulness and acceptance-based therapies (Vollestad, Nielsen, & Nielsen, 2012) and exercise (Jayakody, Gunadasa, & Hosker, 2014). A recent meta-analysis showed that medication may be more effective for the treatment of anxiety than psychotherapy (Bandelow et al., 2015). Despite their long history of working in mental health settings however, the effectiveness of the work of occupational therapists with this population is not clear.

It is apparent that anxiety and stress-related disorders have a profound influence on individuals' ability to participate to their satisfaction in many activities in daily life and that routines and time use are also affected. Stress reduces energy and motivation to complete daily activities (Johansson, Eklund, & Erlandsson, 2012) and is related to resilience and adaptive capacity (Lopez, 2011). Therefore, interventions that focus solely on the biochemical or cognitive aspects of anxiety may not improve an individual's participation in life activities. There is some evidence that unsatisfactory participation in activities may be a *predictor* of anxiety and depression. Losing pleasure in activities is a risk factor for future anxiety disorders and the presence of anhedonia in people with anxiety is a risk factor for future co-morbid depression (Winer et al., 2017). In addition, functioning in daily life appears to be independent of symptoms of anxiety (i.e. poor functioning can continue after the recovery of symptoms) (Rodriguez et al., 2005). It is also known that functioning is a greater predictor of health care usage and cost than severity of depressive or anxious symptoms (Twomey, Cieza & Baldwin, 2017). These findings point to a need to develop and evaluate interventions that focus on how individuals participate in daily activities and that address the maintenance and improvement of functioning, as this may protect against relapse for those with anxiety disorders and may potentially be more cost-effective.

Enabling satisfying participation in activities of daily life is the core domain of concern of occupational therapists who have a long history of practice in mental health settings. However, high quality trials and systematic reviews of the effectiveness of occupational therapy interventions in mental health are few and there has been a call for an urgent increase in rigorous mental health occupational therapy research to improve the

evidence base for the profession (Bannigan & Spring, 2012). Where systematic reviews of the effectiveness of occupational therapy in mental health have been conducted, they have included populations with varying diagnoses. Ikiugu, Nissen, Bellar, Maassen and Van Peursem (2017) carried out a meta-analysis of randomised-controlled trials of occupational therapy interventions based on the profession's conceptual models for people with mental health diagnoses. This review found a medium effect size for occupational therapy intervention in improving occupational performance and a small effect on wellbeing. The reviewed studies included populations as heterogeneous as inpatients with schizophrenia, caregivers and patients with dementia and primary care patients with panic disorder. Spencer, Sherman, Nielsen and Thormodson (2017) reviewed occupational therapy interventions for students with different types of mental illnesses transitioning to higher education, but the quality of the studies found in this review meant that conclusions about effectiveness could not be reached. These reviews increase the evidence-base generally for mental health occupational therapy practice. However, they do not provide evidence for the effectiveness of occupational therapy interventions for people with anxiety and stress-related diagnoses specifically. Given the different aetiologies, symptoms and maintaining factors of mental health conditions (Geddes, Price, & McKnight, 2012), comparing highly heterogeneous populations may not accurately determine which specific type of intervention works for which population.

Where occupational therapy-led interventions for individuals with anxiety and stress-related disorders have been researched, they have shown positive results, albeit in small-scale studies. The Redesigning Daily Occupations programme has demonstrated positive return-to-work outcomes and improved quality of life for women with stress-related disorders (Eklund & Erlandsson, 2011; Eklund, Wastberg & Erlandsson, 2013). An occupational therapy-led lifestyle approach has also been shown to bring about improvements in anxiety when compared with routine General Practitioner (GP) care (Lambert, Harvey, & Poland, 2007). The level of significance of the results in each of these studies varied, but they provide preliminary evidence for the effectiveness of occupational therapy-led interventions. Occupational therapists are core members of the multidisciplinary team in mental health settings, but some clinical practice guidelines for the treatment of anxiety make no reference to this form of intervention due to a lack of systematic review evidence (Canadian Psychiatric Association, 2006). This review aims to evaluate the quality of the research evidence systematically to provide guidance for occupational therapy practice for those with anxiety disorders.

Objective

The aim of this systematic review is to address the question; "What is the evidence for the effectiveness of occupational therapy interventions in improving functioning and mental health outcomes for individuals with anxiety and stress-related disorders?" A systematic review protocol was prepared (Centre for Reviews and Dissemination, 2009), peer-reviewed and published on the PROSPERO International Prospective Register of Systematic Reviews (Fox, Erlandsson & Shiel, 2015).

Methods

Inclusion/exclusion criteria

The included studies: (a) had individuals over 18 years of age with anxiety and stress-related disorders as defined by categories F40 (Phobic anxiety disorders), F41 (Other anxiety disorders including generalised anxiety disorder and mixed anxiety and depression disorder), F42 (Obsessive-compulsive disorder) and F43 (Reaction to extreme stress and adjustment disorders, including post-traumatic stress disorder) in the ICD-10 (World Health Organization, 1992), (b) measured outcomes relating to functioning in daily activities and/or mental health and (c) had an intervention defined as occupational therapy, or led/designed/facilitated by an occupational therapist. Quantitative studies of any type published between 1994 and December 2017 were considered.

The studies found required some flexibility in the inclusion/exclusion criteria. First, studies where individuals had a co-morbid diagnosis were included, since anxiety commonly co-occurs with other conditions (Alonso et al., 2004). Second, a number of studies involved individuals with a variety of mental health diagnoses. These were included if: (a) over 50% of individuals had anxiety disorders, (b) the other diagnoses were mood and/or anxiety disorders and (c) anxiety or functioning was explicitly measured. The Centre for Reviews and Dissemination (CRD) guidance for undertaking reviews in health care states that in the absence of individual patient data, "it is unlikely that inclusion can be restricted to particular types of participants" (CRD, 2009, p. 8). The Cochrane Handbook states that deciding on inclusion of studies that only "partially address the population of interest can be challenging". It is recommended that a common-sense strategy is used so that studies can be included that "keep faith with the objectives of the review" (O'Connor, Green & Higgins, 2011, section 5.2).

Search Strategy

The following databases were searched: PUBMED, MEDLINE, EMBASE, Cochrane Library, CINAHL, SCOPUS, OTSeeker, RIAN, ETHOS and ProQuest Dissertations and Theses. Reference lists of key studies were searched and study authors were contacted for clarification. An example of the search strategy is that used in MEDLINE, using the appropriate MeSH terms: ("adjustment disorders" OR anxiety OR "anxiety disorders" OR "obsessive compulsive disorder" OR phobia OR "phobic disorder" OR "stress disorders, post-traumatic" OR "stress disorders, traumatic" OR "stress disorders, traumatic, acute") AND "occupational therapy".

Data Extraction

Search results were imported into Endnote™ software and the initial screening was completed by the first author. Duplicates and records earlier than 1994 were removed. Studies meeting the inclusion criteria were included by the first author and checked by the other authors. Where there was doubt over inclusion, the paper was reviewed independently by at least two authors and in some cases, three authors. This decision-making process was guided by two principles: whether the intervention was led/facilitated/designed by an occupational therapist and whether the population included a sufficient number of individuals with an anxiety or stress-related diagnosis. A data extraction form was developed and used by all authors (CRD, 2009). Data extracted related to participants, treatment, control group (if used), outcomes measured and results. Papers were critically appraised using the tools designed by Law and MacDermid (2014) and Tate et al. (2008), the methodological quality of studies was assessed and each critical appraisal included a comprehensive evaluation of bias within individual studies.

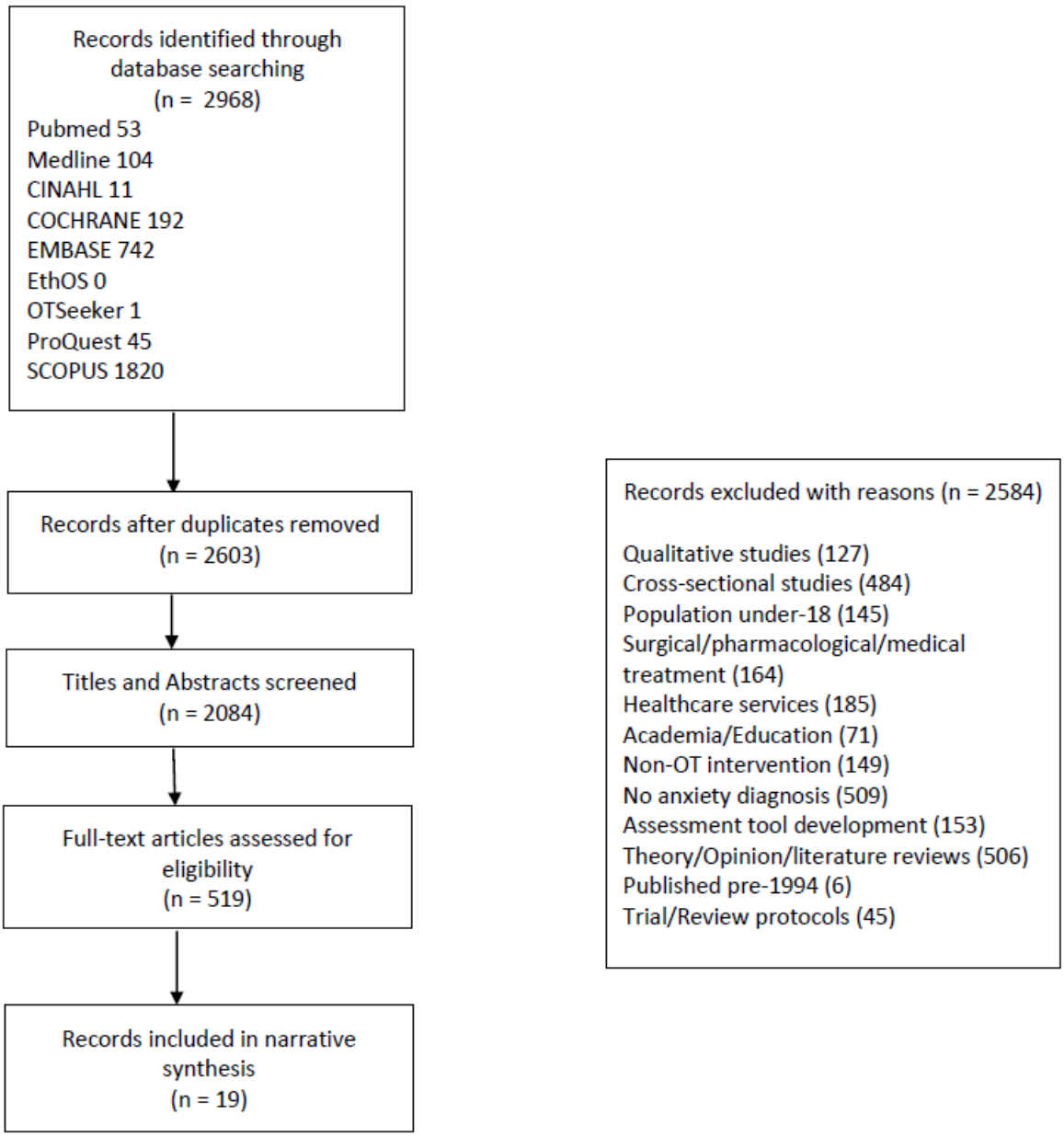

Figure 1. Search strategy

Results

The database searches identified 2968 records and 19 articles met the inclusion criteria. Reasons for study exclusion can be seen in Figure 1 and in the supplemental materials with this article. The 19 articles describe 13 individual studies representing a variety of research designs. Four used some form of controlled design (two randomised controlled trials, one non-randomised controlled trial and one cross-over study). The remaining nine used non-controlled designs (before-and-after comparisons or case studies). The included studies

evaluated interventions as diverse as driving rehabilitation, nutritional advice and cognitive-behavioural strategies using both standardised and non-standardised assessments.

Because of the heterogeneity of the included studies, the results of this systematic review take the form of a realist, narrative synthesis. A realist synthesis attempts to analyse how and why complex interventions work in particular contexts, or with particular populations (Shepperd et al., 2009). The studies were grouped according to the theoretical underpinning of the intervention being studied, as the expected mechanism of change is likely to be similar for interventions with similar theoretical bases (Popay et al., 2006). The effectiveness of occupational therapy interventions for people with anxiety and stress-related disorders will be discussed under five distinct theoretical categories: cognitive-behavioral interventions, health behaviour change interventions, skill-building interventions, occupational science-based interventions and neurological and/or sensory-based interventions.

Table 1. Included studies

Occupational Therapy interventions using Cognitive-Behavioural theory							
Intervention	**Papers**	**Methodology**	**Subjects**	**Description**	**Comparison**	**Mental Health Outcomes**	**Functioning Outcomes**
Stress Control (SC) compared with Anxiety Management (AM) or a waiting list control (WL). Carried out in the UK	(Kitchiner et al., 2009)	Randomised controlled trial	Individuals from primary or secondary care meeting the DSM-IV criteria for an anxiety disorder	An occupational therapy-led anxiety management group. 6 x 2-hour weekly group sessions. Focus: - Psychoeducation - CBT approach - Activity scheduling - Goal-planning - Relaxation techniques - Group support n=24 (mean age 39 , 63% female)	A nurse-led stress control group. 6 x 2-hour weekly group sessions Focus: - Adult education - CBT approach - Limited group interaction n=25 (mean age 45, 32% female) This study also included a waiting list control group n=24, 50% female, mean age 36	No significant difference on the Anxiety subscale of the GHQ-28 between SC, AM or WL. Higher scores on the BDI were associated with poorer outcomes in all three conditions	None measured
Anxiety Management course Carried out in the UK	(Prior, 1998b, Prior, 1998a)	Cross-over design 4 treatment groups were carried out. Waiting list control groups crossed over so that they also received the treatment	Author states; participants "must have had anxiety regardless of diagnosis" (Prior, 1998b) Total n=37 (age range 21-60, 70% female)	Six group sessions over 6 weeks. Focus: - Education about anxiety - Relaxation practice - Lifestyle and stress education - Challenging anxious thinking - Desensitisation to a feared situation	Waiting list control group receiving all usual care in a mental health day hospital.	The HADS showed statistically significant reduction after treatment (p=0.007). STAI showed no difference in stait and trait anxiety. No change in phobic fear (FQ).	Not measured

				- Assertiveness			
Private occupational therapy provided under the "Better Access to Mental Health" program Carried out in Australia	(Kohn et al., 2012)	Pretest-postttest design using retrospectively gathered data	Diagnoses: 13% generalised anxiety, 19% adjustment disorder, 7% unexplained somatic complaints, 32% depression, 29% mixed anxiety and depression n=31 (mean age 17.13 years, 52% female)	The intervention is described as including "motivational interviewing, cognitive behavioural therapy, relaxation strategies, skills training and interpersonal therapy … strategies were devised to deal with the functional implications of the symptoms in the client's everyday life" (Kohn et al., 2012). Participants received differing numbers of sessions.	None	Significant improvements in psychological distress (KPDS) - pretest (mean = 25.68, SD = 9.94) and posttest (mean = 21.00, SD = 9.21) (p = 0.001).	May have been measured, but no results are given.
Occupational Therapy interventions using lifestyle modification theory							
Intervention	**Papers**	**Methodology**	**Subjects**	**Description**	**Comparison**	**Mental Health Outcomes**	**Functioning Outcomes**
Lifestyle Approach to Managing Panic (LAMP) Carried out in the UK	(Lambert et al., 2007, Lambert et al., 2008)	Pragmatic, unblended randomised controlled trial	Individuals meeting the DSM-IV criteria for panic disorders with/without agoraphobia	Up to 10 individual sessions over a 16-week period (3 x 1hr weekly, 3 x ½ hr weekly, 3 x ½ hr fortnightly and 1x 1hr after a month) Focus: - Lifestyle review - Education about the health benefits of making changes in diet, exercise, smoking, fluid intake and caffeine use	Routine GP care. This may have included prescription of medication and/or referral to other agencies if necessary. n=60 (mean age 39, 68% female)	Anxiety symptoms were significantly less at 20 weeks (p<0.001, md -9.8; 95% CI -15.0 to -4.6), measured on the BAI. On specific symptoms of panic attacks (measured on the ADIS), there was a significant mean reduction (-28%) in panic symptoms in the lifestyle group as compared with the GP	Significant changes in positive lifestyle behaviours at both 20 weeks and 10 months for physical exercise, general fluid intake, diet and total scores on the Lifestyle Behaviour Index.

				- Individualised lifestyle changes negotiated with the patient - Monitoring and review of these lifestyle changes. n=57 (mean age 40, 68% female)		group (-14%) (p=0.008).	No significant changes in smoking or alcohol use and a significant change in caffeine use at 20 weeks was not significant at 10 months.
Occupational Therapy interventions using skill-building specifically for those with PTSD or trauma							
Intervention	**Papers**	**Methodology**	**Subjects**	**Description**	**Comparison**	**Mental Health Outcomes**	**Functioning Outcomes**
Life-skills intervention Carried out in the USA	(Helfrich et al., 2011)	Longitudinal repeated measures design Participants were measured at baseline, post intervention, at 3 months and at 6 months post intervention	Participants were homeless, but living in a supportive housing project. All had mental health issues (64% had an affective disorder). Mean score for the group on the IES-R was 38.29 – above the diagnostic threshold for PTSD n=72 (56% male, mean age 46 years)	After evaluation, participants could choose one or more of 4 modules; - Room and self-care management (RSM) - Food management (FM) - Money management (MM) - Safe community participation (SCP) Each module consisted of 6 group sessions and 6 individual OT sessions (12 sessions total)	None	Scores on the IES-R decreased significantly from baseline to the 6 month follow-up (t = -3.55, p = 0.001) Poorer response in those with psychotic conditions.	Measured, but the results are not reported in this paper.

High-intensity sports for PTSD and depression (Ocean Therapy™) Carried out in the USA	(Rogers et al., 2014)	Feasibility study using a pre-test, post-test cohort design	Veterans with a diagnosis of PTSD or depression. n=14 (age range 24-30, 92% male)	5 4-hour sessions on consecutive weeks. Sessions each have a "resiliency" theme and consist of surfing instruction and practice, as well as group processing about how the skills learned can help the individual transition to non-military life.	None	PCL-M median scores decreased from 55 to 34 (median of difference 18.18, $p \leq 0.005$). MDI median scores decreased from 33 to 14 (median of differences, 11.31, $p=0.28$).	Author reports that self-report measures of motivation and daily time use were also used, but findings are not reported.
Occupational therapy driving intervention using a driving simulator by OT-driver rehabilitation specialists Carried out in the USA	(Classen et al., 2014a)	Pretest-post test design	Military veterans. Author confirmed 50% had a diagnosis of PTSD n=8 (mean age 39.83, 100% male)	Three sessions over 6-8 weeks using a driving simulator. - Review of driving errors and strategies - Visual search training for critical driving cues - Practice of strategies in the simulator	none	None measured	Main outcome measure was a simulated driving test in the driving simulator Mean number of driving errors declined from 31.63 to 15.38 post-intervention ($z = -2.24$, $p < 0.05$).
Occupational therapy driving intervention using a driving simulator by OT-Driver rehabilitation specialists Carried out in the USA	(Classen et al., 2014b)	Single-subject design	n = 1. Male military veteran, 31 years old, with PTSD and leg fracture	Three sessions over 1 week using a driving simulator. - Review of driving errors - Visual search training for critical driving cues - Practice of strategies in the simulator	None	Not measured	Main outcome measure was a simulated driving test in the driving simulator Baseline – participant made 33 driving errors. Post-treatment

							– participant made 9 driving errors.
Occupational therapy-led work simulation using exposure therapy Carried out in the USA	(Phillips et al., 1997)	Single case study	n = 1 Male, 34 years old, with PTSD and low back pain and knee injuries	18 individual or group OT sessions over 4 weeks. Only the 5 sessions of exposure therapy are described. Focus was on retraining in work activities walking on scaffolding and elevated beams using a systematic exposure therapy approach	None	Stress decreased over the course of each session as measured on the SUDS.	COPM-P increased +4.75 COPM-S increased +6.5
Occupational Therapy interventions using occupational science theory (occupational balance, value and satisfaction)							
Intervention	**Papers**	**Methodology**	**Subjects**	**Description**	**Comparison**	**Mental Health Outcomes**	**Functioning Outcomes**
Redesigning Daily Occupations™ (ReDO) Carried out in Sweden	(Eklund, 2013, Eklund and Erlandsson, 2011, Eklund et al., 2013, Eklund and Erlandsson, 2013, Eklund and Erlandsson, 2015)	Quasi-experimental study with matched control group	Women on sick leave for stress-related diagnoses (ICD-10 F43 or F32).	16-week group intervention in three phases; 1. Occupational self-analysis, identifying meaningful and valued occupations and personal stressors 2. Goal-setting, problem-solving, developing a satisfying daily pattern of occupations	Care as usual. This varied per participant but may have included other forms of work rehabilitation, psychological therapies and/or meetings with their employer. n=42 (mean age 46, 100% female)	Identified cases measured on the HADS ReDO group: 29 baseline cases of anxiety – 12 cases 1 year later. 15 baseline cases of depression – 7 cases 1 year later. Comparison group: 16 baseline cases of anxiety – 7 cases 1 year later. 6 baseline cases of depression – 2 cases 1 year later.	No statistically significant difference between the groups for Quality of Life. Return to work rate 59% (treatment group) and 37% (control group). Statistically significant improvements in both groups on the SDO (satisfaction

				3. Re-introduction to the workplace n=42 (mean age 45, 100% female)			and performance of daily occupations).
Occupational Therapy interventions using neurological and sensory theories							
Intervention	**Papers**	**Methodology**	**Subjects**	**Description**	**Comparison**	**Mental Health Outcomes**	**Functioning Outcomes**
Cranial electrotherapy stimulation (CES) Carried out in the USA	(Bracciano et al., 2012)	Multiple single case studies with a pretest-posttest design	Military veterans n = 2 Participants had PTSD. Both male. Ages 54 and 38.	Participants were instructed to self-administer CES for 20-60 minutes a day, 3–5 days a week with a current level between 100 and 500 microamperes over a period of 4 weeks Participants kept a daily treatment log recording the severity of symptoms before and after each treatment	None	On the PTSD Symptom Scale, participant 1 scored 34/51 pre-treatment and 13/51 after. Participant 2 scored 29/51 pre-treatment and 10/51 after. Participants rated severity of symptoms pre and post daily treatment on a 10-point scale. The average reduction in score was 3.85 (P1) and 4.30 (P2)	Participant 1: COPM-P increased +5.4, COPM-S increased +7.6 Participant 2: COPM-P change score was -0.2, COPM-S did not change
Wilbarger Protocol Carried out in the USA	Moore & Henry, 2002	Multiple single case studies with a pre-test, post-test design	n = 3 females 2 participants had an anxiety disorder Case #1: Major Depression, PTSD, Bipolar Disorder	Education, the Wilbarger Protocol and support. - Individualised sensory diet including activities like yoga, swimming, massage and other exercise - Deep pressure brushing and joint compression 8-10 times a day	None	Author-created assessment (number of sensory defensive indicators experienced) Case #1: (pre) 29/50 (post) 27/50 No cutting/self-harm/hospitalisation since study Case #2: (pre) 43/47	Individualised problem areas were identified by participants Case #1: Reports being able to brush teeth, able to visit friends and listening to and playing music

			Case #2: Major Depression, PTSD and Dissociative Disorder	Follow-up varied between 8 months and 16 months		(post) 17/47 No thoughts of self-harm or hospitalisation since study	(post-treatment) Case #2: Reports being able to volunteer, attend church and classes (post-treatment)
Sensory modulation programme Carried out in the USA	(Champagne, 2011)	Single-case study	n = 1 42 year old female with PTSD and depression	The sensory modulation programme was developed by the author and has elements of sensory modulation interventions combined with cognitive behavioural techniques. Participant attended 3 months of therapy.	none	May have been measured, but no results are given.	Participant selected their own goals and rated their performance on a scale of 1-10. Example result is; "Showering daily" – improved from 2/10 to 8/10 after 1 month.

Occupational therapy interventions using cognitive-behavioural theory

Three studies evaluated occupational therapy interventions using cognitive-behavioural theory. Kitchiner et al. (2009) reported on a randomised-controlled trial with two treatment conditions: an occupational therapy-led anxiety management group using cognitive-behavioural strategies, relaxation training and goal-setting (n = 24); and a nurse-led "stress control" group which had a psychoeducational approach with limited group discussion (n = 25). They also included a waiting list control group (n = 24). The participants all met the DSM-IV criteria for a diagnosis of an anxiety disorder. Two papers evaluated a six-week group intervention using a cross-over design for people with anxiety (Prior, 1998a, 1998b). The group used cognitive strategies, relaxation, psychoeducation and systematic desensitisation (n = 37). Finally, Kohn, Hitch and Stagnitti (2012) collected retrospective pre- and post- intervention data of 31 individuals from a single occupational therapy practice. Of the 31 participants, 21 had an anxiety disorder, adjustment disorder or diagnoses of anxiety and depression. The intervention was highly individualised, with a differing number of sessions per person and used strategies including "motivational interviewing, cognitive behavioural therapy, relaxation strategies, skills training and interpersonal therapy" (Kohn et al., 2012, p. 439).

These three studies used reliable and valid tools to measure improvements in anxiety and general mental health. Functioning, or participation in daily activities, was not measured in any of the papers. Kitchiner et al. (2009) measured outcomes pre and post intervention and at three follow-up points (1, 3 and 6 months) and found no significant differences between the occupational therapy-led intervention, the "stress control" intervention or the waiting list control group on the Anxiety subscale of the General Health Questionnaire (GHQ-28). Both treatment conditions showed a statistically significant improvement on the Fear Questionnaire after one month compared to the control group, but this was not sustained. Individuals with lower scores on the Beck Depression Inventory showed a greater reduction in anxiety symptoms following the occupational therapy-led group. The participants in Prior's cross-over trial (1998a) showed statistically significant improvements on the Hospital Anxiety and Depression Scale (HADS) ($p = 0.007$), but not on the Spielberger Questionnaire or the Fear Questionnaire and this was maintained after one year. Kohn et al. (2012) found a statistically significant improvement ($p = 0.001$) between the pre-intervention score (mean = 25.68, SD = 9.94) and the post-intervention score (mean = 21.00, SD = 9.21) on the Kessler Psychological Distress Scale.

Two of the three papers in this category reported statistically significant improvements for people with anxiety disorders following occupational therapy

interventions using cognitive-behavioural theory (Kohn et al., 2012; Prior, 1998a, 1998b). However, methodological limitations mean that the results should be interpreted with caution. The treatment, assessment, data analysis and reporting all were completed by the author in the case of Prior's study (1998a, 1998b), introducing possible reporting bias. As a retrospective study, the outcomes reported by Kohn et al. (2012) are only based on individuals who completed treatment, the level of drop-out is unknown and the treatment received is likely to have been highly individualised. Kitchiner et al.'s (2009) high quality randomised-controlled trial reported the randomisation process and treatment fidelity procedures clearly. It is possible that the lack of statistical difference between the treatment conditions in this study is due to the similarity of the interventions – the main difference being the higher emphasis on group process in the occupational therapy intervention. Both Kohn et al. (2012) and Kitchiner et al. (2009) had wide variety in the numbers of sessions attended by participants, but both studies used subgroup analyses to show that outcomes were not associated with this variable.

Occupational Therapy interventions using health behavior change theory

Of the 13 studies reviewed, only one used theory relating to health behavior change to improve anxiety symptoms and so it is discussed separately here. Rodney Lambert and colleagues reported on an intervention delivered over 10 individual sessions by occupational therapists in primary care focused on lifestyle review and goal-setting to improve diet, reduce caffeine and alcohol intake and increase exercise (Lambert, Caan, & McVicar, 2008; Lambert, Harvey, & Poland, 2007). This high-quality randomised-controlled trial compared this intervention (n = 54) to general practitioner care-as-usual for people with panic disorder (n = 59). This intervention draws on studies showing possible links between smoking, poor diet, lack of exercise and alcohol use on anxiety symptoms (Benton, 2002; Breslau & Klein, 1999; Otto et al., 2007). The therapists used strategies like lifestyle diaries, education, goal-setting and monitoring.

This paper shows the emerging potential of occupational therapy interventions using health behaviour change techniques to improve anxiety and stress symptoms. Lambert et al. (2007) found that anxiety symptoms for the treatment group were significantly lower at 20 weeks ($p<0.001$, md -9.8; 95% CI -15.0 to -4.6), measured on the Beck Anxiety Inventory. However, this difference was non-significant at 10 months. There were statistically significant changes in physical exercise, diet, general fluid intake and the overall scores on the Lifestyle Behaviour Index at both 20 weeks and 10 months but no significant changes for smoking or alcohol use. There were no significant changes on any lifestyle variable for the

GP care-as-usual group (Lambert et al. (2007). Scores on the BAI at 10 months suggested that the occupational therapy-led intervention had lower relapse rates than care-as-usual. This trial clearly reported the stratified randomisation process and the data collection and analysis were completed by researchers not involved in intervention-delivery (Lambert et al. 2007). The study did not recruit sufficient participants required to achieve 90% power, but they did use appropriate statistical analysis to account for this discrepancy. The trial lost 43% of participants to follow-up and there were considerable differences in the number of sessions attended (0-10).

Occupational Therapy interventions using skill-building theory

Of the 13 studies identified, five used a skill-building approach to target the difficulties of particular populations in completing daily activities. The populations of these studies predominantly had stress-related conditions such as post-traumatic stress disorder (PTSD). The largest study was that by Helfrich, Peters and Chan (2011) who studied people in transition from homelessness (n = 72). While diagnoses were not specified, the mean score for participants on a PTSD screening tool (The Impact of Event Scale Revised (Weiss, 2004)) was higher than the cut-off score for a diagnosis of the condition. This occupational therapy-led intervention consisted of six group and six individual sessions focused on developing skills in managing food, money and the living space as well as safe community participation. Three studies identified the particular impact of combat trauma on military veterans which can lead to increased risk-taking and aggressive behaviour. Classen, Monahan, Canonizado & Winter (2014b) described a case study and Classen et al., (2014a) did a further pre-test post-test study (n = 8) of a specialist occupational therapy intervention to improve driving skills for veterans with PTSD and associated battlefield injuries such as orthopaedic conditions. The intervention in both cases consisted of three standardised sessions identifying risky driving behaviour and learning strategies to overcome it. Pre and post testing took place in a driving simulator. Rogers, Mallinson and Peppers (2014) also identified the need to redirect this risk-taking behaviour of former veterans and used surfing as an activity to build skills in more socially acceptable adrenaline-seeking behaviour. They carried out five standardised sessions of surfing followed by group discussion on topics such as role identity, leadership and transition with 14 veterans with PTSD. Finally, a single case-study described the rehabilitation of an individual with PTSD in job-related skills including walking on elevated surfaces (Phillips, Bruehl & Harden, 1997).

These studies were mainly concerned with improving trauma symptoms, but some also measured improvements in daily living activities. Helfrich et al., (2011) showed a

significant decrease in trauma symptoms post-intervention ($p = 0.019$) and from baseline to 6-months ($p = 0.001$). Of those who completed the programme described in Rogers et al. (2014), 1/11 participants had clinically sub-threshold levels of PTSD symptoms pre-intervention and post-intervention 8/11 participants were clinically sub-threshold. Classen et al. (2014a, 2014b) both reported a reduction in driving errors following their intervention, which was statistically significant in the larger study, albeit only with 8 participants. Phillips et al. (1997) reported an improvement in performance and satisfaction in daily activities for the participant described in their study using the validated self-rating tool, the Canadian Occupational Performance Measure (Law et al., 1998).

The studies in this category show the potential for occupational therapy interventions using skill-building to improve outcomes for individuals with anxiety and stress-related conditions. However, the small number of participants in many of the studies using this approach and the lack of control conditions means that all these results must be interpreted with caution. Lack of randomisation may have led to participant selection bias in some cases, particularly in Rogers et al. (2014), where it is likely that only those with an interest in surfing would have volunteered. The intervention described in Phillips et al. (1997) was in addition to other treatments being received by the individual and collection of follow-up outcomes by telephone may have led to reporting bias. However, many of the interventions are either clearly described in the published papers (Classen et al., 2014a, 2014b; Rogers et al., 2014) or are available as manuals from the author (Helfrich et al., 2011), which adds to both treatment fidelity and replicability. The authors in Classen et al. (2014a) and Rogers et al. (2014) acknowledge the limitations of having a small sample and use appropriate statistical analyses to take this into account.

Occupational Therapy interventions using Occupational Science theory

One study described over five papers was underpinned by theories unique to occupational science and occupational therapy (Eklund, 2013; Eklund & Erlandsson, 2011, 2013, 2015; Eklund, Wästberg & Erlandsson, 2013). The Redesigning Daily Occupations programme was underpinned by theory about how patterns of daily occupation affect stress, specifically the Value and Meaning in Occupations Model (Erlandsson, 2013; Persson, Erlandsson, Eklund & Iwarsson, 2001). It consisted of a 16 week, twice-weekly group with a focus on returning to work after stress-related sick leave. Forty-two women with stress-related diagnoses defined by F43 in the ICD-10 (World Health Organization, 1992) and 42 matched controls took part in this Swedish quasi-experimental study. The intervention consisted of reflecting on one's occupational history, identifying interests, stresses and rewards,

identifying how time is used and becoming aware of the value and meaning that may be found in everyday occupations (Erlandsson, 2013). The control group received standard work rehabilitation which was highly individualised.

Participants in Eklund and Erlandsson (2011) showed a statistically significant reduction in numbers of identified cases of anxiety up to a year following the intervention. The return-to-work rate was 59% in the treatment group compared to 37% in the control group and satisfaction with and participation in daily occupations improved significantly in both treatment and control groups. Apart from the lack of random allocation, the Redesigning Daily Occupations study used good methodological rigour (Eklund & Erlandsson, 2011). There was a high degree of treatment fidelity with a manualised intervention and transparency in the reporting of drop-outs and missing data. Nevertheless, the lack of random allocation should be considered as it is possible that this led to overly pessimistic results. For example, the control group were significantly better in terms of mental health, self-esteem and other important factors at baseline, so some of the non-significant differences between the groups at follow-up could be due to this. The study also took place during a period of change in the Swedish social insurance system which may have led to the control group being forced back to work at an earlier stage than those in the treatment group (Eklund & Erlandsson, 2011).

Occupational Therapy interventions using neurological and sensory theories

Three case studies described occupational therapy-led interventions for individuals with anxiety that were designed to act on a neural or sensory level to improve symptoms. Bracciano et al. (2012) used cranial electrotherapy stimulation with two individuals with PTSD. This highly specialized therapy is described as clinically legitimate for occupational therapists to consider as an adjunctive method to occupation-focused interventions (Bracciano, 2008). It consisted of a device administering microcurrents to alter electrical currents in the brain self-administered by the participants under the direction of an occupational therapist. Moore & Henry (2002) and Champagne (2011) reported on interventions based on the theory that traumatic experiences can lead to sensory distortion and sensory defensiveness (Kolb, 1987). They carried out single case studies with individuals with PTSD and the intervention mainly consisted of the prescription of a sensory diet of "sensory rich" activities, augmented in the case of Moore and Henry (2002) with deep pressure brushing of the skin.

The two participants in Bracciano et al. (2008) showed a decrease in severity of PTSD symptoms on the PTSD Symptom Scale-Interview (Foa & Tolin, 2000) following four weeks of the intervention. They also self-reported some improvements in performance of activities of daily living such as shopping on the Canadian Occupational Performance Measure (Law et al., 1998). Moore and Henry (2002) used an unpublished questionnaire developed for the study called the Sensory Defensiveness Screening for Adults and reported that participants identified with fewer symptoms of sensory defensiveness following the treatment. Champagne (2011) reported that several baseline measures were carried out with the single participant with PTSD but no results are reported. Some personal goals are measured on a scale of 1-10 e.g. "paying bills on time". Both Champagne (2011) and Moore and Henry (2002) gathered outcome data in an informal way, sometimes over the phone and directly by the clinician delivering the intervention, introducing risk of reporting bias. These two interventions included scheduling many pleasant activities such as yoga and swimming so any positive results seen could have been due to increased participation in these health-promoting activities, rather than the sensory aspect of the intervention.

Discussion

Because of the breadth and scope of interventions that occupational therapists use with people with anxiety and stress-related diagnoses, an overall conclusion about effectiveness cannot be reached. However, clustering interventions according to theory provides a clearer picture of what kind of occupational therapy intervention might work for whom and how (Popay et al., 2006).

The use of psychological theoretical perspectives such as cognitive-behavioural theory is common among occupational therapists working with people with mental health conditions possibly due to the dominance of this perspective in research and practice in psychiatry. Both Prior (1998a, 1998b) and Kitchiner et al. (2009) studied groups that included separate sessions on relaxation, cognitive-behavioural strategies and overcoming avoidance: a "three systems" approach to anxiety management that has a long history in practice (Lang, 1968). Kitchiner et al. (2009) found no differences between the occupational therapy-led group, a nurse-led stress control group and a waiting list control group, but Prior (1998a, 1998b) found significant improvements in her smaller cross-over study. These studies should be considered alongside other research indicating that brief group-delivered interventions including cognitive restructuring and relaxation strategies are effective in treating individuals with anxiety (Erickson , Janeck, & Tallman 2007; Petrocelli, 2002) and

that non-psychologists can deliver CBT-based interventions effectively in primary care (Craske et al., 2009).

The high quality RCT described by Lambert et al. (2007) was the only study found where occupational therapists were providing lifestyle advice around nutrition, smoking cessation and caffeine intake to improve symptoms of anxiety. The focus of the occupational therapist in interventions like this is on health promotion – maintaining one's health is a crucial daily living activity (Brownson, 2008) and this intervention showed potential for occupational therapists in providing education on how to improve participation in this activity. The study resulted in significant improvements in panic symptoms and in healthy lifestyle behaviours when compared with GP care-as-usual (Lambert et al. 2007). This study contributes to a body of literature indicating that lifestyle changes may decrease anxiety symptoms (Forsyth, Deane, & Williams, 2017; Hiles, Lamers, Milaneschi, & Penninx, 2017) and demonstrates that occupational therapists have the skills to deliver these interventions.

A number of studies reviewed for this paper were designed for the specific needs of individuals following stress-related conditions such as PTSD. These studies took a top-down approach to the functional difficulties of participants. Rather than changing the underlying cognitive appraisals about the trauma, which also shows potential for effectiveness with veterans (Sacks, Schwartz, & Mueser, 2017) the occupational therapists used structured practice in meaningful activities to teach people how to manage life differently following traumatic events. Several studies used the theory of "battlemind" either explicitly or implicitly (Rogers et al., 2014; Classen et al., 2014a, 2014b). This phenomenon can be experienced by military veterans when they return to civilian life and find that behaviours appropriate to the battlefield e.g. targeted aggression or combat driving, cause difficulty with community reintegration with families (Castro, Hoge & Cox, 2006). Rogers et al. (2014) and Classen et al. (2014a, 2014b) used participation in valued occupations (surfing and driving respectively) alongside discussion and education on adjusting behaviours to civilian life. Helfrich et al. (2011) showed the potential of teaching life skills to individuals who were traumatised due to homelessness and domestic abuse. Again, the focus was on learning skills in important activities to re-enter the community. These small studies were uncontrolled, but they demonstrated some promising results both in terms of reducing PTSD symptoms (Rogers et al. 2014; Helfrich et al. 2011) and altering behaviours (Classen et al., 2014a, 2014b).

Only one of the studies was based explicitly on an occupational therapy theoretical model, in this case the Value and Meanings in Occupations (ValMO) Model (Persson et al., 2001). Other studies draw on occupational therapy theories, for example Rogers et al. (2014)

cites the Model of Human Occupation (Kielhofner, 2008). The Redesigning Daily Occupations intervention can be seen as contributing to ongoing theory development of the ValMO model, by studying whether the theoretical constructs result in improvements in daily living as hypothesised (Eklund & Erlandsson, 2011). The participants in the programme showed good return-to-work outcomes as compared with standard work rehabilitation, but differences between the groups at baseline are likely to have contributed to the non-significance of the results.

The Redesigning Daily Occupations programme is one of several identified in this review that emphasise self-mastery - the premise being that helping individuals to take control over aspects of their own lives and health will have an impact on their wellbeing (Erlandsson, 2013; Helfrich et al., 2011; Lambert et al., 2007). These studies suggest that improvement in anxiety symptoms and participation in daily living activities may follow different courses of recovery. While the participants in Eklund and Erlandsson (2011) and Helfrich et al., (2011) showed improvements in daily functioning such as returning to work, mental health symptom improvement was more modest. As noted by the authors, it is likely that increased participation in daily occupations e.g. by moving into independent living, may lead to an understandable increase in anxiety symptoms, at least in the short term (Eklund, 2013). The participants in Helfrich et al. (2011) showed an increase in anxiety post-intervention while transitioning out of homelessness, but 6 months post-intervention, their mental health was significantly better than at baseline. These results suggest that occupational therapy interventions focusing on self-mastery and developing individuals' ability to have agency over daily life have potential to improve symptoms of anxiety when measured over the longer term. They also support the idea that anxiety is a natural aspect of living (Horwitz & Wakefield, 2012), particularly when adjusting to challenging life circumstances and that clinicians can help individuals to cope with these times of transition (Besse, Poremski, Laliberté, & Latimer, 2017).

Three final studies used theories relating to sensory processing or neurological sensitivity (Bracciano et al., 2012; Champagne, 2011; Moore & Henry, 2002). These were small-scale case studies with methodological short-comings meaning that the evidence-base for these interventions for people with anxiety disorders is not strong. A recent systematic review concluded that sensory integration therapy with children with autism is not supported by research evidence (Lang et al., 2012) and the American Academy of Paediatrics has described evidence for the effectiveness of sensory-based therapies as limited and inconclusive (Zimmer & Desch, 2012). Urgent high-quality research is required to evaluate this type of intervention as it begins to be used with adults with a range of disorders, including anxiety (Champagne, Mullen, Dickson, & Krishnamurty, 2015). Cranial

electrotherapy stimulation, although implemented by an occupational therapist in the case of Bracciano et al. (2012), is an intervention outside the usual skill-set of a qualified occupational therapist. It is a highly mechanistic intervention, falling far down the continuum suggested by Fisher (1998) away from practice focusing on authentic client-chosen occupations in a naturalistic context. Other interventions in this review are based on higher quality studies with the same population and should be given greater consideration in practice (Classen et al., 2014b; Helfrich et al. 2011; Rogers et al., 2014).

Limitations

A limitation of this systematic review is the small team of reviewers involved. However, a standardised data extraction form was used and included/excluded studies were reviewed by authors independently in a transparent process. Only English language search terms were used in the search so studies published in other languages may have been missed. The review took place over two years, but the searches were repeated to include newly published material. The heterogeneity of the interventions found meant that meta-analysis or pooling of results was not possible and so a realist review approach was taken (Shepperd et al. 2009) by clustering studies based on their underlying theory of change (Popay et al., 2006).

Given the strictness of the inclusion criteria for this review, it is acknowledged that this paper may not accurately represent the reality of occupational therapy in the treatment of those with anxiety disorders. Studies including populations with varying mental health diagnoses were excluded where the particular impact of the intervention on the subgroup with an anxiety diagnosis was difficult to determine (Bonsaksen, 2011; Chesworth, Duffy, Hodnett, & Knight, 2002; Gutman et al., 2004). Multidisciplinary studies where the particular contribution of the occupational therapy practitioner couldn't be determined were also excluded (Reagon, 2011; Speicher, Walter, & Chard, 2014; Van de Vliet et al., 2003). Occupational therapy interventions show some potential to reduce anxiety in populations under stress or with other medical conditions, for example with veterans (Beck et al., 2012; Eakman, Rolle, & Henry, 2017; Stoller, Greuel, Cimini, Fowler, & Koomar, 2012), impoverished populations (Crouch, 2008), individuals with depression (Chen, Pan, Hsiung, & Chung, 2015), patients with multi-morbidities (Garvey, Connolly, Boland, & Smith, 2015) or carers (Martin-Martin et al., 2014; Sheija & Manigandan, 2005), but the lack of an anxiety diagnosis for the participants in these studies meant they were excluded. Finally, this review excluded studies involving children and did not find any studies specifically involving occupational therapy interventions for older adults with anxiety.

Conclusion

This systematic review aimed to determine the effectiveness of occupational therapy interventions for people with anxiety and stress-related disorders. Given the nature of the studies found, it is not possible to make a judgement about overall effectiveness, but individual good quality studies point to the potential for certain replicable interventions to improve mental health and functioning (Eklund & Erlandsson, 2011; Helfrich et al., 2011; Lambert et al., 2007; Prior, 1998a; Rogers et al., 2014,). The review shows that occupational therapists are using interventions as diverse as lifestyle advice, cognitive-behavioural strategies, driving rehabilitation and cranial electrotherapy stimulation in the rehabilitation of individuals with anxiety. It is possible that this breadth of diversity comes at the expense of replicating and consolidating the evidence for clearly-described interventions in high-quality studies.

Future research should report clearly on the impact of occupational therapy interventions on functioning or participation in activity as a key outcome of interest. Functioning was not reported as an outcome in five studies reviewed for this paper, including in two of the randomised-controlled trials (Kitchiner et al., 2009; Lambert et al., 2007). It is recommended that physical functioning and participation in work and social occupations are measured as core outcomes of anxiety interventions in clinical trials according to mental health consumers and experts in the field (ICHOM, 2017). With recent research showing that a decline in satisfactory participation in life activities may actually precede an anxiety diagnosis (Winer et al., 2017), interventions targeting self-mastery, lifestyle changes and life skills are indicated as preventative treatments for the condition.

The results of this systematic review show that occupational therapy interventions using theories such as the Value and Meaning in Daily Occupations model, health behaviour change theory and skill-building have potential to improve outcomes for people with anxiety, albeit in small-scale trials. Future research should focus on replicating studies using some of the manualised and clearly described interventions that show potential e.g. Redesigning Daily Occupations (Eklund & Erlandsson, 2011) and life skills for homeless individuals with mental health needs (Helfrich et al., 2011). The professional role of the occupational therapist is to enable people to participate in the activities of everyday life (World Federation of Occupational Therapists, 2011) and there is growing urgency for high quality research into occupation-based or occupation-focused interventions in all areas of health care (Mackenzie et al., 2017) and for those with anxiety disorders particularly.

Declaration

An early version of these results were presented as an academic poster presentation at the International Society for Affective Disorders conference in London in 2017 and a published abstract is available (Fox, Erlandsson & Shiel, 2017). This written paper presents the most up-to-date version of this systematic review.

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Appendix II: Published Paper 2:

Published in the Scandinavian Journal of Occupational Therapy using the Vancouver/numbered referencing style. This is the Agreed Manuscript without the journal typesetting

A feasibility study of the Redesigning Daily Occupations (ReDO-10) programme in an Irish context

Abstract

Background: Despite high demand, mental health services in primary care in Ireland are underdeveloped. People with mild/moderate anxiety, depression and unspecified psychological distress are frequently seen in primary care settings, mostly by general practitioners (GPs). Occupational therapists have the potential to contribute to service-provision with interventions specially designed for the targeted group e.g. the Redesigning Daily Occupations programme (ReDO-10).

Aims/Objectives: This study aimed to explore the feasibility of a future RCT of the ReDO-10 programme in Ireland and the contextual factors that would influence future implementation.

Material and Methods: Using a multi-phase, mixed-method design, qualitative and quantitative data were gathered from key stakeholders: ReDO-10 participants (n=10), GPs (n=9) and occupational therapists (n=2). Acceptability, satisfaction, cultural fit and demand were explored, as well as methodological issues such as appropriateness of recruitment methods, outcome measures and randomisation.

Results: ReDO-10 was acceptable to participants who reported improvements in their occupational patterns and valued the group-based format. GPs and occupational therapists welcomed the intervention, but acknowledged the limitations of time and resources in the Irish primary care context.

Conclusions: ReDO-10 is feasible to explore in a future RCT in Ireland and this study provides important context for future implementation and/or research.

Keywords: *Occupational Therapy, Women, Psychological Stress, Anxiety, Feasibility Study, Pilot Study, Mixed Methods, Occupational Balance*

Background/Introduction

In their seminal work about stress and coping, Pearlin and Schooler [1] insisted that coping and mastery be understood as an ongoing adaptive response to everyday living rather than something exceptional that people facing extraordinary pressures must achieve. Stress and difficulty managing everyday living is recognised as a European-wide concern by the WHO [2] and is a common reason for attending a general practitioner (GP) in primary care. One Irish study reported that 16.8% of GP attendees presented with signs of psychological distress and a further 16.2% with severe psychological distress [3]. While there is a perception of increased rates of mental health conditions like anxiety and depression, lifestyle characteristics of modern life e.g. poor sleep, low physical activity levels and work pressures may be contributing to this high level of unspecified psychological distress [4]. The DSM-V states that severe emotional reactions to common stressors such as unemployment, financial difficulties or marital disagreements, should not be considered as mental disorder [5]. Nevertheless, subthreshold anxiety and depression are perceived by patients as extremely distressing and disabling [6].

Primary care is the first point of access for those with psychological distress [7] and their experience is well understood by the GPs with whom they develop a trusting clinical relationship. The background to stress in daily life has been described by one British GP as "*a head-spinning cocktail of concern. Seemingly well-intentioned guidelines have become confining and limiting like never before. Our society, which is driven by wealth, individualism and perfectionism, leaves many riven with introspection, indecision and full of unrealistic and unobtainable expectations. Modern life seems little more than a gilded cage for many, with anxiety hardwired in utero*" [8, p.526]. It is estimated that many more people do not seek treatment from their GP [9]. Stress and anxiety are risk factors for developing other medical conditions such as chronic fatigue and irritable bowel syndrome and research shows that high levels of GP attendance and severe psychological distress can predict the onset of these complications [10]. Appropriate treatment of this population with psychological and daily life management interventions in primary care is important and could prevent unnecessary interventions and overtreatment [2, 8].

Women present with higher rates of depression and anxiety than men [11] and there is evidence that men and women face different challenges when navigating the occupations of daily life. For example, working mothers may experience more stress than working fathers because of the likelihood that women experience their professional and parenting identities as being in opposition to each other [12]. Working full-time is a protective factor against anxiety or depression for fathers, but

not for mothers [11]. Men and women may also respond differently to treatment. Men with social anxiety show higher attrition rates from group-based interventions and it has been suggested that attending treatment can be more distress-inducing for men with anxiety [13], thus making them less likely to seek treatment. These differences have led to calls for a "gender-sensitive" approach to mental health promotion and prevention programmes [14, 15] to account for diversity.

In Ireland, general practitioners (GPs) have expressed concern about inadequate treatment for individuals with mental health problems in primary care with 53% stating that the multidisciplinary staff required to provide mental health interventions in the community are not in place [16]. Where available, treatments for those with stress, mild/moderate anxiety or depression in primary care demonstrate a stepped-care approach, as recommended by the National Institute of Clinical Excellence guidelines [17]. GPs offer self-management advice or refer to counselling services in the community [18], often at significant financial cost to the patient. The Committee on the Future of Healthcare in Ireland has called for an increase in multidisciplinary treatments for mild/moderate mental health conditions in primary care [19]. Occupational Therapists form part of the primary care team structure, but evidence for the effectiveness of interventions in this context and for occupational therapy mental health interventions generally needs to be developed [20].

Occupational therapy can contribute both to prevention of health problems, the treatment of heath conditions in the early stages and the management of individuals with complex multi-morbidity [21, 22] A small number of such occupational therapy-led interventions are being explored for feasibility and effectiveness [23, 24]. A systematic review was carried out by the authors to identify an occupational therapy-led intervention that could be implemented in an Irish context and improve the mental health and occupational participation of people with stress and anxiety in primary care [25]. This identified the Redesigning Daily Occupations (ReDO®) programme as having broad applicability and an emerging evidence-base. Thus, this programme was chosen to be explored for feasibility in an Irish primary care context.

The Redesigning Daily Occupations programme

The Redesigning Daily Occupations (ReDO®) programme was developed in Sweden as a 16-week, occupational therapy-led group intervention (ReDO-16) for women with stress-related conditions aiming to improve return-to-work outcomes. The programme content was designed based on research on the complexity of women's patterns of daily occupations and the relationships of these patterns with stress and perceived health [26, 27]. The purpose of the intervention is to provide participants with the tools to analyse their own occupational patterns and make individualised goals for change with the aim of having a more satisfying, healthy, everyday life [28]. It was originally evaluated between September 2007 and March 2009 [29], with a follow-up 3-4 years later [30].

Eighty-four women were assigned to either the ReDO-16 programme or to traditional vocational rehabilitation (CAU) in a quasi-experimental trial. At 12-month follow-up the return-to-work rate of the ReDO-16 participants was 59% as opposed to 37% in the CAU group [29]. However, this difference was no longer present 3-4 years later [30]. The ReDO-16 participants also showed some improvements in quality of life, self-mastery, anxiety and depression as compared to the CAU group, but these differences were not statistically significant [31, 32]. There were significant differences in the groups at baseline: the ReDO-16 participants had lower mental health and self-esteem and had less previous rehabilitation and this may have contributed to the lack of significant differences.

A primary care, 10-week version of Redesigning Daily Occupations (ReDO-10) was developed more recently and is being evaluated in a number of primary care contexts, particularly in Sweden [33]. This shorter version condenses the content and does not focus on return-to-work. It was adapted following feedback from primary care health providers about the feasible length of occupational therapy interventions in that context [34]. Olsson, Erlandsson and Håkansson [34] completed a longitudinal single-cohort study of the ReDO-10 with 152 participants, both male and female, in primary care in Sweden. Pre, post and follow-up data were available for only 86 participants. Statistically significant improvements in mastery, occupational balance, perceived health, work ability and occupational value were found post-intervention and for three of the outcomes at the 6-month follow-up [34]. The intervention content is described in detail in Olsson et al., [34] and in Erlandsson [28], but the session titles are as follows:

(Prior to programme) - Individual meeting with the occupational therapist

Group sessions:

1. Introduction
2. Occupational history
3. Occupational balance
4. Patterns of daily occupations and time (Part 1)
5. Patterns of daily occupations and time (Part 2)
6. Hassles and uplifts in daily life
7. Goal-setting
8. Occupational value
9. Evening seminar (for friends, family, partners or employers)
10. Goals and strategies
11. Concluding
12. Follow-up 1 (After 1 month)
13. Follow-up 2 (After 1 month)

ReDO® facilitators are required to complete a three-day training course and attain certification [28]. The full manual is available to facilitators with guidance for each session, seminar slides, worksheets and additional reading. ReDO® is led in a facilitative leadership style, with a mixture of directed activities (e.g. completing an occupational balance worksheet), occupation-focused exercises and guided discussion.

The feasibility of ReDO-10 in a new context

Carrying out a fully powered randomised controlled trial (RCT) in a new setting is not recommended without consideration of context, stakeholder views and feasibility [35]. The policies, supports and rights for people with mental health needs are considerably different between Ireland and Sweden and these differences mean that those with stress in primary care in the two countries may have different options and pressures regarding sick leave and rehabilitation. For example, people are required (unless they qualify financially for a medical card) to pay for both their GP visits and counselling in Ireland [18]. In addition, an individual has no right under employment law to be paid while on sick leave [36] and there are no statutory rehabilitation or return-to-work schemes for those with stress. This may affect the motivation, choices and feasibility of attending programmes such as ReDO-10. In Sweden, those on stress-related sick leave receive the support of a Social Insurance Officer, with regular follow-ups, meetings with their employer and the potential to avail of work rehabilitation interventions [37]. Both the 16-week and 10-week versions of ReDO® have been evaluated only in the Swedish context [29, 34] and it is unknown how acceptable, feasible, potentially effective or practical this intervention will be in an Irish primary care setting.

Research questions

Bowen et al. [38] provide guidance on the appropriate areas of focus of a feasibility study. These eight areas are: acceptability, demand, implementation, practicality, adaptation, integration, expansion and limited-efficacy testing. They advocate the use of "small-scale experiments that more closely approximate the clinical or community context of an RCT" (p. 456) to test these aspects of intervention feasibility. It was planned to run a pilot RCT for this purpose. However, due to lack of recruitment in the first six months it was deemed pragmatic to change to a pre-test, post-test design and to explore the issue of recruitment with key stakeholders. The ReDO-10 was implemented in 2018 and again in 2019 with the following research questions:

1. What is the feasibility of a future RCT of ReDO-10 in primary care in Ireland?

    - How successful were the recruitment procedures and how acceptable was the research process to stakeholders?

    - How appropriate were the inclusion criteria and data collection tools?

    - Was the intervention delivered with fidelity?

    - Did the intervention show any trends towards effectiveness or perceived benefits in this new context?

2. What are stakeholders' perspectives of the future feasibility of ReDO-10 in primary care in Ireland?

    - How acceptable was the intervention to stakeholders? Were they satisfied with it?

- How did it fit with current services?
- What contextual factors could/did affect implementation and feasibility?

Methods

Design

This was a multi-phase, explanatory, sequential mixed-methods study. Two phases of quantitative (QUAN) data collection were interspersed with qualitative (QUAL) components and the qualitative data were given greater weight in the interpretation of results because of the small sample size [39]. The ReDO-10 programme was evaluated twice using a pre-test, post-test design with follow-up. The qualitative component of the study was influenced by the interpretive descriptive paradigm [40]. This methodology was developed by nurse researchers and academics as a means of generating rich qualitative data to improve understanding of clinical and healthcare situations. Using this methodology allowed the researcher to apply a framework to drive the research questions – in this case, published guidance on feasibility studies [38]. The sequence of data collection phases and analysis is given in Table 1.

Table 1. Data collection phases and analysis

Year	**Type of data**	**Dec-Jan**	**Spring (Jan – April)**			**Summer (May – July)**	
2018	QUAN	Recruitment & Baseline assessment	ReDO-10 Phase 1	Post-intervention assessment	ReDO-10 follow up groups	Follow-up assessment (2 months)	
	QUAL		OT self-reflections	GP interviews			ReDO-10 participant interviews
	QUAL and QUAN analysis. Results guided recruitment strategy for Phase 2						
2019	QUAN	Recruitment & Baseline assessment	ReDO-10 Phase 2	Post-intervention assessment	ReDO-10 follow up groups	Follow-up assessment (2 months)	
	QUAL		OT self-reflections				ReDO-10 participant interviews
	QUAL and QUAN analysis. Integration of results.						

Setting

This study involved a change in usual practice for occupational therapists and to the usual referral pathways for GPs, so a full understanding of the context was required [41]. The Health Research Board Primary Care Clinical Trials Network (HRB PC CTNI) provided support for the

study by promoting it to GPs and providing them with a small financial incentive to participate. A Health Service Executive Primary, Community and Continuing Care (HSE PCCC) Occupational Therapy Department in the west of Ireland supported the study by granting protected time to therapists taking part. The HRB PC CTNI Public and Patient Involvement committee reviewed the study protocol and participant information materials for acceptability and clarity. Full ethical approval was granted for the study by the Irish College of General Practitioners Research Ethics Committee in March 2017 and a protocol was published [42].

Participants

Women were recruited by GPs in both urban and rural areas of the west of Ireland, from practices with a wide range of socioeconomic representation. Posters were placed in primary care centres and family resource centres so women could self-refer. The ReDO-10 groups took place in a city-based primary care centre. Inclusion criteria were; (a) female, (b) between the ages of 18-66, (c) diagnosed with anxiety or had stress-related concerns with/without another diagnosis, (d) had visited their GP on at least two occasions with concerns about stress and/or anxiety (e) self-identified to the GP or researcher as feeling that their life was out of balance, overburdened or lacking in meaningful occupation. Exclusion criteria were; (a) in acute crisis, (b) had current alcohol or drug addiction issues or (c) had other reasons why group participation could have been difficult e.g. cognitive impairment. These inclusion criteria were designed to be broad given the high proportion of co-morbidity of other conditions along with anxiety in primary care settings [43], to include women across the working age-range and to maximise recruitment.

Data collection

Interview protocols were developed addressing the research objectives and were piloted. Audio-recorded qualitative interviews were carried out with the nine GPs who referred to the study, the two occupational therapists who facilitated the ReDO-10 groups and consenting women who attended the ReDO-10 groups in 2018 and 2019. Interviews were between 25-60 minutes long. To evaluate intervention fidelity, the therapists completed a written reflection after each session on how closely they had adhered to the manual, any adjustments made and notes on their facilitation [44].

Quantitative data were gathered to determine whether the outcome measures chosen were appropriate, acceptable and whether the participants showed any improvements [38]. Validated and reliable outcome measures were selected to assess mental health symptoms and daily functioning, as well as outcomes theorised to be influenced by the ReDO-10. The specific outcomes were: levels of depression, anxiety and stress (Depression, Anxiety and Stress scales (DASS) [45]), disability (WHO

Disability Assessment Schedule 2.0 (WHODAS 2.0) [46]), occupational value (Occupational Value instrument with predefined items (OVal-pd) [47]), mastery (Pearlin-Schooler Mastery Scale (PMS) [1] and perception of health (visual analogue scale of the EQ-5D-5L (EQ-VAS) [48]). The self-report measures were completed by the participants at baseline, after the main 10-week portion of the programme and again 2 months later, after the two follow-up group sessions. The post-intervention and follow-up measures were returned to the researcher by post or in person.

Data analysis

The Framework Method was used to analyse the qualitative data. This method allows qualitative data to be analysed at a thematic level across all stakeholders, but also allows the words of a single participant to be connected to all their other statements [49]. This is important where there could be differing/divergent views on feasibility depending on context. Data analysis followed the steps of the Framework Method: (i) transcription of interviews, (ii) familiarisation with interviews, (iii) inductive line-by-line coding, (iv) developing a framework (defining and reducing codes before clustering them into categories. This stage was both inductive and deductive - influenced by the research objectives), (v) sorting the coded transcript sections into the framework and (vi) interpretation (exploring connections, finding disparity, developing conclusions) [49,50]. Using the Framework Method also allowed for the quantitative data to be integrated to better understand the participants' outcomes. Because of the small sample size, no inferential statistical tests were carried out [51]. The non-parametric Friedman test was used to investigate differences over the three time-points.

Results

During the qualitative analysis, an overarching framework of four themes and thirteen subthemes was developed. The quantitative results were integrated during analysis and informed the understanding of outcomes. The four themes (with subthemes) developed are given in Table 2.

Table 2. Themes and subthemes developed

(1) Research design, conduct and processes
a. Recruitment and retention
b. Suitability of the inclusion/exclusion criteria
c. Acceptability and understanding of research

(2) Intervention content and delivery

a. Acceptability of ReDO-10 in principle

b. ReDO-10 structure, layout and format

c. Practical implementation and group facilitation considerations

(3) Outcomes and outcome measurement

a. Collecting data

b. Perceived benefits of ReDO-10

c. Contextual factors and outcomes

d. Harms or unintended consequences

(4) Context.

a. Stress in the Irish context

b. Treatment options in primary care

c. Occupational Therapy in primary care in Ireland

1. Research design, conduct and processes

Recruitment and retention

In total, 31 women were referred or expressed interest in participating in the study over the two phases of feasibility-testing in 2018 and 2019. It is unknown how many women were approached by their doctor or saw the recruitment posters and declined participation. Of this 31, 15 women gave consent and began the ReDO-10 (6 in 2018 and 9 in 2019). The mean age was 44.2 years (Range: 21-65). Participants had a range of work/study experiences: working fulltime (2), working part-time (5), on leave from work (2), working full-time in the home (3) and other, including studying or retired (3). Most women lived with a partner (8) or with a parent (3), while four lived alone. Finally, four women had no children, six had 1-2 children and five had three or more children. There were an average of four participants per week in 2018 and six participants per week in 2019 and the minimum/maximum number of attendees in a session was 3/9.

It was evident from the GP interviews and using the Framework Method that the GPs who spent more time discussing the study with their patients and actively encouraged participation recruited more women. One particular GP selected patients whom they thought would be suitable, rather than asking everyone who met the inclusion criteria. All GPs reported some refusal when

women were told about the study. Patients who refused counselling and other self-management interventions also tended to refuse ReDO-10. This was viewed by GPs as sometimes a "*personality thing*" (GP4) or showing a belief that such interventions are "*airy-fairy*" (GP1). Other GPs felt the 10-week length and 2-hour sessions were a barrier to working or time-poor women. One GP discussed more subtle reasons why recruitment was difficult. For some women, taking time out for therapy would be viewed as "*a luxury*", "*indulgent*" or "*like telling their partner 'I'm going to get my hair done'*" (GP3). Interestingly, this view was echoed by one ReDO-10 participant who had chosen not to tell any of her family she was attending because it felt "*self-indulgent*" and "*a bit American*" (3656). The characteristics of the women who participated demonstrate that a degree of acceptance of self-analysis is necessary for successful recruitment to studies involving therapies like ReDO-10. Those who were recruited wanted to "*better myself*" (6686), were "*always doing bits and pieces of work on myself"* (9421) or wanted to "*start changing myself*" (1558). Participation was considered essential by a further three women who were more acutely distressed, were "*struggling*" (1262) or had "*reached a tipping point*" (1558).

Self-referral (posters and leaflets) and GP referral were used to recruit to the 2019 ReDO-10 group. This was more successful than GP referral alone and participants were recruited more quickly and retained more successfully. OT1 felt that those who self-referred were "*proactive in change*" and were "*motivated to make changes*", leading to more dynamic group discussions. There was reasonable retention of participants. Three women (1 in 2018 and 2 in 2019) dropped out or withdrew. Text reminders sent by the therapists about the follow-up groups were helpful in encouraging attendance. For three women, attending ReDO-10 consistently was a goal they set for themselves. This (for one woman) involved having the assertiveness to ask her spouse to bring their child to an appointment where "*normally, I would just take a back seat and make sure they all get wherever they have to be*" (1558). Two other women cited strong principles about commitment "*I said I'll go, so I will go*" (9421).

Suitability of the inclusion/exclusion criteria

Generally, the inclusion/exclusion criteria were appropriate and broad. In 2018, women who were seeing a Psychiatrist or were over the age of 60 were excluded. Two GPs noted the Psychiatry restriction reduced recruitment - therefore this was changed for 2019. The age limit was also raised and three woman in their 60's were recruited for the second group. GPs appreciated the broader inclusion criteria, as one remarked "*It's what we're seeing every day of the week*" (GP6). Another appreciated that there didn't need to be a formal diagnosis, "*just having difficulty with life...very realistic*" (GP8).

Stakeholders reflected on who could be suitable for future ReDO-10 programmes in this context. Carers or ex-carers, women with responsibility for children and/or grandchildren or people managing stress along with chronic conditions were all mentioned. Stakeholders indicated that this intervention is best as a preventative measure, in order to prevent people "*ending up on medication*" (GP3). One participant in her 60's reported that ReDO-10 would have been more effective earlier in her life, but now she "*has been there - done that*" (9421).

Acceptability and understanding of research

The idea of research was acceptable and understandable to participants. Some had an altruistic motive: "*I hope it'll help someone, the way it's helped me*" (1262). Others reported that they had had gained personally from the experience; "*It was for myself...growth*" (6686). Trust in their doctor and in the researcher made the idea of research more acceptable; "*I asked my doctor first*" (4678). The occupational therapists saw research as a welcome "*break from routine*" (OT1) and are open to future participation if resources are made available. Participation in research involved a time commitment for both therapists, particularly in 2018, when they were less familiar with the material. The occupational therapy manager supported their participation, but there was corresponding pressure on waiting lists and other clinical work as a result: "*It's not as if there was someone picking up the slack, you know?"* (OT2)

Randomisation was viewed by some GPs as; "*not something that everybody appreciates*" (GP8) and two believed that future research should not include randomisation; "*if people … had the guarantee that they would get the service?*" (GP4). However, it was viewed as acceptable by both the ReDO-10 participants and other GPs. The method of recruitment to the study was viewed as "*very straightforward*" (GP5) by one GP but was acknowledged by another to "*take a bit of extra time*" (GP8). The post-group reflections showed that occupational therapists understood the concept of intervention fidelity in the context of a trial: "*Followed manual as presented*" (OT Reflection)

2. Intervention content and delivery

Acceptability of the Redesigning Daily Occupations programme in principle

Overall, stakeholders spoke positively about ReDO-10 as an intervention. Most participants felt that the content resonated with their experiences and their stress: "*No matter what people were talking about, I was like - Yeah, I get that*" (1558) and "*it made sense*" (4678). The central occupational ideas of the programme were described accurately by most participants - indicating that

the content delivered matched the theoretical background of ReDO-10: "*it's redesigning daily occupations*" (6686), "*learning how to do things differently so I'm not so stressed*" (3656). Some participants described ReDO-10 to friends and family as "*an educational thing*" (6686), whereas another saw it as "*group therapy*" (4572). However, two participants found it was not so helpful to them. Both had a long history of anxiety and some content "*was stuff that I had already figured out on my own*" (5505). Interestingly, ReDO-10 was welcomed personally by the occupational therapists who "*both felt it in our personal lives*" (OT1). One of the therapists made changes to her working hours to have better life balance as a result of ReDO-10 discussions "*I used to work four full days.....we changed everything around...which makes life so much easier*" (OT2).

The fact that only women were in the group was welcomed strongly by almost all the stakeholders. Many participants said they felt it was "*easier to share your feelings with just women*" (3656) or even more strongly, that having men in the group would have restricted their participation - "*I wouldn't have said some things*" (1558). This was echoed by the therapists who reported that participants "*wouldn't have felt safe and open to have the conversations they were having*" (OT2) particularly around issues like sexual relationships and the menopause. The only participants who would have been "*comfortable enough with a mixed group*" (6797) were two women in their mid-60's, who felt that gender-specific groups weren't "*that important...at this stage of life*" (9421). Stakeholders felt that a male-only group using ReDO-10 could work, but only if the material was adapted. This appeared to be due to perceived differences between the genders; "*it's not the same for women as it is for men*" (3656) and the importance of female support for women;' "*I think women supporting women is very important*" (4678). One GP felt that while a male-only group might be "*a hard one to run...as they got familiar, it would be very beneficial*" (GP1).

ReDO-10 structure, layout and format

Although the length of the programme (10 weeks plus two follow-ups) was felt by GPs to restrict recruitment, those who participated stated that it should be longer. There were two aspects to this. Firstly, several women felt they were only starting to make changes by the end of the course; "*you are only kind of getting into the swing of it and it's over*" (2612) and secondly, that they needed a longer period of follow-up and support to really embed changes; "*you need to be reminded*" (6686) "*It's harder to keep it going when you're not meeting up with someone, because you forget and you revert back to your own ways*" (1262). Of note however, the evening seminar, which is designed to synopsise the programme content so that women can feel supported in their families or workplaces to make changes, or for family units to make changes together to reduce stress was not acceptable to participants. All but one who spoke about the evening seminar did so negatively. There was a strong view that this group was their personal space and that changes to be made were theirs individually. This came through in

the use of the words "I" and "my" in their accounts: "*It was my course*"(1558), "*This is my thing.....my stuff....It's for me to get independent"(2612), "It's my own personal journey*"(3656). This was corroborated by the therapists who reported that group members were "*horrified*" by the idea of the seminar; "*It was for them to be making changes and it was about what they could do and empowering themselves.....I would have thought...they were making changes that were affecting the whole family, but they felt that this was their change to make. Not someone else's*" (OT2). One participant spoke at length about another reason for disliking the idea of the evening seminar - relating to vulnerability and the perceptions of others; "*I was mortified. I was like, there's no way I can bring somebody. ...people would think of me, 'doesn't she think highly of herself now that she needs to get us all involved in her life plan?*'" (3656). One participant spoke positively about the evening seminar, but as a person born outside of Ireland, she felt this could be related to cultural differences; "*I think it's very good. In Ireland.....people really feel embarrassed if the other people knows you going to the psychologist or counselling. I don't know why? It's the same like other doctors*" (4572). Because of this feedback, the evening seminar was not held in either 2018 or 2019.

Another aspect of the ReDO-10 programme was the homework given during the ten weeks. This may have included an occupation-based task e.g. to do a pleasant, uplifting occupation, or a reflective task e.g. to write a goal. The therapists reported that "*some did and some didn't*" (OT2) do the homework tasks, reflecting that "*that's people*" (OT1) and participants' own accounts reflect this. One women had a strong sense of personal responsibility towards the homework "*I want to do it for me....I was trying to do it to be honest with myself*" (6797), whereas another found it hard to prioritise this over family responsibilities "*I didn't do the going for walk things, really, because with kids there, it doesn't suit timewise. And when my husband would get home, it's too late to go and it didn't suit and I'd get tired and whatever*"(1558). The homework tasks were viewed as important by those who did do them: "*another week was, you write down everything you do for one day. And it was funny, because it made me do a small bit more because I wanted to look good even though no one was going to see it. But even now I can still do, like if I might write down in my diary, I did this, did this, did this and I can check off a few things that I did during the day*"(1262).

Practical implementation and group facilitation considerations

The therapeutic effects of the group-based format were mentioned frequently by participants and were perceived as instrumental to changes that occurred according to the therapists: "*It was the group dynamics within themselves that was creating the change*" (OT2). Dynamics between people at different life stages or with different levels of occupational dysfunction required careful management and the occupational therapists reported that a therapist would require "*really advanced facilitation*

skills" to "*keep it cohesive*" (OT1). Most participants valued the group experience strongly and it seemed to offer different experiences to different people: catharsis "*I was just able to tell somebody*" (1558), a sense of peer support "*you're getting it from people who also have their own issues*" (1558), finding a role model "*If she can do it and she's a single mom….I can try it*" (3656), problem-solving "*the girls has kind of similar problems so we can give advice to each other*" (4572) or reducing isolation "*knowing that you're not alone or….that people will say 'Oh yeah – that's the way I feel too*" (4678). Three participants reported less positive experiences. The experiences of participant 6797 indicate the importance of strong boundaries and rules in a group setting to maintain a therapeutic environment: "*I was getting resentful towards the late timekeeping and it was getting worse as the time was going on. …I was feeling more for the other people….that were there on time, that wanted to talk and wanted the group*". Participants 9421 and 5505 both felt that that the content was not so relevant to them and, understandably, they did not form the same connection with others; "*it was interesting to see what other people's stresses and things were. And kind of frustrating in other ways because I'd hear about something that seemed so miniscule and irrelevant to me but that was a massive thing for them*" (5505)

The strict manual-based intervention required adaptations by the therapists while remaining within the limits of intervention fidelity. Adaptations made included changing the order of content delivered within a session or adapting some of the occupation-based sessions. A particular issue for facilitators was that they believed that essential content had been removed from the ReDO-10 when it was adapted from ReDO-16 and so they reinstated some of this material: "*what we had to do sometimes was take stuff that was in the main manual that they had taken out from the primary care one and put it back in. Because for flow, it didn't work without it*" (OT1). Another adaptation was to do the homework within the sessions.

3. Outcomes and outcome measurement

Collecting data

Baseline data collection was completed without difficulty (n = 15) and post-intervention questionnaires were collected from all those who completed the ReDO-10 programmes (n =12). There was some attrition after the 2-month follow-up period (n = 9). This may have been due to differences in how questionnaires were collected (in person vs by return of post). Completing the five outcome measures took longer than expected for participants. In their interviews, participants reported that most questionnaires seemed appropriate apart from the WHODAS 2.0. Many items on this measure were seen as not relevant, particularly those relating to basic activities of daily living; "*some of it wasn't so relevant for me…..about your day-to-day, like getting up and dressing and washing*"

(4678). This assessment caused some confusion for participants about how to score themselves. Participants couldn't accurately say they were unable to do a task e.g. household chores - feeling instead that they were avoiding these tasks due to stress; "*The one I found difficult to do was the 'has it stopped you from doing stuff' one. Well, not physically no. …I decided not to. I chose not to do it because I was feeling down. So did it stop you? Or did you stop yourself? ….so I found them difficult to answer*" (3656).

Perceived benefits of ReDO-10

The intended occupational outcomes of ReDO-10 [28] were reported by participants. For example, participants reported choosing more meaningful occupations and enjoying them with full awareness: "*I made a conscious effort of being aware of my surroundings and it was a really nice day and listening to the birds and seeing the cattle in the field and just being present in the moment. It was really, really enjoyable*" (1262). These kinds of occupations were seen as important for reducing rumination and improving health; "*I've always loved gardening. But I kind of realise now that the reason why I do love it so much is because it does give me that break and it is a kind of break for myself. I'm doing the stuff that's physical; I'm looking at things and it might be weeding, it might be planting; it's whatever I'm doing, I'm just doing that. My mind kind of goes blank. I just concentrate on what I'm doing. Mindfulness. And that helps. But prior, I suppose I wasn't*." (1558). Choosing these occupations meant that women sometimes had to be assertive, say no to other demands or delegate housework to others in the home. For example, participant 3656 implemented a routine whereby her children help out more with household tasks. As a result she "*was having that hour every evening of just sitting down… the kids were in bed, on time. No messing. …definitely that time is a massive improvement*". The programme gave women the opportunity to identify their personal health-promoting occupations and a drive to choose to prioritise time to participate in them: "*I gave myself permission to lie in bed in the morning*" (6797), "*This is my thing. I'm going out with the choir. The choir is all I have and that's my thing"* (4678) "*I started to book stuff for myself, because they were saying, 'do you ever do anything just for yourself?*"" (3656). Other small, but important changes reported by individual participants were increasing physical exercise (2612), reducing smartphone and social media use (5505) and returning to valued occupations such as reading (4572).

Improvements were also seen on the outcome measures after ReDO-10 and these results were maintained or slightly improved at the 2-month follow-up. These improvements were statistically significant ($p < 0.05$) for all outcomes apart from perceived health. Mental health changes were clinically significant with for example, three women improving from "Extremely severe depression" to "Normal mood" on the DASS instrument. Table 3 outlines the pre, post and follow-up results.

Table 3. Results

	Baseline mean (n=15)	***SD***	**Post-intervention mean (n=12)**	***SD***	**Follow-up mean (n=9)**	***SD***	***Difference over 3 time points (n = 9)***
Perceived Health	55.67	*20.077*	72.92	*13.561*	70.00	*19.203*	$\chi^2(2) = 5.097$, **p = 0.078**
Depression	18.60	*8.65.*	6.67	*6.555*	6.89	*10.624*	$\chi^2(2) = 11.529$, **p = 0.003**
Anxiety	14.93	*9.924*	6.25	*5.379*	6.67	*5.590*	$\chi^2(2) = 7.185$, **p = 0.028**
Stress	21.20	*6.889*	11.25	*9.275*	10.44	*8.676*	$\chi^2(2) = 6.220$, **p = 0.044**
Mastery	17.33	*3.559*	20.58	*4.166*	20.8889	*3.5862*	$\chi^2(2) = 9.484$, **p = 0.009**
Occupational Value	38.73	*7.564*	48.67	*7.750*	47.11	*10.752*	$\chi^2(2) = 8.222$, **p = 0.016**
Disability	31.4913	*13.623*	22.0408	*14.155*	17.239	*11.162*	$\chi^2(2) = 8.629$, **p = 0.013**

Contextual factors and outcomes

From the integration of the qualitative and quantitative data it was evident that contextual and individual person factors could either have contributed to the benefits seen or restricted a woman's ability to make changes during ReDO-10. A clear example was where medication or lifestyle changes occurred at the same time as attending the programme; *"Since January, I started going to the gym and getting more exercise. And I've been having a better balanced diet and I just find that between that and the new anti-depressants – it makes a big difference" (5505).* Participants with other health challenges such as fibromyalgia or chronic pain continued to have daily disability as measured on the WHODAS 2.0 and one found it difficult to engage with group materials; "*My memory isn't good….I can't retain stuff*" (2612). A participant with autism said that some ReDO-10 topics (such as managing complexity in daily life) were not as relevant to her because *"I can't be interrupted when I'm doing something*" (5505). Several participants had experience of other support groups or psychotherapeutic methods and the qualitative data showed that this experience led them to interact with the programme content in a different way, possibly influencing outcomes; *"Cognitive behavioural….I did that one….I kind of brought that element into this course. I definitely feel this course helped me with the last one" (3656).*

Harms or unintended consequences

There were few unintended consequences of ReDO-10 or of this study. Some participants reported feeling tearful or upset during some sensitive group conversations that reminded them of an issue in their own lives: "*They were talking about ….their parents, because a lot of their parents were still alive. …that just got to me a bit*" (1558). The self-analysis involved in ReDO-10 caused one woman some upset as the extent of her occupational imbalance became apparent; "*I found it very hard because a lot of my time was getting overwhelmed ….to go back to bed and I was really ashamed of it….. seeing it made me feel worse. Seeing it down on paper…something I knew to be true*" (1262). For all participants who experienced such incidents however, the support and sensitive group facilitation meant that they continued to feel safe in the group environment: "*They were saying, 'you don't have to share anything you don't want to share"*" (3656).

4. Context

Stress in the Irish context

There was consensus among the general practitioners (GPs) that issues of stress and anxiety formed a large part of their clinical practice: "*every second consultation has an element of anxiety and stress. It's so pervasive"* (GP2). Stress was seen by the GPs as "*having trouble with life*" (GP8) and they cited a wide variety of reasons for stress-related complaints: including "*marital stress*" (GP6), "*anxiety around medical symptoms*" (GP3),"*financial stress*" (GP6), "*post-natal symptoms*" (GP3), "*social anxiety*" (GP2), "*work stress*" (GP7) and even just difficulty managing modern life: "*life is so fast for everybody and everyone is trying to do so many things*" (GP2).

Treatment options in primary care

The doctors make carefully-considered treatment decisions based on a sometimes long-term GP-patient relationship that demonstrate a stepped-care approach [52]. Cardiovascular exercise, mindfulness apps and time off work were recommended first, followed by a referral to the primary care counselling service before medication was prescribed. Frustration about the length of waiting lists for primary care counselling was expressed and there was a perception that referral to the more acute Psychiatric services was unhelpful: "*the feedback (from patients) is…'they always just ask me the same questions. I know what they're going to ask. They tick boxes and then they just put me on more medication' and so (patients) tend to disengage*" (GP2)

Occupational therapy in primary care in Ireland

For the GPs, making a direct referral to occupational therapy in the primary care context for a mental health reason was a new experience. The doctors were aware of the occupational therapy service, but until then had only referred elderly or physically disabled patients: "*the only time I'd tick that box to be honest is something for…an elderly person*" (GP5), "*people with disabilities where ….they need home modifications done…..that'd be it. I'd say it would only be once a month at max*" (GP4). While the GPs were supportive of this study, as it provided "*a positive treatment option*" (GP9), they were equally firm that it shouldn't increase waiting list times for priority occupational therapy recipients; "*occupational therapists already have such a big waiting list for physical disability and you need them for that*" (GP1). The occupational therapists also discussed waiting lists and their frustration with what they referred to as their narrow scope of practice as "*equipment providers*" (OT2). While both therapists reported it had been a positive personal and professional experience to run this new intervention, they commented that adequate resources would be necessary to continue this; "*if you had your OT for every primary care team of 8000 people, you would be able to do these things….this is probably the kind of initiative you would be rolling out within primary care*" (OT2).

Discussion

In this section, the feasibility of ReDO-10 in the Irish primary care context will be discussed from two perspectives: (a) the feasibility of a future randomised-controlled trial (RCT) of ReDO-10 in this context and (b) the feasibility of future implementation of this programme more generally in Irish primary care [53]. When considering a future RCT, it is important to note that evidence for the effectiveness of both ReDO-16 and ReDO-10 is still emerging and research has not yet been conducted outside of Sweden where the intervention was developed. Based on this study, a RCT in Ireland is feasible but would require amendments to be successful in recruitment and implementation. Being part of a research study was acceptable to these women with stress and anxiety, but it is not known how many women declined to participate. Recruitment through GP referral only in 2018 was very slow and a pilot RCT could not be completed as intended. One GP selected patients purposefully for this study and telephoned them directly – achieving a higher recruitment rate. Telephoning patients directly has been shown to improve recruitment to trials that have low recruitment rates and should be considered for a future RCT [54], as would having a dedicated staff member in a GP practice for this work, using self-referral methods and targeting GP practices with a particular interest in women's mental health. The non-diagnostic title "Redesigning Daily Occupations" in the information materials is likely to have been attractive and less stigmatising to a wide range of individuals [55]. As with other studies involving recruitment by GPs to a psychological intervention

in primary care, some of the GPs were uncomfortable with the idea of randomisation and felt that discussing research took extra time out of their consultation with patients [56]. An active comparison condition that is perceived as equally effective as ReDO-10 could overcome discomfort of randomisation and aid recruitment to a future RCT [55].

There was a degree of assessment burden for the participants in this study and there was some uncertainty about how to self-assess daily functioning. The ICHOM core outcome sets recommend measuring social, physical and work functioning using the WHODAS 2.0 as was done in this study [57]. Despite this perceived uncertainty, use of the WHODAS 2.0 should be continued in future trials so that results can be interpreted in comparison to other treatments for anxiety. Other assessments that could be used include measures of occupational value and occupational balance. The OVal-pd was acceptable to participants in this study, but it has not been validated in the Irish context [58]. Participants described feeling more empowered to make choices in the occupations they did every day, so concepts like volition, mastery or assertiveness would also be outcomes of interest to measure. Longer-term measurement of outcomes should be considered, as follow-up evaluations of ReDO-16 have shown that improvements in stress-related sick-leave rates following the intervention were not maintained 3-4 years later [30], although the ReDO-16 participants continued to report better occupational balance after that time-period.

When evaluating complex interventions, it is understood that maintaining rigid fidelity to a manual is not likely to be responsive in local contexts or to individual learning needs of participants [59]. In this study, the occupational therapists were aware of fidelity but made clinical decisions to change some of the content. In this way, they maintained adherence to the underlying theory and "function" of the intervention, while adapting some aspects of its "form" e.g. using material from the original ReDO-16 programme [35]. The therapists called for the manual to be adapted and improved before a trial and this could include allowing for flexibility in the occupation-based activities of the programme or doing an exercise in the group session, rather than for homework.

Randomised controlled trials may provide guidance about the effectiveness of interventions, but have been criticised as not considering how the intervention will be implemented in practice or in real-world contexts [59]. In this study, it was evident that ReDO-10 was valued both personally and professionally by the therapists who facilitated it – notwithstanding the time commitment involved in facilitating it. However, they acknowledged that longer-term use of this intervention in Irish primary care would require more resources, staff and a reconfiguration of the current occupational therapy role in this context as "*equipment providers*" (OT2). GPs recognised the high level of demand for interventions such as ReDO-10 in primary care, but had no experience of referring to occupational therapy for people with mental health concerns in this context. These insights show the importance of close collaboration with stakeholders to understand potential barriers to intervention implementation

[44]. Future research/implementation should be contextualised within the growing emphasis on mental health promotion and prevention in primary care in Ireland [19] and the corresponding policies, strategies and potential funding sources that are emerging e.g. the Healthy Ireland Strategy [60]. There should also be clear reciprocal benefits to any future clinical/research partnership. Providing training in the ReDO-10 free of charge to participating therapists is one such example.

This study was the first to implement either version of ReDO without measuring stress-related sick-leave outcomes and sick-leave was not an inclusion criterion for this study. Participants were in full-time work, part-time work, full-time mothers, students and in retirement. This suggests that ReDO-10 is acceptable to a wide range of people experiencing mild/moderate stress, anxiety, depression or emotional distress in primary care, regardless of their work status. Women can be susceptible to parental burnout as well as work-related burnout and researchers have seen a relationship between feelings of guilt and anxiety symptoms in mothers identified as at risk of burnout [61]. The women who participated in ReDO-10 described letting go of guilt and choosing occupations to protect their own wellbeing and health, pointing to the possibility of ReDO-10 as a preventative intervention for women at risk of burnout. The intervention does not focus on a diagnosed condition or a set of symptoms and this was welcomed by GPs. With regard to suitability, those with cognitive difficulties or those with autism may find the group process more difficult, as two participants in this study discussed. The female-only nature of the group was welcomed by almost all participants and the content was felt to be relevant. This may be due to the strong theory base of ReDO-10 which was developed based on the perspectives of women experiencing stress and complex daily lives [26]. Men may express and react to mental health issues quite differently and masculine-sensitive components could need to be incorporated into ReDO-10 if men are recruited to future trials. [62]. A recent study of the ReDO-10 recruited only 10 male participants out of 165 [34]. It is also unknown how acceptable ReDO-10 would be to those who identify as non-binary or transgender and future research of this intervention should consider the inclusion criteria carefully so as not to alienate gender-diverse people [63].

The World Mental Health Surveys have shown that attitudinal barriers prevent many people worldwide from seeking help for mental health issues. For people with mild/moderate conditions, having a low perceived need for help is a particular barrier [64]. GP3 reported that some women declined to take part in ReDO-10 because it would be seen as "*a luxury*" and participant 3656 echoed this – saying that it felt "*self-indulgent*". Another common barrier to availing of mental health treatment is the desire to handle the problem by oneself. Again, this could be seen in some of the responses to GPs when they suggested ReDO-10. Despite a reported high demand for mental health services at primary care level from the GPs in this study, future ReDO-10 programmes may encounter these attitudinal barriers, as well as the structural barriers that prevent people in their middle years from availing of treatment e.g. time and finances [64]. Offering ReDO-10 in the evenings or at

weekends could be considered, although this requires a substantial change to current primary care service provision models in Ireland.

Methodological limitations

This was a small feasibility study with a number of methodological limitations. While a pilot RCT would have allowed for some comparison between ReDO-10 and a control group, this was not possible because of slow recruitment rates. While stakeholder perspectives provide valuable insights, they can be subject to biases such as (i) demand characteristics – clients reporting improvement in line with what they believe the researcher's hypotheses to be, (ii) selective attrition – those who drop out of treatment tending to have worse outcomes, (iii) palliative benefits – clients feeling better about their symptoms without tangible improvements in them or simply (iii) maturation – the tendency for improvement to occur in treatment because of naturally occurring psychological growth [65]. A large RCT of ReDO-10 is required to determine effectiveness. Recruitment, data collection and interpretation were carried out primarily by the first author for this study – meaning that there is the potential for bias in interpretation. Member checking of the final qualitative themes could have provided some stakeholder confirmation, but this was not within the scope of this study.

Conclusion

When making decisions about future research following feasibility studies, including a wide variety of stakeholders in the generation and assessment of solutions to problems may help to understand issues that could hamper a future trial of an intervention, or affect the likelihood that the intervention is feasible in the real world [53]. The qualitative data from occupational therapists, GPs and ReDO-10 participants provided valuable context and differing perspectives on the feasibility of the programme in the new context of Irish primary care. After the two phases of this feasibility study, it is evident that ReDO-10 was acceptable and valued by the participants who received it and had some perceived benefits in occupational participation and engagement. The group support and the dynamics between members were instrumental in any changes that took place as in other occupational therapy mental health group-based interventions [66]. Both GPs and occupational therapists supported the study although they highlighted the additional workload involved. The intervention itself was acceptable to the therapists who had facilitated it with fidelity to the underlying theory and with a high degree of clinical skill. A future trial of ReDO-10 in the Irish primary care context is feasible with modifications and stakeholder collaboration. However, this intervention is in an early stage of development and this study provides some insights into future adaptations, implementation considerations and contextual factors that need to be considered in future research.

Declaration of Authorship

All authors made substantial contributions to the conception and design of this study. Data collection, analysis and interpretation was done by J.F. The manuscript was drafted by J.F. and critically revised for intellectual content by all authors. All authors gave their approval for this manuscript to be published and agree to be accountable for this work.

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Appendix III: Published Paper 3.

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How does ReDO®-10 work? Understanding the mechanisms of action of an intervention focused on daily activities and health from the perspective of participants

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Highlights

- **Behavioural science frameworks clarified participant perceptions of mechanisms of action in the Redesigning Daily Occupations (ReDO® -10) intervention**
- **Modelling and peer support between women is a facilitator of health-related behaviour change**
- **Self-analysis can empower women to learn the relationship between activities and health.**

Abstract

Evaluation of a complex healthcare intervention should include careful exploration of the mechanisms through which it brings about change. This paper describes a qualitative evaluation of the Redesigning Daily Occupations (ReDO® -10) programme as it was implemented for the first time with women with stress-related issues in a primary care setting in Ireland. The ReDO® -10 is a 10-week group

intervention designed to support participants make changes to their daily activity patterns to have a more satisfying and balanced daily life. Fourteen women were interviewed after completing the programme. The aim was to explore changes that participants perceived they experienced and to understand how the content of ReDO® -10 was thought to bring about this change (if it did). Directed content analysis was used to analyse the qualitative data using the Behaviour Change Wheel and Theoretical Domains Framework as a coding framework. Overall, four BCW functions of ReDO® -10 were identified: Education, Persuasion, Modelling and Enablement. Participants described improved belief in their own capabilities, knowledge and goals around life changes. Many behaviour changes were also described, particularly in relation to doing more restorative activities in daily life. Behaviour change techniques that were identified as important for change were practicing new, restorative occupations in group sessions and as homework and the use of self-analysis activities to understand the relationship between activities and health for these participants. Modelling, support and other effects of group dynamics were also vital in changes that occurred.

Keywords: Health Behaviour Change, Occupational Therapy, Women's Mental Health, Process Evaluation, Behaviour Change Wheel

Introduction

Approximately one in six General Practice (GP) patients in Ireland has a documented mental health condition (O'Doherty et al., 2020) and this prevalence increased to one in five during the recent COVID-19 pandemic (Kelly, 2020). Rates of unspecified psychological distress, a state of emotional suffering that may include symptoms of depression or anxiety along with somatic symptoms like lack of energy (Drapeau, Marchand, & Beaulieu-Prévost, 2012), are likely to be much higher. GPs can be reluctant to give a diagnostic label to what is seen as a reaction to stressors (Ford, Campion, Chamles, Habash-Bailey, & Cooper, 2016) often related to socio-demographic factors (such as poverty), stress-related factors (such as work or family issues) and personal resources (internal and external) (Drapeau et al., 2012). Irish GPs have raised concerns about the lack of multidisciplinary staff to offer mental health interventions in the community (Agyapong, Jabbar, & Conway, 2012) despite strategic Government plans to increase service provision in primary care (Committee on the Future of Healthcare, 2017).

Women are at greater risk of experiencing stress-related ill-health (O'Doherty et al., 2020) because many of the risk factors for poor mental health affect them disproportionally. They are more likely to parent alone, experience violence or sexual assault, be in unstable employment, provide the majority of care and work in the home and be less financially secure (World Health Organisation, 2001). Women may also be more vulnerable to stress emanating from their social roles, particularly in marriage, parenting and in their wider social network (Drapeau et al., 2012). A number of group-based programmes to address stress-related ill-health for women in primary care settings have been developed and evaluated internationally.

The heterogeneity of psychosocial group-based programmes reflect the multiple, possibly over-lapping, causative and maintaining factors for stress in this population. Cognitive-behavioural approaches to stress management are among the most widely accepted treatments in primary care (NICE, 2011). Groups for women incorporating mindfulness approaches (Burnett-Zeigler, Satyshur, Hong, Wisner, & Moskowitz, 2019), positive psychology (Chaves, Lopez-Gomez, Hervas, & Vazquez, 2017) and physical exercise (Mailey & McAuley, 2014) have also shown good outcomes albeit in small-scale studies. Direct comparison of effectiveness between programmes with diverse theoretical perspectives is difficult, but there is consensus that group support and facilitated self-help is generally helpful in managing stress and anxiety in primary care (NICE, 2011).

The aim of occupational therapy is to improve participation in the activities of daily life (World Federation of Occupational Therapists, 2016). Occupational therapists are skilled in both health promotion and the treatment of people with developmental, physical and mental health conditions (Arbesman, Bazyk, & Nochajski, 2013). However, they have not been involved routinely in the facilitation of programmes for mental health concerns in primary care in Ireland (Tinelly & Byrne, 2016). The Redesigning Daily Occupations (ReDO®) programme is an occupational therapy-led group programme designed in Sweden to help women on stress-related sick leave from work make changes to their occupational patterns, improve occupational balance and increase their ability to manage work and life responsibilities (Eklund & Erlandsson, 2011; Erlandsson, 2013). The theoretical background to ReDO® and the underlying principles are based on a number of assumptions, derived from research on the experiences of women with stress and complex daily lives, commonly used health behaviour change theories and occupational therapy theory (Figure 1). In ReDO®, as in occupational therapy generally, the term "occupation" refers to all the everyday activities that people do as individuals, in families and with communities to occupy time and bring meaning and purpose to life.

Figure 1: Theoretical assumptions and guiding principles of ReDO® -10

Occupational balance, complex daily lives and stress

- Imbalance in the occupations of daily life may cause stress and ill-health (Wilcock, 2006).
- The ability to manage work for women with stress may depend on the ability to adapt daily routines and manage daily life as a whole (Baumeister, Vohs, & Tice, 2007; Johansson, Eklund, & Erlandsson, 2012).
- An increase in complexity (such as constant interruptions and unexpected tasks) in daily life may increase stress (Erlandsson & Eklund, 2006).
- A high level of hassles and few uplifts has a negative impact on wellbeing and subjective health (Erlandsson, 2008).
- The social environment for a woman can constrain her ability to find balance, cause hassles and increase complexity (Erlandsson, 2004; Hammen, 2003).

Occupational value and therapeutic occupation

- It is important to have a variety of occupations that give different occupational value experiences in everyday life for wellbeing. For example: occupations provide value because something concrete is achieved or because they are important for the person's self-identity (Persson, Erlandsson, Eklund, & Iwarsson, 2001).
- The practice of occupations during therapy sessions is a vital component of occupational therapy. Occupations have therapeutic "power" in a number of ways including having restorative and pleasurable appeal, being designed to meet the person's goals and being relevant in the person's context (Pierce, 2001).

Group dynamics, empowerment and health behaviour change

- Recognition of the need for change needs to come from the person themselves for effective lifestyle change (Bandura, 1986).
- Group dynamics have therapeutic benefits for participants, increase perceived social support and improve outcomes (Yalom & Leszcz, 1995).
- Raising consciousness of how the person's own behaviour relates to health and making plans for change empowers participants and increases motivation for change (Prochaska & DiClemente, 1982).

ReDO® has improved return-to-work rates, quality of life and self-mastery for women on stress-related sick leave (Eklund & Erlandsson, 2011). More recently, a 10-week programme (ReDO® -10) was designed for primary care settings (Olsson, Erlandsson and Håkansson, 2019). This shorter programme also showed promising outcomes for 86 women with stress in terms of mastery, occupational value, occupational balance, perceived health and perceived work ability. Qualitative data from participants suggest that the programme begins an intrinsic process of analysing one's own situation and need for change, which can lead to performing daily activities differently. However, women interviewed found it difficult to move from these changes at a psychological level (improved self-understanding) to making changes in the home/work environments; "*It's a process of change*"

(Wastberg, Erlandsson, & Eklund, 2013, p.123). Adapting ReDO® for primary care meant removing a 6-week work placement, changing the context from that of vocational rehabilitation and reducing sessions to once-weekly (Olsson et al., 2019). It is important to understand how (or if) the ReDO® -10 brings about change for the heterogeneous primary care population who may have a mixture of life-related stressors and mental health symptoms.

A process evaluation can test causal assumptions and evaluate, not just outcomes, but also mechanisms of change/action and the impact of context (Moore et al., 2014). Despite being theoretically-based, programmes such as ReDO®-10 may not work as expected, can be based on assumptions about the cause of the problem (Wells, Williams, Treweek, Coyle, & Taylor, 2012) and the treatment effect can be due to participant engagement, group dynamics, social context, therapist style or a combination of all these factors (Sheill, Hawe, & Gold, 2008). Theoretical frameworks, such as the COM-B model or the Behaviour Change Wheel (Michie, Van Stralen, & West, 2011), are often used to guide data analysis in process evaluations. Behaviour change is theorised to require the psychological and physical capability to change, the social and physical opportunity and the automatic and reflective motivation to do so (Michie et al., 2011). The Theoretical Domains Framework (TDF) subdivides these six categories and provides more detail about the mechanisms by which reflective motivation can be changed for individuals (Michie et al., 2005). This framework provides a cross-disciplinary tool for identifying and describing the potential targets of a health behaviour change intervention.

Figure 2. The TDF domains linked to the COM-B components (Adapted from (Michie et al., 2014, p.113-114))

COM-B	**TDF**
Physical capability	Physical skills
Psychological capability	Knowledge Cognitive and interpersonal skills Memory, attention and decisional processes Behavioural regulation
Automatic Motivation	Emotion Reinforcement
Reflective Motivation	Intentions Beliefs about Capabilities Optimism Intentions Goals Beliefs about Consequences
Physical Opportunity	Environmental Context and Resources
Social Opportunity	Social Influences

In order to bring about change in TDF domains, an intervention may have several "functions" described in the Behaviour Change Wheel (BCW) (Michie et al., 2011). A description of these functions is given in figure 3. One example of a function of an intervention such as ReDO® -10, which seeks to increase participant's knowledge (psychological capability) about daily activities and health, is Education.

Figure 3. Intervention functions according to the BCW (Michie et al., 2011)

Intervention function	**Definition**
Education	Increasing knowledge and understanding
Persuasion	Using communication to induce positive or negative feelings or simulate action
Incentivisation	Creating an expectation of reward
Coercion	Creating an expectation of punishment or cost
Training	Imparting skills
Restriction	Using rules to reduce the opportunity to engage in the target behaviour (or to increase the target behaviour by reducing the opportunity to engage in competing behaviours)
Environmental restructuring	Changing the physical or social context
Modelling	Providing an example for people to aspire to or imitate
Enablement	Increasing means/reducing barriers to increase capability (beyond education or training) or opportunity (beyond environmental restructuring)

Observable elements of an intervention that aim to change behaviour are known within the BCW as Behaviour Change Techniques (BCTs). There are 93 identified and numbered BCTs in 16 clusters that allow for programmes to be compared and/or replicated in different contexts e.g., Feedback on Behaviour (2.2) or Focusing on Past Success (15.3) (Michie et al., 2013). The BCW has been used extensively in studies of physical activity (García Bengoechea et al., 2021) or diabetes self-management (McSharry et al., 2020) where health behaviours are the target of interventions. ReDO® -10 supports people to make changes in their patterns of daily activity, make different activity choices for wellbeing and uses established BCTs (such as goal-setting) (Erlandsson, 2013). Therefore, the BCW was chosen as an appropriate framework to understand whether the intervention worked as intended. The purpose of this paper is to clarify the mechanisms of action of the ReDO® -10 programme by (1) exploring changes that participants perceived they experienced during and after the intervention using the TDF framework and (2) to understand how the content of ReDO® -10 (Intervention functions and BCTs) was perceived to bring about this change (if it did).

Methods

Design

This was a qualitative process evaluation of the ReDO® -10 programme implemented in Irish primary care (2018-2020). The qualitative methodology was influenced by guidance from the Medical Research Council on the scope of process evaluations (Moore et al., 2014), qualitative evaluation strategies (Patton, 2015) and the interpretive description approach. Interpretive description is a form of qualitative enquiry where the aim is to understand the experiences of healthcare recipients, often interpreting their narratives through an existing framework or theoretical lens, with the aim of producing clinically useful results (Thorne, Kirkham, & MacDonald-Emes, 1997).

Participants

Full ethical approval for this study was received from the Irish College of General Practitioners Research Ethics Committee in March 2017. Participants were recruited in the West of Ireland for the programme over three separate phases; in Spring 2018 (Phase 1), Spring 2019 (Phase 2) and Autumn 2019 (Phase 3). Women between 18-66 years who had attended their General Practitioner (GP) at least twice for stress-related complaints were included. Exclusion criteria were being in acute distress (such as a recent bereavement), having a cognitive impairment such that group participation would be difficult or having current drug/alcohol addiction. Women were recruited through direct GP referral and self-referral. In total, over the three phases, 37 women expressed interest or were referred and 21 began a ReDO® -10 programme. Written consent was obtained from all participants after they were told about the programme content, time commitment and data being collected and before they began the programme. Three dropped out before completing the full series of groups. Reasons for declining participation or dropping out were not always known as women did not respond to further contact, but included having work commitments or starting counselling. Following the completion of the full programme (ten weekly sessions and two follow-ups), 21 participants were invited to an interview and 14 consented to participate (See Table 1 below).

Table 1. Recruitment and data collection for the ReDO® -10 (Phases 1-3)

	Referred/self-referred	Declined to attend programme	Began ReDO® -10	Drop-outs after first session	Post-intervention interviews
Phase 1 (Spring 2018)	13	7	6	-	5
Phase 2 (Spring 2019)	18	9	9	2	5
Phase 3 (Autumn 2019)	6	-	6	1	4

Intervention

The programmes in Phases 1 and 2 were facilitated by two occupational therapists from local primary care teams. Phase 3 was co-facilitated by a primary care occupational therapist and the first author (an academic occupational therapist). All facilitators received training, certification in the ReDO® method and the ReDO® manual. The full content of the ReDO® programme is described in Erlandsson (2013) and the ReDO® -10 version in Olsson et al. (2019) but the topics and main activities of each session are in Figure 4. The target outcomes are that participants make changes in their patterns of daily activity and choose personally satisfying activities for wellbeing.

Figure 4. Topics and activities of the ReDO® -10 programme

Topics and activities of the ReDO® -10 programme
(Prior to programme) Individual meeting with the occupational therapist Group sessions: 14. Introduction 15. Occupational history 16. Occupational balance 17. Patterns of daily occupations and time (Part 1) 18. Patterns of daily occupations and time (Part 2) 19. Hassles and uplifts in daily life 20. Goal-setting 21. Occupational value 22. Evening seminar (for friends, family, partners or employers) 23. Goals and strategies 24. Concluding 25. Follow-up 1 (After 1 month) 26. Follow-up 2 (After 1 month)

Data Collection

Qualitative interviews were used to collect data about how mechanisms of action were experienced by participants and how the programme content (Intervention functions and BCTs) was perceived to bring about change (if it did). Separate informed consent was obtained to record and use qualitative data. To explore mechanisms of action, the women were encouraged to think about key moments where change happened or particular "stand-out" aspects of the intervention. Follow-up questions were used to probe for more detail, where appropriate (See Additional file. Interview topic guide). Retrospective interviews exploring mechanisms in this way have been used successfully in other evaluations of complex interventions (Connell, McMahon, Tyson, Watkins, & Eng, 2016). The interviews were completed by the first author in 2018 and 2019 and by a final year occupational therapy student in 2020. They lasted 30-90 minutes, were audio-recorded and transcribed verbatim.

Data Analysis

Directed content analysis was used to analyse the data. The researcher begins with a theoretical framework that provides some existing codes and relationships between codes (in some cases) (Hsieh & Shannon, 2005). The BCW has been used as a qualitative coding framework for a number of studies exploring mechanisms of action of interventions, including occupational therapy-based programmes (Connell et al., 2016; Fancourt, Wee, & Lorencatto, 2020). The analysis involved a number of stages:

Stage 1: Excerpts of the transcripts were extracted by the first author and broadly coded to (1) an intervention function such as Education or Modelling (2) a change to a TDF domain or (3) codes not fitting the framework. The latter data included references to participants' personal circumstances or data that were related to the research project itself e.g., how they heard about the study. A sample of the transcripts were separately analysed by a second author (*author*) to ensure that there was consistency of the data coded to the different domains of the framework.

Figure 5: Data analysis stage 1

Transcript extract	**Code**
"Yeah we had a very good exercise in the group. The ladies gave us fruits and we needed to just think….just mindfulness….just sit down with the fruit and just eat. And no talking, just ….you know? That was great. That was great. And I'm doing something like that at home now. Just you know……just be in the same time just for myself and with the things what I'm doing. Just the one thing and that was great. That is great (with emphasis). I'm doing that, like twice a week or something" (Participant 4572)	Enablement

Stage 2: The researcher used the 93 BCTs in the Behaviour Change Technique Taxonomy (V1) (Michie et al., 2013) as potential codes to identify specific moments, sessions, activities or group processes occurring within ReDO® -10 and how they related to changes for participants. For example, "behavioural practice/rehearsal" (BCT 8.1) was one BCT. In this example, practicing an activity in a new way (without interruptions) in the group led to the participant continuing this new pattern at home. These BCTs were determined based on participant perceptions of the experience and required a degree of interpretation.

Figure 6: Data analysis stage 2

Transcript extract	**Code**
"Yeah we had a very good exercise in the group. The ladies gave us fruits and we needed to just think….just mindfulness….just sit down with the fruit and just eat. And no talking, just ….you know? That was great. That was great. And I'm doing something like that at home now. Just you know……just be in the same time just for myself and with the things what I'm doing. Just the one thing and that was great.	Enablement *Behavioural practice/rehearsal (BCT 8.1)*

That is great (with emphasis). I'm doing that, like twice a week or something" (Participant 4572)	

Stage 3: The researcher explored mechanisms of action through examples in the transcripts where participants linked specific BCTs and changes that occurred for them. Interpretation was also necessary in this stage, as participants did not use this terminology. The TDF components were used as pre-determined codes here to categorise changes (Michie et al., 2005). In the example below, the experience of practicing a new behaviour (BCT 8.1) led the participant to develop a regular pattern (behavioural regulation) that she continued after the group.

Figure 7: Data analysis stage 3

Transcript extract	**Code**
"Yeah we had a very good exercise in the group. The ladies gave us fruits and we needed to just think….just mindfulness….just sit down with the fruit and just eat. And no talking, just ….you know? That was great. That was great. And I'm doing something like that at home now. Just you know……just be in the same time just for myself and with the things what I'm doing. Just the one thing and that was great. That is great (with emphasis). I'm doing that, like twice a week or something" (Participant 4572)	Enablement *Behavioural practice/rehearsal (BCT 8.1) – link – Psychological Capability (behavioural regulation)*

Stage 4: In this final phase, the researcher noted specific times where BCTs did not seem to work as intended or where a participant did not feel a benefit. An example is a participant describing how feeling that the group session was rushed meant she couldn't work on her goals. In this phase, individual differences such as where the same activity evoked different emotional responses for various participants were also explored.

Results

Participants perceived ReDO® -10 to effect behaviour change by improving many TDF domains (Figure 8). A large number of behaviour change techniques (BCTs) were experienced including those facilitated by the occupational therapists as set out in the manual (e.g., goal-setting (BCT 1.1)) or occurring more naturally during group discussions (e.g., social comparison (BCT 6.2)). Overall, four BCW functions of ReDO® -10 were identified: Education, Persuasion, Modelling and Enablement. Mechanisms of action (how ReDO® -10 influenced change) are explored under these four headings with BCT clusters (Michie et al., 2013) as subheadings (Figure 8).

Figure 8. Results of the qualitative analysis

Perceived Intervention Functions of the ReDO® - 10	**Education**		**Persuasion**		**Modelling**			**Enablement**			
Behaviour Change Techniques Experienced	***Feedback and monitoring*** 2.2 Feedback on behaviour 2.3 Self-monitoring of behaviour 2.7 Feedback on outcomes of behaviour ***Natural consequences*** 5.1 Information about health consequences 5.6 Information about emotional consequences		***Feedback and monitoring*** 2.2 Feedback on behaviour ***Comparison of behaviour*** 6.2 Social comparison 6.3 Information about others' approval ***Identity*** 13.2 Framing/reframing ***Comparison of outcomes*** 9.1 Credible source ***Self-belief*** 15.1 Verbal persuasion about capability		***Comparison of behaviour*** 6.2 Social comparison ***Covert learning*** 16.3 Vicarious consequences			***Goals and Planning*** 1.2 Problem-solving 1.3 Goal-setting 1.5 Review behaviour goals 1.9 Commitment ***Social support*** 3.3 Social support (emotional) ***Associations*** 7.1 Prompts/cues ***Repetition and substitution*** 8.1 Behavioural practice/rehearsal ***Antecedents*** 12.2 Restructuring the social environment ***Self-belief*** 15.4 Self-talk			
COM-B domains	Psychological Capability	Reflective Motivation	Automatic Motivation	Reflective Motivation	Psychological Capability	Automatic Motivation	Reflective Motivation	Psychological Capability	Reflective Motivation	Automatic Motivation	Social Opportunity
TDF domains where change was identified	Knowledge Memory, Attention and Decision Processes Cognitive and Interpersonal Skills Behavioural regulation	Beliefs about Capabilities Beliefs about consequences Intentions Social Role and Identity	Emotion Reinforcement	Beliefs about capabilities Intentions Beliefs about consequences	Cognitive and interpersonal skills Behavioural regulation	Emotion Reinforcement	Beliefs about capabilities Beliefs about consequences	Knowledge Memory, attention and decisional processes Behavioural regulation Cognitive and interpersonal skills	Intentions Beliefs about capabilities Goals	Emotion Reinforcement	Social influences

Education

ReDO® -10 incorporates both formal "education" about occupation (via presentations) and self-analysis activities that facilitate participants learning about their own patterns of occupations. This intervention function was identified as important to changes that occurred for participants. Changes occurred in psychological capability and in reflective motivation. A number of personal and contextual factors were reported to act as barriers to this.

Natural consequences

The opening sessions explored the link between occupational time-use and stress (BCT 5.6) via self-analysis activities and exploring the women's current occupational balance and daily patterns. Participants described changes both in knowledge ("*the course made me aware of everyday and taking time and being mindful and slowing down*" (6686)) and for some, this progressed to having the intention to change ("*the most beneficial was identifying the issues...I think that once that was done, I straight away started to address them*" (7712)). However, making changes based on new knowledge requires agreement with that knowledge and one participant in particular disagreed with the perspectives presented; "*There is a risk, that to individualise a problem that's social, it's like placing the social aspect to those problems in my own psychology. Like if I was self-aware enough and attuned enough and did enough physical exercise…I was going to solve everything"* (8114).

There was also discussion about how occupational balance can affect physical health (BCT 5.1). For women working outside the home, the importance of rest, breaks and recognising risk of burnout was developed via occupational self-analysis activities. One woman described better behavioural regulation of her working day; "*That is direct from that series of looking at things. I do take better breaks in my working time*" (7712). For another, prioritising rest required a change in her confidence to approach her boss; "*I need two days off next week. (My boss) said, 'you would have just kept going...but you've learned to read your body' and I said, 'Yeah'. So, it's all helped*" (6686).

Feedback and monitoring

Following the self-analysis activities, participants discuss their occupational patterns and make plans to change these. This process was a strong influencer of change for the

women. There was a greater belief in capabilities to make changes; "*I found that one brilliant....you had to timetable the day. That was crazy for me. Because I was saying, 'Oh my God – the amount of stuff I'm doing in a day!' And I'm thinking I'm doing nothing?"* (6797), "*I didn't realise that I wasn't actually doing things for myself*" (1558), "*The little separate tasks where you sit down and think about yourself and your own day….it makes you think about what you could change and what you could do for yourself*" (5505). For some women with children, this feedback on their own time-use (BCT 2.2) sometimes led to uncomfortable realisations about their social role: "*It was the timetable. Everything that was on the timetable was for other people"* (6797).

Getting this feedback was not always comfortable, particularly for one woman with depression; *"I knew it in my head, but to see it on paper…. I felt terrible after it. …Something had to change. I thought, 'you're wasting your life going back to bed…. I'm wasting all these opportunities*" (1262). Feedback on occupational patterns led to some women doing their occupations in a new way, either through reducing interruptions to occupation, or through focusing on one occupation at a time; "*It was writing down…the activity what you're doing. So, when I'm cooking now…. I'm just more relaxed. I just focus on the activity what I'm doing. Before, I was doing the laundry, this one, this one, the dog, this one*" (4572). The participant with depression noted that this analysis had the opposite effect for her – she increased the amount of activity in her day; "*Another week was, you write down everything you do for one day. "Now I can write down in my diary – I did this, did this, did this and I can check off a few things that I did during the day. I've accomplished something in the day*" (1262).

The programme also drew attention to the feelings experienced when trying a new way of doing things (BCT 2.7). For some women, this led to a sustained change in behavioural regulation: "*Just do it and the results will follow…. going out for a walk or reading a book. I enjoy it. It takes no length for the task or the interest to become enjoyable* (1262), "*I prioritise my walk first. And then I feel better. Mentally I feel good*" (2612). For other women, this change remained at the level of awareness (knowledge) and self-understanding, rather than behaviour change; "*to acknowledge when I manage something badly*" (7901), "*to understand what's happening*" (9078). However, these women's beliefs in their capabilities to make changes in the future was strengthened by this improved self-knowledge; *"it's within my control, it's my responsibility*" (9078) and one or two participants continued to self-monitor their occupational patterns after the programme (BCT

2.3); "*I'm overwhelmed at the minute…. I've realised, that's actually too much. I'm only one person*" (6686).

Persuasion

ReDO® -10 had a persuasion function in that it "used communication to induce positive or negative feelings or stimulate action" (Michie et al., 2014, p.111). This communication came both from facilitators and group participants, formally (in seminars) and informally. Communication in the group influenced reflective and automatic motivation via a number of BCTs and was a strong influencer of changes that occurred.

Comparison of behaviour/outcomes

Participants compared their own actions and situations to the other women in the group (BCT 6.2). This was an internal process and not directly facilitated by the therapists. Social comparison led many women to have improved beliefs in their own capabilities; "*If they can do it, I can do as well*" (4572) "*realising that I'm not the only person that lives with guilt*" (3656). Social comparison triggered emotions, which could be positive "*letting myself off the hook*" (6797) or negative "*I would be uncomfortable…in the beginning…. sharing*" (3656). Trust and social approval (BCT 6.3) led to a positive emotional response for those who shared personal information; "*When I set it out, it was like, it's ok. Even saying it took the guilt…. took the shame of saying it out*" (1262). Trust was established by seeing that others had similar issues (BCT 9.1); "*you're getting it from people who also have their own issues. I just found it more affirming*" (1558).

Self-belief/Feedback and Monitoring

As the group became more established, group members persuaded peers that changes they wanted to make were possible (BCT 15.1) and in some cases this led directly to a woman acting on this advice; "*I started to book stuff for myself. Because they were saying, 'do you ever do anything just for yourself'?"* (3656). Group members noticed and provided feedback on occupational patterns that the person may not have previously noticed (BCT 2.2). This was particularly evident in contributions from older women to younger women; "*They were saying, 'you could get your children to do a few bits. Have you ever thought of that?*'" (3656).

Identity

A number of participants reframed their stressors (BCT 13.2) through hearing different perspectives in the groups, "*Because they're coming at it from a different angle. And then you think – God! I never thought about it like that before"* (3656). Many mothers in the group spoke about occupational imbalance in the household, but were persuaded that change would actually benefit the family; "*somebody in the course said to me, 'you're not doing them (children) any favours because they need to know how to do these things*." (4678). This reframing brought an emotional boost for those who experienced it ("*I came away better than I went in*" (1558)). Finally, one woman identified no change in her occupational time-use but had reframed her experience of these occupations; "*I did feel a massive shift in myself from the start to the end in…. the way you enjoy doing things*" (3656).

Modelling

While women described making some changes as a result of direct communication (Persuasion), other changes took place by an internal process of observing others and what worked for them (Modelling). Changes were at the level of psychological capabilities, automatic and reflective motivation and again were highly dependent on group dynamics.

Comparison of behaviour/covert learning

Being in a group setting involved an almost constant experience of self-comparison (BCT 6.2) to other women, their coping strategies, experiences and decisions. Finding a peer evoked positive emotion; "*I loved listening to her share because I was like 'she doesn't have it all together, she's like me'*" (1262), but members felt they learned from the whole group; "*on different weeks, depending on who was talking, you would find something in that person*" (3656). In general, social comparison was a positive influence on reflective motivation to make changes – particularly for mothers who learned from other mothers; "*I was saying, God – if she can do it and she's a single mom …I can try it*" (3656). Seeing how new approaches worked for other group members (BCT 16.3) helped overcome initial reluctance to try the suggested strategies; "*You might be apprehensive and like, 'Oh that won't work for me'. But then in the group and listening to how it's worked for other people…I don't think I would have grasped it as well if it was just a single person that had told me*" (1262).

Social comparison requires commonality and two older participants felt this was missing for them; "*I was retired…. if there was a group of us in the same situation as me, we would have been able to feed off one another more*" (6797), creating a barrier to making behaviour changes. However, unfavourable social comparison actually strengthened this participant's belief in her own capabilities; "*One girl came in one day and she had stopped for coffee even though she was over half an hour late…. I thought to myself, 'Is this the way I was all my life? Accepting behaviour like this from people? …That was huge learning for me*" (6797).

Enablement

An intervention has an enablement function when it "increases means/reduces barriers to increasing capability or opportunity" (Michie et al., 2014, p.112). It is a way of "enhancing a patient's ability to control their health and life" (Hudon et al., 2010, p.1301). Enablement was evident in structured programme activities such as goal-setting (BCT 1.3) and occurred through group engagement (BCT 3.3). There was a wide variety of experiences in how enablement was perceived and some barriers to the success of programme activities were discussed.

Repetition and substitution

ReDO® -10 uses relaxing occupations in some sessions and for homework (BCT 8.1) to encourage participants to make different occupational choices for their health. When these occupations were introduced (e.g. doing a craft activity) there was an emotional response for participants. For some, this led to a change in their beliefs about their capabilities, even if their initial emotional response was a negative one; "*The day we were doing the crafting...I went, my God, I don't want to do this! I am not creative at all. But after that…. I did more of (it). Look how much you can enjoy something if you take away the "I'm no good at this*" (3656). In general, these sessions created a different emotional response than the discussion-based ones; "*I loved when we had stuff to do…. we did collective stuff with our hands which was brilliant*" (8114) "*It brings you back to the child inside I think…. that little piece of you that likes to do*" (2612).

The practice of occupations (BCT 8.1) was clearly linked to new health-related occupational choices for some participants; "*We had a very good exercise…. just sit down with the fruit and eat. No talking, you know? That was great. I'm doing something like that at home now. Just be in the same time just for myself and with the thing I'm doing. I'm doing that like twice a week now*" (4572). The homework reconnected people to occupations they had previously enjoyed; "*I went out on the horse. I made a conscious effort of being aware of my surroundings and …. being present in the moment. It was really, really enjoyable*" (1262) and participants individualised the homework to choose their own valued activities; "*I didn't do the going for walk things… but the gardening is a kind of break for myself. My mind kind of goes blank. I just concentrate on what I'm doing*" (1558). Not everyone felt they had the autonomy to choose such occupations in their busy lives however; "*it's being Mum, you know? I constantly have to be there*" (4678), minimising the potential for this BCT to bring about change; "*(The activities are) helpful to make you realise, but I don't know that they change anything. I don't know if I've sat down since*" (4678).

Goals and Planning/Self-belief

Both the structure and expectations of the programme were enablers. Members committed to clear group rules (BCT 1.9), which were important in the development of trust: "*I think it was the establishment of self-imposed guidelines of being respectful to one another, of not interrupting one another…I think that this set us up for a very successful group*" (9078). For some, commitment to attendance was an empowering choice; "*I felt that it was my thing. That was my time*" (2612) "*I loved it…. I'm doing my course today. I liked to be able to say this is my time*" (3656). This more empowered self-talk (BCT 15.4) led some to women making more time for themselves; "*You realise it's actually good for you and your partner…and your kids because you're happier. It's ok to put yourself first….. for me, it was to cut off the guilt*" (3656).

Goal-setting (BCT 1.3) occurs throughout the programme. Basing goals on a thorough exploration of individual issues was valued by participants, particularly when it included problem-solving (BCT 1.2); "*I found it helpful and beneficial…exploring how I spent my time and what caused me stress…what I enjoyed doing and arriving at the goals for change. That particular part, I really, really enjoyed doing*" (7712). Using visual aids to depict the balance between different life domains was particularly helpful for goal-setting; *"We had to draw one of what we would like to see for ourselves. That was like, "yeah, that has to improve". And now, I've tried to keep that as much as possible*" (1558), as was the process of breaking down a long-term goal into shorter-term actions; "*I …sit down and say,*

"hey, is this realistic? No, it's not. Make a smaller goal"" (5505). However, some participants identified that not enough time was spent on this process for them to make changes; "*I couldn't take action on my goals the way I would have liked to have been doing – I felt that maybe it was a little bit rushed that section*" (7712).

Reviewing goals and homework from week to week (BCT 1.5) was an enabler of behaviour change, as participant 1262 states clearly; *"I did what I was asked because I didn't want to go to group not having it done*". Having homework meant that changes were prioritised; "*We need to have homework…otherwise we doing everything else all the time. If you have homework, you just need to focus on the homework*" (4572). Not everyone felt this influence however; "*if you got it done, you got it done and if you didn't, you didn't. You didn't feel in any way pressurised*" (7901).

Antecedents

ReDO® -10 aimed to restructure the social environment (BCT 12.2) to be supportive of women trying to make lifestyle changes by holding an evening seminar to educate families, partners or others on the programme topics. However, married participants (who were in the majority in each group), asked for this seminar to be cancelled, feeling that it would disrupt group dynamics; "*It makes you vulnerable*" (3656) "*I wouldn't have been comfortable with that"* (1558). These women preferred to tell their spouses a limited amount about the programme, seeing their self-development as their personal concern; "*I didn't want him to ruin my idea of my course. I didn't want to…. drag him along. …It's best if I just do it myself*" (1558) "*This is my thing. It's not to do with him*" (2612). Restructuring the social environment was more successful with children, particularly regarding delegating chores; *"That would never have been heard of in my house. They wouldn't even bring their plate from the table to the sink. But they know now…that's the way it goes*" (3656).

In general, the woman's social environment was a very influential enabler ("*He bought an egg swing chair for the garden…and he's saying, 'sure go out there now and read your book. Have 20 minutes. Nobody'll bother you"*" (3656)) or barrier ("*That kind of autonomy about leisure time activities…that was a big challenge for me to go for a walk on my own, because if I'm going out the door its' 'Where are you going? I'll go with you"* (4678)) to changes occurring. This may have reflected individual differences in beliefs in

one's capability to make assertive choices, say no or let go of guilt, often understood retrospectively by the older participants; "*It's always that guilt with women…. I thought that was from our generation. I'd love to shoot them and say, stop it! It doesn't matter*" (3656).

Social support/Associations

Although ReDO® -10 did not change social opportunities outside the programme directly, the group sessions provided a social opportunity within which emotional social support (BCT 3.3) was very evident. This social support was instrumental in changes in capabilities and motivation, particularly as only women were present; "*I liked that it was just women…I do think women have a tougher time…and it's easier to share feelings with just women*" (3656). This supportive environment facilitated sharing, leading to emotional relief; *"I felt a lot of relief, just saying what was going on*" (1558) "*It turned out to be an emotional support as well*" (6686). Because the social support was a strong reinforcer of change, ending the group was disruptive for some participants who valued the two follow-up groups; "*the session after we went back (follow-up)… was the most important session of the whole course. After the 10 weeks…. I thought "I'm back to square one again". And we had the follow-up and just felt good after it. The thing about the ten weeks is you feel like you're propped up…and then you're just left*" (1558). For three women, doing ReDO® -10 directly led to them seeking further support from counselling services; "*When you talk openly and honestly, you know you can share it then with somebody else. I was ready to really talk more deeply*" (6797).

Overall, the creation of this supportive social environment relied on sensitive group facilitation. Where poor group dynamics were perceived, participants' progress was stalled; "*if somebody has something bad going off and somebody else…. cuts in and says 'there's something worse wrong with me'. I found a lot of that went on"* (6797). However, other participants in the same group sessions perceived this differently, perhaps reflecting the benefits they received from being able to share their feelings; *"If something came up, there was room to facilitate that*" (7901). Following ReDO® -10, there were differences in how much participants used the written materials (BCT 7.1) provided by the programme to reinforce change; "*I don't think I'm going to keep using all of them*" (8114), *"I have the book, the notes still. I do go through it every so often*" (6797). Self-monitoring was, for most participants, a process of "noticing" and focusing of attention during a stressful period. For some, this remained at the level of awareness: "*I haven't managed to react as I would like*

to" (7901) that would require "*revisiting…. everybody needs to be reminded*" (6686) in order to continue to be effective.

Discussion

The BCW, TDF and BCT frameworks provided a useful structure within which to analyse perceived changes that participants experienced during and after ReDO® -10. Linking intervention functions/BCTs to these perceived changes highlighted possible mechanisms by which ReDO® -10 worked in this new context. As seen in the narratives, making changes in daily occupations was a highly individualised process, with the ReDO® -10 perceived as helpful or occasionally unhelpful in that process, even for women in the same group sessions. The analysis also identified some lessons learned for future optimisation and implementation of this programme for women with stress-related issues.

Occupational participation and analysis as mechanisms of action

A theoretical assumption of ReDO® -10 (Figure 1) is that self-identification of a need for change is important for effective behaviour change (Bandura, 1986). In this study, participants found the self-analysis tools such as time-use diaries were an important first step in understanding the relationship between their activities and their perceived health. Some participants started to make changes immediately based on this new information, but others needed more time to reflect. Occupational self-analysis may have moved some women who were already quite self-aware from the contemplation stage to the action stage of change as set out in the transtheoretical model of health behaviour change (Prochaska & Velicer, 1997). For other women, this information was new, so they may have begun ReDO® -10 at an earlier, precontemplation stage of change. Orban, Edberg and Erlandsson (2012) describe using a similar "time geography" method where participants reflected on their activities, but included reflection on where they were, who they were with and how they felt. These diaries were complemented by a "simulated recall interview". Orban et al. (2012) found that this method allowed participants to articulate deeper issues such as level of choice, relationship to tradition or roles and "enfolded" occupations where multiple activities are completed at once. The longer programme, ReDO® -16, allows time for a follow-up exercise exploring patterns of occupations more deeply using these diaries (Erlandsson, 2013). The shorter ReDO® -10 programme may have meant that not all participants were guided to reflect on their diaries to this extent, perhaps not influencing other TDF domains sufficiently for behaviour change in those facing bigger challenges (Michie et al., 2014).

Including occupational experiences, such as craft, within group sessions and as homework is another important underlying principle (Figure 1). The participants had strong emotional responses to these experiences, demonstrating how occupations may be perceived by different people depending on the meaning and significance they ascribe to them (Roberts & Bannigan, 2018). This emotional response showed that the occupations had a restorative function, providing stress relief, enjoyment and helping the person feel connected to the present moment (Roberts & Bannigan, 2018). However, for some women, they remained as stand-alone, pleasant experiences, rather than influencing ongoing behaviour change. Individualising the homework and finding their own meaningful, restorative occupations appeared to be most effective. Again, the shorter duration of the ReDO® -10 programme may have meant there was not sufficient practice of new, restorative occupations or sufficient time to individualise and problem-solve barriers to bring about sustained change for some participants.

Social opportunity and social influences

Social determinants of health such as income, living circumstances and childhood experiences are important influencers of health-related behaviour (Alcántara et al., 2020). The living circumstances of these participants were not explored, but social opportunities were identified as important enablers and barriers for them. For women with partners, choices about occupations were not made in isolation. The activities and preferences of other family members also needed to be considered. Choices were also dependent on the perception of autonomy (Powell, 2015) and managing feelings of guilt when choosing occupations for one's own pleasure and health. Changing behaviour to include more self-replenishing occupations, such as gardening or going for a walk was a struggle for the mothers in this study and reflects the experiences of other mothers in Western societies, "*the women…all recognised their need for self-replenishment if they were to adequately meet the endless demands of motherhood. However, the cost of electing to focus on their own needs, even for a few minutes to take a bath or read a magazine, often left them feeling guilty*" (Seagram & Daniluk, 2002, p77). Changes to feelings of guilt, where they occurred, happened via two mechanisms in ReDO® -10: persuasion and modelling. Older women who had "been there" acted as persuasive credible experts (BCT 9.1) pointing out the importance of delegating responsibilities in the household. Other mothers, doing things differently, were also role models (BCT 6.2).

Recognising that it is difficult for a woman to make lifestyle changes in isolation, the programme includes an evening seminar to encourage those around her to be supportive and to make family or workplace-level changes for wellbeing (Erlandsson, 2013). Swedish ReDO® -16 participants welcomed these seminars, invited their workplace managers and suggested holding two such seminars (Wastberg et al., 2013). However, the women in this Irish study, in particular the married women with small children, asked for the seminar to be cancelled. It is possible that this was due to contextual differences. ReDO® -16 was evaluated in a vocational rehabilitation context, with a specific emphasis on return-to-work (Eklund & Erlandsson, 2011), whereas the current study had a mental health focus (albeit in primary care). It is likely that Swedish women felt less stigmatised by sharing the topics of a "vocational course" with their families and employers than the Irish women who were attending what might have been perceived as a mental health support group.

Using the BCW to understand mechanisms

A small number of studies have used the BCW in their analysis of mechanisms in interventions involving occupational therapists. For example, "Breathe Magic" uses magic tricks in a group setting to help children with unilateral spastic cerebral palsy develop motor and bimanual skills, independence and self-confidence (Fancourt et al., 2020). The BCW-based analysis of qualitative interviews with parents and children showed that "automatic motivation" (fun and enjoyment) in the magic activities was an important mechanism supporting engagement and outcomes (Fancourt et al., 2020). The use of the BCW to analyse mechanisms in interventions retrospectively is not without its critics (Teixeira, 2016). This kind of analysis could underestimate the complexity of change and may not account for the "messiness" of real practice and human personalities, where change may occur (or be hindered) by multiple factors simultaneously. It may not account for the "art" of therapy, where skilled clinicians move between many therapeutic approaches (or BCTs) smoothly and invisibly within sessions, with different service users and in different contexts (Ogden, 2016).

The language used in ReDO® and by occupational therapy clinicians and researchers generally, is different to that used by behaviour change researchers in frameworks like the TDF or BCW. One example is the concept of "occupation". In ReDO®, as in many occupational therapy interventions, "participating in occupation" is both the treatment and the intended outcome. The analysis in this study is not an attempt to be reductionistic or to

diminish the discipline-specific nature of ReDO®. However, there were participant accounts that highlighted how occupational experiences can be turning-points for behaviour change. For example, a craft activity provided a hands-on example of a new activity or reconnected the person to a previously valued activity. To do, to be occupied is, according to occupational therapy theory, the way humans develop and adapt to new circumstances (Kielhofner, 2008). Including occupational experiences that are relevant and introduce topics in a new way within group sessions are not just opportunities to do a new "behaviour". They also offer a taste of what one could be or become in the future (Wilcock, 1998). The use of the BCW analysis in this study adds another perspective on why or how occupations have therapeutic potential in healthcare interventions.

Lessons Learned

Although the ReDO® -10 is a manualised intervention, the experiences of participants are vital to consider in future optimisation, refinement and implementation of the programme, particularly in new contexts. From the analysis and discussion above, there are a number of lessons learned from this study.

Firstly, commonality of experience is recognised as an important therapeutic group factor (Yalom & Leszcz, 2005). Younger, unmarried participants and retirees were in the minority in the current study and identified that a group with more participants like themselves would have been more useful. Interestingly, although the older participants did not find commonality with younger women, their presence was a mechanism of action for participants who saw them as role models (BCT 9.1 Credible source). Given the common experiences faced by mothers in the current study, future ReDO® -10 programmes could focus on different life stages; students, working mothers, retirees etc. The single-gender aspect was valued, again particularly by those who were in relationships. There is a research gap exploring both the ReDO® -16 and ReDO® -10 with men (possibly with male facilitators) and with other groups in primary care where different kinds of occupational balance issues have been identified (Jonsson, Borell, & Sadlo, 2000; Wilson & Wilcock, 2005).

Secondly, as described above, the self-analysis of occupational patterns at the start of the programme raised awareness of the link between occupations and health for

participants, but did not always result in a change in time-use. Both internal (guilt) and external (family pressures) were cited as reasons for this. The use of time-use diaries on several occasions across the 10 weeks could facilitate participants in reflection on repeating patterns, ongoing barriers or small positive changes as the programme progresses. The ReDO® -10 manual asks that a journal/note-book be provided to the participants, but does not specify how this is to be used. No participant described using any reflection or self-monitoring in between sessions. Self-directed reflective diaries have shown to have very low uptake in other feasibility studies of healthcare interventions for women (Hennelly, Perman-Howe, Foxcroft, & Smith, 2020). Because the women in the current study showed strong commitment to their group peers and facilitators, it is likely that structured self-reflective homework in between sessions such as asking women to reflect on how they felt after completing uplifting occupations or making a change to their occupational pattern would have been completed. This could allow for additional BCTs such as monitoring of emotional consequences (BCT 5.4) on a regular basis to be incorporated. This reinforcement could also encourage more practice of restorative occupations outside of the group sessions (BCT 8.1). Furthermore, visual tools, such as portraying time-use as a colour-coded pie chart, in the programme, was helpful in developing self-understanding for these participants and could provide an alternative to writing for participants with e.g., poor literacy.

Finally, because of the reaction of the married participants in this study, care should be given in how the ReDO® -10 evening seminar is described to groups where trust and confidentiality are important. It is recognised that "the close connection of men and women in dyadic relationships may lead partners to hinder, promote or control each other's thoughts, behaviour and emotions" (Kenny et al., 2006. As cited in Symoens & Bracke, 2015, p. 51). This interconnectivity shows itself in work-life conflict for both men and women, albeit in different ways. Because the occupational patterns of family members are mutually dependent, it could be useful for future ReDO® programmes to take a more family-system perspective for people in all sorts of relationships and none. Again, recognising that homework was valued by participants, a task for the opening sessions of the programme could be for the participant to have a talk with the others in the home to discuss how the entire household could become more occupationally balanced. Resources to share the ReDO® information with families could be developed e.g., a video or workbook. Marital satisfaction is greater when both individuals in a partnership have satisfactory role balance (Chen & Li, 2012). Therefore, taking a more ecological approach to occupational balance could take the pressure off the individual participant to make all the behaviour changes required (Kantartzis, 2016).

Limitations

A limitation of this study is that two different researchers completed the qualitative interviews over the study period. However, the use of a semi-structured interview tool for all interviews ensured that the same topics were covered and that similar probes and prompts were used. Another limitation is that one of the programmes was co-facilitated by the first author who analysed the data for this paper. However, an occupational therapy student who was not involved in running the groups interviewed the participants of that group series. Those interviews were transcribed and anonymised by the student before they were analysed by the authors. The use of a co-analyst, otherwise unconnected with the delivery or evaluation of the programme, also helped to reduce potential bias arising from this. There is a risk that in using the BCW framework to analyse the qualitative data, participant responses were over-interpreted to fit this framework. Finding codes/themes consistent with existing theories is a known issue in qualitative analysis, even among studies that use purely inductive/emergent coding (Schonfeld & Mazzola, 2013). However, as the BCW and TDF frameworks are a distillation of multiple health-related theories and models, it can be assumed that that they cover the most important factors in behaviour change (Michie et al., 2005).

A limitation of this form of qualitative evaluation is that it is reliant upon the way in which the participants perceived change, which may not always be accurate. In qualitative evaluation, there is a risk that people may attribute changes that occur to the intervention, or only remember change when their attention is drawn to it (Lilienfeld, Ritschel, Lynn, Cautin, & Latzman, 2014). Finally, it is acknowledged that this kind of analysis requires some interpretation by the researcher e.g., in coding participant's narratives to BCT or TDF categories. Sometimes the impact of a ReDO® -10 activity was very apparent. In other cases, discussion of the personal changes occurring and discussion of the programme was separated in the transcript and the researcher had to probe more deeply to understand whether/how this change was related to ReDO® -10 participation (Orford et al., 2009).

Conclusion

This paper provides important insights for healthcare professionals and researchers developing and delivering group-based psychosocial interventions. Some of the mechanisms

identified in this paper, such as the influence of peer persuasion, modelling and self-reflection are likely to be important considerations in other self-management programmes. The paper also provides insights for the future optimisation and refinement of ReDO® programmes and for ongoing research evaluating their effectiveness. Following participation in the ReDO® -10 programme, the participants described changes to their psychological capability, automatic and reflective motivation and, to a lesser extent, their social opportunity to make changes to their occupational patterns and balance for better health. The proposed theoretical mechanisms of ReDO® -10 appear to be relevant for participants in this new context, but group dynamics and the social context had the potential to be strong barriers or enablers of change for participants. The transdisciplinary BCW and TDF frameworks (Michie et al., 2005; Michie et al., 2011) provided a new way of understanding this occupational therapy intervention, illuminating some mechanisms by which knowledge about and participation in restorative occupations could be increased for women with stress.

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Appendix IV: Letter of ethical approval March 2017

15th March, 2017

Ms. Jackie Fox
National University of Ireland Galway
Aras Moyola
Newcastle Road
Galway

A feasibility study and pilot randomised controlled trial of the Redesigning Daily Occupations™ programme for women with anxiety and stress-related disorders in an Irish Primary Care context

Dear Ms. Fox,

I wish to confirm that I have reviewed your clarifications and I am now happy to grant the above named study ethical approval.

If you have any further questions please contact Sally-Anne O'Neill - sallyanne.o'neill@icgp.ie

Yours sincerely,
Sent on behalf of Dr. Kieran Doran
Chair Research Ethics Committee

Appendix V: Distress protocol

Distress Protocol

Participants will be patients in a primary care service and will be under the care of a GP who acts as gatekeeper for this study. They will be experiencing symptoms of anxiety or stress and so it is acknowledged that this may be a vulnerable group. Measures that will be taken to protect this group are;

- Groups will be held during daytime hours in the local primary care centre.
- The facilitators of the ReDO® groups will be fully qualified occupational therapists who are experienced and currently employed by the HSE to work in community settings
- The researcher is a qualified occupational therapist with 7 years clinical experience in mental health settings. Therefore, she is highly experienced in facilitating interviews with people with anxiety. The procedure for supporting an individual who becomes upset in the ReDO® sessions or the qualitative interviews is as follows;
    - If someone becomes upset or shows signs of emotional distress in either the data gathering stage of the research, or in any of the ReDO® group sessions, the same steps will be taken
    - The person will firstly be given time to express any appropriate feelings and then will be asked if they are happy to continue. If they are happy to continue, a facilitator will check in with them after the group to see how they are.
    - If the person feels too upset to continue in the group, one of the facilitators will take them to a quiet space and offer support. They will be asked;
        - Tell me what thoughts you are having
        - Tell me what you are feeling right now
        - Do you feel able to continue with the group today?
        - If no – Do you feel able to go about your day?
    - The person will be asked to contact their GP if they continue to feel upset after the session.
    - Or – with the person's permission, the facilitator will contact their GP on their behalf.
    - If there is a concern about suicidality, the facilitator will use Mental Health First Aid principles to ask directly about suicide risk. If any risk is found, the facilitator will encourage the person to be accompanied to A&E by a family member and will stay with the person until the family member arrives. If the

person does not agree to this and there are serious concerns for safety, the Gardai will be notified. With the person's permission, the facilitator or the principal investigator will contact the person the following day to follow-up. The person's GP will be fully informed of all actions taken.

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Appendix VI: Amendments to research ethical approval 2017-2018

Amendment 1 – Ethical approval to use qualitative perspectives of occupational therapists (August 2017)

Details of Proposed Amendment:

I would like to include *qualitative reflections* from the occupational therapists running the programme in my qualitative analysis. They will keep a short reflection after they have facilitated each of the 10 group sessions and I would like to use this data to help understand their experiences, as this is a vital component of feasibility going forward.

The occupational therapists themselves suggested this change as they felt that it would be valuable to capture the change in their perceptions over the 2-3 month period of the study. Therapists will complete a short reflection sheet and give their written consent for this information to be pseudonymised and analysed.

These sheets will be transcribed and kept with the therapists pseudonymised interview transcript data on an encrypted computer drive. The original signed forms will be stored in a locked filing cabinet to which only I have a key. They will be retained for 5 years and then confidentially shredded under NUI Galway data protection regulations.

1st September, 2017

Ms. Jackie Fox
National University of Ireland Galway
Aras Moyola
Newcastle Road
Galway

A feasibility study and pilot randomised controlled trial of the Redesigning Daily Occupations™ programme for women with anxiety and stress-related disorders in an Irish Primary Care context

Dear Ms. Fox,

I wish to confirm that I have reviewed your proposed amendment received on the 22nd August, 2017. Ethical approval has been granted subject to the following-

- Please ensure that the consent form and reflection sheet are separate documents.

Yours sincerely,

Sent on behalf of Dr. Claire Collins
Chair Research Ethics Committee

Amendment 2 – Ethical approval to include an option for participants to view/edit their transcripts and view emerging findings (March 2018)

Details of Proposed Amendment:

I am proposing one minor amendment to this study:

In line with good practice in qualitative research, I would like to offer the participants of this study the opportunity to view and edit their transcripts prior to qualitative data analysis. Following transcription of the qualitative interviews, the transcripts will be posted back to the participants. I will include the proposed form (See supporting documents) and a stamped addressed envelope.

This opportunity will be offered to the General Practitioners, Occupational Therapists and to the women who have taken part the pilot programme of the Redesigning Daily Occupations group.

Participants can choose whether or not they would like to view emerging findings from the qualitative research also.

12th March, 2018

Ms. Jackie Fox
National University of Ireland Galway
Aras Moyola
Newcastle Road
Galway

A feasibility study and pilot randomized controlled trial of the Redesigning Daily Occupations programme for women with anxiety and stress-related disorders in an Irish primary care context

Dear Ms. Fox,

I wish to confirm that I have reviewed your proposed amendment which was received on the 7th March, 2018 and ethical approval has been granted.

Study amendments:

- Providing participants (General Practitioners, Occupational Therapists and participating women) with the opportunity to view and edit their transcripts prior to qualitative data analysis.
- In addition, participants have the option to view emerging findings from the qualitative research.

Yours sincerely,

Sent on behalf of Dr. Claire Collins
Chair Research Ethics Committee

Appendix VII. Recruitment Poster

NUI Galway
OÉ Gaillimh

HEALTH RESEARCH BOARD
Primary Care CTNI
CLINICAL TRIALS NETWORK IRELAND

LUND UNIVERSITY

Are you a woman experiencing anxiety or stress?

Do you feel your life is out of balance, over-burdened or lacking meaningful activity?

Would you like to take part in a research study designed to see if a group programme could help?

We are looking for women to take part in a study of a new programme called "Redesigning Daily Occupations". This programme is designed to help you;

- **Identify areas of stress and hassle in your daily life**
- **Identify ways to find more enjoyment in the activities of daily life**
- **Set goals for lasting change**

This is a 10 – week programme which will start on the 21st February 2019.

If you are interested in taking part in this research study, please ask your GP to refer you, or you can contact the researcher directly at: Jackie.fox@nuigalway.ie **or 091 495021**

Appendix VIII. Participant Information Leaflet

What is the feasibility of the Redesigning Daily Occupations® programme in an Irish primary care context?

Are you a woman experiencing anxiety or a stress-related condition?

Do you feel your life is out of balance, over-burdened or lacking meaningful activity?

Would you like to take part in a research study designed to see if a group programme could help?

Principal investigator and Data Controller: Jackie Fox
Principal investigator's title: Lecturer, NUI Galway
Telephone number/email of principal investigator: 091 495021 jackie.fox@nuigalway.ie
Data Controller's/joint Controller's Identity: [redacted], Senior HSE Occupational Therapists
Data Controller's/joint Controller's Contact Details: 091 775323
Data Protection Officer's Identity: Mr. Peter Feeney, NUI Galway
Data Protection Officer's Contact Details: dataprotection@nuigalway.ie

Thank you for your interest in this study.

You are being invited to take part in a research study to be carried out in Galway City by Jackie Fox, an occupational therapist and lecturer in NUI Galway.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP (doctor).

Take time to ask questions – don't feel rushed and don't feel under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

You don't have to take part in this study. If you decide not to take part it won't affect your future medical care.

You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason. If you do opt out, rest assured it won't affect the quality of treatment you get in the future.

Why is this study being done?

We know that many women present to their GP experiencing anxiety and stress. Many of these women will be experiencing a hectic lifestyle, may feel overburdened, be juggling multiple roles or might not be happy with their life balance.

It is known that there is a link between how satisfied you are with your daily activities and your health and wellbeing. We know that the Redesigning Daily Occupations® programme has been shown to bring about improvements in mental health, self-esteem and balance in daily activities for women with anxiety, stress and depression in Sweden and it has shown promising results in a small Irish study in 2018.

The study is exploring whether this programme could firstly; be feasible and practical and secondly; whether this programme could bring about improvements in daily life for women with anxiety and stress-related issues.

Who is organising and funding this study?The study is a small project being completed by Jackie Fox, an occupational therapy lecturer in the National University of Ireland, Galway as part of a PhD. The study is supported by NUI Galway, the HSE Community Occupational Therapy service and the HRB Primary Care Clinical Trials network.

Why am I being asked to take part?

You have been asked to take part because you may have sought help from your GP or practice nurse because of anxiety or stress. You can take part in this study if you are:

- A woman aged between 18-66 years

Experiencing stress or anxiety to the extent that you are seeking some help with managing it. Have a stressful daily life and would like to make practical changes to have better balanceUnfortunately, you <u>cannot take part</u> in this study if you are:

- Experiencing an acute crisis in recent weeks e.g. a bereavement or a serious medical diagnosis
- Attending an occupational therapist for help
- Experiencing issues that would make it difficult for you to attend a group therapy session e.g. memory problems, psychosis or addiction

What is the Redesigning Daily Occupations® Programme?

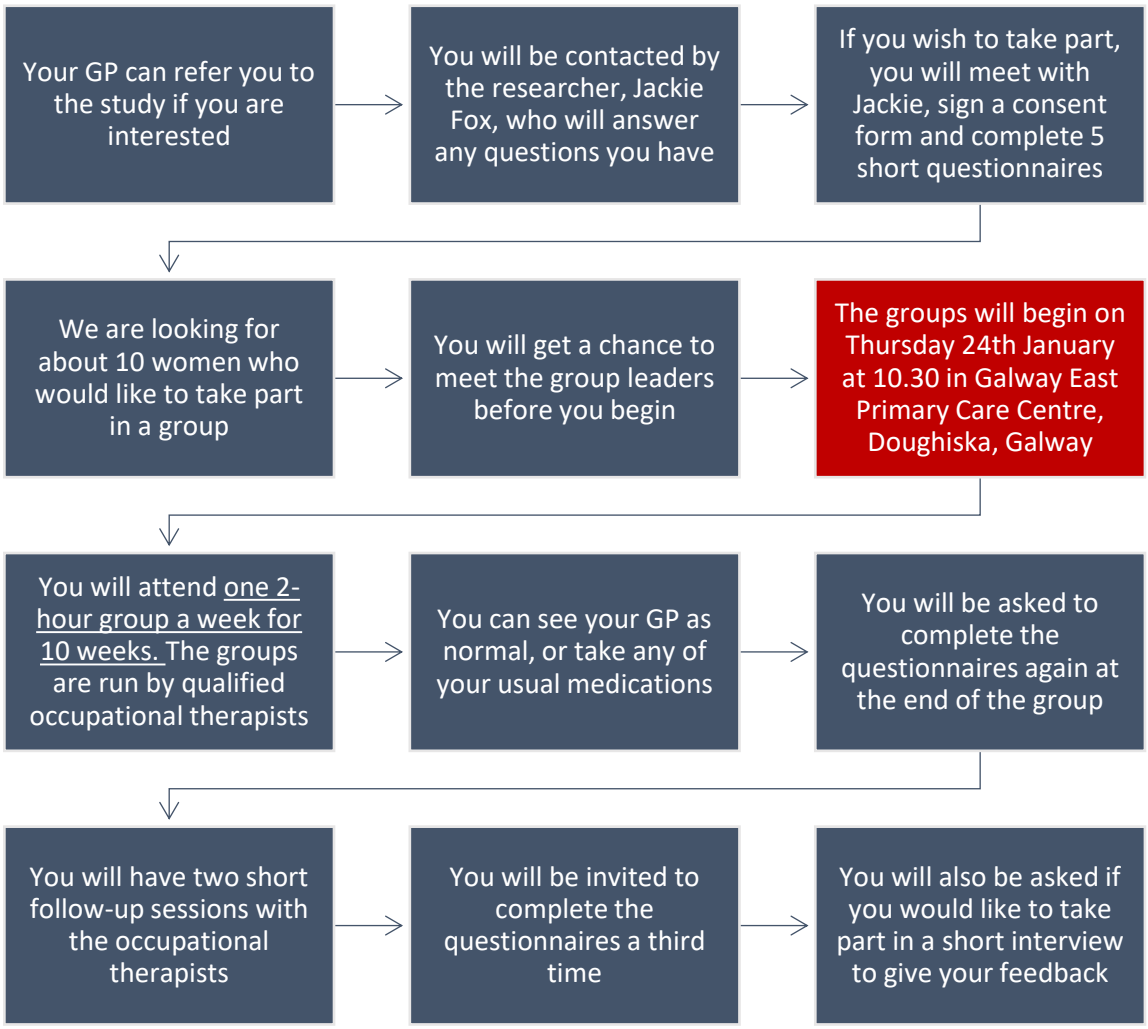
The Redesigning Daily Occupations™ programme was designed and researched by Occupational Therapists in Sweden originally. The programme is based on the understanding that daily life involves a complex pattern of activities; work, household tasks,

parenting, looking after yourself and so on. Your ability to carry out your activities in daily life to your satisfaction can be compromised when you feel anxious, stressed or depressed. And having a stressful, overly demanding, or tedious daily pattern of occupation can place people at risk of burnout and stress.

This programme will help you to explore how you use your time every day and your own pattern of daily stressors and hassles. It will help you to identify activities that give you pleasure and satisfaction and you will set personalised goals. You will look at ways to achieve a more satisfying balance in your activities in daily life. The programme also includes an evening seminar for your spouses, partners, families and/or friends, so that they can be a part of your recovery.

How will the study be carried out?

The following diagram will show you what is involved in this research:



What can I expect if I agree to take part?

The Redesigning Daily Occupations® programme is a once-a-week group, for a period of ten weeks. You will be with approximately 10 other women who will also have experience of stress and anxiety and led by experienced group facilitators. The groups will take place in the Galway East Primary Care centre and there will be refreshments while you are there.

You will be asked to fill in 5 questionnaires before you start the programme, again at the end and once more two months after you finish. The researcher, Jackie Fox, will visit you at home, or another convenient location to give you these questionnaires and answer any questions you have before the programme starts.

You can see your GP as normal, or take any medications that you usually take. You are free to begin any other courses of treatment or therapy during the study.

What if I do not want to take part?

You are free to decline to take part in this study. You are free to start the study and then withdraw at any time. At all time, you will continue to receive all usual care from your GP.

Audio-recording

You will be invited to take part in an interview at the end of the programme to give your feedback. This interview will be recorded with your permission. The interview will be written up word-for-word by the researcher and you have the right if you wish, to review or change these written transcripts. The recorded interview will then be deleted.

What are the benefits for me in taking part?

You may find that you benefit from the Redesigning Daily Occupations® programme, as it has been shown to have positive outcomes for women with stress and anxiety in Sweden.

We ran this programme for the first time in Spring 2018 in Galway and received positive feedback from the women who took that course.
If you take part in the group and give your feedback, your participation will help the researcher to gather valuable information which may lead to improving services in the future. It may be that you do not feel any benefit from your participation, but running this

study will help the researcher to understand whether this programme could be a useful one to provide to people with stress or anxiety in the future.

What are the risks?

The main down-side or cost to you is time. Everyone that is participating in the study will be invited to meet with the researcher to complete questionnaires. If you are selected to take part in the programme, you will be asked to attend a 2 hour group once a week for 10 weeks. These groups will take place on Thursday mornings from 10.30-12.30 so you may have to make arrangements with work or childcare. There will be two follow up groups – once a month for two months after the programme to see how you are getting on.

There are very minimal risks associated with participating in this study. You may find that discussing your experiences with stress and anxiety in a group may be emotional. However, the group will be facilitated by qualified occupational therapists trained in working with individuals in community groups and they will help you seek further support should you wish it. At all times you will continue to receive your usual support from your GP.

There is a small risk to your confidentiality. There is a small chance that you may know someone else attending the programme. The programme is professionally facilitated and topics discussed in the sessions are held in confidence, unless the leaders have a health concern about someone.

Unfortunately, we cannot cover any costs that you might have in attending the programme e.g. bus fare. However, we will provide all the materials needed for the programme and refreshments during the sessions.

What do I need to know about confidentiality?

It is important that you know that:

- The researcher or the group leaders WILL NOT have any access to your medical notes.
- Your confidential details e.g. your name and phone number, will be kept by the researcher in a password-protected computer. They will be deleted as soon as the study is over.
- The researcher will not be giving any information back to your GP on your participation in the programme OTHER than:
    - To let your GP know that you are taking part
    - To give a summary of the results of the WHOLE group.
- The audio-recorded interviews you give will be stored securely and deleted as soon as they have been written out. NO IDENTIFYING information e.g. names, will be written down.
- Only the researcher, Jackie Fox, your GP and the two occupational therapists, [redacted] will know your name and that you are taking part. This information will not be shared with anyone else.
- The researcher will publish results from this study in academic journals, at conferences and/or in HSE publications. These will be the collective results from everyone who takes part and it will not be possible to identify you from these results.

What do I need to know about <u>data protection?</u>

It is important that you understand how your personal information will be gathered and used for this study. We are required by law to give you all this information before you make up your mind about whether to take part in this research or not.

1. ***Why do you need my personal information?*** We need your personal information to be able to contact you and set up meeting times for the ReDO groups or for your interview with the researcher.

Information you give will help us find out if this programme could be helpful for women with anxiety or stress.

- *We are using your information under two legal bases as defined by the General Data Protection Regulations 2016: Because we feel this study is important for scientific research (Article 9(2)(i)) and because we feel the information you provide could be important for the public interest (Article 6(1)(f))*

2. ***Who will have access to my information?*** Only the researcher, Jackie Fox and the group leaders, [redacted].

3. ***How long will you keep my information?*** Your personal details e.g. name, phone number etc. will be deleted once the ReDO programme finishes in Summer 2019. We will still keep some information e.g. your anonymous questionnaires, for a period of 5 years. But you will not be identifiable from these.

4. ***Can I withdraw?*** You can withdraw from this study at any time without giving a reason. If you withdraw while the programme is going on, your data will be deleted. However, if you wish to withdraw at a later date, we will not be able to delete your data because it will be mixed with that of other people. You can contact the researcher at Jackie.fox@nuigalway.ie if you have questions about this.

5. ***What are my rights?***
    a. You have the right to lodge a complaint with the Data Protection Commissioner if you are dissatisfied.

    b. You have the right to request access to your information e.g. a copy of your questionnaires. However, once these have been made anonymous (once they have all been collected), it will not be possible for us to know which questionnaire is yours.

    c. You have the right to restrict or object to processing of your information. But this would make it difficult for us to complete this research.

d. You have the right to have any inaccurate information about you corrected or deleted. For example, you have the right to look over and edit the transcript of any interview with you.

e. You have the right to have your personal information deleted. And your personal information WILL be deleted as soon as all the information is collected and compiled with that of other people participating in the research.

f. You have the right to ask for any of your information in a readable format.

6. ***How will you use my information?***
    a. There will be no automated decision-making or profiling of your personal information in this study. This means that we will not use your personal data to make any predictions about you.

    b. Your information will not be processed for any other reason than for this study. And it will not be transferred to any other country or organisation.

    c. Your information will be held on a password-protected file storage system. Only the researcher has access to this.

Consent to Future Use

The information you give in this study will be held anonymously for a period of up to 5 years in NUI Galway. All identifying details will have been deleted from this information.

This information may be used in future research related to this study e.g. other future studies studying the Redesigning Daily Occupations programme, but for no other purpose.

Where can I get further information?

If you have any further questions about the study or if you want to opt out of the study, you can rest assured it won't affect the quality of treatment you get in the future.

If you need any further information now or at any time in the future, please contact:

Name: *Jackie Fox*

Address: *School of Health Sciences, Aras Moyola, NUI Galway*

Phone No: *091 495021 (Monday-Friday 9am-4pm) OR Jackie.fox@nuigalway.ie*

Appendix IX. Consent to be contacted by the researcher

A feasibility study and process evaluation of the Redesigning Daily Occupations® programme for women with anxiety and stress in an Irish primary care context

Please use this form to refer interested participants to the study.

Inclusion criteria:

- **Women who:**
  - **Are aged 18-66**
  - **Have a diagnosis, or reason of complaint to their GP, of anxiety or a stress-related disorder**
  - **Have visited their GP on at least two occasions with concerns regarding stress or anxiety**
  - **Are not currently experiencing a life crisis like a bereavement**

Consent

Referred participants MUST sign this form to give consent to being contacted by the researcher to get further information.

Giving consent at this stage does not imply consent to participate in the full study. Individuals are still free to withdraw at any stage.

I understand that I will be contacted by a researcher to give me more information about this study (please tick)

I consent to my phone number/email address to be sent to the researcher for this purpose only (please tick)

Signed: _____

Name: _____

Contact details (email or telephone): _____

Appendix X. Consent Form

LUND UNIVERSITY

Study title: A feasibility study and process evaluation of the Redesigning Daily Occupations programme for women with anxiety and stress in an Irish Primary Care context

I have read and understood the **Information Leaflet** about this research project. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	**Yes** ☐	**No** ☐
I understand that I don't have to take part in this study and that I can opt out at any time. I understand that I don't have to give a reason for opting out and I understand that opting out won't affect my future medical care.	**Yes** ☐	**No** ☐
I am aware of the potential risks, benefits and alternatives of this research study.	**Yes** ☐	**No** ☐
I have been assured that information about me will be kept private and confidential.	**Yes** ☐	**No** ☐
I have been given a copy of the Information Leaflet and this completed consent form for my records.	**Yes** ☐	**No** ☐
I consent to take part in this research study having been fully informed of the risks, benefits and alternatives.	**Yes** ☐	**No** ☐
I give informed explicit consent to have my data processed as part of this research study.	**Yes** ☐	**No** ☐
I consent to be contacted by researchers as part of this research study	**Yes** ☐	**No** ☐
Storage and Future Use of Information (please tick YES to ONE option)		
OPTION 1 - I give permission for my <u>anonymous</u> data to be stored for *possible future research* ***related*** to the current study ***<u>only if consent is obtained</u>*** at the time of the future research and the research his approved by a Research Ethics Committee	**Yes** ☐	**No** ☐
OPTION 2 - I give permission for my <u>anonymous</u> data to be stored for *possible future research* ***related*** to the current study ***<u>without further consent</u>*** being required but only if the research is approved by a Research Ethics Committee.	**Yes** ☐	**No** ☐
OPTION 3 – I request that all my data collected for this study can no longer be used by researchers in the future and that it be destroyed		

Participant Name (Block Capitals) | Participant Signature | Date

To be completed by the Principal Investigator or nominee.

I, the undersigned, have taken the time to fully explain to the above patient the nature and purpose of this study in a way that they could understand. I have explained the risks involved as well as the possible benefits. I have invited them to ask questions on any aspect of the study that concerned them.

Name (Block Capitals)| Qualifications| Signature | Date

Principal investigator and Data Controller: Jackie Fox

Principal investigator's title: Lecturer, NUI Galway

Telephone number/email of principal investigator: 091 495021 jackie.fox@nuigalway.ie

Data Controller's/joint Controller's Identity: [redacted], Senior HSE Occupational Therapists

Data Controller's/joint Controller's Contact Details: 091 775323

Data Protection Officer's Identity: Mr. Peter Feeney, NUI Galway

Data Protection Officer's Contact Details: dataprotection@nuigalway.ie

Appendix XI. Consent form for audio-recording

Study title: ***A feasibility study and process evaluation of the Redesigning Daily Occupations® programme for women with anxiety and stress in an Irish Primary Care context***

I understand that I am being asked to take part in an interview as part of this research project. This process has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	Yes ☐	No ☐
I understand that I don't have to take part in this interview and that I can opt out at any time. I understand that I don't have to give a reason for opting out.	Yes ☐	No ☐
I understand that my views will be audio-recorded, transcribed and analysed	Yes ☐	No ☐
I understand that the audio files and transcripts will be kept on an encrypted file to which only the researcher, Jackie Fox, has access	Yes ☐	No ☐
I have been given a copy of this completed consent form for my records.	Yes ☐	No ☐
I consent to take part in this interview having been fully informed of the risks, benefits and alternatives.	Yes ☐	No ☐
I give informed explicit consent to have my interview data processed as part of this research study.	Yes ☐	No ☐
I consent to be contacted by researchers only as part of this research study	Yes ☐	No ☐
I give permission for my <u>anonymous</u> data to be stored for <u>*possible future research related*</u> to the current study <u>*without further consent*</u> being required but only if the research is approved by a Research Ethics Committee.	Yes ☐	No ☐

| | |

Name (Block Capitals) | Signature | Date

To be completed by the Principal Investigator or nominee.

I, the undersigned, have taken the time to fully explain to the above person the nature and purpose of this study in a way that they could understand. I have explained the risks involved as well as the possible benefits. I have invited them to ask questions on any aspect of the study that concerned them.

| | |
---|---|---|---
Name (Block Capitals) | Qualifications | Signature | Date

Appendix XII. Demographic Information

Age _____

Work/study status (please tick)
Working full-time ☐

Working part-time ☐

On leave from work ☐

Working in the home ☐

Studying full-time ☐

Other (please describe) **_____**

Living circumstances (please tick)
Living alone ☐

Living with partner ☐

Other (please describe) **_____**

Family (please give number of children, if any)_____

Are you currently taking any medication? Please give details
_____
_____
__

Are you currently attending any other therapy/service to help with anxiety, stress or low mood? Please give details

---

Appendix XIII. Qualitative interview schedule

ReDO-10 Participant interview schedule

Research Questions	Stakeholder Perspective	Clear interview questions
Feasibility of a future trial		What was your experience like as part of this research study? Why did you decide to take part? How did the GP explain it to you? How did you feel about the questionnaires you were asked to complete? Did they cover the range of your experience with anxiety? Were they too long/short/just right? How do you feel about being part of a research study? What do you think would be important to consider in future research of this programme?
How successful were the trial processes of recruitment, randomization, retention, data collection and analysis? How satisfied were stakeholders with the research process? How did the referral procedure work for them? What factors would need to be considered for a future trial to be implemented successfully? Resources, supports needed and other logistical issues will be explored.	- **What was the acceptability of the trial processes for the occupational therapists?** - **What is the feasibility of a future RCT from the point of view of the women who participated?**	
Perceived effectiveness		
Did the ReDO™ programme show some trends towards effectiveness in improving outcomes for individuals with anxiety and stress-related conditions?	- **What is the perceived effectiveness of the ReDO on individual outcomes from the point of view of the participants?**	Did you find the programme effective? What improved for you? Were there any knock-on effects on other aspects of your life? Did anything not improve? Were there any unexpected or unpleasant effects of the programme? If there were benefits – did they stay the same/get worse/better? What has helped you maintain changes? OR What has been a barrier to change?
Intervention implementation and fidelity		

How was the ReDO™ delivered in this context? Was it acceptable to occupational therapists and was it delivered with fidelity?	- **What processes allowed the intervention to function? (Villeval et al., 2016)** - **What are the key functions of the ReDO?** - **Was the ReDO implemented with fidelity? (the form)**	Did you think of the sessions themselves? What aspects did you like? Not like? How did you feel about the group format? How did you feel about the group facilitation?
Hypothesised causal mechanisms		
How does the ReDO™ programme bring about change, if positive outcomes are seen? Are the hypothesized causal mechanisms confirmed in this context?	- **Do the proposed causal mechanisms of the ReDO hold true in the Irish primary care context?**	For you, what has been the source of your anxiety/stress? What is your understanding of why you were distressed? If positive changes happened for you – why do you think that was? What were the key aspects of the intervention that you found useful or helpful? Did you find yourself making any changes to your life? If so, what were they? And how did you make those changes?
Contextual interaction		
How did the ReDO™ programme fit within the context of Irish primary care and how did the context interact with it and its outcomes?	- **What is the context within which the ReDO is being introduced?** - **How does this context support or hinder a future trial and/or the continuing use of the ReDO by therapists?**	What is your understanding of how women with anxiety/stress would usually be treated in primary care? What other interventions have you tried/been referred to? What supported your facilitation of the ReDO? And your participation in this study? - Family, transport, money, work, childcare, mood, health, motivation, the group? Did anything get in the way of your taking part in the programme/hinder you?

Do you think you will continue to use the strategies? Which ones? Why? Why not?

How did you implement the programme week by week? What did you have to do to prepare?

Appendix XIV. Reflection sheet for OTs

Reflection Sheet

Please complete this short reflection following each ReDO-10 group session. Continue overleaf if necessary

What session did you co-facilitate?

What worked? What were you happy with?

Did you follow the manual exactly or make changes? Can you give details?

What did not go so well (if anything)? Why do you think that was?

Do you see any changes occurring for group members (please do not give names)? What is bringing about change, do you think?

How did the group fit in with your other work this week?

Any further reflections or comments?

Appendix XV. Framework analysis (Published Paper 2)

Person	How the ReDO message was delivered	Reasons for declining	Recruitment – who did GPs invite and why
2612	She (GP) didn't explain…….she didn't say it was about going back to work. But she thought it would really benefit me.		
3656		The idea feels "a bit American". Couldn't tell many people as it would feel "self-indulgent" "God – would you look at your one?"	
4678	talked to doctor. I said to her, "What do you think?" She said, you know, "Absolutely", because I had been talking to her about stuff as well.		
5505	GP rang her directly to invite her. GP said that she could just get more information before making up her mind. She then did some reading online while thinking about it		

OT1			Having a mix of people with children and not was difficult to manage so it was relevant to everybody (first phase) People shouldn't be "too unwell" for ReDO
GP1	I was trying to pitch it saying, "look – give it a go because the people who are there are very similar to you, they'll have similar stuff and you know you might find it helpful to know that there are other people that have the same reaction. And with a nudge, sometimes that can be enough……to kind of send them …..send them considering it. I didn't "harp on" about the research aspect And I did hammer the point home as well too, you know? Like, "this is for you. This is …you need to make this time. And everybody can find an hour here and there if you really, really need to".	People who refused would also refuse counselling "want a quick fix" "weren't ready to put the work in" "Hardened inner city" people might feel it is "airy-fairy". They prefer medication "have their own agenda" Don't believe in counselling "keep it to yourself" "that's how they were raised" Some (with anxiety) didn't like the idea of a group Some were too busy Some unknown reasons for declining Those who really need therapy on self-care are	"For those I offered it to, the bulk or majority would say yes, that's fine" If it was "on my mind the day they were in" – so didn't offer it to everyone possible Didn't offer it to people already doing well

	"I said – this would be a good option"	the ones that are too busy Single parents have no time	
GP2	I suppose I didn't really tell them too much about it. I just asked for permission to pass on their details and I left it to you to engage with them. Because then they knew that you weren't kind of scary … And they felt it was for them. But I don't know ….all three of them were very appreciative	Self-management interventions are hard generally (including even online) Childcare is a barrier Those in full-time work	Contacted people directly – "they were so grateful that I had thought of them". Selected women who had "come so many times" – eager for help Women who had already done Psychiatry or medication "trying their best but just struggling"
GP3	I nearly kind of minimized that (that it was research). I kind of actually left that nearly until the end of the conversation and just said well, "this is now available", you know, "this opportunity has come up". Research for me was…..I obviously mentioned it, but….at that stage their mind was nearly made up anyway, "Oh no, I couldn't. Oh no, that doesn't suit me at all". You know?	ReDO was "in theory it was ideal, but the practicalities were what were prohibitive" Some didn't drive Those who were working "This would have been one more thing to fit into their week" Those not working- it was finances or transport Those who were too busy – it was "just too much"	

		The same people who don't engage in counselling refused ReDO – just too "overwhelming" Older women "can't let their families know because they're holding it all together" The intervention, rather than the research element, decided it for people Issues with group work identified – particularly with anxiety Worry about who might be there Self-management for mental health is a difficult sell ReDO or counselling would be seen as a "luxury" for women. It would be "like telling their partner I'm going to get my hair done for an hour" Context – men wouldn't consider others needs first "who's going to peel the spuds?" but women do Women feel guilty for feeling anxious – "it is	

		a challenge to flip the mindset and to do something for your mental health. It isn't the equivilant of going off to get your nails done". Women put up with things "for the sake of peace" "I don't want to upset the applecart"	
GP4	I think if people knew, if they had the guarantee that they were……that they would get the service – that'd be the big thing I would say	Time-commitment – the two hours. Suggests that shorter sessions would be easier for people "personality thing" – people preferring different interventions	
GP5	(If people were guaranteed to get the service) it would help alright. We could sell it kind of…..	Group session rather than individual was a barrier – particularly for anxiety and for women Some people just don't want self-management (including counselling) – prefer medication Some people have "visited everything before and ….don't want to go through it again".	
GP6		Interruption to work "that was the big issue" - time	

GP7		Time-commitment – "just taking that time". GP appears not to value long interventions "the nature of counselling is that you need to do 10 sessions a leastt"	
GP8	sometimes you say to yourself, well, good old Jackie, but it's not worth it today! Being honest I think with recruiting to any trial it takes a bit of extra time		Recruitment takes "a bit of extra time" or is "something that is mentioned at the end of the consultation" "Good old Jackie – but it's not worth it today"
GP9		Time-commitment – the length of sessions and the number. Suggested shorter sessions	