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The effectiveness of a structured educational reminiscence-based programme for staff in long-stay units on the quality of life of residents with dementia: A cluster randomised trial. The DARES Study.

A thesis presented to the National University of Ireland, Galway in fulfilment of the thesis requirements for the degree of Doctor of Philosophy (Ph.D.)

By

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Declaration

This thesis has not been previously admitted as an exercise for a degree at this or any other University. The research presented in this thesis was part of the DARES study, a cluster randomised trial which was funded by the Irish Health Research Board and evaluated the effectiveness of a structured educational programme for staff in long-stay units on the quality of life of residents with dementia. The study was undertaken by a team of researchers, including myself, from the National University of Ireland, Galway. The Chapters presented in this thesis, represent my contributions to the DARES study and are summarised as follows:

Chapter 1 presents a background to the DARES study, including rationale, aims and objectives for the study. Chapter 2 of this thesis presents a narrative literature review. The literature review made a number of unique contributions to the DARES study, namely it, contextualised dementia. Subsequently, much of the content of the literature review informed the dementia component of the curriculum delivered in the DARES study intervention, i.e., a structured education reminiscence-based programme for staff. The literature review also highlighted the need to collate the existing evidence to support the use of reminiscence therapy for people with dementia living in long-term care and highlighted the need to complete a concept analysis of reminiscence therapy for people with dementia. The published concept analysis, presented in Appendix 1 of this thesis was undertaken by members of the DARES research team, myself included. The concept analysis enabled us to define clearly the type and aims of reminiscence being delivered and evaluated in the DARES study. Chapter 3 presents a systematic review and meta-analysis, undertaken by me, evaluating the effectiveness of reminiscence therapy for people with dementia living in the long-stay setting prior to the DARES study. This review identified the dearth of studies evaluating the impact of reminiscence therapy on the quality of life of residents with dementia and on staff members' burden of care. Findings from the systematic review concluded that there was a demand for more rigorous evaluation of reminiscence therapy for residents' with dementia and future trials should consider the resident's subjective rating of quality of life as a key outcome. Chapter 4 presents my methodology chapter which informed the design, conduct and statistical analysis undertaken in the DARES study. This chapter also informed the structure and content of the DARES study published protocol, presented in Appendix 9 of this thesis. Chapter 5 presents a detailed report of the findings of my analyses for the primary and secondary outcomes from the DARES study. Chapter 6 provides a brief summary of the key findings from the DARES study,

explores possible explanations for how these findings may have occurred and presents the limitations of the study. All of the Chapters presented in this thesis informed the structure, content and reported findings arising from the DARES study, presently submitted for publication.

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Summary

Background

There is a growing appreciation of the potential use of psychosocial interventions in maintaining or improving the quality of life of people with dementia residing in long-stay care settings. Reminiscence is a psychosocial intervention commonly used in dementia and involves the discussion of past activities, events and experiences with another person or group of people, usually with the aid of tangible prompts such as photographs or other familiar items. However, despite being widely used in dementia care, evidence on the effectiveness of reminiscence as a psychosocial intervention for people with dementia residing in long-stay settings is uncertain.

Aims

The aim of this study was to evaluate the effectiveness of a **s**tructured **e**ducational **r**eminiscence-based **p**rogramme for **s**taff in long-stay units on the quality of life of residents with dementia.

Methods

The DARES study was a two-group, single-blind cluster randomised trial (ISRCTN99651465), conducted in public and private long-stay residential settings in Ireland. Randomisation to control and intervention was at the level of the long-stay residential unit. Sample size calculations suggested that 18 residential units each containing 17 people with dementia were required for randomisation to control and intervention groups to achieve power of at least 80% with alpha levels of 0.05. Each resident in the intervention group was linked with a nurse and care assistant who had completed the structured reminiscence-based education programme. Residents allocated to the control group received usual care. The primary outcome was quality of life of residents as measured by the Quality of Life-AD instrument. Secondary outcomes included staffs' perception of the residents' quality of life, residents' perceived levels of agitation, depression and staffs' perceived burden of care. Blinded outcome assessment was undertaken at baseline and at 18-22 weeks post-randomisation.

Findings

Using an intention to treat complete case analysis, on average, there was no statistical significant difference, between residents allocated to the SERPS and residents allocated to usual care. Estimated effect of the intervention on the quality of life of residents was 3.54 (95% CI -0.83 to 7.90, p=0.10), expressed as the difference in

mean improvement between intervention and control group. When the three sites that did not implement the intervention to residents as prescribed were removed for the analysis, per-protocol analysis yielded a significant effect. Estimated effect of the intervention on the quality of life of residents was 5.22 (95% CI 0.11 to 10.34, p=0.04), exceeding the 4-point minimal clinical important difference defined at the outset of the trial.

Conclusion

Reminiscence may be an effective care option for people with dementia in long-stay settings with potential to impact positively on the quality of life of residents.

Publications

In line with thesis submission guidelines, this thesis includes writings published by the DARES study core team of which I was a member and which derive from my research work carried out during the period of my registration on the PhD register. These writings have been integrated into the body of this thesis.

O'Shea, E., Devane, D., Murphy, K., Cooney, A., Casey, D., **Jordan, F.,** Hunter, A. & Murphy, E. (2011) Effectiveness of a structured education reminiscence-based programme for staff on the quality of life of residents with dementia in long-stay units: A study protocol for a cluster randomised trial. *Trials* 12, 41. DOI: 10.1186/1745-6215-12-41.

Dempsey, L., Murphy, K., Cooney, A., Casey, D., O'Shea, E., Devane, D., **Jordan, F.** & Hunter, A. (2012) Reminiscence in Dementia: A concept analysis. *Dementia: The International Journal of Social Research and Practice.* DOI: 10.1177/1471301212456277.

Cooney, A., O'Shea, E., Casey, D., Murphy, K., Dempsey, L., Smyth, S., Hunter, A., Murphy, E., Devane, D. & **Jordan, F.** (2012) Developing a structured education reminiscence-based programme for staff in long-stay care facilities in Ireland. *Journal of Clinical Nursing* 22(13-14), 1977-1987.

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Dedication

I dedicate my thesis to all of the residents with dementia whom I met during my research. Each and every one of you inspired me, thank you! I hope that I have made your voices heard.

'Where once dementia was present and silent, now it's present and heard'

John Keady

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Chapter 1
Introduction

1.1 Background to the study

Dementia is a global term used to describe a variety of illnesses, which although diverse in nature, share common clinical manifestations (Prince & Jackson, 2009). Typified by pervasive impairment of mental functioning, progressive memory loss, language difficulties, confusion and disorientation, dementia leads to a decline in skills required to engage in and carry out everyday living activities (Cotelli *et al.* 2012). Coupled with diminishing cognitive and physical functioning, symptoms of dementia also affect the person's behaviour and mood (Cohen-Mansfield, 1998; Hoe *et al.* 2005; 2006; 2007; 2009). As the disease progresses, the associated increase in frequency and severity of symptoms (Lawlor, 2000) have a devasting effect on the quality of life of the person with dementia and their caregivers (World Health Organisation (WHO), 2012).

Studies on the prevalence of dementia indicate a sharp rise with age, doubling every 6.3 years increment in age in Western Europe (Prince *et al.* 2013). Current estimates suggest that there are 35.6 million people living with dementia worldwide and this is forecast to double by 2030 and more than triple by 2050 (Prince & Jackson, 2009; 2012; Prince *et al.* 2013). The absences of reliable epidemiological studies reporting on the prevalence of dementia make it difficult to provide reliable estimates of the number of people with dementia in Ireland (Cahill *et al.* 2012). However, in an effort to establish Irish prevalence rates of dementia, Cahill *et al.* (2012) applied the European age/gender specific prevalence estimates to the 2006 Census of Population data and estimated that in 2006, there were 41,740 people with dementia living in Ireland and forecast that this would increase to140.580 in 2041, representing a 240% increase from 2006 to 2041.

While the majority of people with dementia are cared for at home, an escalation in symptom severity and the subsequent burden of care experienced by family care givers, almost inevitably leads to the person with dementia entering into long-stay residential care (Cahill, 1997; Banerjee *et al.* 2003; Moïse *et al.* 2004; Argyle *et al.* 2010; Cahill *et al.* 2012). However, as is the case in all care settings, estimating accurate prevalence rates of dementia in long-stay settings is hindered by an under

diagnosis of dementia (Knapp *et al.* 2005; Prince & Jackson, 2009; Prince *et al.* 2013). International evidence suggests that, approximately 50% to 70% of residents living in long-term care facilities have a dementia (Helmer *et al.* 2006*;* Knapp *et al.* 2007). Irish dementia researchers suggest that there are 14,266 people with dementia residing in long-stay care facilities throughout Ireland, representing 63.1% of the total long-stay population (Cahill *et al.* 2012).

Dementia is an expensive condition, costing an estimated US$604 billion worldwide (WHO, 2012). The burden of cost is largely attributable to the provision of informal care, provided by family caregivers, followed by the cost of formal care provided in residential care settings (Wimo & Prince, 2010). In Ireland, the estimated cost of dementia is €1.69 billion and reflecting international trends, the greater burden of cost is attributable to informal care, followed by residential care (Connelly *et al.* 2012).

The increasing prevalence of dementia worldwide and the corresponding economic burden of care has prompted the WHO (2012) to declare dementia an international and national public health priority. Allied to this, a growing number of countries throughout the world have developed National Dementia Strategies to guide present and future healthcare policies for dementia (Cahill *et al.* 2012). In the absence of a cure, established dementia strategies reflect the need to improve the quality of life for the person with dementia throughout all stages of the disease process (WHO, 2012). National Dementia Strategies echo the concerns of a number of researchers, in that they suggest that, limited staff knowledge and understanding of dementia across all care settings is a major obstacle to best practice (Cahill *et al.* 2012) and, impacts negatively on the quality of life of people with dementia, particularly those residing in long-stay care (Moïse *et al.* 2004; Borsbasi *et al.* 2006; Hancock *et al.* 2006; Murphy *et al.* 2007).

In Ireland, long-stay care consists of public, private and voluntary care facilities, the majority of long-stay beds are provided by the private nursing home sector and subsequently the majority of Irish people with dementia in long-term care, reside in private facilities (Cahill *et al.* 2012). There are few alternatives to the nursing home model of care, facilities are generally generic in nature, designed to cater for the needs of older people but not for the complex needs of residents with dementia, thus making the task of care provision to residents with dementia very difficult for professional care

staff. Largely based on the biomedical model of care provision, nursing care in generic long-term care facilities is driven by routine and centers on providing for the physical health needs of residents. Little if any time, is afforded to meeting residents' psychological and social needs (O' Shea, 2007; Cahill *et al.* 2012). The Irish National Quality Standards for Residential Care Settings for Older People dementia-specific Supplementary Standards devised by the Health Information and Quality Authority (HIQA, 2009), stipulate that, staff caring for people with dementia should adopt a person-centred approach to care by using "appropriate therapies" (p.65), and techniques such as "life stories and reminiscence to enhance communication" (p.66). Contrary to these requirements, Irish researchers have demonstrated that staff members caring for people with dementia in long-term residential care settings do not have the knowledge and skills required to deliver such approaches to care, consequently, concern has been raised about the quality of care been delivered and the impact it may have on the quality of life of residents with dementia (Murphy *et al.* 2006; Heath, 2010; Cahill *et al.* 2011). Reflecting international trends, here in Ireland, there is a growing realisation and appreciation for the need to address the quality of residential care for people with dementia and there is an acknowledgement of the need to integrate more person-centred approaches to care delivery (Murphy *et al.* 2006; O'Shea, 2007; Cahill *et al.* 2012)

Person-centred approaches to care have become synonymous with the provision of quality care, because contrary to the biomedical approach which concerns itself with the causes, diagnostic procedures, pharmacological treatments and seeking a cure for dementia, person-centred approaches look beyond the illness and seek to focus on getting to know 'the person' behind the illness (Kitwood, 1997; Bates *et al.* 2004; Boote *et al.* 2006; Brooker *et al.* 2007; O'Shea, 2007; Cahill *et al.* 2012). Person-centred care has the person's quality of life at its core, respect's the person with dementia, acknowledges their individuality and maximises their preserved abilities throughout their journey with dementia (Hoffman, 2006). In integrating person-centred approaches to care, residential care staff adapt strategies that maximise the quality of life the resident with dementia. Strategies adopted include, creating a home-like environment, providing individualised care plans, creation of lifestory books for individual residents, integrating perserved abilities into meaningful activities, establishing meaningful relationships and maximising communication between care staff and the resident with dementia and, maintaining relationships with family and friends (Dewing, 2004; Brooker

& Wooley, 2007; Brooker *et al.* 2007; Vernooij-Dassen, 2007; Schweitzer & Bruce, 2008).

Psychosocial interventions for people with dementia are person-centred in approach, defined as "human interactive behaviour between therapist and client" (Bates *et al.* 2004, p.654), they aim to maximise preserved abilities and quality of life and minimise the risk of excessive disability (Kitwood, 1997; Bates *et al.* 2004). Psychosocial interventions are generally classified into the following four approaches: cognition-oriented interventions, stimulation-oriented interventions, behavioural interventions, and emotion-oriented interventions (American Psychiatric association (APA), 1997; Finnema *et al.* 2000).

Evidence from systematic reviews suggests that, the empirical evidence to support the effectiveness of psychosocial interventions for people with dementia is generally weak (Lin *et al.* 2003; Bates *et al.* 2004; Boote *et al.* 2006; Livingston *et al.* 2005; Douglas *et al.* 2007). The evidence base is strongest in relation to cognition-orientated interventions, namely, cognitive stimulation therapy. Findings from a recent Cochrane systematic review (Woods *et al.* 2012) concluded that cognitive stimulation therapy had a significant effect on improving the cognitive functioning and quality of life of people with dementia. Based on the evidence arising from studies included in the review, the UK guidelines on dementia recommend that people with mild to moderate dementia be afforded the opportunity to participate in a structured group cognitive stimulation programme (National Institute for Health and Clinical Excellence and the Social Care Institute for Excellence (NICE-SCIE, 2006). More recently, this recommendation has been supported by the World Alzheimer's Report (Prince, 2011).

Reminiscence therapy is an emotion-oriented psychosocial intervention used commonly in dementia and "involves the discussion of past activities, events and experiences, with another person or group of people. This is often assisted by aids such as videos, pictures, archives and life story books" (Woods *et al.* 2005, p.2). Its popularity with both the person with dementia and those caring for them, lies in the premise that, it draws on the person's relatively well preserved ability to recall past memories, as distinct from focusing on their diminished capacity to remember more recent events (Woods *et al.* 2005). Memories recalled may be used in a general discussion between the person with dementia and their carers, amalgamated into

individual care plans and/or may be incorporated into a meaningful activity such as the creation of a life story book (Gibson, 2004; 2006; Woods *et al.* 2005; Schweitzer & Bruce, 2008).

While reminiscence is used extensively in dementia care, little is known about its effectiveness as a care intervention (Moos & Bjorn, 2006). Most studies evaluating the effectiveness of reminiscence have employed qualitative, descriptive or observational designs with few robust experimental designs (Finnema *et al.* 2000; Woods *et al.* 2005; McKeown *et al.* 2006). Reminiscence researchers suggest that it may improve the quality of life, mood, wellbeing and reduce behavioural problems in people with dementia (Gibson, 2004; Moos & Bjorn, 2006; Schweitzer & Bruce, 2008). In the most recent Cochrane systematic review on reminiscence therapy in dementia, Woods *et al.* (2005) argue that, following reminiscence therapy, there was some evidence of an improvement in cognition and in general behaviour in people with dementia, a decrease in caregiver strain and an improvement in staff members knowledge of the persons' background. Five randomised controlled trials were included in the review, although only four trials with a total of 144 participants had extractable data. The included studies were small and of relatively low quality, with variations in outcomes and diverse forms of reminiscence therapy, resulting in inconclusive evidence on overall effectiveness. The review authors concluded that, the effectiveness of reminiscence as a psychosocial intervention for people with dementia remains uncertain and, suggest the necessity for further robust evaluation of reminiscence interventions for people with dementia, using treatment protocols that define clearly the type of reminiscence being undertaken and its aims.

The **DementiA** education programme incorporating **Re**miniscence for **S**taff (**DARES**) intervention, a **s**tructured **e**ducation **r**eminiscence-based **p**rogramme for **s**taff (**SERPS**) was designed to address some of the unanswered questions regarding the effectiveness of reminiscence therapy in the care of people with dementia. The trial, which was funded by the Health Research Board, involved the delivery of the SERPS to staff, who subsequently integrated reminiscence into the care of residents with dementia over an 18-week period.

The DARES study defined reminiscence therapy as the deliberate use of prompts, including photographs, smells, music and questioning, to promote the recall of pleasant

memories. Reminiscence was viewed as a one-to-one interaction between the person with dementia and a staff member, except where working in a small group was more appropriate, as determined by the capacity and needs of the individual with dementia. Reminiscence was both planned, i.e., where reminiscence is the specific focus of the interaction with the person with dementia, and spontaneous, i.e., the opportunistic use of reminiscence while providing nursing care. The aim of using reminiscence with residents with dementia was to stimulate the person, provide enjoyment and foster a sense of achievement and self-worth. The anticipated outcomes for participating residents with dementia of using reminiscence were improvement in the person's quality of life, behaviour and mood. Perceived outcomes for staff participants was a reduction in the burden of caring for their designated residents (O'Shea *et al.* 2011; Dempsey *et al.* 2012).

1.2 Aim of the DARES study

The aim of the DARES study was to evaluate the effectiveness of a structured education reminiscence-based programme for staff on the quality of life of residents with dementia in long-stay units.

1.3 Objectives

- To develop a comprehensive structured education reminiscence-based programme for staff caring for people with dementia in long-stay units;

- To evaluate the effectiveness of a structured education reminiscence-based programme for staff on the quality of life, behaviour (perceived levels of agitation) and mood (perceived levels of depression) of residents with dementia in long-stay units within the context of a cluster randomised trial; and

- To evaluate the effectiveness of a structured education reminiscence-based programme for staff on their perceived burden of caring for residents with dementia within the context of a cluster randomised trial.

1.4 Structure of the thesis

The thesis is presented in seven chapters. Chapter 1, this introductory chapter, presents a background to the study, including rationale for the DARES study and outlines the aims and objectives. Chapter 2 presents a literature review of dementia,

including definition, clinical manifestations, dementia sub-types and aetiology, an overview of dementia prevalence and incidence internationally and nationally, an overview of treatments for dementia, both pharmacological and non-pharmacological with a particular focus on reminiscence therapy. Chapter 3 presents a systematic review and meta-analysis of the effectiveness of reminiscence therapy for people with dementia residing in long-stay care. Chapter 4 details the design, conduct and analysis of the DARES study. The structure and content of this chapter is guided by the most recent Consolidated Standards for Reporting Trials (CONSORT) 2010 statement: extension to cluster randomised trials (Campbell *et al.* 2012), which details information to be included in the reporting of a cluster randomised trial. Chapter 5 presents a detailed narrative description of the findings from the DARES study. Chapter 6 provides a brief synopsis of the key findings from the DARES study and explores possible explanations for how these findings may have occurred. The findings from the DARES study are then used to update the current body of evidence on the effectiveness of reminiscence for people with dementia residing in long-term care presented in Chapter 3. Limitations of the DARES study are also discussed here. Chapter 7 details my unique contribution to knowledge and makes recommendations for policy, practice and future research arising from the conduct and findings of the DARES study.

Chapter 2
Literature review

2.1 Introduction

This chapter explores the literature relating to dementia. Following an initial search of the literature retrieved, a number of key themes relevant to this thesis emerged and subsequently informed the structure and content of this chapter. Themes identified from the literature were:

- Definition and clinical manifestations of dementia;
- Dementia subtypes and aetiology;
- Prevalence and Incidence of dementia globally and in Ireland
- Economic burden of dementia;
- Dementia diagnosis globally and in Ireland;
- International dementia strategies/plans and implications for Ireland;
- Approaches to dementia treatments, a brief overview of both pharmacological and non-pharmacological interventions;
- Reminiscence therapy for people with dementia; and
- Conclusion-summary of findings and implications for my research.

2.2 Literature search

The following electronic data bases were searched: Medical Literature Analysis and Retrieval System Online (MEDLINE 1948-2013), Cumulative Index to Nursing and Allied Health Literature (CINAHL 1988-2013), Exerpta Medica (EMBASE, 1980-2013), PsycINFO (1987 to 2013). A search of the Cochrane Dementia and Cognitive Impairment Group Database of Systematic Reviews (1992-2013) was also conducted. Extensive searches using manual discovery were also undertaken. Reference lists of journal articles and books were searched to identify additional relevant literature. Books and relevant PhD theses identified via the literature searches were accessed via the National University of Ireland, Galway, and Nursing & Midwifery library. Search terms used in the literature search were dement*, Alzheimer*, definition, patholog*, clinical manifest*, prevalence, incidence, cause, type*, behavio(u)r, BPSD, national strategy*, national plan*, public polic*, Ireland. Intervention search terms included: non pharmacolog*, pharmacolog* psychotherapy, psychosocial, cognitive therap*,

behavio(u)r, person cent*, emotion-oriented, therap* stimulation-oriented therap*. Search terms were combined with the 'and' and 'or' Boolean operands as appropriate. The search was not limited by date, study design or publication type, except those imposed by the databases themselves. As resources for translation services were unavailable, the search was restricted to literature published in the English language only.

2.3 Dementia: definition and clinical manifestations

The term dementia is derived from the Latin word *demens* meaning 'without mind' (Sachdev, 2000). It is a clinical term used to describe a number of different brain disorders that share common clinical manifestations (Wimo & Prince, 2009; Hoe & Thompson, 2010). Progressive and debilitating in nature, dementia is a terminal disease that is largely, but not exclusively, a disorder of old age (O'Shea, 2007; O'Shea *et al.* 2011). Dementia is one of the main contributing factors to disability and dependency (i.e., need for care) in later life (WHO, 2012).

Characterised by widespread impairment of different parts of the brain, initial manifestations of dementia impact largely on the person's cognitive functioning, leading to progressive memory loss, increasing levels of confusion and disorientation, affecting the person's ability to engage in daily living as well as in social and occupational functioning. As the disease advances, verbal communication becomes increasingly problematic because of the gradual loss of speech and language. Cognitive symptoms are often accompanied by behavioural and psychological symptoms of dementia (BPSD), which are also referred to in the literature as neuropsychiatric symptoms or behaviours that challenge (Finkel *et al.* 1996; Howard, 2001; Lawlor, 2000; Zuidema, 2007; Orgeta *et al.* 2011). Behavioural symptoms include wandering, agitation, aggression, insomnia, sexually inappropriate behaviour, hoarding and cursing. Psychological symptoms include depression, apathy, anxiety and psychosis (hallucinations and delusions) (NICE-SCIE, 2007; International Psychogeriatric Association (IPA), 2008). Prevalence rates of BPSD in dementia range from 61% (Lyketos, 2002) to 92% (Ikeda, 2004) and are most prevalent in people with dementia residing in long-stay care facilities (Brodaty *et al.* 2003). Untreated BPSD impact negatively on the quality of life for all concerned and may result in frequent hospitalisations and early placement into long-stay care facilities (Cohen-Mansfield *et al.* 1989; Cahill *et al.* 1997; Moïse *et al.* 2004; Argyle *et al.* 2010).

Disease progression for dementia is generally described in three stages; early stage (1-2 years), middle stage (2-5 years) and late stage (5th year and after) (WHO, 2012) or may also be described as; mild, moderate and severe stages (Hoe & Thompson, 2010). That said, O'Shea (2007, p.7) reasons that because of the diversity of symptoms throughout the course of the illness, not everybody with dementia will move neatly from one stage to the next but that, "the uniqueness of the disease must therefore, be acknoweldged, in that, no two individuals with dementia are likely to be affected in precisely the same way".

2.4 Dementia subtypes and aetiology

Alzheimer's disease, first described by Dr. Alois Alzheimer, a German psychiatrist and neuropathologist in 1906, is the most common type of dementia, accounting for 60% to 80% of all cases (Alzheimer's Association, 2012). Alzheimer's disease is a neurodegenerative disorder, caused by the development of 'amyloid plaques' and 'neurofibirillary tangles' forming in structures of the brain leading to the progressive degeneration of neurons or braincells (Birks, 2006). The onset of symptoms in Alzheimer's disease are slow and insidious in nature, aptly described by Cahill *et al.* (2012, p.7) as an illness that tends to "creep up on people". Other neurodegenerative causes of dementia are Dementia with Lewy bodies, Frontotemporal Dementias such as Pick's Disease, Parkinson's disease dementia and Huntington's disease.

Vascular dementia is the second most common type of dementia and is caused by the narrowing or blockage of blood vessels, which disrupt the blood supply to the brain, typically caused by stroke or serious of small strokes (Merck, 2007; Rands & Orrell, 2012). The onset of vascular dementia is often sudden in nature, and symptoms of dementia follow a step-wise progression, where periods of stability are often interrupted by periods of rapid decline, following additional strokes or mini strokes (Merck, 2007). Less common causes of dementia are those caused by viral, bacterial and parasitic Infections such as dementia associated with the human immunodeficiency virus (HIV) and Creutzfeldt-Jacob Disease (CJD). Korsakoff's dementia is caused by vitamin B1 or thiamine depletion, which can arise from some toxic or metabolic diseases. Vitamin B1 deficiency is associated commonly with alcoholism (Merck, 2007; Day *et al.* 2004).

With advances in diagnostic testing for dementia, it is becoming increasing apparent that mixed pathologies of dementia subtypes are much more common than 'pure' ones (WHO, 2012). Post mortem results of 1000 peolple with dementia reported that although 86% had pathologies related to Alzheimer's disease, only 43% had 'pure' Alzheimer's disease, 26% had mixed pathologies stemming from Alzheimer's disease and vascular dementia, 10% had pathology related to Alzheimer's disease and Dementia with Lewy Bodies (Jellinger, 2006; WHO, 2012).

2.5 Prevalence of dementia globally and in Ireland

Findings from two epidemiological studies estimating the worldwide prevalence of people aged 60 and over with dementia have reported different prevalence rates. Ferri *et al.* (2005) estimated that in 2001 there were 24.2 million people aged 60 and over living with dementia, forecasting that this figure would double every 20 years to 42 million by 2020, increasing to 81 million by 2040. However, more recent estimates indicate that in the year 2010, 35.6 million people aged 60 and over were living with dementia worldwide and predict that this figure would double every 20 years to 65.7 million in 2030, increasing to 115.4 million by 2050 (Prince & Jackson, 2009). Revised estimates by Prince & Jackson (2009) are approximately 10% higher than those estimated by Ferri *et al.* (2005).

From a Western European perspective, Ferri *et al.* (2005) estimated that in 2001 there were 4.9 million people living with dementia, predicting that this figure would reach 9.9 million by 2040. Revised estimates by Prince & Jackson (2009) were less conservative, indicating that in 2010 there were 7 million Western Europeans with dementia and projections that this figure would increase to 10 million in 2030, increasing to 13.4 million in 2050. Both Ferri *et al.* (2005) and Prince & Jackson (2009) concur that relative to other world regions, Western Europe has the greater number of people with dementia.

From an Irish perspective, the dearth of reliable epidemiological data reporting on the prevalence of dementia in the general population and in people with intellectual disability (ID), including those with Down syndrome, makes it difficult to provide accurate estimates of the number of people living with dementia in Ireland (Cahill *et al.* 2012). Applying the European age/gender specific prevalence estimates to the 2006 Census of Population data, Cahill *et al.* (2012) estimated that there are 41,740 Irish

people with dementia, of whom 3,583 are under 65 years of age, and forecast that this will increase to 67,493 in 2021, representing a 63% increase, rising to 140.580 in 2041, corresponding to a 240% increase from 2006 to 2041. The most discernible growth in the number of Irish people with dementia will be in people aged 85 years and older. Cahill *et al.* (2012) caution that prevalence rates of dementia in Ireland are likely to be marginally underestimated as they do not include the number of people with Down syndrome because, while the Irish Census does provide information on the number of people with an intellectual disability, the Census does not specify disability type.

2.6 Incidence of dementia globally and in Ireland

Estimates of worldwide incidence of dementia indicate 7.7 million new cases of dementia each year, equating to one new case of dementia every four seconds of which 2.3 million (31%) will impact on Europe (WHO, 2012). Ireland will have approximately 4000 new cases of dementia per year (O'Shea, 2007).

2.7 Cost of dementia: globally and in Ireland

The worldwide cost of dementia has been estimated at US$604 billion (Wimo & Prince, 2010). Reviewing the economic burden of dementia in Europe, Wimo *et al.* (2011) reported that the total cost of dementia disorders is approximately €160 billion. In Ireland, Cahill *et al.* (2012) estimated the annual cost of dementia in Ireland in 2010 was €1.69 billion, equating to €40,511 per person with dementia.

2.8 Dementia diagnosis

Dementia is under diagnosed worldwide and when it is diagnosed it is usually late into the disease process (Prince *et al.* 2013). Globally, fewer than 1 in 4 people with dementia receive a clinical diagnosis of dementia (Prince *et al.* 2011). At a primary care level, Prince *et al.* (2011) suggest that in high-income countries, only 20% to 50% of dementia cases are identified and documented accordingly. The World Alzheimer Report (Prince *et al.* 2011) identified three barriers to dementia diagnosis, namely, the associated stigma, a misguided belief that cognitive decline is a normal part of the aging process and the erroneous belief that nothing can be done for people with dementia and their families.

Cahill *et al.* (2012) suggest that there are 26,104 people living with dementia in the community in Ireland, the majority of who do not have a formal diagnosis of dementia. Long Stay Activity Statistics compiled by the Department of Health and Children (2009), estimated that, in 2008 there were 22,613 Irish people residing in long-stay care facilities and 26% of those were described as having dementia, representing just under 5,880 of the long-stay population. Given that in Ireland, as in other European countries, dementia diagnosis is frequently the exception rather than the rule (Leifer *et al.* 2003; Bamford *et al.* 2004; Wilkins *et al.* 2007; Cahill *et al.* 2008), Cahill & Diaz-Ponce (2010) suggest that this official estimate of 26% is a gross underestimation, arguing that it is out of line with international figures, which indicate that in the United States and Europe approximately 50-60% of residents in long-stay residential care are reported as having dementia (Helmer *et al.* 2006; Knapp *et al.* 2007). Cahill *et al.* (2012) estimate that there are 14,266 people with dementia residing in public and private long-term care facilities in Ireland, representing 63.1% of the total long-stay population. This figure is considerably greater than the 26% suggested by the Department of Health and Children (2009). A recent Irish study undertaken in four long-stay care facilities in the Eastern region of Ireland reported that 89% of residents were cognitively impaired (Cahill *et al.* 2010) and 42% had severe cognitive impairment. Such findings are contrary to the official reported figures. However, it is worth noting that in the same study, Cahill *et al.* (2010) acknowledge that moderate to severe cognitive impairment as indicated by the Mini Mental State Examination (MMSE) (Folstein *et al.* 1975) is not synonymous with a diagnosis of dementia, but they suggest that, of the total sample of nursing home residents included in the study, it is likely that there may have been a high degree of undiagnosed or undetected dementia.

2.9 International dementia strategies/plans and implications for Ireland.

It comes as no surprise that, given the seriousness of the impact of dementia on all associated with the illness, the aging population and the increasing prevalence of dementia with advancing age, the World Health Organization (2012) has declared dementia a national and world health priority. Many countries around the world including Australia, Canada, the United States, France, England, Scotland, Norway and the Netherlands have responded to the growing epidemic of dementia and have developed National Dementia Strategies underpinned by evidence-based approaches (Cahill *et al.* 2012). National Dementia Strategies provide for the financing of

appropriate infrastructure and the provision of adequate services for people with dementia with the aim of enabling them to live well with dementia from diagnosis to the end of life (WHO, 2012).

In the Irish context, in order to inform public policy and guide the development of the proposed Irish Dementia Strategy, a core group of Irish dementia researchers' reviewed National Dementia Strategies from seven European countries. Additional reviews were carried out on best practice approaches to dementia care in Canada and Australia and input was sought from international experts in the field of dementia (Cahill *et al.* 2012). The subsequent report titled '*Creating Excellence in Dementia Care. A Research Review for Ireland's National Dementia Strategy'* (Cahill *et al.* 2012) identified a number of key elements that should be incorporated into the proposed Dementia Strategy for Ireland. Briefly summarised here, they include: greater prominence on primary prevention of dementia, addressing modifiable risks factors such the prevention of obesity, diabetes and heart disease; improved access to memory clinics to facilitate early and differential diagnosis of dementia; development of support services for family caregivers; provision of training and education in dementia specific skills for staff caring for people with dementia in all care settings; the need to integrate psychosocial approaches that may be used by trained staff to promote wellbeing and improve the quality of life for people with dementia residing in long-term residential care; development of appropriate care environments that offer an alternative to the conventional nursing home model of care, to include, hostels, sheltered housing and specialist care units; expansion of palliative care facilities for people dying from dementia and; the development of services for people with early onset dementia, including people with Down syndrome (Cahill *et al.* 2012) .

Currently, staff members working with people with dementia in the long-stay setting in Ireland are required to have the knowledge, skills and attitudes necessary to meet the specific needs of residents with dementia including integrating psychosocial approaches to care (HIQA, 2009). The HIQA dementia-specific Supplementary Standards (2009), criteria 18.8 (p.65) states that, staff should "use personal items, appropriate therapies and activities to promote quality of life and well-being for each resident". Criteria 18.9 (p.65) stipulates that "person-centred communication is encouraged in all interactions" and criteria 18.10 (p.66) proposes that "techniques such as life stories, reminiscence…. are used to enhance communication". Cahill *et al.*

(2012) highlight that, contrary to these requirements, health care professionals caring for people with dementia in long-stay settings in Ireland are inadequately trained to provide for the needs of residents with dementia. This view is supported by a number of Irish studies (Murphy *et al.* 2006; Heath, 2010; Cahill & Diaz-Ponce, 2011). For example, in a survey of healthcare professionals working in long-stay care facilities, Cahill *et al.* (2011) reported that only 26% of nurses and 17% of healthcare assistants had received dementia training. Research undertaken by the All Ireland and Gerontological Nurses Association (AIGNA) (Heath, 2010) reported that nurses felt they needed to be trained in "complimentary therapies" (p.52), thus enabling "residents to live a more full life while in a long term-care facility" (p.52).

The need to improve the quality of life for people with dementia in all care settings is a key theme across all established National Dementia Strategies (WHO, 2012) and is well regarded as a key outcome in the provision of care (Edelman *et al.* 2005; Cahill *et al.* 2012). That said, there is evidence to suggest that residents with dementia residing in long-term care rate their quality of life lower than people with dementia residing at home (Selwood *et al.* 2005; Hoe *et al.* 2007). Brooker *et al.* (2007) argue that residents with dementia face enormous challenges in terms of their quality of life, coupled with an on-going deterioration in cognition and a greater need for familiarity and human interaction, they are often faced with having to cope with a busy, unfamiliar environment, cared for by staff who may know little about the individual resident's background and whose motivation is, predominantly, in providing for the residents' physical health needs, rather than providing for their emotional wellbeing. Echoing the sentiment of dementia researchers, National Dementia Strategies suggest that, there is an urgent need to change the culture of care for residents with dementia living in long-term care to one of personhood, dignity and empowerment (WHO, 2012).

2.10 Treatments for dementia

There is no single cause of dementia and as yet there is no known cure. There are, however, a variety of pharmacological and non-pharmacological approaches to dementia treatment.

2.10.1 Pharmacological interventions

The biomedical model of care underpins pharmacological interventions for dementia (Boote *et al.* 2006). The biomedical model centres on understanding the 'cause' and

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seeking a 'cure' for dementia (Cahill *et al.* 2012). Failing that, there is an over-arching focus on symptom control using pharmacological approaches, which are not always agreeable with a mind and body already compromised by the degenerative nature of dementia (Bates *et al.* 2004; Boote *et al.* 2006). Pharmacological interventions seek to slow down the rate of cognitive decline and alleviate behavioural and psychological symptoms associated with such decline (Qaseem *et al.* 2008). Drugs such as acetylcholinesterase inhibitors (AChEIs), specifically, donepezil (Aricept), galantamine (Reminyl) and rivastigmine (Exelon), are used to treat symptoms in the mild to moderate stages of Alzheimer's disease while Mementine (Ebixa) is indicated in the moderate to severe stages of Alzheimer's disease (Overshott & Burns, 2005; Birks, 2006; Hogan *et al.* 2008; Hoe & Thompson, 2010).

In addition to AChEIs and Mementine, a number of other pharmacological interventions are available for the treatment of behavioural and psychological symptoms, including multiple classes of medications such as antidepressants, benzodiazepines, mood stabilizers and antipsychotics medications. However, because these medications have demonstrated limited efficacy in the treatment of BPSD (Tampi *et al.* 2011; Prince *et al.* 2011) and are associated with side-effects that can adversely affect the person with dementia, best practice guidelines recommend that non-pharmacological approaches are initiated as first-line treatment for BPSD (NICE-SCIE, 2006; WHO, 2012; Alzheimer's Disease International, 2012). Nonetheless, contrary to best practice guidelines, there is evidence to suggest that these medications are being used as a first line treatment for BPSD (Banerjee, 2009).

Concerns have been raised internationally about the over prescribing of antipsychotic medications for the treatment of behavioural and psychological symptoms of dementia, particularly in long-stay care facilities (Fossey *et al.* 2006; Ballard *et al.* 2006; Murphy & O'Keeffe, 2008; Banerjee, 2009; Richter *et al.* 2012). Extensive research has demonstrated that antipsychotic medications can cause significant harm to people with dementia including increased risk of cardiovascular accident events and mortality (Schneider *et al.* 2006; Ballard, 2006; 2009; Banerjee, 2009). Banerjee (2009) estimated that in 2009, 180,000 people with dementia across the United Kingdom were prescribed antipsychotic medication of which 20% (n=36,000) were expected to derive some benefit from the treatment. Banerjee (2009) cautioned that should this prescribing trend continue, it would equate to 1,620 cerebrovascular adverse events

and to an additional 1,800 deaths per year beyond that which would occur if antipsychotics medications were not prescribed for people with dementia.

2.10.2 Non-pharmacological interventions in dementia

The fact that not everyone with dementia responds favourably to pharmacological approaches has pioneered the way for alternative approaches to care. Non-pharmacological or more commonly referred to as psychological or psychosocial interventions have become popular in the field of dementia and accordingly, their effectiveness for people with dementia have been increasingly researched over recent years (Bates *et al.* 2004; Boote *et al.* 2006). Bates *et al.* (2004) define the word 'psychosocial' as "implying human interactive behaviour between therapist and client" (p.645). Unlike the biomedical model of care, which is focused on the 'disease' and not the 'person' with the disease, a psychosocial framework informs psychosocial interventions where "the person with dementia is central to and involved in their care" (Bates *et al.* 2004, p.645). Common to all psychosocial approaches is the endeavour to understand the affected individual's experience of dementia and, to employ strategies which optimise functioning and quality of life (Clare *et al.* 2003; Douglas *et al.* 2004). Dementia researchers suggest that integrating evidence-based psychosocial approaches with medical and nursing models of care delivery is fundamental to cultivating a person-centred approach for people with dementia (Kitwood, 1997; Keady *et al.* 2004; Brooker *et al.* 2007; Schweitzer & Bruce, 2008; Cahill *et al.* 2012). However, O'Shea (2007) suggests that, if healthcare professionals caring for people with dementia are expected to integrate psychosocial approaches into routine care, staff training in psychosocial approaches is essential.

2.10.3 Psychosocial interventions in dementia

Psychosocial interventions take on a variety of forms but they are typically classified into four approaches: cognitive-oriented, stimulation-orientated, behaviour-oriented and emotion-oriented approaches. Outcomes associated with psychosocial interventions include an improvement in behaviour, mood and cognition (American Psychiatric Association (APA), 1997; Finnema *et al.* 2000; Douglas *et al.* 2004).

2.10.3.1 Cognitive-oriented approaches

Cognitive-oriented approaches target the cognitive symptoms of dementia, and are generally implemented in the early stage of the illness (Clare *et al.* 2003). Cognitive-oriented approaches are classified into three main strands, namely, cognitive stimulation therapy, cognitive training and, cognitive rehabilitation (Takeda *et al.* 2012).

2.10.3.1.1 Cognitive stimulation therapy

Cognitive stimulation therapy incorporates the techniques and principles of reality orientation (Claire *et al.* 2003). Woods *et al.* (2012, p.1) describe cognitive stimulation therapy as a form of mental exercise which "offers a range of enjoyable activities providing general stimulation for thinking, concentration and memory usually in a social setting, such as a small group". Cognitive stimulation includes a variety of activities, including word games, puzzles, discussion of past and present events, and engagement in activities such as gardening and cooking. A recent Cochrane review (Woods *et al.* 2012) evaluating the effectiveness of cognitive stimulation to improve the cognitive functioning of people with dementia included fifteen RCTs with a total of 718 participants concluded that cognitive stimulation interventions improved the cognitive functioning and quality of life of people with mild to moderate dementia.

2.10.3.1.2 Cognitive training and cognitive rehabilitation

Cognitive training "involves guided practice on a set of tasks that reflect particular cognitive functions, such as memory, attention, or problem-solving, which can be done in a variety of settings and formats" (Clare *et al.* 2003, p.2). Cognitive rehabilitation "involves identifying and addressing individual needs and goals, which may require strategies for taking in new information or methods of compensating such as using memory aids" (Clare *et al.* 2003, p.2). A Cochrane review (Clare *et al.* 2003) evaluating the effectiveness of both cognitive training and cognitive rehabilitation interventions for early Alzheimer's disease and vascular dementia concluded that, there was no evidence of the effectiveness of cognitive training and insufficient evidence to evaluate the effectiveness of cognitive rehabilitation interventions. Nine RCTs of cognitive training interventions were included in the review. Evaluation of the benefit of cognitive training for dementia was hampered because the interventions used across the included studies were diverse in nature and targeted the person with dementia and/or their caregivers. The nine included studies reported a total of 86 outcomes between

them, and the review authors argued that the diversity of outcome measurements across studies limited the possibilities for meta-analysis. The review authors conclude that there is a need for more rigorous evaluation of cognitive training in dementia which adheres to a core set of outcome measurements.

No trials of cognitive rehabilitation were identified by the review authors and, in the absence of clinical trials the effectiveness of cognitive rehabilitation for people with dementia could not be evaluated. The review authors conclude that, in order to allow a rigorous evaluation of individualised cognitive rehabilitation interventions in early-stage dementia, there is a need for well-designed RCTs of such approaches (Claire *et al.* 2003).

2.10.3.2 Stimulation orientated approaches

Stimulation orientated interventions are diverse in nature and include music therapy, pet or animal assisted therapy, physical therapy and occupational therapy. Outcomes associated with stimulation-orientated approaches to care include a reduction in agitation, increased wellbeing and improved social interactions (Douglas *et al.* 2004). Both music and physical therapies have been evaluated in Cochrane reviews (Forbes *et al.* 2008; Vink *et al.* 2011) and the findings suggest that, as yet, there is insufficient evidence of the benefits of either of these approaches for people with dementia. Review authors, in both reviews, suggest the need for more rigorous evaluations of music and physical therapy interventions and highlight the need to incorporate validated outcome measurements.

2.10.3.3 Behaviour-oriented approaches (Functional analysis interventions)

'Behavioural therapy', 'behavioural management' and, 'behavioural modification', intervention programmes are collectively described as functional analysis programmes (NICE, 2006). Functional analysis interventions are underpinned by the unmet needs theory, which proposes that behavioural and psychological symptoms of dementia, or 'behaviours that challenge,' are manifestations of distress in the person with dementia or distress in their caregivers, which arise from an unmet need(s) of a physical or psychological nature (Gibson, 2006; Bird & Moniz-Cook, 2008). Typically, functional analysis intervention programmes require the trained therapist to develop an

understanding of the possible causes and behavioural consequences of unmet needs, and use this understanding to devise individually tailored strategies, aimed at both the person with dementia and their caregivers, to address their unmet need(s), with the aim of alleviating their distress (Moniz-Cook *et al.* 2012). A recent Cochrane review (Moniz-Cook *et al.* 2012) evaluating the effectiveness of functional analysis-based interventions for challenging behaviour in dementia, included 18 trials of functional analysis-based interventions, conclude that the evidence to support the use of functional analysis approaches in managing challenging behaviour in dementia is promising but suggest that it is too early to draw any definitive conclusions about its effectiveness. The review authors suggest the need for further rigorously designed RCTs of functional-analysis interventions in family care and home care settings.

2.10.3.4 Emotion-oriented approaches

Finnema *et al.* (2000, p.142) describe emotion-oriented care as: "care aimed at improving emotional and social functioning, and ultimately the quality of life, of people suffering from dementia by supporting them in the process of coping with the cognitive, emotional and social consequences of the disease and by linking up with individual functional possibilities and the subjective experience of the person in question". Such interventions include multisensory stimulation and reminiscence therapy (Finnema *et al.* 2000).

2.10.3.4.1 <u>Multisensory stimulation</u>

Multisensory stimulation, also called snoezelen therapy, stimulates the primary senses using tactile surfaces, soft music, lighting effects and scented oils (Chung & Lai, 2008). The rationale for multisensory stimulation lies in the assumption that the provision of a sensory environment for the person with dementia places less stress on diminishing cognitive abilities and maximises their remaining sensorimotor abilities. Initial evaluations of snoezelen therapy indicated that it was useful in the treatment of behavioural and psychological symptoms (Chung *et al.* 2002; Livingston *et al.* 2005). However, findings from an updated Cochrane systematic review by Chung & Lai (2008), in which two RCTs with a total of 246 participants are included, concluded that, snoezelen did not have a significant positive effect on mood, behaviour or communication.

2.10.3.4.2 <u>Reminiscence therapy</u>

Reminiscence therapy was first introduced into dementia in the mid-1980's (Norris, 1986) and involves the recall of past events, activities and experiences, with another person or group of people. The recall of past memories is often stimulated with the aid of tangible prompts or triggers such as old photographs, films and music (Woods *et al.* 2005). Reminiscence therapy is used commonly in dementia and is rated highly by both the person with dementia and their carers (Woods *et al.* 2005; Wang, 2007; Cotelli *et al.* 2012). Researchers suggests that reminiscence therapy may improve the quality of life of people with dementia, improve mood and wellbeing and reduce behavioural problems (Douglas *et al.* 2004; Woods *et al.* 2005: Moos & Bjorn, 2006).

<u>How Reminiscence therapy works</u>

Although sooner or later dementia affects all cognitive functions, recent or short term memory is typically lost in the early stages of the disease process, while remote or long term memory, which stores autobiographical details of one's life, remain's relatively intact far into the illness (Clare *et al.* 2003; Basso *et al.* 2003; Klein *et al.* 2004). Reminiscence therapy draws on the person's preserved ability to recall past memories, events or experiences and in this way averts from other diminishing cognitive functions, namely, recent or short term memory functioning, for which there is no redress (Kasl-Godley & Gatz, 2000; Woods *et al.* 2005; Gibson, 2006; Schweitzer & Bruce 2008; Woods *et al.* 2012). Similar to snoezelen therapy, reminiscence therapy uses the five senses to stimulate the retrieval of past memories. Differents smells, textures, photographs, sounds, and food stuffs are just some of the triggers or prompts that are utilised in the reminiscece process (Wang *et al.* 2007; Tadaka & Kanagawa, 2007; Hsieh *et al.* 2010)

Memories recalled can be used in a general discussion between the person with dementia and their carers or might be used in creating a life story book. Accessing remote memory and linking into autogiographical memories via multisensory stimuli is associated with positive changes in integration of the self, in affecting functioning in a positive way and in improving social interaction (Aldridge, 2000; Thorgrimsen *et al.* 2002; Greenyer, 2003; Gibson, 2006; Moos & Bjorn, 2006). It also provides the person with a sense of personal continuity by linking past knowledge and skills that are familiar into the present (Parker, 1995; Gibson, 2006). Moos & Bjorn (2006) contend that, in the spirit of person-centred care, staff caring for the person with dementia in

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long-stay care facilities should use reminiscence therapy to enhance their knowledge of the resident's past and integrate this knoweldge into delivering care that is, both individual and personal in approach.

Effectiveness of reminiscence therapy in dementia

Although reminiscence therapy is used extensively in dementia, little is known about its effectiveness as an intervention (Moos & Bjorn, 2006). Evaluations have employed qualitative, descriptive or observational methods with few large, robust trials evaluating its effectiveness (Finnema *et al.* 2000; Lin *et al.* 2003; Woods *et al.* 2005; McKeown *et al.* 2006; Coteilli *et al.* 2012). Findings from the most recent Cochrane systematic review on reminiscence therapy for dementia indicated that there was some evidence to suggest that reminiscence therapy had a positive impact on behaviour, cognition, mood, caregiver strain and improved staff knowledge of the residents' background. Table 1 presents a summary of studies included in the review, which consisted of five RCTs (Bains *et al.* 1987; Goldwasser *et al.* 1987; Morgan, 2000; Thorgrimsen *et al.* 2002; Lai *et al.* 2004) with a total of 171 participants. Data from one trial (Goldwasser *et al.* 1987) could not be extracted; consequently only four trials with a total of 144 participants were included in the meta-analyses.

A review of the quality of included studies

Sample sizes across included studies were small, with the exception of Lai *et al.* (2004), which had a total of 101 participants. Although a pilot study, which by their very nature always have smaller sample sizes, Thorgrimsen *et al.* (2002) had a total of 11 participants with dementia. Assessing the risk of selection bias in the included studies, the review authors judged that only one of the included studies (Thorgrimsen *et al.* 2002) had used an 'adequate' allocation concealment method, suggesting a low risk of selection bias. Allocation concealment in each of the other included studies (Baines *et al.* 1987; Goldwasser *et al.* 1987; Morgan, 2000; Lai *et al.* 2004) was judged 'Unclear'.

Four of the included studies were conducted in long-stay care settings (Baines *et al.* 1987; Goldwasser *et al.* 1987; Morgan, 2000; Lai *et al.* 2004) and staff members in all four studies were expected to deliver both reminiscence and the comparator intervention, which is likely to have caused contamination across study groups (Woods *et al.* 2005). The review authors comment that the risk of contamination across study

groups would have been considerably reduced had included studies been guided by clear treatment protocols.

Description of treatment interventions and treatment fidelity procedures are generally inconsistent across all of the studies. For example, the reminiscence intervention delivered to participants in the Thorgrimsen *et al.* (2002) study was based on a standardised manual, but, the trial authors did not provide any details of how they assessed adherence to the treatment protocol. Lai *et al.* (2004) failed to give any description of the reminiscence intervention, merely stating that "the intervention adapted a life-story approach" (p.33), but, the trial authors did provide a detailed account of how adherence to the treatment protocol was monitored during the study.

Different types of reminiscence approaches are also apparent across included studies; for example, Morgan (2000) describes the type of reminiscence intervention undertaken as 'individual life review'. Despite the conceptual differentiation provided by Burnside & Haight (1992), researchers continue to use the terms reminiscence and life review interchangeably. The concept of reminiscence therapy for the person with dementia needs to be defined clearly so that the type of reminiscence being undertaken in this population and its aims can be more readily evaluated (Lin *et al.* 2003; Woods *et al.* 2005).

Participants' demographics and clinical characteristics

Table 2-1 demonstrates the heterogeneity in study participants' demographics and clinical characteristics across the different study settings of included trials. It is evident that the mean age was older, and level of cognitive impairment greater, in participants with dementia residing in long-stay care, compared with people with dementia living in the community. Boote *et al.* (2006) argue that review authors have not given due consideration to the appropriateness of psychosocial interventions in the different stages of dementia and suggest that this raises questions about the degree to which evidence stemming from such reviews can be generalised for people in the mild, moderate and more severe stages of dementia. Findings from the Cochrane systematic review evaluating the effectiveness of reminiscence therapy for people with dementia (Woods *et al.* 2005) are therefore limited in this regard.

2.11 Conclusion: summary and implications for my research

Dementia is a multifaceted disease, of which our knowledge and understanding is constantly evolving. Epidemiological evidence presented in this chapter is compelling in demonstrating that dementia is a worldwide epidemic, which has serious consequences for the person with dementia and those caring for them. Dementia is a national and international health priority requiring considerable resources at both a community and residential level to ensure that the person with dementia lives well with dementia.

Pharmacological interventions have limited efficacy and their associated side-effects pose a risk to the person with dementia. National Dementia Strategies and best practice guidelines recommend that staff members caring for the person with dementia in long-stay residential care setting be trained to integrate psychosocial approaches into care delivery. Psychosocial interventions promote wellbeing and improve the quality of life for the person with dementia, because, contrary to the biomedical model of care, they offer a more person-centred approach to care and seek to maximise the preserved abilities of the person with dementia. On the other hand, the absence of sound empirical evidence to support the use of some non-pharmacological or psychosocial approaches is also evident. Reminiscence therapy is a popular psychosocial intervention in dementia, enjoyed by the person with dementia and those caring for them (Woods *et al.* 2005; Woods *et al.* 2012) but evaluations of its effectiveness for dementia are limited by the quality of the evidence arising from a small number of RCTs.

This literature review has identified three key issues that need to be addressed for progress to be made in strengthening the evidence-base for reminiscence therapy for people with dementia: Firstly, there is a need to be clear on the type and aims of the reminiscence being delivered and evaluated. To that end, before undertaking any further empirical research, to inform the development of a reminiscence-based intervention, there is an urgent need to undertake a concept analysis of reminiscence therapy for people with dementia.

Secondly, the most recent Cochrane review evaluating the effectiveness of reminiscence therapy for people with dementia was indiscriminate in terms of the setting in which reminiscence therapy was delivered, and, the different levels of severity of dementia between people with dementia living in the community and people

with dementia living in long-term care. Therefore, our understanding of the value of reminiscence therapy for people with dementia in any particular care setting is unclear. Advancing our knowledge of the value of reminiscence therapy for residents with dementia and how it may impact on their quality of life is pertinent to my research. To that end, there is an urgent need to undertake a systematic review to evaluate the current evidence to support the use of reminiscence for people with dementia residing in long-term care. I acknowledge that findings from this systematic review will be generalisable to people with dementia residing in long-term care settings only.

Thirdly, details presented in Table 2-1, highlight the variation in the modality of reminiscence interventions undertaken i.e., individual and group approaches, heterogeneity of comparator interventions and choice of outcome measures, inconsistency in the frequency, length and duration of reminiscence across studies, different stages of dementia severity, different settings and the disparity in the types of reminiscence undertaken. These factors, coupled with the methodological shortcomings of included studies, have thus far prohibited the rigorous evaluation of reminiscence interventions for people with dementia. To that end, to advance our knowledge of the benefits of reminiscence therapy for people with dementia living in the long-stay care setting, there is an urgent need to conduct a large trial of reminiscence in this setting.

Undertaking such empirical research will contribute to our understanding of reminiscence therapy and how it may impact on the quality of life of residents with dementia. It will inform policy, practice and future research in the care of the person with dementia.

Table 2-1: Summary of reminiscence studies included in Cochrane review (2005)

Author (year)	Interventions	Participants and setting	Study design	Frequency/duration	Outcome (Scale)	Follow-up
Baines et al. (1987)	Group RT. Three groups: Group 1: ROT followed by RT. Group 2: RT followed by RO. Group 3: No treatment	15 nursing home residents (5 to RT followed by ROT, 5 to ROT followed by RT, 5 no treatment). Moderate to severe cognitive impairment. Mean age: 81.5	Cross over design	RT for 30 minute sessions, 5 days per week for 4 weeks. 4 week washout period. RO for 30 minute sessions, 5 days per week for 4 weeks.	Cognition: CAPE Behaviour: CAPE BRS, PBRS Communication: HCS Wellbeing: LSI Staff knowledge of residents' background: PIQ	None
Goldwasser et al. (1987)	Group RT. Three groups: Group 1: RT Group 2: Support group Group 3: No treatment	27 nursing home residents (9 to RT, 9 to supportive therapy, 9 to control). Mean MMSE score:10.1 Mean age: 82.3	RCT	RT group: 30 minute sessions, twice weekly for 5 weeks. Support group: 30 minute sessions, twice weekly for 5 weeks. Control group: no treatment	Cognition: MMSE Behaviour: Katz ADL Wellbeing: BDI	6 weeks
Morgan (2000)	Individual life review. No treatment	17 nursing home residents (8 to RT, 9 to no treatment). .Each with mild to moderate dementia on CDR scale	RCT	Individual life review for an average of 12 sessions.	Wellbeing: LSI Cognition: AMI Mood: GDS	6 weeks
Thorgrimsen et al. (2002)	Group RT. Two groups: Group 1: RT Group 2: No treatment	11 people with dementia living in the community (7 to RT, 4 to no treatment). Mean MMSE score: 12.8 Mean age: 76.3	RCT	RT group: one session per week for 18 weeks for family caregivers, 7 of which were joint sessions with both family caregiver and person with dementia.	Cognition: MMSE Behaviour: CAPE BRS Communication : HCS Wellbeing: QOL-AD Caregivers' stress: GHQ-12, RSS	None
Lai (2004)	Individual RT Individual social contact No treatment	101 nursing home residents (36 to RT, 35 to social contact, 30 to no treatment). Mean age: 85.7 Mean MMSE score: 9.4	RCT	RT: one session per week for 6 weeks Social contact group: one session per week for 6 weeks.	Cognition: MMSE Behaviour: MDS-ADL Communication: SES Wellbeing: WIB	6 weeks

RT: Reminiscence therapy; ROT: Reality orientation therapy; CAPE: Clifton Assessment Procedures for the Elderly; CAPE BRS: Clifton Assessment Procedures for the Elderly Behaviour Rating Scale; PBRS: Problem Behaviour Rating Scale; HCS: Holden Communication Scale; LSI: Life Satisfaction Index; PIQ: Personal Information Questionnaire; MMSE: Mini Mental State Examination; Katz ADL: Katz Index of Activities of Daily Living; BDI: Beck's Depression Inventory; AMI: Autobiographical Memory Interview; GDS: Geriatric Depression Scale; GHQ-12: General Health Questionnaire; RSS: Relative Stress Scale; MDS-ADL: Minimal Data Set- Home Care (self-care scale)SES: Social Engagement Scale; WIB: Wellbeing/Ill-being Scale.

Chapter 3

Systematic review of reminiscence therapy for dementia

3.1 Introduction

This chapter presents a systematic review and meta-analysis of the effectiveness of reminiscence therapy for people with dementia in long-stay residential care settings. This review updates and extends the current Cochrane systematic review by Woods *et al.* (2005) on reminiscence therapy for dementia in the following three ways:

1. It takes cognisance of the most recent recommendations to improve the assessment and reporting of publication bias, heterogeneity and statistical methods undertaken in a meta-analysis (Riley *et al.* 2011);

2. Searches were extended beyond randomised controlled trials (RCTs) and controlled clinical trials (CCTs)[1] to include eligible controlled before and after studies (CBAs)[2] and interrupted time series studies (ITSs)[3]; and

3. The diagnosis of dementia in participants was extended beyond a formal diagnosis as determined by the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) (American Psychiatric Association (APA), 1994) and/or the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) (WHO, 1992) to include a more pragmatic approach to diagnosis (see section 4.3.1.2).

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[1] An experimental study in which people are allocated to different interventions using methods that are not random. Cochrane Effective Practice and Organisation of Care Review Group (EPOC) (2010) *Data Collection Checklist* [Online]. Available: http://epoc.cochrane.org/epoc-resources-review-authors

[2] A study in which observations are made before and after the implementation of an intervention, both in a group that receives the intervention and in a control group that does not. Cochrane Effective Practice and Organisation of Care Review Group (EPOC) (2010) *Data Collection Checklist* [Online]. Available: http://epoc.cochrane.org/epoc-resources-review-authors

[3] A study that uses observations at multiple time points before and after an intervention (the 'interruption'). The design attempts to detect whether the intervention has had an effect significantly greater than any underlying trend over time. Cochrane Effective Practice and Organisation of Care Review Group (EPOC) (2010) Data Collection Checklist [Online]. Available: http://epoc.cochrane.org/epoc-resources-review-authors

3.1.1 Why is it important to do this review?

The most recent Cochrane review evaluating the effectiveness of reminiscence for people with dementia was indiscriminate in terms of the setting in which reminiscence therapy was delivered and the different levels of severity of dementia between people with dementia living in the community and people with dementia living in long-term care. Therefore, our understanding of the value of reminiscence therapy for people with dementia in any particular care setting is unclear. Advancing our knowledge of the value of reminiscence therapy for residents with dementia and how it may impact on their quality of life is pertinent to my research. To that end, this review considered studies evaluating the effects of reminiscence therapy for people with dementia living in long-stay care settings only. To my knowledge, this is the first systematic review reporting the effects of reminiscence therapy for people with dementia residing in long-stay care settings specifically.

3.2 Objective

The objective of this systematic review and meta-analysis is to evaluate the effectiveness of reminiscence therapy for people with dementia living in long-stay care settings.

3.3 Methods

All methods undertaken in this review, including the review objective and types of included studies, were determined *a priori*.

3.3.1 Criteria for considering studies for this review

3.3.1.1 Types of studies

Although RCTs, with randomisation of participants to control and experimental groups at the level of the individual, are considered to be the most rigorous method in evaluating the effectiveness of healthcare interventions, such an approach is not always feasible or practical in the clinical setting (Cochrane Effective Practice and Organisation of Care Group (EPOC), 2010). This review includes RCTs (including cluster randomised trials), CCTs, CBAs and ITS studies. The design characteristics of included study types were based on criteria used in the EPOC 2010 group guidelines. The required criteria are outlined in the EPOC study design screening form (Appendix

2). Studies reported as abstracts only were excluded unless there was sufficient information in the abstract to meet the inclusion criteria.

3.3.1.2 Types of participants

Older adults (55 years of age or older) with a diagnosis of dementia of any type and severity who were residing in long-stay care facilities.

For the purpose of this review, long-stay care facilities were defined as collective institutional settings, where care is provided for older people with dementia 24 hours a day, seven days a week. Given that formal clinical diagnosis of dementia in residential care in Ireland (Cahill *et al.* 2010) and other countries (Knapp *et al.* 2007; WHO, 2012; Prince *et al.* 2013) is rare, diagnosis of dementia in residents may have been determined in any one, or more, of the following four ways:

1. A formal diagnosis of dementia determined by the DSM-1V (APA, 1994) and/or the ICD-10 (WHO, 1992) criteria for dementia;
2. Any other diagnosis of dementia by a medical clinician;
3. Residents' receiving treatment with acetyl cholinesterase inhibitors; and/or
4. Nurses' judgement and/or nursing records indicate that the person has dementia.

3.3.1.3 Types of interventions

3.3.1.3.1 <u>Intervention</u>

Reminiscence interventions considered in this review were based on the concept of reminiscence therapy as distinct from the concept of life review (Burnside & Haight, 1992; Dempsey *et al.* 2012). They included individual or small group sessions, which involved the process of recollecting past pleasant memories, experiences and/or events, induced by verbal or non-verbal means (Woods *et al.* 2005). Reminiscence approaches may have embraced the purposeful use of prompts or triggers to stimulate any of the five senses: touch, smell, sight, hearing and taste (Woods *et al.* 2005; Moos & Bjorn, 2006; Bohlmeijer *et al.* 2007; Schweitzer & Bruce, 2008). Only reminiscence interventions facilitated by healthcare professionals formally trained in the reminiscence process were considered (Gibson, 2004; 2006). With regard to the dose-response characteristics i.e., the length, frequency and duration of reminiscence interventions, Sellers & Stork (1997), proposed that reminiscence therapists should conduct 6-12

treatment sessions. Kim *et al.* (2006) suggest that more frequent sessions may result in greater effects. For the purpose of this review, study participants (residents with dementia) must have been exposed to the reminiscence intervention for a minimum of one session per week for at least six weeks duration (minimum of six sessions). This is similar to the Cochrane review (Woods *et al.* 2005), where participants were required to be exposed to the intervention for a minimum of four weeks and a minimum of six sessions.

3.3.1.3.2 Comparator intervention

For studies using a control group i.e., RCTs, CCTs and CBAs, comparator interventions are limited to no intervention/usual care. Interrupted time series studies do not make use of a control group.

3.3.1.4 Types of outcome measures

3.3.1.4.1 Primary outcomes

The primary outcomes considered in this review were pertinent to residents. Preferably, assessed by trained raters, using validated dementia specific instruments as opposed to generic scales and ideally outcome measurements should also have been validated in the long-stay setting and be suitable for use across all severities of dementia (Sansoni *et al.* 2007; Moniz-Cook *et al.* 2008). Outcomes of interest were clinical factors that have the potential to impact on the quality of life of residents with dementia (Hoe *et al.* 2009) and included:

1. Residents' quality of life;
2. Residents' perceived levels of depression; and
3. Residents' perceived behaviour.

3.3.1.4.2 Secondary outcomes

Secondary outcomes evaluated pertained to formal caregivers caring for the residents with dementia. In the context of this review, formal caregivers were defined as paid healthcare professionals. The focus was on assessing the impact of reminiscence interventions on:

1. Formal caregivers' perceived burden of care.

3.3.2 Search methods for identification of studies

The following electronic databases were searched:

- ALOIS: This is a comprehensive register of dementia studies maintained by the Cochrane Dementia and Cognitive Improvement Group (CDCIG). The register includes records of RCTs and CCTs of completed and on-going studies in the area of dementia and cognitive improvement. Studies are identified from monthly searches of an extensive number of databases. Databases searched by ALOIS are detailed in Appendix 3.
- Medical Literature Analysis and Retrieval System Online (MEDLINE), from 1948 to 2011;
- The Cumulative Index to Nursing and Allied Health Literature (CINAHL) from 1988 to 2011;
- Exerpta Medica Database (EMBASE), all years;
- PsycINFO via Ovid from 1987 to 2011.

I developed and tested a comprehensive search strategy for each database. To exploit the probability of retrieving potentially eligible studies, no limits were applied for study design, comparators, outcomes or setting. I also checked the reference lists of published reviews and retrieved articles were checked for additional relevant studies. As resources for translation services were unavailable, the search was restricted to studies published in the English language only. Search terms used were: Dement*, Alzheimer*, Reminisc* (see Appendix 4).

3.3.3 Data collection and analysis

Data collection and analysis methodology were informed by the Cochrane Handbook of Systematic Reviews of Interventions (Higgins & Greene, 2011) and the EPOC group guidelines (EPOC, 2010). All citations identified from the search were merged into one Endnote library and duplicate records were identified and removed.

3.3.3.1 Selection of studies

Studies identified from the searches were assessed against the review eligibility criteria independently by a colleague (S.S) and I. This was done first by screening citation title. If the title was vague, the abstract was read. If any doubt remained after reading the

abstract, the full text was obtained and read. If the study was not rejected at the full text stage, the data extraction process was initiated. Any disagreement or uncertainties that emerged during the study selection process were generally resolved by discussion between both reviewers. A third person, my supervisor (D.D) with expertise in systematic reviews and trial methodology, was available to resolve disagreements but this was not required. Studies that did not meet the eligibility criteria were excluded. A list of the excluded studies and the reasons pertaining to their exclusion from the review are outlined in Appendix 5.

3.3.3.2 Data extraction and management

I developed a data extraction form (Appendix 6) for the purpose of extracting data from the types of studies included in the review. Prior to the commencement of the review, I pilot tested the form on one randomly selected included study. The main lesson learnt from the pilot was to only extract data that is relevant to the review. Following refinement to the data extraction form, the process became more efficient and less time consuming. To ensure reliability and accuracy during the data extraction process, both reviewers (S.S and F.J) extracted data independently from each included study. Any disagreements were generally resolved by discussion and consensus. A third colleague (D.D) was available to resolve disagreements but this was not required.

3.3.3.3 Assessment of risk of bias in included studies

A systematic review, based on Cochrane methodology, seeks to assess the quality or internal validity of each included study i.e., the extent to which the study design and its conduct are likely to minimise bias. Bias is defined as a systematic error or digression from the truth in the results or conclusions derived from a study (Jadad, 1998). Studies with a low risk of bias are associated with greater methodological rigour and are more likely to generate findings that accurately reflect the effects of the intervention being evaluated. Conversely, studies with a high risk of bias are associated with exaggerated estimates of treatment effect (Begg *et al.* 1996; Moher *et al.* 1998; Chan & Altman, 2005; Dwan *et al.* 2008; Schulz *et al.* 2010). Randomised and non-randomised studies are associated with different sources of bias and therefore, in the realm of this systematic review, the risk of bias of included studies was assessed and reported using an adaptation of the Cochrane Collaboration's tool for assessing risk of bias (Higgins *et al.* 2011), adapted to incorporate the EPOC group's standard criteria for assessing risk of bias for studies with a separate control group i.e., RCTs, CCTs and CBAs. Each

included study was assessed for: selection bias (sequence generation, allocation concealment); detection bias (blinding of outcome assessors); attrition bias (incomplete outcome data); reporting bias (selective reporting); comparability of baseline outcomes; comparability of baseline characteristics; potential for contamination and other sources of bias (other sources of biases not addressed elsewhere). Studies included in this review were not assessed for performance bias; reasons pertaining to this decision are detailed in section 3.3.3.3.2.

During my search of the literature, I did not unveil any ITS study designs but I had planned to assess risk of bias in included ITS studies using the EPOC group's standard criteria specific to this type of study design (Appendix 6). Review authors described and judge the risk of bias for each domain as 'Low risk' of bias, 'High risk' of bias and 'Unclear risk' of bias. I completed risk of bias tables for all included studies (Appendix 8) and my supervisor (D.D) checked the precision of my descriptions and judgements.

3.3.3.3.1 <u>Selection bias (Sequence generation, allocation concealment)</u>

Selection bias is systematic differences in baseline characteristics between intervention and control groups (Higgins *et al.* 2011). The randomisation process minimises this type of bias. Random assignment is more likely to generate comparable groups by ensuring that study participants with both known and unknown characteristics and prognosis factors are dispersed evenly across groups (Pildal *et al.* 2005). When both groups are comparable at baseline, differences in outcomes post-intervention can be confidently attributed to the effects of the trial intervention and nothing else (Deeks *et al.* 2003). Effective randomisation depends on the successful execution of two fundamental but intrinsically linked processes i.e., sequence generation and allocation concealment.

3.3.3.3.1.1 Sequence generation
The initial key step in the randomisation process is sequence generation (Schulz & Grimes, 2002a). This is the procedure used to assign participants randomly to study groups. Various methods of sequence generation are classified as low or high risk of bias. Truly random sequence generation approaches cannot, by their very nature, be subverted by the trial investigators and are therefore at low risk of selection bias. Adequate methods of sequence generation include computer generated random numbers, throwing a dice or tossing a coin. Non-random methods undertaken

commonly include study participants' dates of birth or dates of admission. Such approaches cannot be adequately concealed and are deemed to be at high risk of selection bias (Schulz & Grimes, 2002b; Higgins & Greene, 2011).

3.3.3.3.1.2 Allocation concealment

Following random sequence generation, the second and crucial step in the randomisation process is concealing the allocation sequence from the study participants and its investigators, prior to and until the initiation of the study intervention (Hill *et al.* 2002). Several studies have demonstrated that trials with inadequate or unclear allocation concealment are biased, favouring the study intervention (Schulz *et al.* 1995). Hewitt *et al.* (2005) reviewed 234 randomised trial published in four key medical journals over a one year period and established that regardless of researchers acknowledging the importance of adequate allocation concealment, approximately one-fifth of trials reviewed used inadequate allocation concealment and a quarter did not illustrate how allocation was concealed. Pildal *et al.* (2007) reviewed the effects of allocation concealment on the assumptions drawn from 70 published meta-analyses of randomised trials, and deducted that two-thirds of the findings in support of study interventions were no longer compelling if studies with inadequate allocation concealment were excluded from the analysis.

3.3.3.3.2 <u>Performance bias (Blinding of participants and personnel)</u>

Performance bias is defined as systematic differences in the care provided to the participants in the comparison groups other than the intervention under investigation. This type of bias occurs when participants and personnel have knowledge of the allocated intervention during the study. Blinding, sometimes referred to as masking, is the methodological approach undertaken to avert this type of bias. Blinding seeks to conceal knowledge of the group allocation from study participants and personnel after randomisation (Higgins *et al.* 2011). However, blinding of participants and personnel is not always feasible. In this review it is was not possible to expect blinding of participants and personnel as invariably both participating residents and staff were aware of which intervention if any, they were receiving or delivering, hence, included studies were not assessed for performance bias.

3.3.3.3.3 <u>Detection bias (Blinding of outcome assessment)</u>

Detection bias is systematic differences between study groups in the way outcomes are ascertained and can arise when the outcomes assessor has knowledge of the group allocation. This form of bias can be minimised by blinding (or masking) outcome assessors to group allocation (Higgins *et al.* 2011). Blinding outcome assessors is particularly important when assessing subjective outcomes (e.g., quality of life), which are perceived to generate more biased judgements of treatment effects than more objective outcomes such as death (Woods *et al.* 2008; Nuesch *et al.* 2009). In the context of this review, blinding of outcome assessors was regarded as a reasonable expectation in determining the risk of bias of included studies. Included studies were judged 'Low risk' of detection bias, if blinding of outcome assessment was ensured, and it was unlikely that the blinding could have been broken.

3.3.3.3.4 <u>Attrition bias (Incomplete outcome reporting)</u>

Attrition bias can occur when there are differences between participating groups in the number of withdrawals or drop-outs from a study after randomisation (Higgins *et al.* 2011). Attrition bias can be minimised when the proportion and characteristics of participants lost to follow up are accounted for and are comparable across study groups (Ryan *et al.* 2011). Exclusion of participants from analysis results in biased estimates of the treatment effect in favour of either the intervention or control (Tierney & Stewart, 2005; Nuesch *et al.* 2009). Ideally, analysis should be based on the intention to treat principle. According to this principle, all randomised participants are analysed as per their original group allocation, irrespective of whether they received the intervention or not. Such an approach seeks to preserve the unbiased comparison of study groups afforded by randomisation until the trial is over (Heritier *et al.* 2003). Within this review, included studies were judged 'Low risk' of bias if there were no missing outcome data or missing outcome data was balanced in numbers across groups with similar reasons for missing data across groups.

3.3.3.3.5 <u>Reporting bias (Selective reporting)</u>

Reporting bias can arise when the reporting of research findings are determined by the nature and direction of the research results (Sterne *et al.* 2008). Outcomes demonstrating statistically significant findings are more likely to be reported and published while statistically non-significant finding are more likely to be withheld from publication (Chan *et al.* 2004; Dwan *et al.* 2008). Reporting bias was assessed in this

review by cross-checking outcomes detailed in the published report with outcomes detailed in the study protocol where available. Reports of all included studies were judged free of selective outcome reporting if all outcomes detailed in the trial protocol and/or all relevant outcomes in the methods section are reported in the results section. Study protocols were sought by searching in PubMed and in the World Health Organisation (WHO) International Clinical Trials Registry Platform (ICTRP). The WHO ICTRP provides a single point of search access for trials registered by contributing registers (http://www.who.int/ictrp/about/en/).

3.3.3.3.6 Publication bias

Publication bias arising from selective reporting of research findings is a real cause of concern in the context of meta-analyses. If present, and not identified and reported, then it has the potential to contribute to overzealous or biased meta-analysis results (Deeks *et al.* 2011). This review was guided by the most recent recommended procedures for assessing and investigating publication bias devised by Riley *et al.* (2011). Assessment of publication bias is not recommended in a meta-analysis with fewer than ten studies, as the tests used to evaluate such bias do not have sufficient power to differentiate chance from real asymmetry (Sterne *et al.* 2011; Riley *et al.* 2011). This review had fewer than 10 studies and therefore publication bias was not assessed. I had planned to undertake an assessment of publication bias for each analysis that had ten or more studies. Funnel plot asymmetry would have been assessed both visually and statistically. For continuous outcomes with intervention effects measured as mean difference, I had proposed to use the Egger's test (Egger *et al.* 1997). However, I acknowledge that publication bias may not be the only cause of funnel plot asymmetry. If a small study effect was apparent, I had planned to explore other potential reasons, for example, diversity in methodological quality, bias and genuine heterogeneity in the intervention effect all contribute to funnel plot asymmetry. If justified, I had intended to investigate other possible causes by undertaking a sensitivity analysis (Sterne *et al.* 2011).

3.3.3.3.7 Comparability of baseline outcomes and characteristics

Allocation of participants to study groups through random or non-random processes can potentially create groups that are not comparable at baseline. This can arise through chance alone or it may be attributable to inadequate allocation concealment methods. Baseline imbalance on factors that are related directly to the outcome

measures can bias the effect of the study intervention. Reporting baseline comparability and measures of statistical adjustments undertaken to address imbalances between study groups facilitates assessment regarding the potential effects of baseline imbalance (Higgins *et al.* 2011). Within this review, included studies were assessed for both the comparability of baseline outcome measures across study groups and comparability of baseline characteristics across study groups. Included studies were judged; 'Low risk' if participating residents' baseline outcomes were measured prior to the intervention and no important differences in outcome measures was present across study groups. Within this review included studies were judged 'Low risk' if, baseline characteristics of the study and control groups were reported and similar across study groups.

3.3.3.3.8 <u>Risk of contamination</u>

Contamination occurs when the control arm is exposed to the study intervention, potentially contributing to dilution of the intervention effect (Murphy *et al.* 2006). Study designs that have an intervention and control group (RCTs, CCTS and CBAs) within the same setting are a potential contamination risk (Ryan *et al.* 2011). Within this review, included studies were assessed for risk of contamination, included studies were judged; 'Low risk' of contamination, if allocation was by long-stay unit and it is unlikely that the control group received the intervention.

3.3.3.3.9 <u>Other sources of bias</u>

Concerns about other possible sources of bias not addressed elsewhere in the risk of bias table or risk of bias pertaining to a particular type of study design are assessed in this category. For example, although this review did not include any cluster randomised trials, provision was made in the risk of bias table under other sources of bias, to assess the risk of bias in the recruitment of participants in cluster randomised trials. Had a cluster randomised trial been included in this review, it would have been judged 'Low risk' of recruitment bias, if those involved in the identification and/or recruitment of the cluster participants did not have knowledge of the group allocation because one of the following, or an equivalent method, was employed; cluster participants were recruited prior to randomisation of clusters to groups and the same participants were followed up over time or; cluster participants were recruited after randomisation of clusters to groups but carried out by a person who was blinded to the group allocation (Puffer *et al.* 2003; Hahn *et al.* 2005).

3.3.3.4 Measures of treatment effect

3.3.3.4.1 <u>Continuous data</u>

For continuous outcomes, the mean change score, calculated as the difference in mean scores from baseline (T1) to post-intervention (T2), the standard deviation of the mean change and the number of participants for each treatment group of individual studies was extracted or calculated. If the standard deviation of the mean change score was not reported, the standard deviation at T2 was used. Differences in outcomes measured on a continuous level using the same scale were reported using the difference in means (mean difference), which measures the absolute difference between the mean value on a given outcome for the control and intervention groups, with 95% confidence intervals (CI). If I had combined studies that reported the same outcome but used different scales, I would have reported the standardised mean difference (SMD). The SMD expresses the size of the intervention effect in each study relative to the variability observed in that study (Deeks *et al.* 2003).

3.3.3.5 Unit of analysis issues

3.3.3.5.1 <u>Cluster-randomised trials</u>

In the context of a meta-analysis, a cluster randomised trial in which clustering has been ignored will give too much weight to the study and will give confidence intervals for the overall estimate of the treatment effect that are overly narrow (Higgins & Green, 2009). Although, this review did not include any cluster randomised trials, planned analysis for this type of study design was guided by the recommendations in section 16.3.4 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins *et al.* 2011). If cluster randomised trials had been included, I would have adjusted their sample size using an estimate of the intracluster correlation co-efficient (ICC), preferably from the relevant study (if available), alternatively, from a similar study or from a study of a similar population. If I had used ICCs from other sources, I had planned to report this and conduct sensitivity analyses to investigate the effect of variation in the ICC.

3.3.3.6 Dealing with missing data

In this review, all participants reported as excluded were, where data were available within the trial publication(s), restored to the group to which they were randomised.

This facilitated an intention to treat analysis for all participants for whom data were available (see section 3.3.3.3.4).

3.3.3.7 Assessment of heterogeneity

Statistical heterogeneity is the variation in reported effects of an intervention across studies beyond that which is expected by chance (Fletcher, 2007). I used three statistical tests for heterogeneity; they included Chi^2, Tau^2 (T^2) and I^2.

Chi^2 assesses whether the observed difference in results are consistent with chance alone. The level of significance for this test is often set lower than the arbitrary level of 0.05 because the test has low power to detect heterogeneity, particularly if there are few studies in the meta-analysis. Conversely if there are a number of large studies in the meta-analysis, Chi^2 may indicate significant results. If Chi^2 is statistically significant, that is, $p<0.1$, there is definite heterogeneity (Riley *et al.* 2011).

T^2 provides an approximation of the between-study variation, if >1, this suggests the presence of substantial statistical heterogeneity. For the purpose of this review, I regarded heterogeneity as substantial if T^2 was greater than zero (Riley *et al.* 2011).

I^2 measures the percentage of variation in the observed effects estimates that is attributable to between-study heterogeneity as distinct from within-study sampling error (Higgins *et al.* 2003). It takes values from 0% to 100%, with the value of 0% indicating no heterogeneity. I regarded heterogeneity as substantial if I^2 was greater than 30% (Riley *et al.* 2011). I had planned to explore potential sources of heterogeneity if it existed by undertaking a subgroup or sensitivity analyses as appropriate. T^2 and I^2 are reported for all primary outcomes in sections 3.5.1. Chi^2 and p values are reported for studies included in the meta-analysis.

3.3.3.8 Data synthesis

I carried out statistical analysis using the Review Manager software (RevMan, 2011). The decision to use a fixed-effect or random-effects model of analyses is the cause of considerable debate. The arguments on both sides of the divide are compelling. The fixed-effects model assumes that all of the studies included in the meta-analysis share a common effect size and subsequently, there is no between-study heterogeneity. Conversely, a random-effects model presumes that the estimate of the treatment effect

is different across included studies and that there is between-study heterogeneity (Riley *et al.* 2011).

Riley *et al.* (2011) argue that, prior to making the decision to use a fixed-effect or random-effect model of meta-analysis; review authors must give consideration to both statistical and clinical reasoning. Approaches undertaken in this review to assess and report statistical heterogeneity were guided by recommendations by Riley *et al.* (2011) and are detailed in section 3.3.3.7. Clinical reasoning alludes to heterogeneity between studies in key characteristics of study participants, the study interventions and outcomes. Decisions on clinical heterogeneity are based on clinical observations and do not necessitate any statistical effort (Fletcher, 2007).

I had planned to perform a fixed-effect analysis where both statistical and clinical heterogeneity were not perceived as a problem. However, where there was evidence of substantial clinical and/or statistical heterogeneity that could not be explained by a subgroup or sensitivity analysis, I had planned to perform a random-effects analysis where the pooled results are interpreted as the average intervention effect across studies (Riley *et al.* 2011).

3.3.3.9 Subgroup analysis and investigation of heterogeneity

Subgroup analyses are used to investigate sources of heterogeneity across studies. However, findings from multiple subgroup analyses can be misleading. Multiple testing can produce spurious results as they increase the chance of finding a significant result by chance alone. They are also based on observational as opposed to randomised comparisons: therefore differences between groups may exist due to confounding by other factors (Riley *et al.* 2011). Planned sub-group analyses were therefore limited to:

1. Comparing individual randomised trials with cluster randomised trials to explore possible relationships between treatment effect and unit of randomisation;
2. Comparing randomised trials (i.e., RCTs) with non-randomised trials (i.e., CCTs, CBAs and ITS studies); and
3. To explore possible causes of substantial statistical heterogeneity.

3.3.3.10 Sensitivity analysis

Planned sensitivity analyses were:

1. To explore the effects of variation in ICC values;
2. Compare high quality trials included in the review with overall effect estimates. For the purpose of this review, trials that scored 'Low risk' of bias on sequence generation, allocation concealment, blinding of outcome assessment, incomplete missing data, selective reporting bias, publication bias and other sources of bias in the risk of bias table were classified as high quality trials; and
3. To explore possible causes of substantial statistical heterogeneity that could not be explained by a subgroup analysis.

3.4 Results

3.4.1 Description of studies

3.4.1.1 Results of the search

As detailed in the study selection flowchart (Appendix 7), the search identified 344 citations of which 16 were considered for inclusion (Youssef, 1990; Cook, 1991; Bass, 1996; Cook, 1998; Chao *et al.* 2006; Haight *et al.* 2006; Ito *et al.* 2007; Wang, 2007; Chung, 2009; Yasuda *et al.* 2009; Wang *et al.* 2009; Hsieh *et al.* 2010; Chiang *et al.* 2010; Gudex *et al.* 2010; Haslam *et al.* 2010 and Lin, 2010).

3.4.1.2 Included studies

Of the 16 potential studies, three met the inclusion criteria for the review (Wang, 2007; Wang *et al.* 2009 and Hsieh *et al.* 2010) (see Appendix 8 for characteristics of included studies). All included studies were conducted in Taiwan, two in Southern Taiwan (Wang, 2007; Wang *et al.* 2009) and one in Northern Taiwan (Hsieh *et al.* 2010). Two of the studies reported that they used an RCT design (Wang, 2007; Hsieh *et al.* 2010) and the third study (Wang *et al.* 2010) used a CCT design. All studies randomised at the level of the individual. The three included studies are described below.

Wang 2007

Wang (2007) included 102 nursing home residents from five care facilities in Southern Taiwan. All participants had a diagnosis of mild to severe dementia according to the Clinical Dementia Rating Scale (CDR) (Hughes *et al.* 1982) score of 1-3. Mean CDR scores in both groups were below 2, indicating mild to moderate dementia. The mean ages of the intervention and control groups were 79 years and 78 years respectively. Participants were assigned randomly to either experimental (group reminiscence) or

control (usual care) with 51 participants in each group. Six reminiscence groups were conducted sequentially, each including between 8-10 residents. Staff nurses with extensive experience in either psychiatric or geriatric nursing facilitated group sessions. All facilitators had undergone 32 hours of training in reminiscence therapy and group dynamics. Sessions were delivered for one hour per week, for an eight-week period. Each of the eight sessions focused on different life event themes and involved the use of triggers to evoke memories. Themes included 'First meeting', 'Childhood experiences', 'Older flavours of food', 'Old style music', 'Festivals', 'My family', 'Younger age' and 'My achievements'. Memory triggers used included old photographs, old music, household and other familiar items from the past. The outcome was residents' levels of depression as measured by the Chinese version of the Geriatric Depression Scale (GDS-SF) (Yesavage *et al.* 1983) and the Chinese version of the Cornell Scale for Depression in Dementia (CSDD) (Alexopolous *et al.* 1988). The Chinese version was developed and validated by the trial investigators. The authors report a satisfactory inter-rater agreement (Kappa = 0.44-0.76, p = 0.015-0.000) and good internal consistency (Cronbach's alpha of 0.84). Outcome assessments were undertaken one week prior to and one week post the intervention delivery.

<u>Wang *et al.* 2009</u>

Wang *et al.* 2009 included 77 nursing home residents from four care facilities. Although in the text of this study the authors state that this sample was drawn from Wang 2007, contact with the authors clarified that the sample in this study was recruited from settings different to Wang 2007, and thus was independent. However, both studies delivered the same structured intervention protocol with some minor variations in themes. Participants had a clinical diagnosis of mild to moderate dementia as determined by a CDR score of 1-2. The mean age of the intervention and control groups was 79 and 78 years respectively. Thirty-eight participants were assigned to intervention (group reminiscence) and 39 to control (usual care). Each group consisted of 8-12 participants and was facilitated by two group leaders. Similar to Wang 2007, group facilitators underwent 32 hours of training in reminiscence therapy before delivering the intervention and all had extensive experience in working in geriatric care. Reminiscence groups participated for one hour per week for eight weeks. The primary outcome was residents' behavioural competence as assessed by the Chinese version of the Behaviour Rating Scale (BRS) a subscale of the Clifton Assessment Procedures for the Elderly (CAPE) (Pattie & Gilleard, 1979). The Chinese version of the CAPE-

BRS used in this study was translated and validated by the trial investigators. The study authors report a satisfactory inter-rater agreement (Kappa = 0.65-0.86) and good internal consistency (Cronbach's alpha of 0.81)

<u>Hsieh *et al.* 2010</u>

Hsieh *et al.* (2010) evaluated group reminiscence therapy in 61 residents with dementia from two private nursing homes. Dementia diagnosis was determined by a number of criteria and included the DSM IV (APA, 1994) a review of the resident's medical records, laboratory findings and physical examination results. Participating residents had a diagnosis of mild to moderate dementia as measured by a score of 1-2 on the CDR scale. Sixty-seven per cent of participants had a diagnosis of mild dementia (n=41) and 32.8% (n=20) had a diagnosis of moderate dementia. The mean age was 77 years in both groups. Participants were assigned randomly to group reminiscence (intervention) (n=29) or treatment as usual (control) (n=32). The reminiscence groups were facilitated by research teams who specialised in "geriatric psychiatric nursing" (p.74). Facilitators followed a structured intervention protocol and included residents sharing their personal stories of life experiences pertaining to friendships, work and other significant life events. The focus was on creating an environment that was conducive to relaxation, having fun and maximising communication between facilitators and residents. A total of 12 sessions were delivered for 40-50 minutes per week. Outcomes measured included depression as measured by the GDS-SF (Yesavage *et al.* 1983) and a sub scale of the Neuropsychiatric Inventory (NPI) (Cummings *et al.* 1994). Outcomes were evaluated one week before and three months after intervention delivery.

3.4.1.3 Excluded studies

Thirteen studies were excluded (Youssef, 1990; Cook, 1991; Bass, 1996; Cook, 1998; Chao *et al.* 2006; Haight *et al.* 2006; Ito *et al.* 2007; Chung, 2009; Yasuda *et al.* 2009; Chiang *et al.* 2010; Gudex *et al.* 2010; Haslam *et al.* 2010 and Lin, 2010). Two of the studies (Youssef, 1990 and Yasuda *et al.* 2009) used a CBA design but neither fulfilled EPOC criteria, that is, having at least two intervention and two control sites. Characteristics of excluded studies and reasons for exclusions are detailed in Appendix 5.

3.4.2 Risk of bias in included studies

Risk of bias tables for each included study is presented in Appendix 8. Judgements about each risk of bias item as a percentage across all included studies are presented in Figure 3-1. Judgements about each risk of bias item assessed for each included study are presented in Figure 3-2.

Figure 3-1: Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies
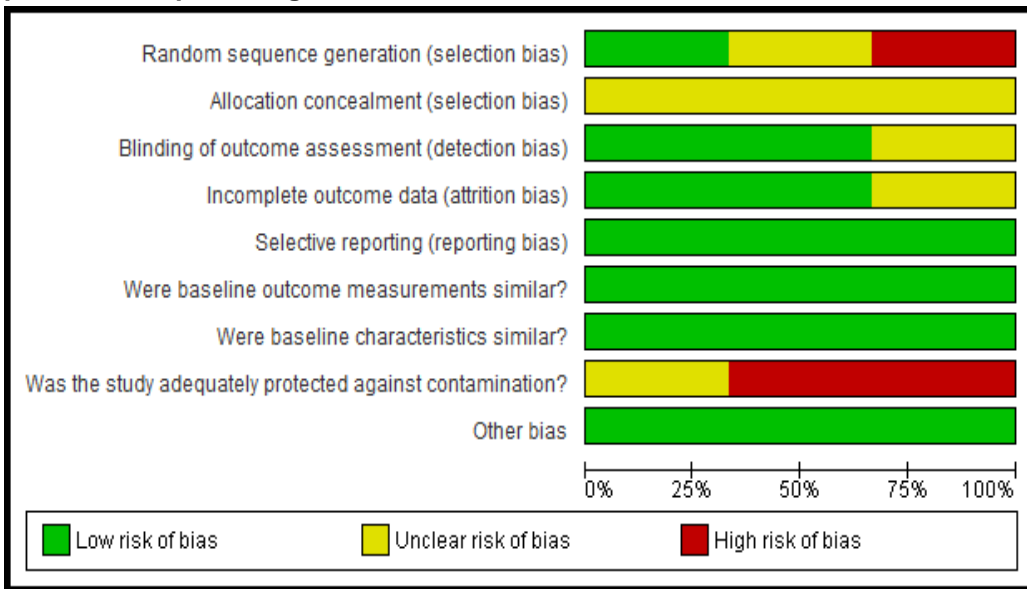
Figure 3-2: Risk of bias summary: review authors' judgements about each risk of bias item for each included study

3.4.2.1 Minimising selection bias

3.4.2.1.1 <u>Sequence generation</u>

Wang (2007) reported an adequate method of sequence generation and was therefore assessed as 'Low risk' of bias on sequence generation. Participants were allocated to study groups "based on a table list" (p.1236). Wang *et al.* (2009) was judged 'High risk' of bias on sequence generation as participants were "assigned" (p.228) using recruitment sequence table lists, participants with even numbers were allocated to the experimental group. Hsieh *et al.* (2010) provided insufficient information to judge methods of sequence generation and was therefore judged as 'Unclear risk' of bias on sequence generation (see Figure 3-2).

3.4.2.1.2 <u>Allocation concealment</u>

None of the three included studies reported measures taken to conceal allocation to study groups and therefore all three were judged 'Unclear risk' of bias on allocation concealment (see Figure 3-2).

3.4.2.2 Minimising detection bias (Blinding of outcome assessment)

Risk of bias for outcome measures was judged 'Low risk' for two studies (Wang, 2007; Wang *et al.* 2009). In Wang (2007), outcome assessors included two graduate nurses who were "blinded to subject assignment" (p.1237). Similarly, Wang *et al.* (2009) stated that pre- and post- outcome data were assessed by the same researcher, who was "masked to group membership" (p.229). In Hsieh *et al.* (2010), outcomes measures were assessed by a "single investigator" (p.74) but no detail of blinding is provided and the risk of bias was therefore judged an 'Unclear risk' on detection bias (see Figure 3-2).

3.4.2.3 Minimising attrition bias (Incomplete outcome reporting)

Of the 102 randomised participants, Wang (2007), lost 10 participants (10%) to follow-up: three in the experimental group (6%) and seven (14%) in the control group. Reasons for dropout were not provided in the text. However, this study was judged as 'Low risk' on attrition bias as the author carried out an intention to treat analysis, and all 102 randomised participants were included in the analysis, regardless of whether they received the reminiscence intervention or not. Wang *et al.* (2009) allocated 77 participants (38 to intervention and 39 to control). Loss to follow-up was comparable

across groups with five (6%) participants lost from the intervention group and four (4.5%) from the control group. Reasons for dropout included conflict with prior appointments, ill-health and death. As attrition rates were relatively small and comparable in both groups, this study was judged 'Low risk' on attrition bias. Hsieh *et al.* (2010) reported "there were 33 participants in each group at the beginning of the study" (p.75). However the authors reported that four participants dropped out of the experimental group and one in the control group. They provided an explanation for only one dropout, reporting that one participating resident died during the study but did not provide any information on the four other residents. Participants lost to follow-up were not included in baseline or post- data analysis. This study was judged an 'Unclear risk' on attrition bias (see Figure 3-2).

3.4.2.4 Minimising reporting bias (Selective reporting)

Protocols were unavailable for the three included studies. However, all studies reported all outcomes detailed in the methods section in the results section of the study publication and were therefore judged 'Low risk' on selective reporting bias (see Figure 3-2).

3.4.2.5 Assessment of publication bias

As there were fewer than 10 included studies, it was not feasible to assess publication bias as outlined in section 3.3.3.3.6 (see Figure 3-2).

3.4.2.6 Comparability of baseline outcomes and characteristics

All included studies reported baseline characteristics and outcomes assessment in detail. Study groups within each study were comparable and were therefore judged as 'Low risk' of bias (see Figure 3-2).

3.4.2.7 Risk of contamination

Two of the included studies were assessed as 'High risk' of contamination (Wang, 2007; Wang *et al.* 2009) because in both studies, staff members delivering the intervention were also expected to provide usual care. Hsieh *et al.* (2010) was assessed as 'Unclear risk' of contamination as there were insufficient details to judge risk of contamination (see Figure 3-2).

3.4.2.8 Other sources of bias

As the review did not identify any cluster randomised trials of reminiscence therapy for people with dementia residing in the long-stay care setting, other sources of bias were non-applicable within this review (see Figure 3-2).

3.5 Effects of interventions

Outcomes extracted from each of the included studies, and considered and reported in this review are detailed in the characteristics of included studies (Appendix 7). Forest plots are used to graphically represent the relative strength of treatment effects. Point and summary effect estimates to the left of the vertical line of no effect indicate beneficial effects, favouring the intervention group i.e., reminiscence therapy over the control group/usual care. As detailed in section 3.4.1.2, the clinical characteristics of participating residents across all three included studies were similar so, consistent with my reasoning in section 3.3.3.8, in the absence of both statistical and clinical heterogeneity, I choose to undertake a fixed model of analysis.

3.5.1 Comparison: reminiscence therapy versus usual care

For this comparison, all participants randomised in Wang (2007), Wang *et al.* (2009) and Hsieh *et al.* (2010) were included (n=240).

3.5.1.1 Primary outcomes

3.5.1.1.1 <u>Residents' quality of life</u>

Residents' quality of life was not measured as an outcome in any of the included studies.

3.5.1.1.2 <u>Residents' perceived levels of depression as measured in individual studies</u>

Residents' perceived levels of depression were measured in two of the studies included in the review (Wang, 2007; Hsieh *et al.* 2010). Wang (2007) measured depression using both the GDS and the CSDD. Likewise, Hsieh *et al.* (2010) measured depression using the GDS and a sub scale of the NPI. The Wang (2007) study produced a significant result for depression in favour of reminiscence as measured by the CSDD (Mean Difference (MD) -2.97; 95% Confidence Interval (CI) -5.21 to -0.73, Figure 3-3). In the same study, the results using the GDS were less favourable (MD -1.09; 95% CI -2.52 to 0.34, Figure 3-3). The discrepancy in the strength of the findings

between the two instruments may have arisen in this study because the CSDD, contrary to the recommended administration of the instrument was completed by the caregiver only and the GDS was completed by the person with dementia. It is well documented in dementia research that there are discrepancies in the correlations between self-reports as completed by the person with dementia and proxy reports as completed by the caregiver (Sansoni *et al.* 2007; Moniz-Cook *et al.* 2008).

The CSDD is usually administered by a trained clinician, who conducts two-semi-structured interviews, one with the person with dementia and the second with the caregiver. During each interview the clinician assigns a provisional score to each of the 19-items on the scale. Should any discrepancies arise between the two ratings, the clinician re-interviews both the participants. The final rating on the CSDD is made by the clinician (Alexopolous *et al.* 1988). The strength of the CSDD is its reliance on both the perspective of the person with dementia and their caregiver (Moniz-Cook *et al.* 2008).

Hsieh *et al.* (2010) produced significant results for depression in favour of reminiscence as measured by the GDS (MD -1.63; 95% CI -2.51 to -0.75, Figure 3-3) and the NPI (MD -1.81; 95% CI -3.15 to -0.47, Figure 3-3). Here again, there is an inconsistency in the strength of the findings between the two instruments used to measure depression, but again, the GDS-SF was completed by the person with dementia and the NPI was completed by their caregivers.

Figure 3-3: Forest plot of comparison: Depression

	Reminiscence			Usual care			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	IV, Fixed, 95% CI	IV, Fixed, 95% CI
1.1.1 Wang 2007: CSDD								
Wang 2007	-1.14	4.81	51	1.83	6.61	51	-2.97 [-5.21, -0.73]	
1.1.2 Wang 2007: GDS								
Wang 2007	-1.07	3.56	51	0.02	3.78	51	-1.09 [-2.52, 0.34]	
1.1.3 Hsieh: GDS								
Hsieh 2010	-1.38	1.43	29	0.25	2.06	32	-1.63 [-2.51, -0.75]	
1.1.4 Hsieh: NPI								
Hsieh 2010	-1.72	1.78	29	0.09	3.38	32	-1.81 [-3.15, -0.47]	

-10   -5   0   5   10
Favours reminiscence   Favours usual care

3.5.1.1.2.1 Residents' perceived levels of depression as measured by the GDS: meta-analysis

As the GDS was used to measure depression in two studies, all participants randomised to Wang (2007) and Hsieh *et al.* (2010) were included (n=163) in the meta-analysis. In comparison with usual care, reminiscence therapy was associated with a statistically significant improvement in depressive symptoms (MD -1.48; 95% CI -2.23 to -0.73, Chi^2 = 0.40, p=0.53, T^2 = 0.00, I^2 = 0%, Figure 3-4).

Although there are only two studies included in the meta-analysis and Chi^2 has low power to detect heterogeneity in a meta-analysis with a small number of studies, Chi^2 in this meta-analysis is 0.40 and p>0.1 (p=0.53), suggesting heterogeneity is not significant between the included studies. This is result is consistent with the findings from the other two tests for statistical heterogeneity in that, T^2 is zero and I^2 is also zero (< 30%), far less than the parameter set in section 3.3.3.7.

Clinical heterogeneity was not a problem as both studies were similar with respect to the demographics and clinical characteristics of the study participants, the type of intervention and study outcomes.

Figure 3-4: Forest plot of comparison: Depression as measured by the GDS
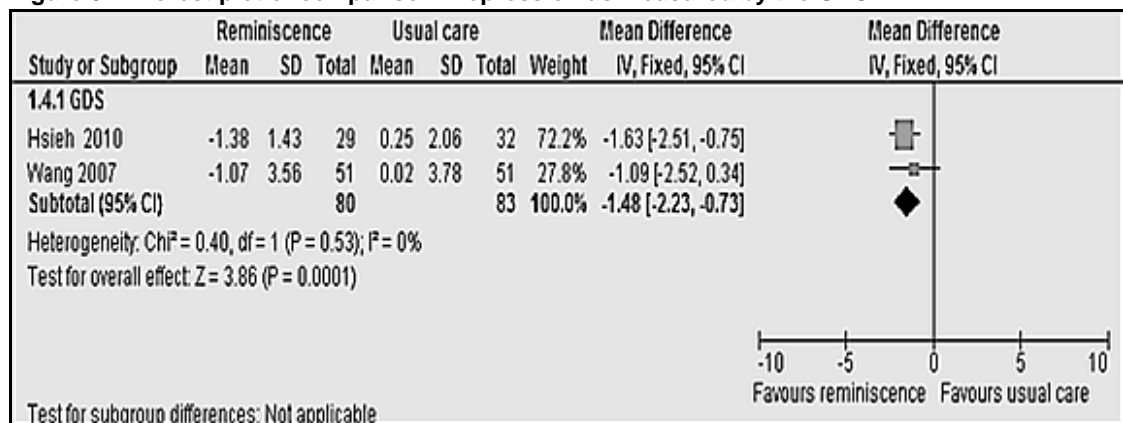
3.5.1.1.3 Behaviour

One study, Wang *et al.* (2009), evaluated the effects of reminiscence therapy on behaviour. There were no significant differences between study groups in behavioural competence as indicated in overall CAPE-BRS (MD -1.57; 95% CI -4.17 to 1.03, Figure 3-5).

Figure 3-5: Forest plot of comparison: Behaviour

Study or Subgroup	Reminiscence Mean	SD	Total	Usual care Mean	SD	Total	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
1.3.1 CAPE-BRS								
Wang 2009	-1.1	5.96	38	0.47	5.69	39	-1.57 [-4.17, 1.03]	

-10   -5   0   5   10
Favours experimental   Favours control
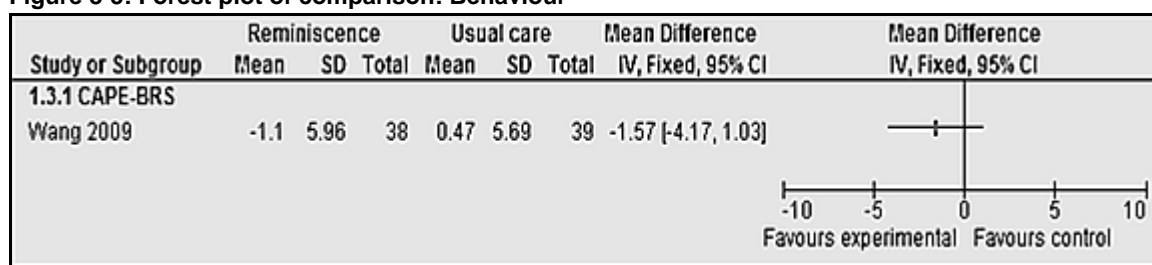
3.5.1.2 Secondary outcomes

There was no evaluation of the impact of reminiscence therapy on the formal caregivers' perceived burden of care in the studies included in this review.

3.5.2 Subgroup analysis and investigation of heterogeneity

In the absence of heterogeneity across included studies, planned subgroup analysis outlined in section 3.3.3.9 were unnecessary. Trials pooled in the meta-analysis (Wang, 2007 and Hsieh *et al.* 2010) were both randomised controlled trials (RCTs). The third study, Wang *et al.* (2009), used a controlled clinical trial (CCT) design but outcomes used in this study were not common to any other included study thus data from this trial were not pooled for meta-analysis.

3.5.3 Sensitivity analysis

Planned sensitivity analysis detailed in section 3.3.3.10 were unnecessary as cluster randomised trials were not included in the review and none of the included studies fulfilled the criteria for high quality trials i.e., scoring 'Low risk' of bias on sequence generation, allocation concealment, blinding of outcome assessment, incomplete missing data, selective reporting bias, publication bias and other sources of bias in the risk of bias table.

3.5.4 Summary of main results

The key findings from this review are summarised in Table 3-1. Each outcome for which data were available is detailed, including the number of studies and number of participants included in the meta-analysis and analysis. The table also indicates the statistical methods undertaken in analysing each outcome, as well as detailing the magnitude and direction of the treatment effect.

Table 3-1: Summary of findings: Reminiscence therapy versus treatment as usual

Outcome	Studies	Participants	Statistical method	Effect estimate
Depression (results of meta-analysis)				
Wang 2007/Hsieh 2010: GDS	2	163	Mean Difference (IV, Fixed, 95% CI)	-1.48 [-2.23, -0.73]
Depression (individual studies)				
Wang 2007: CSDD	1	102	Mean Difference (IV, Fixed, 95% CI)	-2.97 [-5.21, -0.73]
Wang 2007: GDS	1	102	Mean Difference (IV, Fixed, 95% CI)	-1.09. [-2.52, 0.34]
Hsieh 2010: GDS	1	61	Mean Difference (IV, Fixed, 95% CI)	-1.63 [-2.51, -0.75]
Hsieh 2010: NPI	1	61	Mean Difference (IV, Fixed, 95% CI)	-1.81 [-3.15, -0.47]
Behaviour (individual studies)				
Wang 2009: CAPE-BRS	1	77	Mean Difference (IV, Fixed, 95% CI)	-1.57 [-4.17, 1.03]

3.6 Discussion

A rigorous review methodology was adopted in this review in order to evaluate the effectiveness of reminiscence therapy for older people with dementia in the long-stay setting. The eligibility criteria for participating residents, type of reminiscence interventions, comparator intervention and outcomes being assessed were clearly defined at the outset.

The search methods used to identify studies for inclusion were extensive, and it is unlikely that any relevant trials published in the English language were excluded. Nevertheless, because I did not have the resources required for translation, only trials published in the English language were included. It cannot be excluded that I missed trials that were suitable for inclusion in this review and therefore the reader could reasonably conclude that this review was biased in this respect.

I reviewed and summarised three trials, which included 240 residents with dementia residing in long-stay care settings. Residents randomised to group reminiscence therapy were more likely to experience a reduction in symptoms of depression when compared with residents randomised to usual care. As only one trial, (Wang *et al.* 2009), evaluated the effects of reminiscence on residents' behaviour, evidence to suggest that reminiscence can improve behaviour is weak and warrants further investigation.

Outcomes of interest, reported across the included studies, are all clinically important measures in evaluating the effectiveness of reminiscence therapy in older people with dementia living in long-stay settings. Evaluating residents' quality of life is perceived as a key outcome in dementia research and while none of the included studies evaluated the residents' quality of life as an independent variable, other reported outcomes such as perceived levels of depression and, behaviour are considered important indicators of residents' quality of life (Hoe *et al.* 2009).

The GDS-SF was used as an outcome measurements for residents' perceived levels of depression in both of the studies included in the meta-analysis; however, although commonly used in dementia research, the GDS-SF is not a dementia specific measurement tool (Sansoni *et al.* 2008). The validity the GDS (all versions) in dementia is questionable as it is completed by the person with dementia and depends on their ability to recall their emotions over the past week, which is unreasonable, given that the person with dementia's ability to recall recent events is compromised early in the illness (Moniz-Cook *et al.* 2008). The Internal consistency of the GDS reduces with dementia severity (Muller-Thomsen *et al.* 2005); therefore, while it may be a useful measure of depression in the mild stage of dementia, it may not perform well in the moderate stage of dementia (McCabe *et al.* 2006).

On the other hand, the CSDD is a dementia specific measurement tool and was used to measure dementia in one of the included studies (Wang, 2007) but, the validity of findings arising from the CSDD in this study are questionable because, Wang (2007) did not adhere to the correct administration of the CSDD in that, Wang (2007, p.1237)) clearly states that scoring of the CSDD was based on "interviews with the subjects' caregiver". The perspective of the person with dementia and the subsequent final clinical rating were disregarded in this study. The benefit of the CSDD is that it relies on

the perspective of both the person with dementia and their carer (Alexopolous *et al.* 1988). That said, when administered correctly, the CSDD has emerged well from comparative studies with the GDS and other instruments measuring depression in dementia (Mayer *et al.* 2006); it has demonstrated sensitivity to change in dementia intervention studies and is recommended by the European consensus (Moniz-Cook *et al.* 2008) as the outcome measurement of choice in dementia research, evaluating the impact of psychosocial intervention on perceived levels of depression.

Sansoni *et al.* (2007) and Moniz-Cook *et al.* (2008) suggest that, when evaluating the effectiveness of psychosocial interventions for people with dementia, outcomes should be measured using tools that have been developed with dementia-specific populations and are suitable for use across all stages of the illness and in all care settings. Future researchers in this area should take cognisance of such recommendations. Likewise, the notable absence of evaluations of the impact of reminiscence-based interventions on residents' quality of life and on formal caregivers' perceived burden of care is disappointing and highlights the need to incorporate these outcomes into future research in this field.

The population in the included studies were comparable in terms of demographic and clinical characteristics. Residents across all three studies had a diagnosis of mild to moderate dementia and all were under eighty years of age. Reminiscence was delivered at a group level in all three studies, regardless of the individual resident's stage of dementia. Sessions were conducted by experienced healthcare professionals, trained in the reminiscence process. Residents had been exposed to a minimum of six reminiscence sessions, over a minimum of six weeks. In the absence of both clinical and statistical heterogeneity, it is reasonable to suggest that findings arising from this review are generalisable to all people with dementia residing in long-stay settings. On the other hand, as all included studies were conducted in Taiwan, it is also reasonable to argue that the findings are generalisable to that specific population only.

Figures 3-1 and 3-2 indicate that the risk of bias was inconsistent across included studies. Key reasons for studies having a risk of bias pertained to: selection bias (sequence generation and allocation concealment); detection bias (blinding of outcome assessors); attrition bias (incomplete outcome data) and the potential for contamination between study groups. Comparability of groups was apparent in the trial reports and all

trials were judged 'Low risk' of bias in the areas of comparability of groups on both baseline clinical measurements and baseline characteristics. Future studies need to give considerable thought to the design, conduct and reporting of trials as it is worth noting that, although the two trials included in the meta-analysis, Wang (2007) and Hsieh *et al.* (2010), were both RCTs, their findings were not reported according to the CONSORT (CONsolidated Standards of Reporting Trials) Statement, which details information to be included in the reporting of a randomised trial (Schulz, Altman & Moher, 2010).

3.7 Conclusion

This review is the first of its kind to evaluate the effectiveness of reminiscence for people with dementia in the long-stay setting only, and consequently its findings are generalisable to people with dementia living in long-stay care settings only. A limitation of this review is that all of the included studies were conducted in Taiwan and therefore its finding may not be generalisable to people with dementia residing in long-term care in other countries. That said, findings from the review indicate that, reminiscence therapy has the potential to reduce symptoms of depression in people with dementia living in long-stay care but, it requires more rigorous evaluation in similar settings across different countries, using dementia-specific outcome measurements and appropriately designed, high quality trials, incorporating residents' quality of life, behaviour and staff members burden of care as important outcomes, before any definitive conclusions about the use of reminiscence for people with dementia, living in long-stay care settings can be ascertained.

Chapter 4
Methods

4.1 Introduction

This chapter details the design, conduct, and analyses of the DARES Study. The structure and content of this chapter are guided by the most recent Consolidated Standards for Reporting Trials (CONSORT) 2010 statement: extension to cluster randomised trials (Campbell *et al.* 2012) which details information to be included in the reporting of a cluster randomised trial.

4.2 Trial design

The DARES Study is a two-group, single blind, cluster randomised trial conducted in public and private long-stay residential settings in Ireland. Randomisation to study groups is at the level of the long-stay residential unit. The DARES trial methodology is outlined in Figure 1.

4.2.1 Rationale for adopting a cluster randomised trial

A well planned and executed randomised controlled trial (RCT), randomised at the level of the individual, is considered the gold standard research methodology in providing evidence of the effectiveness of an intervention (Hahn *et al.* 2005). Its strength lies in its ability to establish causality i.e., whether a cause-effect relationship exists between an intervention (cause or independent variable) and outcome (effect or dependent variable) (Kendall, 2003). Friedman *et al.* (1998) suggest that a rigorous randomisation process has three distinct advantages: (i) it eliminates the potential for bias in the allocation of participants to study groups; (ii) random assignment tends to produce comparable groups, that is, known and unknown prognostic factors, as well as other characteristics of the study participants, are distributed evenly between the intervention and control groups; and (iii) finally randomisation enables the establishment of causal inference, that is, the extent to which the study intervention, rather than other factors, caused the difference, if any, in outcome or effect between the study groups.

However, if there is a risk of contamination between study groups, that is, when individuals randomised to the control group are inadvertently exposed to the trial intervention, it is preferable to randomise groups of people, for example, hospitals,

communities or general practices (Puffer *et al.* 2003). Contamination of control groups through their exposure to the intervention under investigation dilutes the effects of the study intervention thus increasing the risk of type 2 errors, which occurs when no intervention effect is found when one exists (Torgerson, 2001). In the context of the DARES study, participating staff allocated to the intervention arm were expected to implement reminiscence with their allocated residents and staff allocated to the control group continued with usual care. However, it was reasonable to expect that had randomisation to study groups occurred in the same long-stay unit, participating staff would have found it challenging to provide both reminiscence and usual care to participating residents without the risk of contamination occurring between study groups. For this reason, a cluster randomised trial design was adopted.

The limitations of cluster trials is that they necessitate larger sample sizes (see section 4.11 on sample size) and require more complex statistical analyses (see section on statistical analysis 4.15) than trials randomised at the individual level. The growing popularity of cluster randomised trials as a research design has initiated an extension to the CONSORT statement to accommodate "the reporting of the special features of the cluster randomised trials" (Campbell *et al.* 2004, p.703). Issues pertaining to the design and analysis of cluster randomised trials and how they were considered in the DARES study are addressed within each of the relevant domains detailed in this methodology chapter.

Prior to the enrolment of the first participant, the protocol for the DARES study (Appendix 9) was registered with the International Standard Randomised Controlled Trial Number Register (ISRCTN99651465, http://www.controlled-trials.com/ISRCTN99651465). No important changes were made to the methods after the trial started.

Figure 4-1: Flowchart of the DARES methodology adopted from the DARES study protocol (O'Shea *et al.* 2011, p.4).
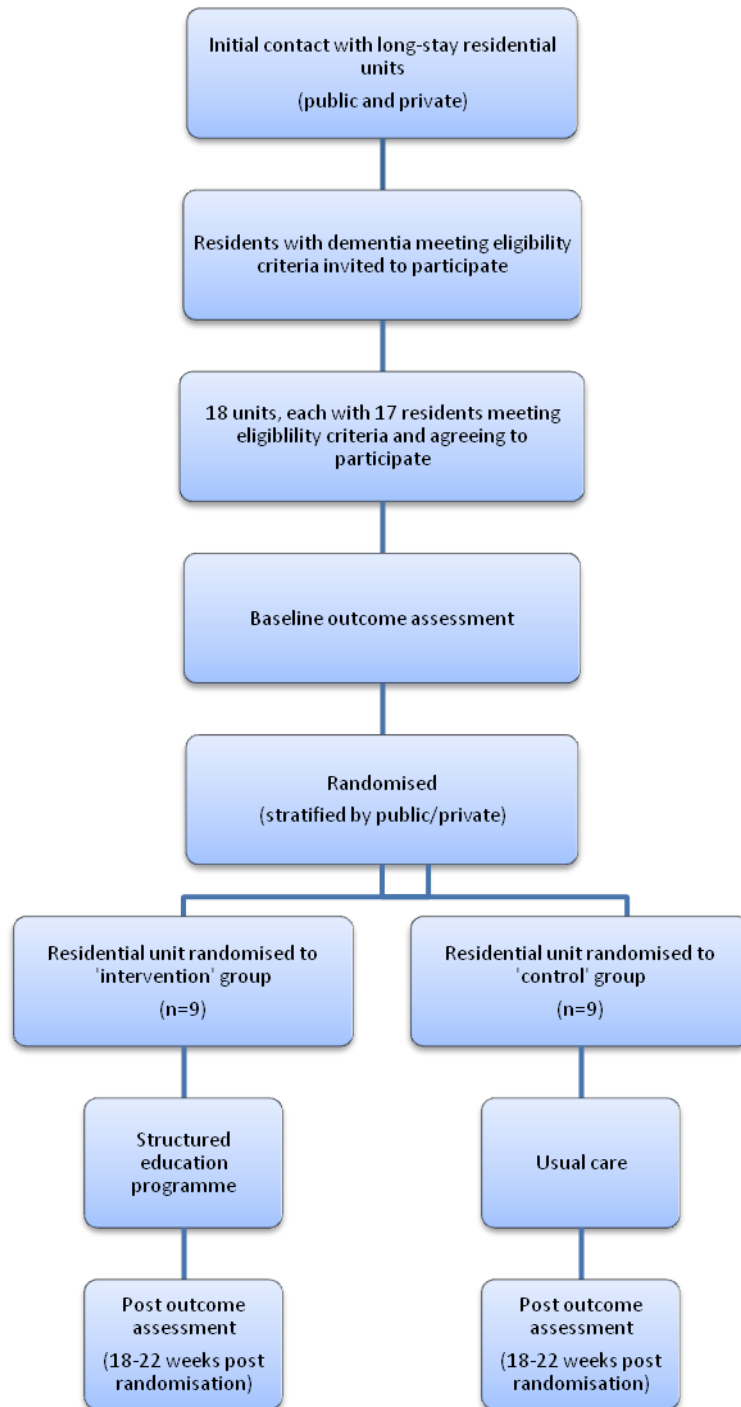
4.3 Participants: long-stay residential units

4.3.1 Settings and locations

The DARES Study was conducted in public (n=6) and private (n=12) long-stay residential units in the Western, South-western and Midland regions of the Republic of Ireland (Galway, Mayo, Roscommon, Clare, Limerick, Tipperary and Longford). All long-stay units meeting the eligibility criteria detailed in section 4.3.2 were invited to participate by the DARES Study project manager.

4.3.2 Eligibility criteria for long-stay residential units

Long-stay residential units were eligible to participate if they had:

a) A minimum of 17 residents with dementia who agreed either directly or through proxy to participate in the study; and

b) A commitment from management of the long-stay unit and the clinical staff to participate in the study.

4.3.3 Enrolment and consent procedures for long-stay residential units

The DARES project manager was responsible for:

a) Compiling a list of all potential participating long-stay units;

b) Identifying the Director of Nursing and/or the proprietor of each long-stay unit;

c) Sending written information about the study and an *Agreement to Participate* form (Appendix 10) to all potential participating long-stay units, requesting the Director of Nursing /proprietor to sign and return the form if they were willing to be part of the study;

d) Making a follow-up telephone call, where necessary, to explain the study in more detail and to answer any queries the Director of Nursing/proprietor may have had. During this phone call, the Director of Nursing/proprietor had the opportunity to speak to a member of the research team to ask questions on any aspect of the study; and

e) Obtaining a signed *Agreement to Participate* form (Appendix 10) from the Director of Nursing/Proprietor.

4.4 Participants: residents

4.4.1 Eligibility criteria for participating residents

Residents were eligible to participate if they fulfilled the following criteria:

a) Had lived in the residential unit for at least one month; and
b) Were likely to be there for the duration of the study.

Rationale: The one-month period facilitated the staff getting to know the resident. This was important in allowing the Director of Nursing or Nurse in Charge time to determine if the resident was eligible to participate (see section 4.4.3). It was also important to establish, insofar as was possible, if the resident would be there for the duration of the trial, so that the resident would receive the intervention as intended and that trial attrition rates could be minimised.

A diagnosis of dementia determined in any one, or more, of the following ways:

a) A formal diagnosis of dementia determined by DSM-IV (APA, 1994) and/or the ICD-10 criteria (WHO, 1992) for dementia;
b) Any other diagnosis of dementia by a medical clinician;
c) Resident was on anti-Alzheimer's medications, including Aricept (donepezil), Ebixa (memantine) and Exelon (rivastigmine);
d) Nurses' judgement advised and/or nursing records noted that the person had dementia.

The DARES research team decided to undertake this pragmatic approach to dementia diagnosis because dementia researchers strongly suggest that a formal diagnosis of dementia in residential care in Ireland is the exception rather than the rule (Cahill *et al.* 2010). For example, the most recent Long Stay Activity Statistics presented by the Department of Health and Children (2009) suggested that, 26% of residents in long-stay settings in Ireland have a diagnosis of dementia. International studies suggest that this official figure of 26% is a gross underestimate (Cahill *et al.* 2012). Cahill *et al.* (2010) screened a sample of residents (n=100) from four nursing homes in the Leinster region of Ireland for cognitive impairment. They reported that 32% (n=32) of the total sample had a clinical diagnosis of dementia. Of the remaining 68% (n=68) of residents, 27% (n=19) were mildly cognitively impairment, 25% (n=17) were moderately

cognitively impairment, 32% (n=22) were severely cognitively impairment and only 15% (n=10) of residents were deemed to be cognitively intact. As discussed in section 2.8, Cahill *et al.* (2010), concede that moderate to severe cognitive impairment as indicated by the Mini Mental State Examination (MMSE) (Folstein *et al.* 1975) is not synonymous with dementia, but suggest that, of the total sample of nursing home residents surveyed in the study, it is likely that there may have been a high degree of undiagnosed or undetected dementia.

4.4.2 Exclusion criteria for residents with dementia

Residents were excluded if they had any one or more of the following:

a) A sensory impairment that in the judgement of the nursing staff, impaired their ability to participate;

Rationale: The nature of the trial intervention required that the participating resident had some ability to communicate with their designated dyad. The National Disability Authority (2010) deems it unethical to "place excessively burdensome demands on research subjects with disabilities" (p.4). The residents' comfort and wellbeing were considered at all stages of the research process. Therefore, any resident whom staff felt would be unduly distressed or compromised in any way from inclusion were not asked to participate.

b) An acute physical illness that in the judgement of the nursing staff impaired their ability to participate.

Rationale: The purpose of the intervention was to improve the resident's quality of life. However, if the resident was physically unwell, it was judged unreasonable and not in their best interests to expect them to participate actively in the study intervention.

4.4.3 Enrolment and consent procedures for residents with dementia

The Director of Nursing/Nurse in Charge or a nominee was asked by the DARES Study Project Manager to identify all residents fulfilling the resident's inclusion criteria. Care staff introduced the research nurse to each potential participant. The research nurse, myself included, sought to obtain consent from each potential participant as follows:

a) The research nurse spent time building a rapport with each potential participant. This process involved working closely with staff members, who guided the research nurse on the best way to approach the resident. To maximise

communication and understanding, the research nurse explained the purpose of the study briefly, using clear, simple language, and explored with the resident whether she/he was interested in participating. If the resident said 'no' or indicated he/she was not interested in participating, the research nurse did not pursue the conversation any further. If the resident agreed to have the study explained further, the research nurse did so at a time and place that was appropriate to the needs of the individual resident. The resident was provided with a study information sheet, which outlined the purpose, process, potential benefits and harms, data collection procedures and time commitment required for participation (Appendix 11). It was made clear that participation was voluntary and that the resident had the right to withdraw at any point without prejudice. Residents were also provided with an assurance of confidentiality. Where a potential participant expressed an understanding of the purpose of the study, its voluntary nature and a willingness to participate, the research nurse completed the consent form with the resident (Appendix 11).

b) When it was not possible to gain consent directly from the resident, consent by proxy was used. In this instance, the older person's next-of-kin was asked to give formal written consent on behalf of the potential research participant (Good, 2001). The next-of-kin was asked to make their decision on the basis of their knowledge of the individual's prior attitudes and values (Fisk *et al.* 2007). The resident's next-of-kin were provided with information on the study, which outlined the purpose of the DARES Study, the potential benefits and harms of participation from the resident's perspective (Appendix 12) and if they agreed to participate on behalf of the resident they were asked to sign a consent by proxy form (Appendix 12).

In the context of the DARES Study, although all participating residents were involved initially through either giving consent themselves or through proxy, consent was not considered an *a priori* event but rather a continuous process (Hubbard *et al.* 2003). Resident's assent, defined as an on-going willingness to participate (Slaughter *et al.* 2007), was assessed continually throughout the duration of the study. Where assent was not forthcoming at any stage, the resident was withdrawn from the study without consequence.

4.5 Participants: staff in long-stay residential units

4.5.1 Eligibility criteria for staff participants

In the delivery of the trial intervention, participating staff were expected to work in dyads, that is, a nurse paired with a healthcare assistant. Staff members were eligible for inclusion if:

a) They had worked within the care setting for at least three months and were likely to be there for the duration of the trial.

Rationale: The three-month period reflected the need for the participating staff member to be familiar with the routine and challenges of working in the long-stay environment. They also had to have experience of working with residents with dementia.

4.5.2 Exclusion criteria for staff members

Nurses and healthcare assistants were excluded if:

a) They were not involved in the direct care of residents with dementia.

Rationale: The nature of the DARES Study intervention required both members of the dyad to work directly with their participating residents.

4.5.3 Enrolment and consent procedures for participating staff

In each participating long-stay residential unit, five dyads (five staff pairs, each pair consisting of one nurse and one healthcare assistant) were required. This was based on the number of residents required per cluster (n=17). Each participating dyad was allocated three or four participating residents. The ratio of two staff members to three or four residents was tested in the pilot study and was accepted as a reasonable distribution of workload between the dyads.

In each participating long-stay care unit, the DARES research team worked with the Director of Nursing or person nominated by the Director of Nursing to enrol staff members as follows:

a) The Director of Nursing, or a person nominated by the Director of Nursing, prepared a list of staff pairs who met the eligibility criteria and were willing to take part in the study;

b) All potential staff participants received a study information sheet and a staff consent form (Appendix 13). The DARES project manager allocated a research nurse (myself included) to each of the participating long-stay units and this designated research nurse was available to staff to answer any questions or clarify any issues they may have had.

4.6 Ethical issues

4.6.1 Ethical approval

Ethical approval for the DARES Study was granted by the Research Ethics Committee of the National University of Ireland, Galway and from the five hospital-based Research Ethics Committees responsible for the public long-stay units participating in the trial (Appendix 14). The hospital-based Research Ethics Committees were: Merlin Park Hospital, Galway; Sligo General Hospital, Sligo; Mayo General Hospital, Castlebar, Health Services Executive (HSE) - Midlands Area, Tullamore, Co. Offaly and the Mid-Western Regional Hospital, Limerick.

4.6.2 Residents' consent to participate

People with dementia have the right to participate in dementia research (Fisk *et al.* 2007; Slaughter *et al.* 2007; Alzheimer Europe, 2010). People with dementia have the ability to communicate subjective experiences of their quality of life even into the late stages of the illness (Thorgrimsen *et al.* 2003; Edelman *et al.* 2005; Hoe *et al.* 2005; 2006; 2009). Indeed, as the incidence and prevalence of dementia increases worldwide, it is well accepted that researchers of both pharmacological and non-pharmacological treatments for dementia view patient participation in the research process as essential. The participation of people with dementia informs key decision-making in many areas, including the evaluation of treatment programmes, service provision and identification of training needs (Good, 2001). Patient involvement is more likely to contribute to research findings that are relevant to the population being studied, guide the delivery of meaningful outcomes and enable research to be carried out in a way that is sensitive to their specific needs (National Disability Authority, 2010).

Although patient contribution to research is well respected, people with dementia are perceived as a vulnerable population and conducting research with them requires careful attention to their particular needs and vulnerabilities. At the same time, researchers must be mindful of the person's right to equality, inclusion, respect and autonomy (Slaughter *et al.* 2007; Fisk *et al.* 2007). By the very nature of the disease itself, people with dementia experience social isolation and a loss of sense of self (Kitwood, 1997), excluding them from the research process is to potentially exacerbate an already existing vulnerability (Dewing, 2002).

The main concern lies in how capacity to give consent to participate in research is determined and achieving a balance between paternalism i.e., the perceived need to protect the vulnerable, while at the same time respecting the person and their right to autonomy (O'Shea *et al.* 2008). The Irish Law Reform Committee (2006) defines capacity as "the ability to understand the nature and consequences of a decision in the context of available choices at the time the decision is to be made" (p.172). In the Irish context, to date, there is a distinct absence of definitive legal guidelines in how capacity to give consent is to be assessed (National Advisory Council on Aging, 2004; O'Shea *et al.* 2008). There have been a number of assessment approaches proposed but the *functional approach* to assessing capacity to give consent is the preferred approach and is favoured by the Law Reform Commission (2006) in their report *on Vulnerable Adults and the Law* (Donnelly, 2002). The functional approach demands that capacity is assessed on an issue specific basis (Law Reform Committee, 2006). O'Shea *et al.* (2008), explain that in the functional approach, "the capacity of the individual is assessed in relation to a particular decision at a particular time and has the important benefit that it ensures the least invasion of a person's decision-making autonomy" (p.67). The *National Quality Standards for Residential Care Settings for Older People* (HIQA, 2009) also support the functional approach, suggesting that "the resident's lack of capacity to give informed consent on one occasion is not assumed to be on another occasion" (p. 26).

The National Bioethics Advisory Commission (1998) state that it is ethically unacceptable to presume that persons with some decision making deficit cannot be assisted to achieve a level of functioning that would allow them to give valid consent. Donnelly (2002) suggests that consent can be facilitated by sharing information on the nature, purpose and likely effects of the proposed intervention in a form and language

that the older person with reduced decision making capacity can understand. The National Council on Ageing and Older People (2005) propose that decision-making capacity is enhanced when adequate time is taken to explain all aspects of the proposed treatment. Dewing (2002), an advocate of Kitwood's (1997) philosophy of personhood, recommends that during the consenting process, the researcher "must include face to-face encounters with the person with dementia in order to seek and maintain permission or consent" (p.164). Dewing rationalises this approach, arguing that, by getting to know the person with dementia the researcher gains an understanding of the person's needs and subsequently comprehends their readiness or reluctance to become involved in the research process.

Prior to the beginning of the trial, all participating research nurses were trained in the process of seeking consent from the person with dementia. The focus of the training was on the research nurse building a rapport and getting to know the resident. By building a relationship, the research nurse could represent the best interest of the person with dementia. The research nurse was mindful of acknowledging the older person's right to autonomy and equality and facilitated the person in making an informed, voluntary decision without coercion (Donnelly, 2002). Dewing (2002), suggests that researchers working in the area of dementia "require particular skills in relating to people who have dementia" (p.168). All of the research nurses, myself included, had considerable experience in working with people with dementia and this experience was invaluable throughout the data collection process. In working with people with dementia, we had first-hand experience of the disease process and how it impacts on the person. We understood that the person's ability to communicate had been and continued to be impoverished by the illness. The circumstances necessitated that we, as research nurses, had to maximise our own communication skills to counteract the deficits of the person with dementia. Throughout the whole research process, we exchanged both written and verbal Information at an appropriate level with the person with dementia while being mindful of the person's needs and level of functioning from both physical and psychological perspectives. We also used communication enhancement strategies such as larger font sizes on all of the documentation relevant to the resident. We checked that individual resident's hearing aids were working and if they wore glasses, we ensured they were clean. For residents with compromised hearing, we endeavoured to communicate in writing.

As stated in section 4.4.3, the resident's on-going willingness to participate in the study was validated by the research nurses throughout the research process and if the resident expressed a reluctance to continue to participate, they were withdrawn from the study immediately.

As detailed in sections 4.3.3 and 4.4.3, information about the trial was made available to all participating long-stay units, residents, staff and residents' next-of-kin. Information sheets provided details of the purpose of the study, potential benefits/harm, explanation of data collection points, time commitment, availability of the research team to answer any questions, voluntary participation and consent, the right to withdraw at any time, assurance of confidentiality and the project manager's details.

Assigning each participating long-stay unit, resident and staff member a unique study code protected confidentiality of all participants' data. This code was used on all data collection forms used by the research team. The names of participating long-stay units, residents and staff were stored separately from their study codes. The project manager was responsible for both the allocation of codes and compiling the master list (Appendix 15) for each unit. All data pertaining to each participating unit was individually filed and kept in a locked facility. In accordance with the Data Protection (Amendment) Act 2003 (Government of Ireland 2003), all electronic data i.e., data stored in Statistical Package for the Social Sciences version 20 (IBM Corp, 2012) files and master coding lists for each long-stay unit, residents and staff are stored in an electronic storage system which has coded access, accessible to members of the DARES research team only.

4.7 Trial interventions

4.7.1 Control arm

Residents in the control group received usual care. Usual care meant that a resident's care continued to be guided by current nursing and medical care plans. While the research team acknowledged the complexity and potential heterogeneity of usual care, substantial effort was made to describe clearly the components of usual care for residents with dementia using the following three methods: The research nurses completed a context of care form for each participating unit (Appendix 16), and as part of the qualitative component of the DARES study (not included in this thesis) members of the DARES core team carried out nine structured interviews with Clinical Nurse

Managers in the control sites and they also completed a documentary analysis of residents care plans.

4.7.2 Intervention arm

Staff participants in long-stay units randomised to the experimental arm attended the DARES study intervention i.e., a **s**tructured **e**ducation **r**eminiscence-based **p**rogramme for **s**taff (**SERPS**)**.** The SERPS was designed by members of the DARES research team, of which I was a member. The aim of the programme was to enable staff to develop the knowledge, skills and attitudes necessary to implement reminiscence successfully with their residents with dementia.

The approach undertaken in developing and validating the SERPS was based on the model developed by Van Meijel *et al.* (2004) (Cooney *et al.* 2012). The model was devised specifically to inform the development and refinement of nursing interventions in a systematic way and consists of the following four stages:

4.7.2.1 Stage 1: Problem definition

This first stage involved identifying the 'problem', which provided the focus of the intervention. The problem was developing a structured educational programme and identifying the key components underpinning such an approach. This was largely a theoretical phase, which involved a review of the empirical evidence to establish if similar research had been undertaken. A review of the literature revealed that previous research had been carried out in this area, particularly in the United Kingdom (UK). Criteria used to inform the SERPS stemmed largely from recommendations for best practice in the development and implementation of patient education programmes as outlined by the National Institute of Clinical Excellence (NICE, 2003) and the Department of Health UK and Diabetes UK (2005). Four key elements relevant to structured educational programmes were identified and integrated into the SERPS i.e., a structured curriculum, trained educators, quality assurance and audit of programme outcomes.

4.7.2.2 Stage 2: Accumulation of building blocks for intervention design

This stage consisted of both a theoretical phase and a needs analysis that sought to 'build' on the content of the trial intervention. In the theoretical phase, the DARES

research team undertook a concept analysis to define the key attributes of reminiscence (Dempsey *et al.* 2012). This concept analysis informed the development of the programme philosophy. A literature review was undertaken to contextualise dementia and informed programme content and the development of resource materials such as the type of triggers staff should use to stimulate the reminiscence process. A content analysis of existing educational programmes on dementia also guided the selection of programme content and delivery approaches undertaken in the SERPS. However, while the literature provided much of the SERPS content, the literature also unveiled the need for other building blocks and, as recommended by Meijel *et al.* (2004), a needs analysis was incorporated into this second stage. The needs analysis involved seeking input from key stakeholders including educationalists experienced in the delivery of dementia and/or reminiscence programmes, nursing staff and other healthcare professionals working with people with dementia and people with dementia residing in the long-stay setting and their families. Advice was also sought from other healthcare professionals, for example, speech and language therapists, occupational therapists and a clinical psychologist. The aim of this consultation was to identify the practical needs of staff from the perspective of key stakeholders and provide for them in the SERPS. The needs analysis was facilitated through an interview schedule and was conducted by four members of the DARES research team. Following the data analyses, taxonomy of recommendations for delivering and developing the SERPS was created, which enabled the refinement of the programme content as well as directing learning outcomes and assisting with the development of learning resources to best meet these outcomes.

4.7.2.3 Stage 3: Intervention design

The focus at this stage was to devise an initial draft of the SERPS. Responsibility for this was delegated to three members of the DARES research team. The foundation of the programme was based on adult learning theory and, consistent with such an approach, a philosophy of staff empowerment was adopted. Learning outcomes identified by staff members in Stage 2 were integrated into the training programme. The SERPS was delivered by a core group of five experienced nurse educators who adopted facilitator roles as distinct from didactic teaching roles. The SERPS consisted of nine sessions delivered over a three-day period. Days 1 and 2 were delivered consecutively and involved the facilitation of eight sessions. Day 3 was delivered six weeks later. On completion of the two-day training programme, each dyad

(nurse/healthcare assistant) was expected to implement reminiscence strategies learned in the programme with their allocated number of participating residents. Each dyad was asked to conduct at four sessions of reminiscence with each of their designated residents per week, regardless of the individual resident's severity of dementia. Sessions must have included one formal or planned session and three informal or spontaneous sessions. To ensure adherence to the treatment protocol, Dyad members were required to record the number of weekly sessions and the output of each session for each of their designated residents in 'Reminiscence Record Sheets' provided to them by the DARES research team. Parallel to this, each dyad was expected to complete a life story book with each participating resident, engaging the co-operation of the resident's family if deemed appropriate by both the resident and staff. The purpose of the life story book was to provide a basic structure for the subsequent use of reminiscence. The focus was on the recall of pleasurable memories personal to the individual resident. Dyad members could use triggers or prompts to stimulate recall. The training team provided each dyad with weekly reminiscence recording sheets, in which dyads were expected to document the output of both formal and informal reminiscence sessions for each of their designated residents. They were also expected to embed reminiscence into individual resident's care plans. The approach guiding Day 3 was that of experiential learning, which was again consistent with adult learning theory. Dyads members were encouraged to discuss their experiences of implementing reminiscence since completion of the previous two days of training. Sharing stories provided a forum for peer learning and support. Discussion was facilitated by asking participants to complete a 'Report card' outlining what went well, what could have gone better and why. Facilitators offered support and advice as required. Day 3 also enabled the trainers to evaluate staff adherence with the study intervention to date. Continued adherence was facilitated by asking dyad members to prepare an action plan for the remaining weeks. To evaluate progress and to provide guidance or advice if necessary, dyad participants in intervention sites were provided with at least one support visit from a facilitator, approximately three weeks after Days 1 and 2 of the SERPS. Each dyad member was provided with the facilitators' telephone numbers, in case they had any issues or concerns during the study period.

The SERPS curriculum included the following sessions:

- Introduction;
- Understanding the person with dementia;

- How memory works;
- Reminiscence explained;
- Communicating with persons with dementia;
- Behaviours that challenge;
- Using reminiscence in practice including learning how to respond to situations where reminiscence results in the recall of negative or upsetting events in the lives of residents; and
- Person-centred care planning for people with dementia.

4.7.2.4 Stage 4: Intervention validation

A number of approaches were undertaken to validate the content and proposed delivery of the SERPS. Content validity was ensured by undertaking a concept analysis and a review of the literature, to define the core elements of reminiscence work in dementia. Input was sought from people with dementia and their carers, which included both family members and healthcare professionals as appropriate.

The SERPS draft was reviewed by the DARES team and then by two external reviewers. Both reviewers had expertise in the area of dementia research and dementia education. Following some minor changes, the programme was piloted (section 5.7) in two long-stay residential units. After piloting the SERPS, the programme was validated through a qualitative field study, which explored the experiences of participating in the SERPS from the perspective of the resident with dementia and dyad members. A staff nurse, healthcare assistant and a resident were interviewed from each site (n=6). Both residents and staff were positive in their evaluation of the SERPS. Staff reported that the life story book enabled them to get to know the resident better than they had previously and the intervention was enhanced further by using the resident's life story book to inform their care plan (Cooney *et al.* 2012).

4.7.3 Treatment fidelity monitoring

To maximise treatment fidelity, standardised delivery of the programme in each of the intervention sites was assured by presenting the SERPS as a structured education programme, within the context of a comprehensive, formal curriculum, delivered by five experienced educators. As detailed in Stage 2 of the intervention design, detailed in

section 4.7.2.2, a number of strategies were embedded into the intervention design to maximise adherence to the treatment protocol from the perspective of staff. They included:

1. A member of the delivery team visiting each intervention unit between the initial two-day training and Day 3. They met with dyad members to discuss progress with the life story book and dealt with any concerns or issues with regard to the implementation of the intervention thus far;

2. On Day 3 (six-weeks later), completion of report cards enabled facilitators to again monitor staff adherence with the trial intervention and identify if any remedial action was necessary;

3. Validation of the required dose of reminiscence: Dyad members were asked to engage their allocated residents with dementia in one formal and three spontaneous sessions of reminiscence each week regardless of the resident's stage of dementia. As an integral part of the treatment fidelity monitoring process, to ensure that residents were exposed to the required dose of reminiscence, each dyads was required to document the output of both formal and informal reminiscence sessions for each of their designated residents in the weekly Reminiscence Record Sheets provided to them by the DARES research team. At the end of the trial, each dyad had to provide evidence of completing the required four weekly sessions of reminiscence for all of their designated residents. Reminiscence Record Sheets were analysed at the end of the trial to validate that dyad has delivered the required dose of reminiscence to their designated residents;

4. Dyad members were provided with the telephone number of an appointed member of the training team and were encouraged to contact this person should they have required any additional support with the delivery of the intervention at any point throughout the study.

4.8 Study outcomes

4.8.1 Primary outcome

4.8.1.1 Residents' quality of life

The primary outcome in this study was the quality of life of residents as measured by the care recipient's self-report version of the Quality Of Life in Alzheimer's disease (QOL-AD) scale (Logsdon *et al.* 1999).

4.8.1.1.1 An overview of the QOL-AD scale

The QOL-AD scale is a dementia specific measurement tool and it is the recommended instrument of choice when measuring quality of life in dementia care (Sansoni *et al.* 2007; Moniz-Cook *et al.* 2008). The QOL-AD has two versions, (i) a care recipient self-report version and (ii) a caregiver proxy version; both versions of the QOL-AD scale are identical in structure, content and method of rating. Hoe *et al.* (2007) argue that the subjective rating of their own quality of life by the older person with dementia is the gold standard measurement. However, eliciting valid responses from people with dementia is challenging, particularly in the advanced stages of the illness (Logsdon *et al.* 2002). To overcome this difficulty, proxy ratings by care givers are used routinely, together with or instead of, the care recipient's rating. Proxy reports are obtained usually from a close relative or caregiver of the affected person. They circumvent the cognitive limitations that are associated with dementia and can be used for all stages of the illness (Sansoni *et al.* 2007). From a methodological perspective, proxy measures may help minimise the potential for missing data and low completion rates associated with self-report measures in severe dementia (Hoe *et al.* 2005). Nevertheless, researchers indicate that there are discrepancies in the correlations between self-report and proxies. Proxies rate the quality of life of the person with dementia consistently lower (Logsdon *et al.* 2002; Hoe *et al.* 2005; Edelman *et al.* 2005; Woods *et al.* 2006; Hoe *et al.* 2006; 2007). Proxy ratings may be influenced by the proxy's own expectations, belief system, and relationship with the person being rated, current levels of depression or burden of care (Logsdon *et al.* 1999). On the other hand, Hoe *et al.* (2007) demonstrated that the quality of life of the person with dementia is influenced by their mood and living environment, reporting that residents in long-term care have higher levels of depression and lower quality of life than those being cared for at home.

There is considerable evidence of the ability of people with mild, moderate and severe dementia to rate their own quality of life using the QOL-AD instrument (Logsdon *et al.* 1999; 2002; Thorgrimsen *et al.* 2003; Hoe *et al.* 2005). Hoe *et al.* (2005), examined the usefulness of the QOL-AD instrument in people with severe dementia by considering Mental State Examination Scores (MMSE) (Folstein *et al.* 1975) scores of <12. In an already small sample size (n=79), only 52% (n=41) were able to complete the QOL-AD self-report version, even with the assistance of an interviewer. The mean MMSE score of those able to complete the self-report was 7. Participants who were unable to complete the self-report (42%, n=33) had a mean MMSE score of 2.2. Although it must be noted that MMSE scores indicate the level of cognitive impairment, it does not indicate the severity of dementia and the normal cut-off-score for severe cognitive impairment in the MMSE is <10 (Folstein *et al.* 1975; Boote *et al.* 2006).

4.8.1.1.2 Structure of the QOL-AD scale

The QOL-AD scale, both care recipient self-report and caregiver proxy versions, consists of 13 items that measure the domains of physical health, mood, memory, functional abilities, interpersonal relationships, ability to participate in meaningful activities, financial situation, and global assessments of self as a whole and quality of life as a whole. To facilitate its use with cognitively impaired individuals, the QOL-AD uses simple and straightforward language. All items have the same four response options (1=poor; 2=fair; 3=good; 4=excellent). All items are rated according to the person's current quality of life.

4.8.1.1.3 Scoring of the QOL-AD scale

Scale scores range from 13 to 52, with higher scores indicating greater quality of life. All 13 items are summed to give a total score. The recommended scoring of the QOL-AD scale was adhered to in the DARES analysis i.e., in the complete case or available case analysis up to two missing items were replaced with the mean score of the remaining items, but if more than two items were missing, the entire measure was considered missing (Logsdon *et al.* 2002; Hoe *et al.* 2005; 2006; 2009). Further details pertaining to the scoring and analyses of the QOL-AD in the DARES study are presented in section 4.15.

4.8.1.1.4 Psychometric properties of the QOL-AD scale

4.8.1.1.4.1 Reliability

Homogeneity

Homogeneity or internal consistency reliability is the extent to which items in a scale are inter-correlated. The most commonly used method to evaluate internal consistency is Cronbach's alpha (LoBiondo-Woods & Haber, 2002; McDowell, 2006). Cronbach's alpha should be between 0.70 and 0.90 (Sansoni *et al.* 2007). The QOL-AD instrument has demonstrated good to excellent internal reliability with Cronbach's alpha values ranging from 0.78 to 0.94 for the care recipient version and 0.79 to 0.88 for the proxy or caregiver version (Logsdon *et al.* 1999; Logsdon *et al.* 2002; Thorgrimsen *et al.* 2003; Hoe *et al.* 2005; Edelman *et al.* 2005).

Stability

Stability is the measuring instrument's ability to consistently produce the same results with repeated testing over a period of time and it is most commonly measured by the test-retest procedure (LoBiondo-Wood & Haber, 2002). An intraclass correlation coefficient (ICC) of >0.70 is desired (Sansoni *et al.* 2007).

The QOL-AD scale has demonstrated good to excellent test-retest reliability, Logsdon *et al.* (1999) reported intraclass correlations of 0.76 for the care recipient version and 0.92 for the caregiver version at one week re-test. Thorgrimsen *et al.* (2003) indicated test-retest reliability for the care recipient version only, reporting an intra-class correlation coefficient of 0.6.

Equivalence

Equivalence is the extent to which results obtained by different raters or interviewers, using the same measuring instrument, on the same study participants and under similar conditions will agree (LoBiondo-Wood & Haber, 2002; McDowell, 2006). It is measured using inter-rater reliability. The kappa statistic measures the level of agreement between raters: poor (kappa < 0.2), fair (kappa 0.21-0.40), moderate (0.41-0.60), good (0.61-0.80) or very good (0.80-1.00), (Beer *et al.* 2009). Thorgrimsen *et al.* (2003) assessed the inter-rater reliability of the QOL-AD caregiver version using two staff members and demonstrated that agreement was good (kappa=0.60-0.74) for one item 'memory' and was very good (kappa= 0.75-1.00) for the other 12-items.

Conversely, Beer *et al.* (2009) who evaluated the inter-rater reliability of the QOL-AD caregiver version with two staff in a residential setting reported kappa scores for individual items as generally poor (kappa=0.2 or less) to moderate (kappa=0.41-0.60).

4.8.1.1.4.2 Validity

Content validity

Content validity is the extent to which the construct of interest is represented adequately by the items in the questionnaire (LoBiondo-Wood & Haber, 2002). Researchers employ various means of validating the content of a new instrument. The most common approach to content validity is to engage a panel of experts in the form of focus groups to evaluate and agree with the scope of the items and the extent to whch they represent the concept under consideration.

To ensure an adequate representation of the appropriate quality of life domains, patients and a panel of experts were involved in the selection of items for the QOL-AD (Logsdon *et al.* 1999). Thorgrimsen *et al.* (2003) reported that the scale had good content validity with all items essential and no additional items deemed necessary.

Construct validity

Construct validity is the degree to which items in an instrument adequately represent the theoretical concept being measured. Strategies for assessing construct validity include convergent and divergent validity approaches. With convergent validity, researchers formulate a hypothesis stating that the measurement instrument being tested will correlate with other instruments that measure the same construct. Whereas, in divergent validity tests, researchers hypothesise that the measurement instrument will not correlate with other instruments that measure different constructs (McDowell, 2006). Correlations between measures are generally explored using Pearson's correlation coefficient (*r*), which is suited to data measured at an interval scale level. Pearson's correlation coefficient values range from -1 and +1. The sign in front of the value, indicates the direction of the correlation. A minus sign suggests a negative relationship between the measurements, that is, as one increases the other decreases. A positive sign suggests a positive relationship, that is, as one increases the other also increases. Although the sign indicates the direction of the relationship, it does not give any indication of the strength of the relationship. Pallant (2007, p.132) recommends using the guidelines proposed by Cohen (1988) to interpret the strength of the

relationship i.e., If r=0.10 to 0.29 (small); r=0.30 to 0.49 (modest) and if r=0.50 to 1.0 (large). Alternatively, p values may be used to indicate whether the relationship is significant or not. In convergent validity, correlations would be expected to be significant, the opposite is expected in divergent validity, that is correlations are not expected to be significant (McDowell, 2006).

<u>Convergent validity of the QOL-AD scale</u>

Logsdon *et al.* (2002) hypothesised that higher QOL-AD scores would be correlated with "less impairment on measures of behavioral competence, better psychological status, better physical function and better interpersonal environment" (p.513). The authors reported that their hypotheses were supported. For behavioural competence, they reported negative correlations between both the care recipient and caregiver versions of the QOL-AD and the Physical and Instrumental Self-Maintenance Scale (PIS-ADL) (Lawton & Brody, 1969), (r=-0.31 and r=-0.37 respectively; p<.001). For psychological status, the Geriatric Depression Scale (GDS) (Yesavage *et al.* 1983) correlated negatively with QOL-AD scores (r=-0.51 and r=-0.52 respectively; p<.001). Physical health function as measured by the Medical Outcome Scale (MOS) (McHorney *et al.* 1993) was correlated positively with both the care recipient and caregiver versions of the QOL-AD (r=0.22 and r= 0.43, p<0.01 and p<0.001, respectively). Finally, for the interpersonal environment as measured by the Screen for Caregiver Burden (SCB) (Vitaliano *et al.* 1991), caregiver burden was correlated negatively with both the caregiver and care recipient QOL-AD scores but the correlation was more significant with the caregiver QOL-AD scores (objective burden: r=-0.52, p<.001; subjective burden: r=-0.53, p<.001) than with the care recipient QOL-AD scores (objective burden: r=-0.21, p<.01; subjective burden: r=-0.19, p<.01). Thorgrimsen *et al.* (2003) reported that the care recipient version of the QOL-AD indicated positive correlations with both the Dementia Quality of Life scale (D-QOL) (Brod *et al.* 1999), (r=0.69, p< 0.0001) and the EQ-5D (EuroQoL Group, 1990), (r=0.54, p<0.001). In the same study, the authors hypothesised that levels of depression would be closely correlated to quality of life. They reported that the QOL-AD as rated by the care recipient and levels of depression as measured by the Cornell Scale for Depression in Dementia (CSDD) (Alexopolous *et al.* 1988) were correlated negatively (r=-0.20, p<0.01). Woods *et al.* (2006) reported negative correlations at baseline between higher quality of life as measured by the QOL-AD and lower symptoms of depression (r=-0.195, p<0.01) as measured by the CSDD and lower levels of anxiety

as measured by the Rating for Anxiety in Dementia scale (RAID) (Shankar *et al.* 1998), (r=-0.120, p=0.052). Furthermore, higher levels of functioning as measured by the Clifton Assessment Procedures for the Elderly-Behaviour Rating Scale (CAPE-BRS) (Pattie & Gilleard, 1979) correlated negatively with higher quality of life (r=-0.139, p< 0.05).

Divergent validity of the QOL-AD scale

A number of authors have reported that they did not find any correlation between quality of life, as measured by the QOL-AD scale, and levels of cognition as indicated by the MMSE. Logsdon *et al.* (2002) reported that MMSE scores were not "significantly correlated with" (p.514) for either the care recipient or caregiver QOL-AD scores (r=0.12 and r=0.02, respectively, p values were not reported). Logsdon *et al.* (2002) also observed that caregiver depression as measured by the Centre for Epidemiologic Studies Depression Scale (CESD) (Radloff, 1977) were not correlated with care recipient reported QOL-AD scores (r=-0.12, p values were not reported). In another study, Thorgrimsen *et al.* (2003) hypothesised that cognitive abilities would not be correlated with quality of life. The authors reported that quality of life as measured by the care recipients version of the QOL-AD and levels of cognition as measured by the MMSE were not positively correlated (r=0.09, p=0.19).

4.8.1.1.5 Method of administration of the QOL-AD scale

- Care recipient self-report version

In the DARES study, the care recipient self-report version of the QOL-AD was completed by the resident and was administered as a structured interview using standardised instructions as detailed in the QOL-AD training manual (Logsdon *et al.* 2002). The research nurses, myself included, administered the QOL-AD form with the resident, regardless of the severity of dementia. If the resident was unable to choose a response to a particular item or items, the research nurse recorded this on the comments section. For item 7 (marriage), residents who were unmarried were asked to rate their closest personal relationship or relationship with their current family caregiver (Logsdon *et al.* 2002).

- Caregiver proxy version

In the DARES study, a member of the dyad (nurse or healthcare assistant) completed the caregiver version of the QOL-AD. The research nurse advised the designated dyad

member on how to complete the proxy version of the QOL-AD form, answering any questions in the process.

4.8.1.1.6 Administration time for the QOL-AD scale

The administration time for both versions of the QOL-AD scale is approximately 10 minutes each (Logsdon *et al.* 2002).

4.8.2 Secondary outcomes

Secondary outcomes measured were:

- Staff rating of the residents' quality of life
- Residents' levels of agitation
- Residents' levels of depression
- Staff nurses' burden of care
- Healthcare assistants' burden of care

4.8.2.1 Staff rating of the residents' quality of life

The caregiver proxy version of the QOL-AD scale was used to measure staff response to residents' quality of life.

4.8.2.2 Residents' levels of agitation

Residents' levels of agitation were measured using the Cohen-Mansfield Agitation Inventory (CMAI) (Cohen-Mansfield *et al.* 1986). The CMAI has a number of versions but the CMAI long form was used in the DARES study as it is recommended for use in the nursing home population (Cohen-Mansfield *et al.* 1989; Sansoni *et al.* 2007).

4.8.2.2.1 Structure of the CMAI

The 29-item scale was developed specifically to assess the frequency of agitated behaviours in older people with cognitive impairment. It is completed by a staff member who rates each of the 29 items on a seven-point Likert scale based on the frequency with which the resident has engaged in the behaviour in the previous two-weeks.

4.8.2.2.2 Scoring of the CMAI

Scores range from 1 (never) to 7 (several times an hour). Item scores are summed to give a total score ranging from 29-203 with higher scores indicating higher levels of agitation and aggression. Further details of how the CMAI was scored and analysed are detailed in section 4.15.

4.8.2.2.3 Psychometric properties of the CMAI

4.8.2.2.3.1 Reliability

In a review of nine studies evaluating the psychometric properties of the CMAI, Sansoni *et al.* (2007) reported that the CMAI has demonstrated:

Homogeneity

Excellent internal consistency, with Cronbach's alpha for the total scale ranging from 0.75 to 0.91.

Stability

Excellent test-retest reliability. ICC values were greater than 0.70 with correlations ranging from 0.79-0.97,

Equivalence

Good to excellent inter-rater reliability, with correlations varying from 0.76 to 0.96.

4.8.2.2.3.2 Validity

Content validity

Cohen-Mansfield *et al.* (1986) developed the CMAI scale from three sources: a review of the literature, a panel of experts and interviews with nursing home staff working with cognitively impaired residents. The items on the scale were devised without input from patients. Sansoni *et al.* (2007) reported that the CMAI had "an adequate coverage of the relevant domains" (p.276).

Construct validity: convergent validity

The CMAI correlates as expected with other scales that measure similar constructs (Sansoni *et al.* 2007). Finkel *et al.* (1992) investigated levels of agitated behaviours as

measured by the CMAI over three nursing shifts described as CMAI-Day, CMAI-Evening and CMAI-Night. They reported significant positive correlations with the Behavioural Pathology in Alzheimer's Disease scale (Behave-AD) (Reisberg *et al.* 1987) for the day and night shift (CMAI-Day, r=0.4322, p=0.003; CMAI-Evening, r=0.2760, p=0.042, respectively) but correlations for the night shift were not correlated significantly (CMAI-Night, r=0.2097, p=0.097). Similarly, across three nursing shifts the CMAI demonstrated significant positive correlations with the Behavioural Syndromes Scale for Dementia (BSSD) (Devanand *et al.* 1992) for the day and evening shift (CMAI-Day, r=0.5157, p=0.000; CMAI-Evening, r=0.4270, p=0.003) but again, correlations were not significant for the night shift (CMAI-Night, r= 0.0592, p=0.426).

Cohen-Mansfield & Libin (2005) demonstrated that the CMAI was positive correlated with the Agitated Behaviours Mapping Instrument (ABMI) (Cohen *et al.* 1989). Analyses of total scores for verbal agitation, physical agitation and overall combined agitation were significantly positively correlated (r=0.317, p<0.001; r=0.389, p<0.001; r=0.203, p=0.007, respectively).

Construct validity: divergent validity

Cohen-Mansfield & Libin (2005) reported no correlation between physical non-aggressive agitation behaviours (which include wandering or pacing, repetitious mannerisms, handling objects inappropriately, general restlessness and fidgeting) as measured by the CMAI and impairment to activities of daily living as measured by the minimum data set (MDS) (Morris *et al.* 1999) (r=0.235 and p=0.001).

4.8.2.2.4 Method of administration of the CMAI

The CMAI training manual (Cohen-Mansfield *et al.* 1989) gives a detailed account of the recommended methods of administration, outlined under instructions for the interviewer. For the purpose of this study, we adhered to a face-to-face interview format between the research nurse and the formal caregiver, which could be either member of the dyad i.e., either the staff nurse or the healthcare assistant.

4.8.2.2.5 Administration time of the CMAI

Administration of the CMAI takes approximately 20 minutes (Sansoni *et al.* 2007)

4.8.2.3 Residents' levels of depression

Residents' levels of depression (if any) were measured using the Cornell Scale for Depression in Dementia (CSDD) (Alexopoulos *et al.* 1988). The CSDD was developed to assess signs and symptoms of major depression in patients with dementia. It is the measure of choice for assessing patients' mood and it is used widely in dementia research (Sansoni *et al.* 2007; Moniz-Cook *et al.* 2008). The CSDD is particularly appropriate in the long-stay setting as it facilitates the rating of depression scores across the whole range of dementia severity (Alexopoulos *et al.* 1988).

4.8.2.3.1 Structure of the CSDD

The CSDD is a 19-item scale. Items are grouped under the following headings: mood-related signs, behavioural disturbance, physical signs, cyclical functions and ideational disturbance.

4.8.2.3.2 Scoring of the CSDD

Each of the 19 items is rated for severity on a scale of 0 to 2 (0 = absent; 1 = mild or intermittent and 2 = severe). All 19 items are summed to give a total score. If one item is missing, the entire measure is disregarded. Total scores range from 0 to 38. Higher scores indicate higher levels of depression. A score of 10 or more indicates a probable major depression. Scores above 18 indicate a definitive major depression. Scores below 6 are, as a rule, associated with absence of significant depressive symptoms (Alexopoulos *et al.* 1988). A score of 7 or more indicates clinical depression in residents in long-stay care facilities (Watson *et al.* 2003; Woods *et al.* 2006; Watson *et al.* 2006). Further details of the scoring and analyses of the CSDD in the DARES study are presented in section 4.15, Psychometric properties of the CSDD

4.8.2.3.3 Psychometric properties of the CSDD

4.8.2.3.3.1 Reliability

Homogeneity

Alexopoulos *et al.* (1998) assessed the internal consistency of the CSDD in a sample of 48 participants from both the hospital and nursing home setting and reported a Cronbach's alpha of 0.84.

<u>Stability</u>

Sansoni *et al.* (2007) report that there is no evidence of test-retest reliability for English speaking samples.

<u>Equivalence</u>

Alexopoulos *et al.* (1988) reported a good inter-rater reliability score (kappa 0.67).

4.8.2.3.3.2 Validity
<u>Content validity</u>

The 19 items on the CSDD were selected after reviewing the literature on the phenomenology of depression in patients with and without dementia. Alexopolous *et al.* (1988) also sought input from psychiatrists of old age and other experts in the field of dementia.

<u>Construct validity: convergent validity</u>

Korner *et al.* (2006) tested the convergent validity of the CSDD with the four versions of the Geriatric Depression Scale (GDS) (Yesavage *et al.* 1983), that is, the 30-item version and the later 15-, 10- and 4-item versions. Correlations were positive with all four versions: GDS-30 ($r=0.82$, $p<0.05$); GDS-15 ($r=0.77$, $p<0.05$); GDS-10 ($r=0.72$, $p<0.05$) -the GDS-4 ($r=0.69$, $p<0.05$). In the same study, the CSDD demonstrated a positive correlation with the Hamilton Depression Rating Scale (HDRS) (Hamilton, 1960) ($r=0.91$, $p<0.05$) and with the Clinical Global Impression (CGI) (Guy, 1976) scale ($r=0.82$, $p<0.05$).

<u>Construct validity: divergent validity</u>

There is limited evidence of divergent validity of the CSDD. However, Maixner *et al.* (1995) established that the CSDD differentiates between depressed and non-depressed individuals with a clinical diagnosis of depression.

4.8.2.3.4 <u>Method of administration of the CSDD</u>

The developers of the CSSD (Alexopoulous *et al.* 1988) provide comprehensive guidelines on the scoring and administration of the instrument. As suggested in the guidelines, the research nurse completed two semi-structured interviews, one with the resident and the other with a member of the dyad. During each of the interviews, the

research nurse assigned a provisional score to each of the items on the scale. Each interview focused on the extent to which depressive signs and symptoms occurring during the week preceding the interview. Many of the items during the resident's interview could be completed after a period of direct observation. If there were discrepancies in ratings between the resident and dyad member then the research nurse re-interviewed both parties to resolve the discrepancies. The final ratings of the CSDD items represented the research nurses' clinical judgment.

4.8.2.3.5 Administration time of the CSDD

Administration and scoring of the CSDD takes approximately 30 minutes (approximately 20 minutes with the dyad member and approximately 10 minutes with the resident) (Sansoni *et al.* 2007).

4.8.2.4 Staff burden of care

Both staff nurses' and healthcare assistants' burden of care was measured using the Modified-Zarit Burden Interview (M-ZBI) scale (Sourial *et al.* 2001).

4.8.2.4.1 Structure of the M-ZBI scale

The M-ZBI scale consists of 13 items. Sourial *et al.* (2001) selected these 13 items from the original 22-item Zarit Burden Interview scale (ZBI scale) (Zarit *et al.* 1980).

4.8.2.4.2 Scoring of the M-ZBI

Each item on the interview is a statement, which the caregiver is asked to rate on a frequency scale ranging from 0 to 4 (0 = Never; 1 = Rarely; 2 = Sometimes; 3 = Frequently and 4 = Nearly always). Scores range from 0 to 52. All 13 items are summed to give a total score with higher scores representing greater levels of burden. If any items was missing then the entire measure was considered missing. Further details of the scoring and analysis of the M-ZBI scale in the DARES study are detailed in section 4.15.

4.8.2.4.3 Psychometric properties of the M-ZBI scale

The M-ZBI scale devised by Sourial *et al.* (2001) has limited psychometric properties. Those reported in the literature are derived from one study only.

Reliability

Homogeneity

Sourial *et al.* (2001) reported that the M-ZBI scale had "satisfactory" (p.185) internal consistency with Cronbach's alpha values ranging from 0.74 to 0.87.

Stability

Sourial *et al.* (2001) provide no evidence of test-retest reliability for the M-ZBI scale

Equivalence

Sourial *et al.* (2001) provide no evidence of inter-rater reliability for the M-BI scale.

4.8.2.4.5 Validity

Content validity

There is limited evidence of the content validity of the M-ZBI scale. The authors state merely that the 13 items were selected to reflect their appropriateness and applicability to nursing care staff working with older people with dementia residing in the long-stay setting. However, items on the original 22-item version were, it is stated, derived from clinical and research experience with caregivers of older people with dementia (Zarit *et al.* 1980).

Construct validity: convergent validity

There is no evidence of convergence validity for the M-ZBI scale.

Construct validity: divergent validity

There is no evidence of divergent validity for the M-ZBI scale

4.8.2.4.6 Method of administration of the M-ZBI scale

Each member of the dyad self-completed the M-ZBI scale for each of the participating residents allocated to them at both Time 1 and Time 2. The research nurse was available to answer any questions or clarify any issues the dyad members may have had in completing the questionnaire.

4.8.2.4.7 <u>Administration time of the M-ZBI scale</u>

Administration of the M-ZBI scale took approximately 15 minutes.

4.9 Additional data completed

At baseline, in addition to other relevant resident demographic and clinical data (summarised in Table 4-1 and presented in Table 5-1a), the research nurse screened each participating resident's global cognitive functioning using the MMSE. Demographic data were collected for participating, staff nurses and healthcare assistants (summarised in Table 4-1 and presented in Table 5-1b and Table 5-1c).

4.10 Data collection

4.10.1 Timing of data collection

Data on both participating residents and staff members were collected at:

i.   Trial entry and pre-randomisation. Data collected at this time were indicated on all data collection forms as Time 1; and

ii.   18 to 22 weeks post-randomisation. Data collected at this time were indicated on all data collection forms as Time 2.

4.10.2 Data collection methods

Prior to visiting the participating unit, the DARES project manager provided one of four research nurses (one of whom was myself), with a folder, which contained all the necessary codes and documentation required for data collection. In advance of any data collection, the research nurse in the presence of the Director of Nursing/proprietor of the long-stay unit signed an *Agent Nomination and Confidentiality Form* (Appendix 17*)*. Baseline data collection in each participating long-stay unit consisted of the research nurse visiting the unit over a five-day period. The research nurse was flexible and adaptable in his/her approach. The focus was on facilitating residents and dyad members in the research process in every way possible. The research nurse arranged to meet with both residents and dyad members at a time and place that was appropriate for them. The same approach was undertaken at Time 2 data collection. All data collected and timing of collection are summarised in Table 4-1.

Table 4-1: Summary of data collection

Data	Outcome	Baseline (Time 1)	18-22 weeks (Time 2)
QOL-AD scale:	Quality of life		
Care recipient self-report version		X	X
Caregiver proxy version		X	X
CMAI scale	Agitation	X	X
CSDD	Depression	X	X
M-ZBI scale:	Burden of care		
Staff nurse		X	X
Healthcare assistant		X	X
Resident demographics		X	
Staff nurse demographics		X	
Healthcare assistant demographics		X	

4.10.3 Controlling data collection quality

The quality of data collection was enhanced by having a small team of trained research nurses (n=4) involved in the process and by adherence to detailed assessment protocols. All research nurses underwent a rigorous two-day training programme, the content of which was guided by the pilot study. Training focused on assessing residents for eligibility, enrolment of residents and staff, the process of consent, data collection procedures and completion of primary and secondary outcome instruments. The programme also had an evaluation component, where research nurses participated in a simulation of the data collection process. The quality of data collection was further enhanced by the implementation of a rigorous data auditing system, which was an integral part of my role throughout the trial. I completed data collection audits on all Time 1 and Time 2 data (n=13), except for those long-stay units in which I completed data collection (n=5). The accuracy of my data collection was checked by my supervisor (DD), who was also a member of the DARES research team.

Prior to the entry of data into Statistical Package for the Social Sciences v. 20 (IBM Corp, 2011), I devised a unique code for all data variables and recorded them in a coding book. I cleaned and checked all data prior to data entry. Responsibility for single

data entry was assigned to a person employed by the DARES research team. The quality of all data entered into SPSS version 20 (IBM Corp, 2011) from data collection forms was checked by me on an on-going basis using a continuous sampling plan as detailed below (section 4.10.4).

4.10.4 Verification of the quality of data entry

Single data entry into SPSS was performed with visual verification of a sample of records from the data set created from the single entry using a continuous sampling plan (CSP-1) approach devised by King & Lashley (2000). A CSP-1 gives the number of successive records with no data entry errors that must be inspected (denoted as *i*) before a sample fraction (denoted as *f*) of records begin. Whenever an error is found, the error is corrected and the successive record checking using *i* is repeated.

An incoming data field error rate of 0.45% was calculated from a visual inspection of 226 completed fields (1 field error on all outcomes). To maintain an average outgoing quality (AOQ) of 0.4%, any of the CSP-1 plans identified in Figure 2 of King & Lashley (2000) are appropriate. To further optimise data integrity, my supervisor and I implemented a conservative CSP-1 of $i = 5$ and $f = 0.1$ (10%).

As recommended by King & Lashley (2000), I implemented the CSP-1 as follows:

  a) Inspecting i (n = 5) successive records for data entry errors
  b) If no errors were found, sampling a fraction f (10%) of record data and checking for errors
  c) If an error was found, I logged and corrected the error and repeated step 1.

A CSP-1 log was maintained for all data entered at baseline and post-intervention.

4.11 Sample size

To retain statistical power equivalent to trials randomised at the individual level, cluster trials require larger sample sizes. This is because individuals within a cluster tend to be more alike and are therefore more likely to respond in a similar manner. For example, residents in long-stay units may be more alike because they tend to be treated in the same way and because of this they may be likely to respond in the same way. Subsequently, their data can no longer be treated as independent of one another. This

lack of independence or intracluster dependence can, if ignored in the sample size calculation, contribute to a loss in statistical power (Donner & Klar, 2000).

In calculating the sample size required in the DARES study, we used methods for standard sample size estimates for trials randomised at the level of the individual (Devane *et al.* 2004) and adjusted for clustering by inflating the sample size estimates by the design effect (Deff). The design effect is the amount a sample size in a cluster trial needs to be inflated by to allow for clustering as compared with an equivalent trial, randomised at the individual level and is calculated as: Deff = 1+ (m – 1) *p*, where m is the average cluster size and *p* (rho) is an estimate of the Intra-cluster Correlation Coefficient (ICC). The ICC is a statistical test of the clustering effect and is described as the amount of variation in the response outcome that can be explained by the variation between clusters (Donner & Klar, 2004; Campbell *et al.* 2004; Murphy *et al.* 2006; Campbell *et al.* 2012).

Sample size estimates were based on the primary outcome which was the residents' quality of life, as measured by the care recipient self-report version of the QOL-AD scale, expressed as the mean difference between intervention and control groups. Based on a mean care recipient self-report QOL-AD score of 32.5 (SD=6.6; n=70) for people with dementia in residential care homes (Hoe *et al.* 2009) and an ICC value of 0.1 identified from pilot work on reminiscence groups for people with dementia for the REMCARE Trial (Woods *et al.* 2009), a total of 18 residential units were required, each comprising of 17 people with dementia, to detect a 4-point difference in mean QOL-AD scores between control and experimental groups, for power of at least 80% with alpha levels of 0.05. This calculation allowed for a loss to follow-up of 20% of residents and up to three residential units. ICC values lower than 0.1 would have increased the power of the study.

4.12 Randomisation

Randomisation to intervention and control was at the level of the long-stay residential unit. As detailed in section 4.2, the strength of the randomised trial is its capacity to overcome selection bias and produce comparable groups at the beginning of the trial. This is achieved by implementing two interlinked processes i.e., random sequence generation and allocation concealment. Cluster randomised trials are prone to selection bias at both the individual and cluster level. This can occur if clusters are randomised

prior to the recruitment of study participants. We minimised the potential for this type of bias by recruiting the clusters and participants before undertaking the randomisation process (Puffer *et al.* 2003).

Randomisation was on a 1:1 ratio, that is, for every one unit randomised to the intervention, one was randomised to the control. Randomisation was stratified by public and private residential units to ensure an appropriate representation of private and public long-stay residential units; a ratio of two-thirds private and one-third public reflected the general distribution of beds in the region.

4.12.1 Random sequence generation

Sequence generation is the process used to assign participants to study groups. Trials that have implemented inadequate sequence generation methods have been associated with exaggerated estimates of the intervention effects as distinct from trials that have used adequate methods (Schulz, Altman & Moher, 2010). The random allocation sequence was generated using a computer generated random number list (the Mersenne Twister, StatDirect). This random process ensured that each unit (cluster) had an equal chance of being allocated to either intervention or control groups.

4.12.2 Allocation concealment

Following the generation of a random sequence, concealment of the upcoming allocation is the second part of the randomisation process. Inadequate allocation concealment has also been associated with over estimation of the treatment effects (Schulz, Altman & Moher, 2010). In the DARES Study, an independent statistical researcher was responsible for implementing the randomisation process.

4.12.2.1 Implementation of the randomisation process

The independent statistical researcher produced a consecutive list of 12 unnamed private units, numbered 1-12, and a separate list of six unnamed public units, numbered 1-6. A random allocation sequence was generated and based on this sequence each unnamed unit was assigned to either the intervention or control group. As units agreed to enter the trial, the research team provided the independent statistical researcher with an anonymised list of unit(s) that met the eligibility criteria

and which had agreed to participate. The independent statistical researcher then documented the unique identification code assigned to that unit in the next 'unnamed' position in the randomised public or private list and released the corresponding group allocation for the unit.

4.13 Blinding

This was a single-blind cluster randomised trial. Due to the nature of the intervention, it was not possible to blind participating residents and staff to group allocation. However, all research nurses, including myself, who were responsible for outcome assessment were blinded to the group allocation of participating units and, when undertaking data analyses, I was blinded to the group allocation as the database of outcomes were identifiable only by number. Lack of blinding in outcome assessment is regarded as the most serious source of bias and has the potential to compromise the internal validity of the trial (Schultz & Grimes, 2002).

4.14 Pilot study

As referred to previously, a pilot study was conducted in two long-stay units, one public and one private. I was the research nurse on both sites. The purpose of the pilot was to assess the feasibility of all dimensions of the DARES Study methodology. This included recruitment and consent processes, data collection procedures and the delivery of the trial intervention. The pilot study informed the refinement of the SERPS, research nurse training programme and the final drafting of the trial protocol. All data acquired in the pilot study was excluded from the main trial analysis.

4.15 Statistical methods

The focus of data analysis was on the long-stay care setting with the resident as the unit of analysis. Quantitative data were analysed, in aggregate, using SPSS version 20 (IBM Corp, 2011). Data were coded and entered into SPSS. Levels of statistical significance for the final analyses were set at 5% (two-sided).

Intention to treat and per protocol analysis

As discussed in section 3.3..3.3.4 according to the intention to treat principle, all randomised participants are analysed as per their original group allocation, regardless of whether they received the intervention or not. The advantage of the intention to treat

approach is that it preserves the unbiased comparison of study groups afforded by randomisation until the trial is over (Heritier *et al.* 2003*).* However, strict intention to treat analysis has a number of limitations, in that, it requires the replacement of missing outcome data and it ignores non-adherence to the treatment protocol. To address the issue of missing outcome data, trialists can choose to deviate from a strict intention to treat analysis and address the problem of missing data by excluding participants with missing outcome data by completing an intention to treat 'complete case' or 'available case analysis', which includes only study participants with complete data (Altman, 2009). Although commonly used, complete case analysis will lose power because it reduces the sample size. Bias may also be introduced if losses to follow-up differ across study groups. Alternatively, trialists can choose to strictly adhere to the intention to treat principle by imputing missing outcome data (Schultz, Altman & Moher, 2010).

Alluded to earlier, the intention to treat principle ignores participants' non-adherence to the treatment protocol. Subsequently, if the treatment is effective but non-adherence to the treatment protocol is substantial, analysis conforming to the intention to treat principle underestimates the magnitude of the treatment effect in adhered participants. Per protocol analyses addresses the issue of non-adherence to the study intervention because it excludes participants who did not receive the intervention as prescribed from the analysis. Conversely, the disadvantage of per protocol analysis is that, it eliminates the unbiased comparability of randomised groups and can lead to biased estimates of the treatment effect (Montori & Guyatt, 2001).

Although intention to treat analysis was traditionally the preferred option, more recently the 2010 CONSORT checklist has discontinued the particular request for intention to treat analysis, preferring a detailed description for each group, number of participants included in each analysis and whether the analysis was by original assigned groups (Schultz, Altman & Moher, 2010; Campbell *et al.* 2012).

In my analyses, I undertook both an intention to treat complete case analysis and an intention to treat imputed data analysis on the primary and secondary outcomes. I did this to explore the effects of both approaches on the direction and magnitude of the treatment effect for each of the outcomes. To address the issue of non-adherence to the treatment protocol in the DARES study, I undertook a per protocol analysis on the primary and secondary outcomes. As with the primary analysis, I carried out per

protocol complete case analysis and then per protocol analysis with missing data imputed. Again, the purpose of using the both approaches was to explore the effects of both types of analyses on the direction and magnitude of the treatment effect.

Statistical analyses undertaken by me are presented in sections and are detailed as follows:

Section 4.15.1 presents details of the intention to treat analysis on primary and secondary outcomes using complete cases (or available cases) only;

Section 4.15.2 presents details of the intention to treat analysis on primary and secondary outcomes using imputed data;

Section 4.15.2.1 presents details of how missing data were managed;

Section 4.15.3 presents sensitivity per protocol i.e., the three sites that did not deliver reminiscence to the participating residents as prescribed were removed from the analysis. Per protocol analysis was completed on primary and secondary outcomes using both (i) complete cases only and (ii) imputed data;

Section 4.15.4 details the analyses of baseline demographics and clinical characteristics for participating residents and analyses of baseline demographics for participating staff nurses and healthcare assistants;

Section 14.15.5 presents a detailed account of how each treatment effect was calculated;

Section 14.15.6 presents details of how ICC values were calculated.

4.15.1 Intention to treat complete cases analysis

I undertook an intention to treat complete cases analysis, which included only residents whose outcomes were known. Analysis was undertaken on the primary and secondary outcomes as follows:

4.15.1.1 Primary outcome:

4.15.1.1.1 Residents' quality of life

As recommended by Logsdon *et al.* (1999; 2002), prior to computing total scores for the residents' response to QOL-AD both at baseline (Time1) and post-intervention

(Time 2), residents who had up to two items missing had those items replaced with the mean of the remaining items. Total scores were then calculated for both baseline and post-intervention. As higher scores on the QOL-AD scale indicate an improvement in quality of life, change scores or improvement from baseline to post-intervention were calculated by subtracting residents' baseline total QOL-AD scores from residents' post-intervention total QOL-AD scores (Time 2-Time 1).

4.15.1.2 Secondary outcomes:

4.15.1.2.1 Staff rating of the residents' quality of life

Staff responses to residents QOL-AD were analysed using exactly the same approaches detailed in the intention to treat complete case analysis of the residents' response to QOL-AD, including the approach to missing values and calculation of improvement scores.

4.15.1.2.2 Residents' levels of agitation

Analysis of the CMAI scale was based on total scores. If any of the 29 items were missing the complete measure for that resident was disregarded. As higher scores on the CMAI scale indicate higher levels of agitation, change scores or improvement from baseline to post-intervention were calculated by subtracting post-intervention total scores from baseline total scores (Time1-Time 2).

4.15.1.2.3 Residents' levels of depression

Analysis of the CSDD was based on total scores. If any of the 19 items were missing the complete measure for that resident was disregarded. As higher scores on the CSDD indicate higher levels of depression, change scores or improvement from baseline to post-intervention were calculated by subtracting post-intervention total scores from baseline total scores (Time 1-Time 2).

4.15.1.2.4 Staff nurses' burden of care

Scores on the M-ZBI scale for staff nurses' was analysed using total scores. If any of the 13 items were missing then the complete measure for that resident was disregarded. As higher scores on this scale indicate greater levels of staff burden, change scores were calculated by subtracting post-intervention total scores from baseline total scores (Time 1-Time 2).

4.15.1.2.5 <u>Healthcare assistants' burden of care</u>

Scores on the M-ZBI scale for healthcare assistants was analysed using total scores. If any of the 13 items were missing then the complete measure for that resident was disregarded. As higher scores on this scale indicate greater levels of staff burden, change scores were calculated by subtracting post-intervention total scores from baseline total scores (Time 1-Time 2).

Summary statistics, including measures of central tendency (means) and measures of variability (standard deviations (SD)) are presented in the intention to treat complete case analysis for all continuous primary and secondary outcomes for baseline (Time 1), post-intervention (Time 2) and improvement scores for both study groups. An estimate of the treatment effect for each outcome, in addition to 95% confidence intervals (CIs) for the treatment effect and p-values are also presented.

4.15.2 Intention to treat imputed data analysis

Missing values were replaced using multivariate imputations by chained equations as described in section 4.15.2.1. After missing data were imputed, I recalculated total scores for the primary and secondary outcomes for Time 1 and Time 2. I then calculated the change scores for each outcome. An estimate of the treatment effect for each outcome, in addition to 95% CIs for the treatment effect and p values are presented.

4.15.2.1 Dealing with missing data

Missing data is unavoidable in all trials but it is a particular challenge in dementia research where the expectation is for participants with dementia to decline over time and, regretfully, participants are regularly lost to follow-up due to death or illness (Woods *et al.* 2010). An intention to treat imputed data analysis was performed on the primary and secondary outcomes, where missing data were imputed using multivariate imputation by chained equations in SPSS version 20 (IBM Corp, 2011). Imputations were completed at the individual item level rather than for total scores.

Multiple imputation is well regarded as an advanced approach to addressing the issue of missing data because this approach uses all information from the available data to replace the missing data and is therefore regarded as a more efficient method then the last observation carried forward (LOCF) method (White *et al.* 2011). Multiple imputation

ensured that more residents were included in the analysis than would have been possible had missing data not been imputed. This helped retain the study's statistical power and contributed to more reliable statistical inference than if missing data had not replaced (Altman & Bland, 2007).

4.15.3 Per protocol sensitivity analysis

Analysis of the Reminiscence Record Sheets at the end of the study indicated that dyads in three of the intervention sites did not deliver any reminiscence sessions to their designated residents and because of their non-adherence to the treatment protocol, those three sites were removed for the analysis. A per protocol analysis was performed on the primary and secondary outcomes using data only from those sites that implemented the intervention as prescribed. As detailed in sections 4.15.3.1 and 4.15.3.2, both per protocol complete case and per protocol imputed data analyses were undertaken. The purpose of undertaking both analyses was to explore the effects of each approach on the direction and magnitude of the treatment effect.

4.15.3.1 Per protocol complete case analysis

After excluding the three sites which did not deliver the intervention to the participating residents as prescribed, per protocol complete case analysis was undertaken on the primary and secondary outcomes as described in section 4.15.2.

4.15.3.2 Per protocol imputed data analysis

In the per protocol analysis, missing values were replaced using multivariate imputations by chained equations as described in section 4.15.2.1. After missing data were imputed, I recalculated total scores for the primary and secondary outcomes for Time 1 and Time 2. I then calculated the change scores for each outcome. An estimate of the treatment effect for each outcome, in addition to 95% CIs for the treatment effect and p values are presented.

4.15.4 Analysis of baseline demographics

Descriptive statistics (means and standard deviations for continuous data and percentages for categorical data) were used to summarise and compare baseline demographics and clinical characteristics between study groups for participating

residents. For each study group, demographic details are also presented for both participating staff nurses and healthcare assistants.

4.15.5 Estimate of the treatment effect

The normal assumption in statistical analysis is that all data included in the analysis is independent and not correlated in any way. However such an assumption is not reasonable when data are collected from the same individual or individuals in a cluster over time. In the DARES trial, data were collected from the same individuals in the same long-stay units at baseline and again post-intervention. Data collected at both time points from the same individuals were expected to be correlated and therefore this correlation needed to be captured and adjusted for in the statistical analysis for each primary and secondary outcome. Linear mixed modelling is a flexible approach to statistical analysis that allows for correlated data to be adjusted for in the analysis. An estimate of the treatment effect was undertaken separately for each primary and each secondary outcome for the intention to treat complete cases, intention to treat imputed data, per protocol complete cases and per protocol imputed data as follows:

4.15.5.1 Selection of variables to include in each linear mixed model

Prior to completing the linear mixed model for each outcome separately, I used two different approaches to select the variables to include in the linear model i.e., (i) stepwise regression modelling and (ii) best subsets, that is, automatic linear regression modelling.

4.15.5.1.1 Stepwise regression modelling

Residents' mean change scores from baseline to post-intervention were entered into the stepwise regression model as the 'dependent' variable. Residents' baseline demographics and clinical characteristics such as gender, age in year, dementia diagnosis, MMSE score, type of consent and ethnicity were entered into the stepwise regression model as independent variables. Other variables included as independent variables in the stepwise regression model were site allocation, which is whether allocation was to the intervention or control arm, site status, which is whether the long-stay unit was either public or private and the residents' baseline total outcome score. If the stepwise regression model demonstrated that specific independent variables did not have a significant correlation with the dependent variable, the stepwise regression model removed them from the model. However, independent variables found to be

significantly correlated with the dependent variable were retained and adjusted for in the model.

4.15.5.1.2 <u>Best subsets</u>

In the best subsets model, residents' mean change scores from baseline to post-intervention were entered into the best subsets model as the 'target' variable. In this model, residents' baseline demographics and clinical characteristics, which again consisted of gender, age in years, dementia diagnosis, MMSE score, type of consent and ethnicity were entered as 'predictors'. Other variables entered into the model as predictors were site allocation, site status and residents' baseline outcome total scores. In the best subsets model, predictors that did not have a significant correlation with the target variable were removed from the model and predictors that were correlated significantly with mean change score (i.e., the target variable) were retained and adjusted for in the model.

4.15.5.2 Linear mixed modelling

The residents' mean change scores from baseline to post intervention were entered into the linear mixed model as the dependent variable. Independent variables found to be significantly correlated with the dependent variable in the stepwise regression model and predictors found to be significantly correlated with the target variable in the best subsets model were entered into the linear mixed model in SPSS as covariates. Site allocation was entered into the linear mixed model as a covariate to adjust for the possibility that the change in the resident's response might be related to whether they were allocated to either the intervention or control arm of the trial. Site status was the stratified' variable and it was also entered into the linear model as a covariate to adjust for the possibility that changes in the resident's response may be related to whether they were from a long-stay public unit or a long-stay private unit. Baseline outcome scores were entered as a covariate in order to adjust for differences in residents' responses between groups at baseline and the possibility that the change in the resident's response might be related to their initial response (Klar & Darlington, 2004). Covariates are defined as variables that are strongly correlated with the dependent variable and subsequently, they have to be adjusted for in the analysis. To adjust for any differences in the covariates across the study groups, all covariates were entered into the linear model as fixed effects and because clusters (long-stay units) are just a

sample from a population of long-stay units, site codes were entered into the linear mixed model as random effects.

4.15.6 Calculation of the intra-cluster correlation coefficient (ICC)

The ICC is the statistical measure of the clustering effect i.e., the degree of similarity in responses from individuals within a cluster. I used a general linear mixed model approach to calculate the ICC for each of the response variables at baseline. For each outcome in the intention to treat complete case analysis and per protocol complete cases analysis, resident's baseline total score were entered into the model as the dependent variable and the site code was entered as the random factor.

4.16 Harms/Adverse events

The purpose of reminiscence is this study was to assist the resident in recalling positive and happy thoughts that enhanced communication and connectivity with self and others, thereby improving their quality of life. The risks and harmful side-effects from participating in DARES were therefore likely to be low and no adverse reactions were reported from the two pilot sites or from previous trials in the literature (Woods *et al.* 2005). During the structured education programme, participating staff members were prepared to deliver reminiscence training that fosters positive thoughts and happy memories. Staff participants were also guided in how to respond to situations where reminiscence may have resulted in the recall of negative or upsetting events in the lives of residents. Staff members were instructed in how to record such events on the Reminiscence Record Sheets. The research team asked staff during each point of contact (support visit, support telephone calls) whether any adverse events had occurred and offered support as required. If a resident became unduly distressed because of reminiscence, staff responded to the situation in an appropriate manner and if unresolved raised the issue with the research team. During the enrolment process, residents and their families were informed fully of the potential risks and benefits of the project both verbally and in writing. The resident had the right to withdraw from the study at any stage during the research process.

4.17 Summary

Guided by the structure and content of the most current CONSORT 2010 statement: extension to cluster randomised trials (Campbell *et al.* 2012), this chapter provides a

detailed account of, the design, conduct and analyses of the DARES study, the results of which are presented in the next chapter.

Chapter 5

Results

5.1 Introduction

This chapter provides a detailed description of the findings of the DARES Study, arising from the analysis I carried out. This chapter is structured and informed by the requirements of the most recent CONSORT 2010 Statement: extension to cluster randomised trials (Campbell *et al.* 2012).

Results are presented in sections and are detailed as follows:

Section 5.2 presents details of the assessment for eligibility, enrolment, allocation, randomisation, loss to follow up and numbers analysed for both participating clusters and residents.

Section 5.3 presents a summary of the baseline demographics and clinical characteristics for participating residents. Baseline demographics for participating staff (staff nurses and healthcare assistants) are also detailed in this section.

Section 5.4 presents summary statistics including measures of central tendency (means) and measures of variability (standard deviations) for both the intention to treat complete case analysis and the per protocol complete case analysis for all continuous primary and secondary outcomes for baseline (Time 1), post-intervention (Time 2) and improvement scores for both study groups. An estimate of the treatment effect for each outcome, in addition to 95% confidence intervals (CIs) for the treatment effect and p values are also presented. Estimates of the ICC for each outcome and covariates adjusted for in the linear mixed model for each outcome are also detailed. This section also presents the analysis of the intention to treat imputed data for all primary and secondary outcomes. Missing data was imputed for all outcomes using multivariate imputation by chained equations. Imputations were completed at the questionnaire level rather than for total scores. For the intention to treat imputed data and per protocol imputed data, an estimate of the treatment effect for each outcome, in addition to 95% CIs for the treatment effect and p values are presented.

5.2 Cluster and participant flow

Figure 5-1 illustrates the flow of both participating clusters and residents throughout the DARES Study based on CONSORT principles (Campbell *et al*. 2004; 2012; Schulz *et al.* 2010).

5.2.1 Assessed for eligibility

5.2.1.1 Long-stay units

Sixty-seven clusters/long-stay units across the Western half of the Republic of Ireland were assessed for eligibility. Twelve long-stay care units did not meet the eligibility criteria, as they did not have enough residents with dementia in their care. Thirty-seven long-stay care units declined to participate because they were short staffed and therefore could not release staff to participate in the three-day training programme. Eighteen long-stay units, consisting of six public and twelve private units were recruited to participate. Generally, participating units were 40-60 bedded, generic facilities, largely based on the biomedical model of care provision, designed to cater for the physical health needs of residents, not for the specific needs of residents with dementia.

5.2.1.2 Residents with dementia

Fifty-two residents were screened for eligibility but did not meet the study's inclusion criteria. The main reason for residents' ineligibility, documented by the research assistants, was an indefinite diagnosis of dementia.

5.2.2 Enrolment

Eighteen clusters each with 17 participating residents per cluster, with the exception of one cluster which recruited 15 residents were enrolled and randomised. To minimise the potential for recruitment bias, all clusters and residents had consented to participate and all baseline data were collected prior to randomisation of clusters into study groups.

5.2.3 Randomisation

Randomisation was on a 1:1 ratio, which is nine clusters were allocated randomly to each study group. One hundred and fifty-three residents (n=153) were allocated to the

SERPS and one hundred and fifty-one (n=151) to usual care (see Figure 5-1). Randomisation was stratified by public and private residential units to ensure an appropriate representation of private and public long-stay residential units; a ratio of two thirds private and one-third public reflects the general distribution of beds in the region.

5.2.4 Received allocated intervention

The intervention was delivered successfully in six (67%, n=102 residents) of the nine clusters. Although all staff in the intervention sites attended the SERPS training programme, staff in three clusters randomised to the intervention arm did not implement the study intervention as prescribed with their designated residents (33%, n=51). Each of these three sites were offered additional support from the DARES research team; however all three indicated that the main reason for not implementing the study intervention was due to staffing difficulties.

5.2.5 Follow-up

In the sample size calculation, the study was powered to allow for a loss of three clusters (17%, n=51 residents) and a further loss of 20% of residents (n=61). At the follow-up stage in each cluster, approximately 18-22 weeks post-randomisation, no clusters were lost. The number of residents lost to follow-up (17%, n=52) and reasons pertaining to their loss across the intervention (16%, n=25) and control (18%, n=27) groups were similar. The major factor contributing to residents' drop-out was death, with mortality rates identical in the intervention (12%, n=18) and control (12%, n=18) groups (see Figure 5-1).

5.2.6 Analysis

As detailed in section 4.15, analyses presented in this chapter were based on an intention to treat complete cases analysis, where only residents with complete data sets were included in the analysis. I also completed an intention to treat imputed data analysis where all missing data were imputed using multivariate imputation by chained equations (see section 4.15.3.1). The purpose of using both approaches was to explore the effects of both types of analyses on the direction and magnitude of the treatment effect.

Analysis of Reminiscence Record sheets at the end of the study indicated that residents allocated to the intervention arm either received all four weekly reminiscence sessions over the period of the trial or no reminiscence sessions. Residents in three interventions sites did not receive any reminiscence. The effects on outcomes of the three sites, which did not implement the study intervention with their designated residents as prescribed, were explored through per protocol analysis. This consisted of excluding those three sites from the analysis. As with the primary analysis, I carried out per protocol complete case analysis and then per protocol analysis with missing data imputed. Again the purpose of using the two approaches was to explore the effects of both types of analyses on the direction and magnitude of the treatment effect.

Figure 5-1: DARES Study flowchart for participating clusters and residents.

Assessed for eligibility: 67 long-stay units

Enrolment

Excluded: 49 long-stay units

Not meeting inclusion criteria: 12 long-stay units

Declined to participate: 37 long-stay units

Residents excluded: 52 did not meet eligibility criteria

Randomised: 18 clusters

Allocation

Allocated to SERPS: 9 clusters/153 residents. Cluster sizes: 17

- Received allocated intervention: 6 clusters/102 residents (67%)
- Did not receive allocated intervention: 3 clusters /51 (33%) residents. Reason: Staffing issues.

Allocated to usual care: 9 clusters/151 residents. Cluster sizes: 15-17

- Received allocated intervention: 9 clusters/151 residents
- Did not receive allocated intervention: N/A

Follow-Up
18-22 weeks post-randomisation

Clusters lost to follow-up: 0 clusters

Residents lost to follow-up: 25 (16%)

Reasons: 18 RIP; 1 transferred; 2 in hospital; 3 too ill to complete and 1 withdrawn by staff, as resident diagnosed with terminal illness.

Clusters lost to follow-up: 0 clusters

Residents lost to follow-up: 27 (18%)

Reasons: 18 RIP; 8 in hospitals; 1 too ill to complete.

Analysis

Clusters analysed: 9 clusters

Clusters excluded from analysis: 0 clusters

Residents analysed: 128/153 (84%)

Residents excluded from analysis: Lost to follow-up (n=25).

Clusters analysed: 9 clusters

Clusters excluded from analysis: 0 clusters

Residents analysed: 124/151 (82%)

Residents excluded from analysis: Lost to follow-up (n=27).

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5.3 Baseline demographics

5.3.1 Demographic and clinical characteristics for residents

Table 5-1a provides a description of the baseline demographic and clinical characteristics for participating residents allocated to the SERPS (n=153) and usual care (n=151). Details are also provided for the group as a whole (n=304). The table indicates that there were more residents in private residential units (72%, n=219) than in public units (28%, n=85). This was expected because, as detailed in section 5.2.3, randomisation was stratified by public and private residential units to ensure an appropriate representation of private and public long-stay residential units. Sixty-nine per cent (n=209) of participating residents were female and 98% (n=297) were of White Irish background. The mean age was 85 years and MMSE scores indicated that residents across both groups had moderate levels of cognitive impairment. Table 5-1a provides a detailed account of the levels of cognitive impairment as determined by the MMSE instrument, across both study groups and for the group of resident participants as a whole. The majority of residents allocated to the SERPS (97%, n=148) and to usual care (89%, n=134) groups gave consent to participate themselves. All four methods of dementia diagnosis were of comparable proportions across groups, with the most prevalent being a nursing diagnosis (97%, n=296). Baseline mean scores for the primary and secondary outcomes were similar across groups (Table 5-2). Overall, baseline data suggests that randomisation was effective in producing comparable groups at baseline.

5.3.2 Demographics for staff nurses

Table 5-1b provides a description of the baseline demographics for participating staff nurses (n=95) allocated to the SERPS (n=49) and usual care (n=46). The majority of staff nurses were female (96%, n=91), 58% (n-55) were of White Irish background and 32% (n=30) were of Asian background. All age ranges were represented and of similar proportions across study groups and across the whole sample. General nursing was the most prevalent professional qualification (92%, n=87) and 44% (n=42) of nurses had qualified in the last ten years. Fifty-seven per cent (n=54) had been working with older people for a period of one to ten years but only 9% (n=9) of nurses had a qualification in Gerontology. Educational qualifications consisted of: Diplomas (37%, n=35), Bachelor Degrees (36%, n=34), Higher Diplomas (8%, n=8), Post Graduate Diploma (3%, n=3) and Masters Degrees (1%, n=1).

5.3.3 Demographics for healthcare assistants

Table 5-1c provides a description of the baseline demographics for participating healthcare assistants (n=95) allocated to the SERPS (n=50) and usual care (n=45). As with nursing staff, healthcare assistants were predominantly female (88%, n=84) and 81% (n=77) were of White Irish background. A small percentage (4%, n=4) were under 21 years of age with the remainder varying in age ranges from 21-30 (25%, n=24), 31-40 (27%, n=26), 41-50 (21%, n=20) and 50 plus years of age (23%, n=21). Fifty-seven per cent (n=60) had completed a healthcare assistants training programme and although only 8% (n=8) described themselves as having a qualification in Gerontology, 32% (n=30) had completed an educational programme in dementia. Other educational qualifications consisted of: Diplomas (11%, n=10), Bachelor Degrees (6%, n=6), Post Graduate Diploma (1%, n=1) and Masters Degrees (2%, n=3). Experience of working with older people was diverse across the whole sample but 50% (n=48) had one to ten years' experience.

Table 5-1a: Baseline demographics and clinical characteristics for participating residents

Characteristics	SERPS n=153		Usual care n=151		Overall n=304	
Allocation by site: n (%)						
Private	119	(78)	100	(66)	219	(72)
Public	34	(22)	51	(34)	85	(28)
Age in years:						
Mean (SD)	85.2	(7.1)	85.7	(7.1)	85.5	(7.1)
Gender: n (%)						
Male	43	(28)	52	(34)	95	(31)
Female	110	(72)	99	(66)	209	(69)
MMSE[1]:						
Mean (SD)	12.98	(5.5)	11.70	(5.4)	12.34	(5.5)
Level of cognitive impairment: n (%)						
Severe	43	(28)	50	(33)	93	(31)
Moderate	56	(37)	58	(38)	114	(38)
Mild to moderate	30	(20)	31	(21)	61	(20)
Mild	22	(14)	10	(7)	32	(10)
Cognitively intact	2	(1)	2	(1)	4	(1)
Ethnicity: n (%)						
White Irish	151	(99)	146	(97)	297	(98)
Any other White background	0	(0)	3	(2)	3	(1)
Missing	2	(1)	2	(1)	4	(1)
Type of dementia diagnosis:						
Dementia diagnosis (DSM IV or ICD-10)						
Yes: n (%)	5	(3)	15	(10)	20	(6)
No: n (%)	130	(85)	115	(76)	245	(81)
Missing: n (%)	18	(12)	21	(14)	39	(13)
Dementia diagnosis (Medical clinician)						
Yes: n (%)	93	(61)	74	(49)	167	(55)
No: n (%)	43	28)	58	(38)	101	(33)
Missing n (%)	17	(11)	19	(13)	36	(12)
Dementia diagnosis: (Anti-Alzheimer's medication)						
Yes: n (%)	53	(35)	39	(26)	92	(30)
No: n (%)	83	(54)	94	(62)	177	(58)
Missing: n (%)	17	(11)	18	(12)	35	(12)
Dementia diagnosis: (Staff nurse's judgement)						
Yes: n (%)	152	(99)	144	(95)	296	(97)
No: n (%)	1	(1)	7	(5)	8	(3)
Missing: n (%)	0	(0)	0	(0)	0	(0)
Type of consent: n (%)						
Consent from resident	148	(97)	134	(89)	282	(93)
Consent by proxy	5	(3)	17	(11)	22	(7)

[1]MMSE: Scores range from 0-30. Scores <10 indicate severe cognitive impairment; 10-14 indicate moderate cognitive impairment; 15-19 indicate mild-moderate cognitive impairment; 20-24 indicate mild impairment: 25-30 indicates cognition is intact (Booth *et al.* 2006).

Table 5-1b: Baseline demographics for participating staff nurses

Characteristics	SERPS n=49		Usual care n=46		Overall n=95	
Gender: n (%)						
Male	3	(6)	1	(2)	4	(4)
Female	46	(94)	45	(98)	91	(96)
Age range: n (%)						
21-30	12	(24)	3	(28)	25	(26)
31-40	13	(26)	12	(26)	25	(26)
41-50	10	(21)	10	(22)	20	(22)
50+	14	(29)	11	(24)	25	(26)
Nursing qualification (s)						
General: n (%)						
Yes	43	(88)	44	(96)	87	(92)
No	6	(12)	2	(2)	8	(8)
Psychiatry: n (%)						
Yes	8	(16)	2	(4)	10	(11)
No	41	(84)	44	(96)	85	(89)
Midwifery: n (%)						
Yes	6	(12)	7	(15)	13	(14)
No	43	(88)	39	(85)	82	(86)
Other: n (%)						
Yes	0	(0)	0	(0)	0	(0)
No	49	(100)	46	(100)	95	(100)
Number of years qualified: n (%)						
<1 year	0	(0)	1	(2)	1	(1)
1-10 years	21	(43)	21	(46)	42	(44)
11-20 years	10	(21)	8	(17)	18	(19)
21-30 years	8	(16)	7	(15)	15	(16)
31-30 years	9	(18)	9	(20)	18	(19)
41-50 years	1	(2)	0	(0)	1	(1)
Number of years working with older people: n (%)						
<1	2	(4)	5	(11)	7	(7)
1-10 years	25	(55)	29	(63)	54	(57)
11-20 years	12	(25)	10	(22)	22	(23)
21-30 years	7	(14)	2	(4)	9	(10)
31-30 years	1	(2)	0	(0)	1	(1)
Missing	2	(4)	0	(0)	2	(2)
Educational qualifications: n (%)						
Diploma	20	(41)	15	(33)	35	(37)
Degree	16	(33)	18	(39)	34	(36)
Higher Diploma	3	(6)	5	(11)	8	(8)
Post Graduate Diploma	1	(2)	2	(4)	3	(3)
Masters	1	(2)	0	(0)	1	(1)
Missing	8	(16)	0	(0)	8	(8)
Qualification in Gerontology: n (%)	6	(12)	3	(6)	9	(9)
Any previous Reminiscence training: n (%)	4	(8)	2	(4)	6	(6)
Ethnicity: n (%)						
White Irish	30	(61)	25	(54)	55	(58)
Other White background	5	(1)	4	(9)	9	(10)
Asian background	13	(27)	17	(37)	30	(31)
Other	1	(2)	0	(0)	1	(1)

Table 5-1c: Baseline demographics for participating healthcare assistants

Characteristics	SERPS n=50		Usual care n=45		Overall n=95	
Gender: n (%)						
Male	4	(8)	5	(11)	9	(10)
Female	44	(88)	40	(89)	84	(88)
Missing	2	(4)	0	(0)	2	(2)
Age range: n (%)						
<21	2	(4)	2	(4)	4	(4)
21-30	12	(24)	12	(27)	24	(25)
31-40	16	(32)	10	(22)	26	(27)
41-50	9	(18)	11	(25)	20	(21)
50+	11	(22)	10	(22)	21	(23)
Completion of HCA[1] programme: n (%)	28	(56)	29	(64)	57	(60)
Number of years working with older people: n (%)						
<1	4	(8)	8	(18)	12	(13)
1-10 years	27	(54)	21	(47)	48	(50)
11-20 years	16	(32)	15	(33)	31	(33)
21-30 years	2	(4)	1	(2)	3	(3)
31-30 years	1	(2)	0	(0)	1	(1)
Educational qualifications:						
Diploma	3	(6)	7	(16)	10	(11)
Degree	4	(8)	2	(4)	6	(6)
Post Graduate Diploma	0	(0)	1	(2)	1	(1)
Masters: n (%)	1	(2)	2	(4)	3	(2)
Qualification in Gerontology: n (%)	4	(8)	2	(4)	6	(6)
Any previous Reminiscence training: n (%)	4	(8)	4	(9)	8	(8)
Completed an education programme on dementia: n (%)	17	(34)	13	(29)	30	(32)
Ethnicity: n (%)						
White Irish	41	(82)	36	(80)	77	(81)
Other White background	5	(10)	8	(18)	13	(14)
Asian background	0	(0)	1	(2)	1	(1)
Other	1	(2)	0	(0)	1	(1)
Missing	3	(6)	0	(0)	3	(3)

[1]HCA = Healthcare assistant

5.4 Outcomes and estimation

Table 5-2 presents the mean scores for primary and secondary outcomes at baseline (Time 1) and post-intervention (Time 2) for the intention to treat complete cases in both the SERPS and usual care groups. Table 5-3 presents the differences in mean scores (change scores) from baseline (Time 1) to post-intervention (Time 2) for primary and secondary outcomes for the intention to treat complete cases in each group. Table 5-4

presents details of the estimate of the treatment effect, 95% CIs and p values for the intention to treat complete case analysis and the intention to treat imputed data analysis for each of the six outcomes. Estimates of the ICC, which is a measure of the similarity of responses within a cluster, are presented for each outcome. Covariates adjusted for in the linear mixed model are also described.

Results are also presented for the per protocol analysis, i.e., by removing from the analysis the three sites in which staff did not deliver the prescribed intervention to participating residents. Table 5-5 presents per protocol mean scores for primary and secondary outcomes at baseline (Time 1) and post-intervention (Time 2) for the complete cases in both the SERPS and usual care groups. Table 5-6 presents per protocol differences in mean scores (change scores) from baseline (Time 1) to post-intervention (Time 2) for primary and secondary outcomes for the complete cases in both the SERPS and usual care groups. Estimates of effect, 95% CIs and p values for per protocol complete case analysis and per protocol imputed data analysis are presented in Table 5-7. Estimates of the ICCs and covariates adjusted for in the linear mixed model are also given.

5.4.1 Primary outcome

5.4.1.1 Residents' quality of life

5.4.1.1.1 Results for intention to treat analysis- complete cases and imputed data

As detailed in section 4.11, an *a priori* 4-point difference in mean scores on the residents' QOL-AD scale between the intervention and control groups was identified as the minimum clinically important difference in the quality of life of residents with dementia in the long-stay setting as measured by the QOL-AD instrument (Logsdon et al. 1999). There was no statistically significant difference, on average, in residents' QOL-AD mean scores between residents in clusters randomised to the SERPS and those in clusters randomised to usual care using complete case analysis (mean difference (MD) 3.54, 95% CI -0.83 to 7.90, p=0.10) and when imputed data were used (MD 2.89, 95% CI -0.83 to 5.86, p=0.06). Covariates adjusted for in the linear mixed model for in the intention to treat complete case and imputed data were: site allocation, site status, residents' baseline (Time 1) response to QOL-AD total scores and a formal diagnosis of dementia determined by the DSM IV or ICD 10. The ICC was estimated as

0.17, which is, the degree of similarity in residents' responses to QOL-AD scores at baseline in each cluster (Table 5-4).

5.4.1.1.2 Results for per protocol analysis- complete case and imputed data

Using per protocol analysis, there was a statistically significant improvement, on average, in residents' QOL-AD mean scores in residents in clusters randomised to the SERPS compared with scores for those in clusters randomised to usual care using complete case analysis (MD 5.22, 95% CI 0.11 to 10.34, p=0.04) and when imputed data were used (MD 3.72, 95% CI 0.43 to 7.01, p=0.03). The magnitude of the improvement in the per protocol complete case analysis is greater than that determined *a priori* but the intention to treat imputed data is less than the 4-point difference in mean scores determined *a priori*. Covariates adjusted for in the linear mixed model were: site allocation, site status, residents' baseline (Time 1) response to QOL-AD total scores and a formal diagnosis of dementia determined by the DSM IV or ICD 10. The ICC was estimated as 0.15, which is, the degree of similarity in residents' responses to QOL-AD scores at baseline in each cluster (Table 5-7).

5.4.2 Secondary outcomes

5.4.2.1 Staff rating of the residents' quality of life

5.4.2.1.1 Results for intention to treat analysis- complete case and imputed data

There was no statistically significant difference, on average, in the staff response to residents' QOL-AD mean scores between staff in clusters randomised to the SERPS and those in clusters randomised to usual care using intention to treat complete case analysis (MD 1.14, 95% CI -0.35 to 3.62, p=0.35) and when intention to treat imputed data were used there was no statistically significant difference, on average, in staff response to residents' QOL-AD mean scores between staff in clusters randomised to the SERPS and those in clusters randomised to usual care (MD 0.58, 95% CI -1.52 to 2.70, p=0.06). Covariates adjusted for in the linear mixed model were: site allocation, site status, staff baseline (Time 1) response to residents' QOL-AD total scores, dementia diagnosis 2 and 3 (diagnosis 2 indicated a diagnosis by a medical clinician and diagnosis 3 indicated the resident was on anti-Alzheimer's medications), residents' MMSE scores and type of consent. The ICC was estimated as 0.04, which is, the degree of similarity in staff responses to residents' QOL-AD scores at baseline in each cluster (Table 5-4).

5.4.2.1.2 Results for per protocol analysis- complete case and imputed data

There was no statistically significant difference, on average, in the staff response to residents' QOL-AD mean scores between staff in clusters randomised to the SERPS and those in clusters randomised to usual care using per protocol complete case analysis (MD 1.40, 95% CI -1.75 to 4.55, p=0.35) and when per protocol imputed data were used (MD 0.81, 95% CI -1.85 to 3.46, p=0.06). Covariates adjusted for in the linear mixed model were: site allocation, site status, staff baseline (Time 1) response to residents' QOL-AD total scores, dementia diagnosis 2 and 3 (diagnosis 2 indicated a diagnosis by a medical clinician and diagnosis 3 indicated the resident was on anti-Alzheimer's medications), residents' MMSE scores and type of consent. The ICC was estimated as 0.01, which is the degree of similarity in staff responses to residents' QOL-AD scores at baseline in each cluster (Table 5-7).

5.4.2.2 Residents' levels of agitation

5.4.2.2.1 Results for intention to treat analysis- complete case and imputed data

There was no statistically significant difference, on average, in residents' CMAI mean scores between residents in clusters randomised to the SERPS and those in clusters randomised to usual care using intention to treat complete case analysis (MD -3.35, 95% CI -8.10 to 1.82, p=0.19) and when intention to treat imputed data were used (MD -0.94, 95% CI -5.70 to 3.82, p=0.70). Covariates adjusted for in the linear mixed model were: site allocation, site status, residents' baseline (Time 1) CMAI total scores, ethnicity, type of consent, age in years, dementia diagnosis 2 and 3. The ICC was estimated as 0.00. An ICC of zero suggests there was no similarity in residents' CMAI scores at baseline either in or between clusters.

5.4.2.2.2 Results for per protocol analysis- complete case and imputed data

There was no statistically significant difference, on average, in residents' CMAI mean scores between residents in clusters randomised to the SERPS and those in clusters randomised to usual care using per protocol complete case analysis (MD -2.14, 95% CI -7.94 to 3.67, p=0.43) and when per protocol imputed data were used (MD -1.15, 95% CI -7.68 to 5.38, p=0.73). Covariates adjusted for in the linear mixed model were: site allocation, site status, residents' baseline (Time 1) CMAI total scores, ethnicity, type of consent, age in years, dementia diagnosis 2 and 3. The ICC was estimated as 0.02,

which is the degree of similarity in residents' CMAI scores at baseline in each cluster (Table 5-7).

5.4.2.3 Residents' levels of depression

5.4.2.3.1 Results for intention to treat analysis- complete case and imputed data

There was a statistically significant reduction, on average, in residents' CSDD mean scores between residents in clusters randomised to usual care compared with those in clusters randomised to the SERPS using intention to treat complete case analysis (MD-1.33, 95% CI -3.04 to 0.36, p=0.03) and when intention to treat imputed data were used (MD -1.59, 95% CI -3.03 to -0.16, p= 0.03). Table 5.2 suggests that the control groups' CSDD mean scores at post-intervention (Time 2) were lower (i.e., residents had, on average, lower depression scores) than those of the intervention groups mean CSDD post-intervention (Time 2) scores. Similarly, Table 5-3 suggests that the reduction in depression scores from baseline (Time 1) to post-intervention (Time 2) were greater in the control group. However, neither group demonstrated the presence of significant depressive symptoms at baseline or at follow-up as determined by the CSDD. For residents in long-stay facilities, a score of 7 or more on the CSDD indicates a probable major depression (Watson *et al.* 2003; 2006). Covariates adjusted for in the linear mixed model were: site allocation, site status, residents' baseline (Time 1) response to CSDD total scores and age in years. The ICC was estimated as 0.28, which is the degree of similarity in residents' CSDD scores at baseline in each cluster (Table 5-4).

5.4.2.3.2 Results for per protocol analysis- complete case and imputed data

There was no statistically significant difference, on average, in residents' CSDD mean scores between residents in clusters randomised to the SERPS and those in clusters randomised to usual care using per protocol complete case analysis (MD-0.86, 95% CI -2.66 to 0.93, p=0.32) and when per protocol imputed data were used (MD -1.36, 95% CI -2.89 to 0.16, p=0.08). Covariates adjusted for in the linear mixed model were: site allocation, site status, residents' baseline (Time 1) response to CSDD total scores and age in years. The ICC was estimated as 0.29, which is, the degree of similarity in residents' CSDD scores at baseline in each cluster (Table 5-7).

5.4.2.4 Staff nurses' burden of care

5.4.2.4.1 Results for intention to treat analysis- complete case and imputed data

There was no statistically significant difference, on average, in the staff nurse M-ZBI scale mean scores between nursing staff in clusters randomised to the SERPS and those in clusters randomised to usual care using intention to treat complete case analysis (MD 0.97, 95% CI -1.13 to 3.08, p=0.36) and when intention to treat imputed data were used (MD -0.31, 95% CI -2.12 to 1.50, p=0.73). Covariates adjusted for in the linear mixed model were: site allocation, site status, staff nurses' baseline (Time 1) total scores on the M-ZBI scale, residents' MMSE scores and dementia diagnosis 1 and 2. The ICC was estimated as 0.13, which is the degree of similarity in staff nurse M-ZBI scale scores baseline in each cluster (Table 5-4).

5.4.2.4.2 Results for per protocol analysis- complete case and imputed data

There was no statistically significant difference, on average, in the staff nurse M-ZBI scale mean scores between nursing staff in clusters randomised to the SERPS and those in clusters randomised to usual care using per protocol complete case analysis (MD 1.50, 95% CI –0.73 to 3.74, p=0.18) and when per protocol imputed data were used (MD 0.47, 95% CI -1.17 to 2.10, p=0.06). Covariates adjusted for in the linear mixed model were: site allocation, site status, staff nurses' baseline (Time 1) total scores on the M-ZBI scale, residents MMSE scores and dementia diagnosis 1 and 2. The ICC was estimated as 0.10, which is the degree of similarity in staff nurse M-ZBI scale scores at baseline in each cluster (Table 5-7).

5.4.2.5 Healthcare assistants' burden of care

5.4.2.5.1 Results for intention to treat analysis- complete case and imputed data

There was no statistically significant difference, on average, in the healthcare assistant M-ZBI scale mean scores between healthcare assistants in clusters randomised to the SERPS and those in clusters randomised to usual care using intention to treat complete case analysis (MD 0.42, 95% CI -1.83 to 2.67, p=0.70) and when intention to treat imputed data were used (MD 0.23, 95% CI -1.76 to 1.30, p=0.77). Covariates adjusted for in the linear mixed model were: site allocation, site status, healthcare assistants' baseline total score on the M-ZBI scale, age in years and type of consent. ICC was estimated as 0.15, which is the degree of similarity in healthcare assistant M-ZBI scale scores at baseline in each cluster (Table 5-4).

5.4.2.5.2 Results for per protocol analysis- complete case and imputed data

There was no statistically significant difference, on average, in healthcare assistant M-ZBI scale mean scores between healthcare assistants in clusters randomised to the SERPS and those in clusters randomised to usual care using per protocol complete case analysis (MD 0.86, 95% CI -1.22 to 2.94, p=0.40) and when per protocol imputed data were used (MD 0.30, 95% CI -1.19 to 1.77, p=0.70). Covariates adjusted for in the linear mixed model were: site allocation, site status, healthcare assistants' baseline total score on the M-ZBI scale, age in years and type of consent. The ICC was estimated as 0.15, which is the degree of similarity in healthcare assistant M-ZBI scale at baseline in each cluster (Table 5-7).

Table 5-2: Means (SD) for primary and secondary outcomes by group and time for intention to treat complete cases

Response variable	SERPS				Usual care			
	Baseline (Time 1)		Post-intervention (Time 2)		Baseline (Time 1)		Post-intervention (Time 2)	
Residents' response to QOL-AD	34.32	(4.54)	35.22	(4.29)	33.76	(5.27)	31.77	(6.55)
Staff response to residents' QOL-AD	30.38	(5.54)	30.42	(6.31)	30.13	(5.83)	29.09	(6.01)
CMAI	41.39	(13.68)	43.13	(15.65)	43.90	(14.51)	43.78	(15.76)
CSDD	4.12	(4.53)	5.19	(5.36)	4.64	(4.81)	3.62	(4.50)
M-ZBI scale (SN)[1]	9.74	(8.49)	9.30	(7.29)	11.58	(8.50)	10.21	(7.97)
M-ZBI scale (HCA)[2]	8.55	(7.02)	7.41	(6.91)	11.03	(8.87)	9.57	(8.24)

[1]SN = Staff nurse; [2]HCA = Healthcare assistant

Table 5-3: Change scores per group from baseline (Time 1) to post-intervention (Time 2) intention to treat complete cases

Response variable	SERPS Mean (SD)		Usual care Mean (SD)		Calculated as:
Residents' response to QOL-AD	0.78	(5.33)	-1.82	(7.22)	Time 2-Time1
Staff response to residents' QOL-AD	-0.21	(6.49)	-1.33	(6.00)	Time 2-Time1
CMAI	-1.93	(15.10)	1.04	(13.77)	Time 1-Time 2
CSDD	-1.06	(6.08)	0.80	(5.89)	Time 1-Time 2
M-ZBI scale (SN)[1]	1.24	(7.77)	1.11	(8.57)	Time 1-Time 2
M-ZBI scale (HCA)[2]	0.80	(5.62)	1.58	(7.23)	Time 1-Time 2

[1]SN = Staff nurse; [2]HCA = Healthcare assistant

Table 5-4: Effect estimates for primary and secondary outcomes for intention to treat complete cases and imputed data

Response variable	Estimate effect[1]	95% CI	p value	MI[2] Estimate effect 95% CI p value	ICC	Covariates adjusted for[3]
Residents' response to QOL-AD	3.54	(-0.83, 7.90)	0.10	2.89 (-0.83, 5.86) (0.06)	0.17	Dementia diagnosis 1.
Staff response to residents' QOL-AD	1.14	(-0.35, 3.62)	0.35	0.58 (-1.52, 2.70) (0.06)	0.04	Dementia diagnosis 2, 3; Type of consent; MMSE.
CMAI	-3.35	(-8.10, 1.82)	0.19	-0.94 (-5.70, 3.82) (0.70)	0.00	Type of consent; Age in years; Dementia diagnosis 2, 3.
CSDD	-1.33	(-3.04, 0.36)	0.03	-1.59 (-3.03,-0.16) (0.03)	0.28	Age in years
M-ZBI scale (SN)	0.97	(-1.13, 3.08)	0.36	0.31 (-2.12, 1.50) (0.73)	0.13	MMSE; Dementia diagnosis 1, 2.
M-ZBI scale (HCA)	0.42	(-1.83, 2.67)	0.70	0.23 (-1.76, 1.30) (0.77)	0.15	Age in years; Type of consent.

[1] Baseline and covariates adjusted mean difference between intervention and control groups (complete case analysis).

[2] Baseline and covariate adjusted mean difference between intervention and control groups (multiple Imputation).

[3] Covariates also adjusted for included: site allocation, site status and baseline total response scores for each outcome.

Table 5-5: Per protocol means (SD) for primary and secondary outcomes by group and time for intention to treat complete cases

Response variable	SERPS				Usual care			
	Baseline (Time 1)		Post-intervention (Time 2)		Baseline (Time 1)		Post-intervention (Time 2)	
Residents' response to QOL-AD	33.50	(4.81)	36.01	(3.58)	33.76	(5.27)	31.77	(6.55)
Staff response to residents' QOL-AD	29.53	(5.46)	29.67	(5.97)	30.13	(5.83)	29.09	(6.01)
CMAI	41.72	(13.38)	42.35	(14.12)	43.90	(14.51)	43.78	(15.76)
CSDD	4.76	(4.79)	5.39	(5.21)	4.64	(4.81)	3.62	(4.50)
M-ZBI scale (SN)[1]	10.96	(8.95)	8.98	(7.05)	11.58	(8.50)	10.21	(7.97)
M-ZBI scale (HCA)[2]	9.19	(7.19)	7.36	(6.63)	11.03	(8.87)	9.57	(8.24)

[1]SN = Staff nurse; [2]HCA = Healthcare assistant

Table 5-6: Per protocol change scores per group from baseline (Time1) to post-intervention (Time2)

Response variable	SERPS Mean (SD)		Usual care Mean (SD)		Calculated as:
Residents' response to QOL-AD	2.36	(4.86)	-1.82	(7.22)	Time 2-Time 1
Staff response to residents' QOL-AD	-0.17	(6.55)	-1.33	(6.00)	Time 2-Time 1
CMAI	-0.74	(14.41)	1.04	(13.77)	Time 1-Time 2
CSDD	-0.65	(5.95)	0.80	(5.88)	Time 1-Time 2
M-ZBI scale (SN)[1]	1.44	(7.74)	1.11	(8.57)	Time 1-Time 2
M-ZBI scale (HCA)[2]	1.07	(4.70)	1.58	(7.23)	Time 1-Time 2

[1]SN = Staff nurse; [2]HCA = Healthcare assistant

Table 5-7: Per protocol estimate of effect for primary and secondary outcomes for complete cases and imputed data

Response variable	Estimate effect[1]	95% CI	p value	MI[2] Estimate effect 95% CI (p value)	ICC	Covariates adjusted for[3]
Residents' response to QOL-AD	5.22	(0.11, 10.34)	0.04	3.72 (0.43, 7.01) (0.03)	0.15	Dementia diagnosis 1
Staff response to residents' QOL-AD	1.40	(-1.75, 4.55)	0.35	0.81 (-1.85, 3.46) (0.06)	0.01	Dementia diagnosis 2, 3; Type of consent; MMSE.
CMAI	-2.14	(-7.94, 3.67)	0.43	-1.15 (-7.68, 5.38) (0.73)	0.02	Type of consent; Age in years; Dementia diagnosis 2, 3.
CSDD	-0.86	(-2.66, 0.93)	0.32	-1.36 (-2.89, 0.16) (0.08)	0.29	Age in years.
M-ZBI scale (SN)[4]	1.50	(-0.73, 3.74)	0.18	0.47 (-1.17, 2.10) (0.06)	0.10	MMSE; Dementia diagnosis 1, 2.
M-ZBI scale (HCA)[5]	0.86	(-1.22, 2.94)	0.40	0.30 (-1.19, 1.77) (0.70)	0.15	Age in years; Type of consent.

[1] Baseline and covariates adjusted mean difference between intervention and control groups (using per protocol complete cases).
[2] Baseline and covariates adjusted mean difference between intervention and control groups (using per protocol multiple imputation data).
[3] Covariates also adjusted for included: site allocation, site status and baseline total response scores for each outcome.
[4] SN = Staff nurse
[5] HCA = Healthcare assistant

5.5 Harms/Adverse events

No adverse effects from participation in the DARES study were reported.

5.6 Summary

This chapter has provided a descriptive summary of the findings of the analyses of the DARES study data undertaken by me. The principle findings of the data analyses will be discussed in Chapter 6.

Chapter 6
Discussion

6.1 Introduction

This chapter provides a summary of the main findings of my research presented in Chapter 5 and considers the possible explanations as to how and why these results may have happened. The generalisability (external validity, applicability) of the DARES study findings are discussed and interpreted in the context of the findings on the effectiveness of reminiscence for people with dementia, residing in long-stay settings, presented in the systematic review and meta-analysis in Chapter 3. Limitations of the DARES study are also discussed here. As recommended by the CONSORT 2010 statement (Schulz *et al.* 2010), the structure of this discussion chapter was guided by the *Annals of Internal Medicine. Information for authors* (2012).

Using a cluster randomised trial design, 18 long-stay units with a total of 304 residents with dementia were recruited to participate in the study. Nine long-stay units (n=153 residents with dementia) were allocated randomly to the intervention group and nine (n=151 residents with dementia) were allocated randomly to the control group. Staff participants in the intervention group attended the DARES intervention i.e., a structured education reminiscence-based programme (SERPS) and were trained to implement reminiscence with their designated residents. Long-stay units allocated to the control group did not receive any training, and staff in those units continued to deliver usual care to their designated residents. Outcomes were measured for both the intervention and control groups at baseline, and again at 18-22 weeks post-randomisation. The primary outcome was the resident's quality of life as measured by the care recipient's version of the QOL-AD scale, which was completed by the resident. The secondary outcomes were participating staff members response to resident's quality of life, as measured by the caregiver's version of the QOL-AD scale; residents levels of agitation as measured by the CMAI; residents levels of depression as measured by the CSDD; staff nurses and healthcare assistants burden of care as measured by the M-ZBI scale.

6.2 Outcomes discussion

Each of the outcome instruments used in the DARES study was chosen because of their psychometric properties and because of their variability in methodological approaches, including proxy reports. Choice of outcome measurements was also

guided by the recommendations made by Moniz-Cook *et al.* (2008) in a report on a European consensus on outcome measures to use when evaluating the effectiveness of psychosocial interventions in dementia care. The authors highlighted the need to agree on a core set of outcomes for evaluating psychosocial interventions in residents with dementia so that meaningful comparisons can be made between different studies and different interventions. We were also guided by recommendations made by the Dementia Outcomes Measurement Suite (Sansoni *et al.* 2007).

6.2.1 Primary outcome: Residents' response to QOL-AD (care recipient self-report version)

A 4-point difference in mean scores on the care recipient self-report version of the QOL-AD scale (completed by residents) was identified *a priori* as the minimum clinically important difference in the quality of life of residents with dementia in the long-stay setting (section 4.12). However, analysis by both intention to treat complete case and imputed data indicated that there was no statistically significant difference in resident QOL-AD mean scores between residents in units randomised to the intervention and those in units randomised to usual care (section 5.4.1.1.1). However, staff in three of the nine intervention sites did not deliver reminiscence to participating residents as prescribed. When these sites were removed from the analysis i.e., per protocol analysis, there was a statistically and clinically significant improvement in residents' QOL-AD mean scores in residents in units randomised to the intervention compared with scores for residents in units randomised to usual care (section 5.4.1.1.2). The difference in the intervention effect exceeded the four-point minimum clinically important difference. However, when imputed data were used, the effect, while remaining statistically significant, was marginally below the four-point difference in mean scores required for clinical significance.

The DARES study intervention, SERPS, was based on the philosophy of empowering participating staff by providing them with the knowledge, skills and attitudes necessary to enable them to deliver a reminiscence-based intervention to their designated residents with dementia. The SERPS curriculum focused on understanding the person with dementia, how memory works, particularly remote memory and how it may be used in the reminiscence process to recall past memories, experiences or events. Another important aspect of the SERPS focussed on understanding how the participating staff could use reminiscence to enhance communication and manage

behaviours that challenge. The emphasis was on integrating reminiscence into the provision of 24-hour care and incorporating reminiscence into the residents care plans with the intention of providing a more person-centred approach to care. The purpose of reminiscence was to stimulate the resident, provide a source of enjoyment and foster a sense of self-worth and achievement (O'Shea *et al.* 2011; Dempsey *et al.* 2012). The anticipated outcomes for the residents with dementia were incorporated into the DARES definition of reminiscence and included enhancement of the resident's quality of life. From this perspective, the DARES study has achieved what it set out to achieve and demonstrates that when staff participants were trained in a reminiscence-based intervention and consequently delivered reminiscence to their designated residents as prescribed, reminiscence enhanced the quality of life of their designated residents.

The DARES results are strongest on a per protocol basis, emphasising the importance of attending the training programme and adhering to the treatment protocol as agreed. Analysis of the Reminiscence Records Sheets at the end of the trial indicated that residents allocated to the intervention arm either received all four reminiscence sessions per week for the duration of the study as prescribed or no reminiscence sessions. Dyads in six of the intervention sites adhered to the treatment protocol and delivered all of the required informal and formal weekly reminiscence sessions to their designated residents. Dyads in three of the intervention sites did not adhere to the treatment protocol and did not deliver any reminiscence sessions to their designated residents. However, the fact that staff in three intervention sites did not deliver reminiscence to their designated residents reflects the complexity of carrying out a trial and evaluating a healthcare intervention in routine clinical practice. Very early in the research design, we, the DARES research team, gave serious consideration as to how long-stay units would be selected and recruited. Units had to have the ability to support and sustain the research process in terms of having the required number of consenting residents with dementia (n=17), and the required number of consenting staff participants (n=10). The systematic approach to the selection and recruitment of long-stay units is outlined clearly in Chapter 4 of this thesis, and also in the DARES study protocol (O'Shea *et al.* 2011). Largely the responsibility of the DARES project manager and the research nurses, in the face of adversity, namely staff shortages, the required number (n=18) of public (n=6) and private (n=12) units were ultimately recruited.

Staff shortage is an inherent problem in long-stay care setting in Ireland (O'Shea *et al.* 2008), and testimony to this is that 37 long-stay units declined to participate because of poor staffing levels (Figure 5-1). Recruiting the required number of public long-stay units (n=6) was particularly difficult because public facilities were exposed to restrictions in staff recruitment, again resulting in staff shortages. This meant that existing staff members already had demanding workloads and the prospect of taking on more work was not welcomed by staff members.

Likewise, staff members in three of the long-stay units that agreed to participate and were subsequently randomised to the intervention arm of the study, were also affected by inadequate staffing level, which meant that their existing workload was extensive, affecting their attendance at the training programme and ultimately their ability to deliver reminiscence sessions to their designated residents as prescribed. Attendance at the training programme was also affected by sickness, absenteeism, staff turnover and last minute changes to duty rosters. Moreover, scheduling of support visits to all sites was continually disrupted because of part-time working and staff holidays, arranging support visits for days when the majority of participating staff would be on duty was particularly difficult in the three sites that breached the intervention protocol.

6.2.2 Secondary outcomes

6.2.2.1 Staff response to residents' QOL-AD (caregiver proxy version)

Findings from the study indicated that although there was an improvement in the caregivers mean QOL-AD scores in the intervention group from baseline to follow-up and a decline in the caregiver QOL-AD mean scores in the control group from baseline to follow-up, there was no significant difference in the estimate of the treatment effect between the intervention and control groups (section 5.4.2.1).

Consistent with findings from other intervention and quality of life studies conducted with both cognitively intact and cognitively impaired individuals and their caregivers in both community and long-stay settings, using a variety of quality of life measurements (Logsdon *et al.* 1999; Sansoni *et al.* 2007), results from this study indicated that the caregivers' proxy ratings of the residents' quality of life were lower than the care recipients' self-reported ratings, both at baseline and post-intervention. Although, caregiver proxy reports of quality of life in dementia are used widely, researchers report relatively low levels of agreement between the caregivers and the person with

dementia ratings of quality of life with care recipient subjective ratings of their quality of life consistently higher than the caregiver's objective ratings (Edelman *et al.* 2005; Woods *et al.* 2006; Sansoni *et al.* 2007). A number of studies have assessed the predictive and explanatory factors associated with changes in the quality of life of people with dementia and their caregivers and have demonstrated that the ratings made by the person with dementia are negatively correlated with symptoms of depression and anxiety. While the ratings made by the caregiver are negatively correlated with cognition, severity of dementia, functional dependency, burden of care, depressive and behavioural symptoms (Logsdon *et al.* 1999; 2002; Hoe *et al.* 2005; 2006; 2007; 2009; Spector & Orrell, 2006; Banerjee *et al.* 2009). Hoe *et al.* (2006) contend that, the discrepancy between proxy ratings and self-ratings of quality of life, is not a question of right and wrong but merely a matter of differing perceptions, but it does suggest that, proxy ratings do not replicate the care recipients' views of their quality of life and therefore should not be substituted for the care recipients' self-rating. Dementia quality of life researchers argue that, if clinicians really want to understand what makes a difference to the quality of life of the person with dementia, they must seek the subjective opinion of the person with dementia (Hoe *et al.* 2006; Spector & Orrell, 2006; Cahill & Diaz-Ponce, 2011).

Similar to a number of international studies (Logsdon *et. al* 1999; 2002; Sloane *et al.* 2005; Hoe *et al.* 2006), findings from the DARES study have demonstrated that, the majority (n=259, 85%) of participating residents with dementia were able to respond to all questions about their quality of life and that caregiver proxy reports may not accurately reflect the opinions of the person with dementia.

6.2.2.2 Residents levels of agitation

The DARES study found no statistically significant difference between control and intervention groups on residents' levels of agitation as measured by the CMAI (section 5.4.2.2). However, it is worth noting that participating residents' levels of agitation in both study groups were low at baseline as indicated by mean CMAI total scores of 41.39 (SD 13.68) in the intervention group and 43.90 (SD 14.51) in the control group (Table 5-2). To put this into context, scores on the CMAI range from 29-203 and higher scores indicate higher levels of agitation. There is no formal cut-off for agitation on the CMAI (Pelletier & Landreville, 2007) and studies of agitation in nursing home residents with dementia report a variety of baseline mean CMAI total scores. For example,

Rabinowitz *et al.* (2005) studied agitated behaviour in residents with dementia in three different samples across a number of different countries (Europe and Canada, n=344; Australia, n=304; United States, n=616) and reported baseline mean CMAI total scores of between 65, 67 and 78 respectively. Ballard *et al.* (2009) in an evaluation of a brief psychosocial intervention in people with dementia (n=318), reported baseline mean CMAI total scores of 63.3. More recently, Fox *et al.* (2012) in a study of the efficacy of Mamantine for agitation in nursing home residents with Alzheimer's dementia (n=149) used a score of 45 or more on the CMAI to indicate clinically significant agitation, the baseline mean CMAI total scores for residents in both study groups was 68.3. It is reasonable to conclude that, compared with CMAI mean scores derived from other studies, mean CMAI scores in the DARES study indicate that on average residents' across both study groups did not have clinically significant agitation at baseline or post-intervention follow-up.

It is well accepted by dementia researchers that there is a negative correlation between the frequency of agitated behaviours and levels of cognition (Cohen-Mansfield *et al.* 1990; Cohen-Mansfield & Libin, 2005; Gudex *et al.* 2010). Perhaps then, it is reasonable to conclude that, the low mean CMAI total scores observed in the DARES study reflected the fact that, on average participating residents in both study groups were moderately cognitively impaired, indicated by mean MMSE scores of 12.98 in the intervention group and 11.70 in the control group.

Consideration must also be given to pharmacological interventions and while residents' prescribed medications, with the exception of prescribed anti-Alzheimer's drugs, were not documented in the DARES study, because of time and budget constraints, it is possible that residents' mean CMAI total scores were relatively low at baseline in both study groups because residents with a history of agitated behaviours were receiving pharmacological treatment for agitation. For example, as detailed in Table 5-1a, at baseline 35% (n=53) and 26% (n=39) of residents in the intervention and control groups respectively, were prescribed anti-Alzheimer's medications which are indicated for the cognitive, behavioural and psychological symptoms of dementia (Fox *et al.* 2012).

Although non-pharmacological interventions are recommended as first-line treatment for agitation and other behavioural and psychological symptoms of dementia (NICE,

2006), evidence suggests that this is not the case in many long-stay residential units (Murphy & O'Keeffe, 2008). As discussed in Chapter 2 of this thesis, concerns have been raised by a number of dementia researchers that, despite best practice guidelines, pharmacological approaches, particularly anti-psychotic medications, are frequently used as a first-line treatment for agitation and other symptoms of behavioural disturbance (Fossey *et al.* 2006; Ruths *et al.* 2008; Murphy & O'Keeffe, 2008; Banerjee, 2009; Richter *et al.* 2012).

6.2.2.3 Residents levels of Depression

There was a statistically significant reduction in residents' CSDD mean scores in units randomised to usual care compared with those in units randomised to SERPS, using both intention to treat complete case and intention to treat imputed data analyses (section 5.4.2.3). Given that, a number of dementia researchers (Logsdon *et al.* 1999; 2002; Hoe *et al.* 2005; 2006; 2007; 2009; Spector *et al.* 2006; Banerjee *et al.* 2009) have demonstrated that, both subjective and proxy ratings of quality of life are negatively correlated with depression, the negative effect of reminiscence on residents' levels of depression demonstrated in the DARES study is counter-intuitive, given the positive effect of the DARES intervention on the residents' quality of life. However, there are a number of explanations why the significantly negative effect of reminiscence on depression reported in this study should be considered cautiously. Firstly, neither of the study groups demonstrated the manifestation of clinically significant depression at baseline or at follow-up as determined by the CSDD because, as detailed in section 5.4.2.3.1, Watson *et al.* (2003; 2006) recommend that, for residents in long-stay facilities, a score of 7 or more on the CSDD indicates a probable major depression. Baseline CSDD mean scores in the intervention and control groups were 4.12 (SD: 4.53) and 4.64 (SD: 4.81) respectively. Post intervention CSDD mean scores in the intervention and control groups were 5.19 (SD: 5.36) and 3.62 (SD: 4.50) respectively. As discussed in section 6.2.2.2, it is possible that, the absence of clinically significant depression at baseline could be attributable to the effects of prescribed medications.

Secondly, despite the rigorous data checking procedures undertaken in the DARES study, analysis of CSDD mean change scores across study groups and long-stay units demonstrated that, one long-stay unit in the control arm had an inexplicable improvement in mean depression scores, in that, the CSDD mean score at baseline

was 12.5 and 1.1 at follow-up. This site was cross checked for coding errors but none were identified. When this site is excluded from the analysis, the significant effect on depression in the control group is eliminated. Thirdly, per protocol analysis indicated that when the three sites that did not deliver reminiscence to their designated residents as prescribed were excluded from the analysis, there was no statistically significant difference, on average, in residents' CSDD mean scores between residents in units randomised to the SERPS and those in units randomised to usual care (section 5.4.2.3.2).

6.2.2.4 Staff nurses' and healthcare assistants' burden of care

Although there was a reduction in the mean scores from baseline to post-intervention in both the intervention and control groups, the decline in burden of care, as measured by the M-ZBI scale completed by staff nurses and healthcare assistants, was not statistically significant in either group (sections 5.4.2.4 and 5.4.2.5). However, qualitative data derived from the study (not as part of this PhD thesis and currently accepted for publication) suggests that staff allocated to the SERPS were supportive of the intervention, and saw it as having a positive impact on their relationship with their individual designated resident (Cooney *et al.* 2012). Contrary to what one would expect, staff participants' positive responses to reminiscence captured in qualitative data are not reflected in a significant reduction in the burden of care for staff allocated to the reminiscence arm of the study.

The absence of a significant difference in burden of care may well be explained by the fact that, both staff nurses' and healthcare assistants' mean burden of care scores in both study groups were very modest at baseline. Scores on the M-ZBI scale range from 0-52 and baseline burden of care mean scores for staff nurses and healthcare assistants in the intervention group were 9.74 (8.49) and 8.55 (7.02) respectively. Baseline burden of care scores for staff nurses and healthcare assistants in the control group were 11.58 (8.50) and 11.03 (8.87) respectively (Table 5-2).

This finding is contrary to what evidence suggests, in that, research derived from mainly qualitative data suggests strongly that, the duty of caring for cognitively impaired residents in the long-stay setting is associated with high levels of stress in care staff (Brodaty *et al.* 2003; Cahill *et al.* 2012). Stress stems from many sources, including limited staff knowledge and understanding of dementia (Borbasi *et al.* 2006), reflective

of limited staff training, inadequate dementia-specific skills in dealing with behaviours that challenge (McGlade *et al.* 2009; Cahill *et al.* 2012) and staff shortages, exacerbated by high staff turnover (O'Shea *et al.* 2008). Furthermore, generic care facilities, which are typical of the vast majority of Irish nursing homes, make the task of providing care to residents with dementia very difficult for staff (Murphy *et al.* 2006). People with dementia require time, but affording this time in a busy care environment is, all too often, a real challenge and source of great stress for care staff (Cunningham & Archibald, 2006). Testimony to this fact, using the M-ZBI scale, Sourial *et al.* (2001) conducted 167 burden of care interviews with staff members working with people with dementia in the long-stay setting, staff responses indicated an average burden of between 'never' and 'rarely'. In the same study, in response to Question 6 of the M-ZBI, 66% of staff indicated that they 'sometimes' felt that the person with dementia was 'dependent upon them', in response to Question 13 of the M-ZBI, 39% of staff indicated that they 'sometimes' felt they 'could do a better job' and in response to Question 12, 35% of staff indicated that they 'sometimes' felt that they 'should be doing more' for the person with dementia. Perhaps the low baseline and post-intervention burden of care scores across both study groups in the DARES study, reflects the fact that, staff felt they should be doing more for their residents with dementia and are therefore reluctant to acknowledge their burden of care. The paucity of literature in this area makes it difficult to shed any further insight but definitively an area warranting further investigation.

6.3 Systematic review and meta-analysis of relevant evidence: the contribution of the DARES study

6.3.1 Introduction

In this section findings from the DARES study are interpreted in the context of the existing body of evidence on the effects of reminiscence for residents with dementia living in long-stay care settings presented in the systematic review and meta-analysis in Chapter 3. In the absence of evidence evaluating reminiscence for people with dementia living in long-stay settings, findings from the DARES study will be considered in the context of evidence evaluating reminiscence for people with dementia living in community settings.

6.3.2 Quality of life of residents' with dementia

6.3.2.1 Care recipients self-report of quality of life

As identified in the systematic review, there was a distinct absence of trials evaluating the effectiveness of reminiscence on the quality of life of residents with dementia in the long-stay setting from the perspective of the resident. The DARES study is unique in this regard. The study has demonstrated that training staff in a reminiscence-based intervention and subsequently facilitating them to delivering reminiscence sessions to their designated residents as prescribed; enhanced the quality of life of their designated residents, as rated by the residents themselves. However, the fact that previous trials did not measure the effects of reminiscence interventions on the quality of life of residents with dementia from the subjective view of the resident made it difficult to position and compare the findings from the DARES study in the context of existing evidence presented in the systematic review in Chapter 3. However, in the context of evidence for reminiscence for people with dementia derived from other care settings, the positive effects of reminiscence in the DARES study are inconsistent with findings reported by Thorgrimsen *et al.* (2002) and Woods *et al.* (2012). Both studies were carried out in community settings and involved the delivery of joint reminiscence sessions between the person with dementia and a family caregiver. Findings from both studies indicated that reminiscence therapy did not have a significant effect on the quality of life of people with dementia as measured by the care recipient's version of the QOL-AD instrument.

6.3.2.2 Caregiver proxy report of quality of life

Prior to the DARES study, previous studies had not evaluated the impact of reminiscence on the residents quality of life from the viewpoint of their formal caregivers. Findings from the caregiver proxy version of the QOL-AD scale are less favourable than the subjective view of the resident, indicating that from the staff participant's perspective, a reminiscence-based intervention did not have a significant impact on the quality of life of residents with dementia. Here again, the fact that previous trials did not measure the effects of reminiscence interventions on the quality of life of the resident with dementia as rated by the formal caregiver, made it difficult to position and compare the findings from the DARES study in the context of existing evidence presented in the systematic review in Chapter 3. With regard to the effectiveness of reminiscence therapy on informal caregivers' ratings of the quality of

life of the person with dementia living in the community, the DARES study findings are consistent with the findings from both Thorgrimsen *et al.* (2002) and Woods *et al.* (2012).

6.3.2.3 Residents' behaviour/levels of agitation

The DARES study results indicated that reminiscence had no significant impact on residents' levels of agitation as measured by the CMAI. This finding is consistent with one of the studies included in the review in Chapter 3. Wang *et al.* (2009) measured the effects of reminiscence on residents' general behaviour using the CAPE-BRS and showed no significant difference between the two study groups.

6.3.2.4 Residents' levels of depression

Contrary to the findings from the DARES study, results from the meta-analysis presented in Chapter 3, indicated that, residents with dementia allocated to reminiscence therapy had a statistically significant reduction in depression compared to residents with dementia allocated to usual care. The updated analysis with the DARES results included is shown in Figure 6-1. However, as detailed in section 3.3.3.5.1 of Chapter 3, prior to updating the meta-analysis, because the DARES study was a cluster randomised trial; I had to adjust the sample size. Using the estimate of the ICC for depression derived from the DARES study and reported in Chapter 5 of this thesis, my approach to sample size adjustment was guided by the recommendations in section 16.3.4 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins *et al.* 2011). Results from the updated meta-analysis indicate that residents with dementia allocated to reminiscence therapy had a statistically significant reduction in depression compared to residents with dementia allocated to usual care (Standardised Mean Difference (SMD) -0.29; 95% CI -0.56 to -0.02, p=0.03, Chi^2 = 10.02, T^2 = 0.24, I^2 = 80%, Figure 6-1). The inclusion of the DARES study does not alter the findings from the original meta-analysis. However, the statistical tests for heterogeneity demonstrated in the updated meta-analysis, exceed the parameters detailed in section 3.3.3.7 (Chi^2 p < 0.1, T^2 > 0, I^2 > 30%), suggesting that there is significant between study heterogeneity. To explore the possible causes of the between study heterogeneity, I undertook a subgroup analysis, details of which are presented in section 6.3.2.4.1.

Figure 6-1: Forest plot of comparison: Depression

Study or Subgroup	Experimental Mean	SD	Total	Usual care Mean	SD	Total	Weight	Std. Mean Difference IV, Fixed, 95% CI	Std. Mean Difference IV, Fixed, 95% CI
Hsieh 2010	-1.38	1.43	29	0.25	2.06	32	26.0%	-0.90 [-1.43, -0.37]	
DARES study 2012	1.06	6.08	28	-0.8	5.89	28	26.2%	0.31 [-0.22, 0.83]	
Wang 2007	-1.07	3.56	51	0.02	3.78	51	47.8%	-0.29 [-0.68, 0.10]	
Total (95% CI)			108			111	100.0%	-0.29 [-0.56, -0.02]	

Heterogeneity: Chi² = 10.02, df = 2 (P = 0.007); I² = 80%
Test for overall effect: Z = 2.14 (P = 0.03)

-10 -5 0 5 10
Favours reminiscence   Favours usual care

6.3.2.4.1 Subgroup analysis to explore potential causes of heterogeneity

The test for subgroup differences indicated that there was significant heterogeneity between the two studies included in the original meta-analysis (Hsieh *et al.* 2010 and Wang, 2007) and the DARES study (Chi^2 = 6.77, p=0.009, I^2 =8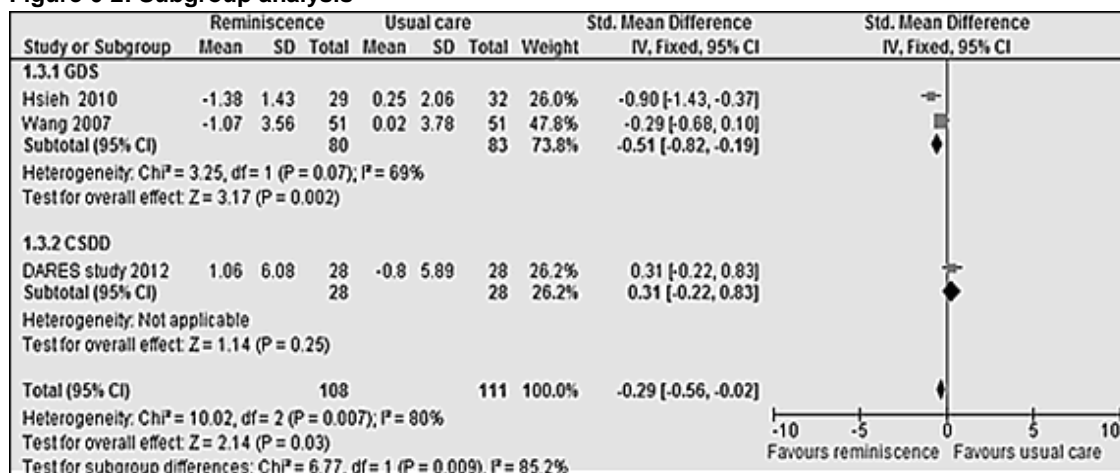5.2%, Figure 6-2). The finding of a significant subgroup interaction between the two subgroups may be attributed to differences in the clinical characteristics of the participants in each of the subgroups. The mean age of participants in Hsieh *et al.* (2010) and Wang (2007), was 77 and 78 years respectively and participants in both studies had a clinical diagnosis of mild to moderate dementia as determined by a CDR score of 1-2. Participants in the DARES study were older and had moderate cognitive impairment, indicated by a mean age of 85.5 years across both study groups and a mean MMSE score of 12.34. The significant heterogeneity between the two groups may also be explained by the different modalities in which reminiscence was delivered to participants in each of the subgroups, in that both Hsieh *et al.* (2010) and Wang (2007) delivered group reminiscence therapy and the DARES study delivered individual reminiscence therapy to their respective participants.

Figure 6-2: Subgroup analysis

Study or Subgroup	Reminiscence Mean	SD	Total	Usual care Mean	SD	Total	Weight	Std. Mean Difference IV, Fixed, 95% CI	Std. Mean Difference IV, Fixed, 95% CI
1.3.1 GDS									
Hsieh 2010	-1.38	1.43	29	0.25	2.06	32	26.0%	-0.90 [-1.43, -0.37]	
Wang 2007	-1.07	3.56	51	0.02	3.78	51	47.8%	-0.29 [-0.68, 0.10]	
Subtotal (95% CI)			80			83	73.8%	-0.51 [-0.82, -0.19]	

Heterogeneity: Chi² = 3.25, df = 1 (P = 0.07); I² = 69%
Test for overall effect: Z = 3.17 (P = 0.002)

Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight		
1.3.2 CSDD									
DARES study 2012	1.06	6.08	28	-0.8	5.89	28	26.2%	0.31 [-0.22, 0.83]	
Subtotal (95% CI)			28			28	26.2%	0.31 [-0.22, 0.83]	

Heterogeneity: Not applicable
Test for overall effect: Z = 1.14 (P = 0.25)

Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight		
Total (95% CI)			108			111	100.0%	-0.29 [-0.56, -0.02]	

Heterogeneity: Chi² = 10.02, df = 2 (P = 0.007); I² = 80%
Test for overall effect: Z = 2.14 (P = 0.03)
Test for subgroup differences: Chi² = 6.77, df = 1 (P = 0.009), I² = 85.2%

-10 -5 0 5 10
Favours reminiscence   Favours usual care

6.3.2.5 Formal caregivers burden of care

Although staff members working with residents with dementia regularly engage in and enjoy reminiscence work (Woods *et al.* 2005), the systematic review of the reminiscence literature detailed in Chapter 3, unveiled that previous work in this area did not consider the effects of reminiscence interventions, facilitated by staff, on their burden of care. The DARES study has met this gap in the evidence base, and has shown that a reminiscence-based intervention had a positive effect on staff nurses and healthcare assistants burden of care, although the effects were small and did not reach statistical significance. Previous trials did not consider the effects of reminiscence interventions on formal caregivers burden of care, so accordingly, this made it difficult to position and compare the findings from the DARES study in the context of existing evidence presented in the systematic review in Chapter 3.

6.4 Limitations of my research and the DARES study

My research and the DARES study has a number of limitations that are acknowledged here.

6.4.1 Treatment setting

Findings from the systematic review and meta-analysis presented in Chapter 3 of this thesis are limited in that included studies were all conducted in the same country thereby limiting generasability. Similarly, the DARES study evaluated the effectiveness of a reminiscence-based intervention on the quality of life of residents with dementia living in long-stay settings only and reminiscence was delivered to participating residents by formal caregivers trained in the reminiscence process. Therefore, findings from the DARES study are generalisable to the dementia population residing in long-term care only.

6.4.2 Dementia diagnosis

Four different approaches were used to identify potential participating residents with dementia; this decision was based on the fact that the majority of residents living in the long-stay setting in Ireland do not have a formal diagnosis of dementia (Cahill *et al.* 2012). Testimony to this is that, only 6% (n=20) of the overall number of participating residents (n=304) had a formal diagnosis of dementia determined by the DSM IV (APA, 1994) or ICD-10 (WHO, 1992). Yet, the mean MMSE score was 12.24, suggesting that

on average, participating residents were moderately cognitively impaired (Boote *et al.* 2006). Data from resident records indicated that all participating residents had a dementia. Ninety-seven per cent (n=296) of participating residents had a nursing diagnosis of dementia, 55% (n=167) had a medical diagnosis and only 6% (n=20) had a formal diagnosis. If we had only included residents with a formal diagnosis of dementia, it would not have been feasible to carry out the study as we would not have achieved the required sample size.

6.4.3 Treatment fidelity

Undertaking a trial of this complexity requires careful monitoring in relation to adherence to the treatment protocol. Even with support and monitoring, staff in the DARES study were challenged in their endeavours to implement the study intervention with their residents. Expecting participating staff, who were already challenged in terms of existing work load, staff shortages and high staff turnover, to deliver an intervention to their residents with dementia as prescribed was ambitious. As part of the treatment fidelity monitoring process, staff were required to record both informal and formal weekly reminiscence sheets in the Reminiscence Record Sheets provided to them by the research team, analysis of the recording sheets undertaken at the end of the study indicated that staff in three of the intervention sites did not deliver any reminiscence to their residents as prescribed, staff in the remaining six intervention sites did deliver the prescribed dose of reminiscence to their designated residents and as a result, the quality of life of their designated residents was better than before their participation in the study.

6.4.4 Outcome measurements
6.4.4.1 Timing of outcome measurements

It is important to consider the timing of the outcomes assessment in interpreting the findings from this study as outcomes were measured at baseline and post-intervention, approximately 18-20 weeks later. The qualitative evidence and feedback during the trial suggests that participants enjoyed the experience of reminiscence, but because of the time-lapse between outcome measurements these benefits may have dissipated somewhat before post-intervention measurements were undertaken. Previous studies evaluating the effectiveness of reminiscence in dementia have shown that improvements in outcomes following exposure to reminiscence therapy had a better

short than long-term effect (Goldwasser *et al.* 1987; Tadaka & Kanagawa, 2004; Wang *et al.* 2009). Brooker & Duce (2000) demonstrated that the benefits of reminiscence for the person with dementia are more readily observed during and immediately after reminiscence sessions. Woods *et al.* (2005) argue that, because of the cognitive deficits associated with dementia, namely, diminishing recent memory, maintaining change is anticipated to be an issue in reminiscence interventions.

6.4.5 Minimum clinical important difference

There is a notable absence in the literature on what constitutes a clinically significant difference in the quality of life of residents with dementia in any care setting, which is a concern given that researchers have expressed concerns about the quality of life of people with dementia particularly, those living in long-term care facilities (Hoe *et al.* 2006; 2007). A 4 point minimum clinical important difference in the QOLAD care recipient self-report version was dictated by sample size calculations (O'Shea *et al.* 2011). Based on baseline QOL-AD mean scores, the DARES study has demonstrated that this represents a 12% improvement in residents' quality of life. This was a daunting target, which was exceeded on a per protocol basis and just marginally short on an intention to treat basis. However, it is likely that any improvement in the residents' quality of life would have been appreciated by the residents and staff in long-stay care settings, considering what we understand about the quality of everyday life for residents in long-stay care settings in Ireland, which are less than favourable (Murphy *et al.* 2007).

6.5 Conclusion

The DARES study has demonstrated that a structured educational reminiscence-based programme for staff in long-stay units has the potential to improve the quality of life of residents with dementia when reminiscence is delivered by staff to their designated residents as prescribed. The findings from the study provide new information on how reminiscence may impact on the residents' quality of life from the point of view of the resident with dementia and their formal caregivers, as well as contributing to our understanding of the effects of reminiscence on residents' levels of agitation and formal caregivers' burden of care.

Chapter 7

Unique contribution to knowledge and recommendations

7.1 Introduction

This chapter details the unique contribution of my research to knowledge and recommendations will be made in relation to the implications of my research for practice, policy and research.

7.2 Unique contribution to knowledge

My research has made a number of unique contributions to knowledge, which I summarise here:

7.2.1 Clearly defined reminiscence and its aims for residents with dementia

The literature review on dementia I conducted and presented in Chapter 2 of this thesis highlights the fact that, previous evaluations of reminiscence therapy for people with dementia have been hampered by the diversity of definitions, types and, aims of reminiscence interventions been delivered across different studies. Findings from the literature review suggested that prior to undertaking any further empirical research; in order to inform the development of a reminiscence-based intervention, there was an urgent need to undertake a concept analysis of reminiscence therapy for people with dementia. The subsequent concept analysis was undertaken by members of the DARES search team, of which I was a member. It identified the core attributes of reminiscence in dementia and was fundamental to informing the design of the reminiscence-based intervention delivered in the study. The DARES study's definition of reminiscence, which arose from this concept analysis, is an important addition to the evidence-base in that it defines reminiscence for residents with dementia, which thus far tended to be generic in nature. It is explicit in that it indicates the type of reminiscence that was undertaken in the DARES study, the sort of triggers used to recall past happy memories, the modality in which reminiscence was undertaken, how and when it occurred i.e., whether it was spontaneous or planned, the role of the staff member facilitating the process and finally the anticipated outcomes for the resident with dementia. Future researchers or clinician can adopt this definition to execute a clear treatment protocol when carrying out future evaluations of reminiscence or in using reminiscence as a care pathway for residents with dementia.

7.2.2 First systematic review of reminiscence for residents with dementia

I undertook the first systematic review and meta-analysis of reminiscence therapy for people with dementia living in the long-stay setting. The systematic review revealed that, two (Wang, 2007; Hsieh *et al.* 2010) of the three included studies measured residents' levels of depression. One study (Wang *et al.* 2009) measured the effects of reminiscence on residents' general behaviour. Both mood and behaviour are well accepted by dementia researchers as important clinical factors that have the potential to impact on the quality of life of the individual resident (Logsdon *et al.* 2002; Thorgrimsen *et al.* 2003; Woods *et al.* 2006; Hoe *et al.* 2006; 2007). Findings from the review indicated that none of the included studies evaluated the impact reminiscence therapy may have on the resident's quality of life. Selwood *et al.* (2005) contend that quality of life assessment provides a forum for both the person with dementia and their carers to consider whether an intervention, like reminiscence, has made a significant difference to the resident's quality of life. Hoe *et al.* (2007) suggest that the gold standard rating of quality of life is the resident's subjective rating and for that reason the primary outcome in the DARES study was the resident's quality of life as measured by the care recipient self-report version of the QOL-AD scale. Measuring the resident's personal rating of their quality of life gave voice to a group of people who are rarely heard (Fisk *et al.* 2007). In this way, the residents who participated in the DARES study have made their own unique contribution to new knowledge and in so doing, their voices will resonate, guiding future reminiscence-based research and practice so that residents with dementia now and in the future may live well with dementia.

7.2.3 Demonstrated feasibility

My work presented in Chapter 4 of this thesis i.e., my methodology chapter, informed the design, conduct and analysis of the DARES study. The DARES study is to date, the largest randomised trial of reminiscence for people with dementia in the long-stay setting. The DARES study has demonstrated that carrying out a large randomised trial of a reminiscence-based intervention, which the evidence suggests has not been done so far, is feasible, as well as desirable.

A total of 304 residents with dementia participated in the study. Only 7% (n=22) required proxy consent with 93% (n=282) of the participating residents giving consent to participate themselves and in so doing exercising their right to participate in research (Slaughter *et al.* 2007; Alzheimer Europe, 2010). The fact that the majority of

residents consented to participate themselves may be ascribed to the person-centred approach to the consenting process undertaken in the study. As described in section 4.4.3, the focus on this issue in the research nurses training was on the nature of consent, making sure that resident's consent was informed and voluntary without coercion.

The four different approaches to dementia diagnosis assumed in the study facilitated the identification of the required number of participating residents with dementia (n=17) in each participating long-stay unit (n=18). Data from resident records indicated that all participating residents had a dementia. Ninety-seven per cent (n=296) of participating residents had a nursing diagnosis of dementia, 55% (n=167) had a medical diagnosis and only 6% (n=20) had a formal diagnosis. At baseline, the research nurse completed an MMSE with each participating resident; this indicated the resident's current level of cognitive impairment. The mean MMSE score of participating residents across both the intervention and control groups was 12.34, suggesting that on average; participating residents were moderately cognitively impaired. While a formal diagnosis of dementia is difficult in the long-stay setting, this study has established that although estimating the number of residents with dementia requires diligent examination of resident records, it is achievable.

7.2.4 New evidence-base on the effectiveness of reminiscence for residents with dementia

The aim of my research was to evaluate the effectiveness of a structured educational reminiscence-based programme for staff in long-stay units on the quality of life of residents with dementia; I did this in the context of a cluster randomised trial. To that end, I have made an important contribution to new knowledge by demonstrating that a structured educational reminiscence-based programme for staff in long-stay units has the potential to improve the quality of life of residents with dementia when reminiscence is delivered by staff to their designated residents as prescribed. The findings from my research provide new information on how reminiscence may impact on the residents' quality of life from the point of view of the resident with dementia and their formal caregivers, as well as contributing to our understanding of the effects of reminiscence on residents' levels of agitation, depression and formal caregivers' burden of care.

7.3 Recommendations for policy and practice

➢ I recommend that, from an Irish perspective, there is an urgent need to develop clinical guidelines for dementia diagnosis, focusing on early and differential diagnosis of dementia so that appropriate pathways to care can be accessed throughout the different stages of the disease process;

➢ I recommend the need for on-going training for staff caring for residents with dementia in all care settings but with a particular focus on staff working in long-stay care facilities. Training programmes should focus on understanding the clinical syndrome of dementia, including behavioural and psychological symptoms, assessment strategies and person-centred approaches to care, incorporating individualised care plans which are regularly reviewed and updated;

➢ I recommend that reminiscence therapy is used by trained staff to promote wellbeing and improve the quality of life of people with dementia living in long-term care settings.

7.4 Recommendations for research

➢ While findings from this study are generalisable to all residents with dementia and their formal caregivers living and working in the long-stay setting in Ireland, further research is needed to determine whether the same effect is found in similar populations in other long-stay settings, cultures and societies to establish if reminiscence is an effective psychosocial intervention for residents with dementia;

➢ Researchers evaluating the effects of reminiscence interventions for residents with dementia living in the long-stay setting should develop a minimum set of core outcome measures. Repeated consistent measurement using the same instruments and reporting of these outcomes in clinical trials facilitates more direct comparisons of results across different studies. This approach will also enhance systematic reviews and the pooling of results in meta-analyses;

➢ As discussed in Chapter 6, because of the cognitive deficits associated with dementia, specifically deteriorating recent memory, maintaining change is an issue in reminiscence interventions. Previous studies evaluating the effectiveness of reminiscence in dementia have demonstrated that improvements in outcomes following exposure to reminiscence interventions had a better short than long-term effect. In order to capture the benefits of

reminiscence for the person with dementia, future trials evaluating the effectiveness of reminiscence therapy for dementia should consider assessing outcomes during and immediately after exposure to reminiscence sessions;

➢ Further research is required on the type of psychosocial interventions that are appropriate in the different types of dementia and at the various stages of the disease process;

➢ This study has highlighted the paucity of literature on formal caregivers' burden of caring for residents with dementia, suggesting that there is a need to carry out further research on this issue.

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Appendix 1

Concept Analysis

Reminiscence in dementia: A concept analysis

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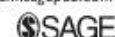
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Abstract

This paper is a report of an analysis of the concept of reminiscence in dementia and highlights its uses as a therapeutic intervention used on individuals with dementia. No single definition of reminiscence exists in healthcare literature; however, definitions offered have similar components. The term life review is commonly used when discussing reminiscence; however, both terms are quite different in their goals, theory base and content. This concept analysis identified reminiscence as a process which occurs in stages, involving the recalling of early life events and interaction between individuals. The antecedents of reminiscence are age, life transitions, attention span, ability to recall, ability to vocalise and stressful situations. Reminiscence can lead to positive mental health, enhanced self esteem and improved communication skills. It also facilitates preparation for death, increases interaction between people, prepares for the future and evaluates a past life. Reminiscence therapy is used extensively in dementia care and evidence shows when used effectively it helps individuals retain a sense of self worth, identity and individuality.

Keywords

Analysis, concept, dementia, reminiscence

Introduction and background

An estimated 35.6 million people are living with dementia worldwide (Alzheimer's Disease International, 2009). The number of people living with dementia is expected to double every 20 years, reaching 81.1 million by 2040 (Ferri et al., 2005). Dementia is ranked as the sixth most common cause of death in high income countries, accounting for 3.4% of the total deaths worldwide in 2004 (World Health Organisation, 2008). Recent Western European studies on the prevalence of dementia indicate there are currently 700,000 people (over 1% of the population) with dementia in the UK and this figure is expected to rise to 940,000 by 2021, a 28% increase (Knapp, Prince, & Albabese, 2007). Similar growths in prevalence

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rates are indicated for Ireland, from a present figure of 38,000 to over 100,000 by 2036 (O'Shea, 2007). While many people with dementia are cared for at home, it is estimated that 40% require residential care (Egan et al., 2007). The percentage of the older population living in nursing homes and residential care homes in England was 5.5% in 2006, 6.8% in Northern Ireland (based on 2002 figures), 4.6% in Scotland and 5.1% in Wales (Knapp et al., 2007). In Ireland, approximately 4.3% of older people live in public and private residential care facilities (Department of Health and Children, 2005). Knapp et al. (2007) estimated the prevalence of dementia in residential care in the UK to be over 60%. Long-stay care statistics list the percentage of residents with dementia in Ireland varying between 26% and 50%, higher in the eastern part of the country (Department of Health and Children, 2005). Given the increasing prevalence of dementia, increasing attention has been given to psychosocial interventions aimed at improving care for people with dementia.

Reminiscence is a psychosocial intervention commonly used in dementia (Wang, 2007). Reminiscence is the process of recalling personal events or experiences from one's past that are memorable to the person (Lin, Dai, & Hwang, 2003). While reminiscing is associated with older adults it is an activity well distributed across the adult life span (Cappeliez, Rivard, & Guidon, 2007; Hwang, Lin &, Dai, 2003). Reminiscence and reminiscence therapy are recent phenomena, promoted in practice in the 1980s. Prior to this, reminiscence was likely to be associated with senility (Buhler, 1935 in Bluck and Levine, 1998, p. 185; Coleman, 2005; Kasl-Godley & Gatz, 2000; Lin et al., 2003). The cultural shift in favouring past events has come about due to a rise in gerontological research and theory. Interest in reminiscence has been further stimulated by Erikson's life span developmental theory where the last psychosocial task of life, being the achievement of 'integrity', is described as 'the acceptance of one's one and only life cycle as something that has to be and that, by necessity, permitted of no substitutions' (Erikson, 1963 in Coleman 2005, p. 260).

Despite its popularity with both patients and staff there is little evidence to support its use as an effective healthcare intervention (Bates, Boote, & Beverley, 2004; Boote, Lewin, Beverley, & Bates, 2006; Moos & Bjorn, 2006; Lin et al., 2003; Woods, Spector, Jones, Orrell, & Davies, 2005). In the most recent Cochrane systematic review on reminiscence work in dementia, Woods et al. (2005) argued that there was evidence of an improvement in cognition and mood in people with dementia as well as a decrease in caregiver strain following reminiscence interventions. Nevertheless, they concluded that a number of factors contributed to the difficulty in providing conclusive evidence of its effectiveness including variation in the operational definitions of reminiscence used in the included studies. The implications for future research were that reminiscence needs to be clearly defined for the population it is targeting; the type of reminiscence and its aims also need to be explicitly described and outcome measures should appropriately reflect both.

Aim of the analysis

The concept work was part of a larger cluster randomised trial, titled: The DementiA education programme incorporating REminiscence for Staff (DARES) which sought to evaluate the effectiveness of a structured reminiscence-based education programme for care staff on the quality of life of residents with dementia in long-stay units. The aim of this concept analysis is to define reminiscence, identify its attributes and consequences in order to contribute to understanding and evaluating its use as a psychosocial intervention in dementia care using Rodgers (2000) evolutionary approach to concept analysis.

Concept analysis method

Rodgers' (2000) evolutionary approach to concept analysis was selected to analyse the concept of reminiscence. This approach was favoured for its 'evolutionary view' where the process of concept analysis and development is dynamic. This differs from Walker and Avent's (1995) method of concept analysis, which, according to Rodgers (1989), presents a static model whereby concepts are unchanging over time. Rodgers' (2000) evolutionary approach appears ideally suited to analyse the concept of reminiscence due to the fact that reminiscence is a process entered into by individuals across a whole adult life span. Thus what one individual considers the term to mean or the activity to engage in may invariably differ from another individual's interpretation depending on the age and the circumstances of the reminiscence. Additionally, reminiscence is a broad concept that occurs in a variety of contexts. This paper provides a concept analysis of reminiscence in the context of its therapeutic use for the person with dementia.

Data sources

To examine its use specifically in the health care context, a computerised search using data sources such as CINAHL, MEDLINE, EMBASE and PsychINFO were searched yielding 2988 citations relating to reminiscence. Dates used to refine the literature search were 1990–2010. The search was limited further to full text and scholarly (peer reviewed) journals, and selected to have references available and literature in the English language. The additional keywords of 'therapy' and 'dementia' were employed with the 'and' and 'or' Boolean operands, which focused the search, resulting in 108 citations. Additionally an incremental search was conducted where the reference lists of retrieved paper documents from these data sources were examined for additional relevant literature. Articles were selected by two methods: (1) by title search and (2) by reading all abstracts for relevancy to the concept being analysed. Relevant articles were then selected and read in their entirety. Rodgers (2000) contends that 20% of the total retrieved literature search is necessary to facilitate a reliable concept analysis. From the 108 selected papers a sample of 45 were retained for in-depth analysis of the concept of reminiscence, therefore adhering to Rodgers' guidelines.

Results

Definition, uses of the concept and surrogate terms

Rodgers (2000) contends that evolutionary concept analysis begins with identifying and naming the particular concept of interest and locating surrogate terms and relevant uses of the concept. Reminiscence has no standard definition in health literature; however, it is evident that all definitions offered have similar components and terms. Some definitions of reminiscence are 'the recalling of personally relevant memories from the past' (Cappeliez, Guindon, & Robitaille, 2008, p. 266), 'a selective process in which memories are evoked and reconstructed' (Cohen & Taylor, 1998, p. 601), 'the vocal or silent recall of events in a person's life either alone or with another person or group of people' (Bohlmeijer, Roemer, Cuijpers, & Smit, 2007, p. 291).

The definition offered by Woods et al. (2005, p. 1) appears quite frequently in the literature on dementia and gives a more detailed account of the various processes involved in a reminiscence activity: 'reminiscence therapy involves the discussion of past

activities, events and experiences with another person or group of people, usually with the aid of prompts such as photographs, household and other familiar items from the past, music and archive sound recordings'. Lin et al. (2003) and Woods et al. (2005) argue that the variation in definitions, types, functions and conceptualisations of reminiscence across studies highlight the challenge in extrapolating and analysing data to support its effectiveness as a psychosocial intervention.

> What the literature does suggest is that certain commonalities exit such as reminiscence involves memory and remembering and that these memories or experiences are of earlier events occurring in the individual's past. What is dissimilar about all definitions is that several authors posit that in order for reminiscence to occur prompts or triggers must be used to evoke a response from an individual (Parker, 2006; Woods et al., 2005; Yamagami, Oosawa, Ito, & Yamaguchi, 2007). Others say that reminiscence may be a silent, solitary experience (Chin, 2007; McKee et al., 2005; Parker, 2006) or it may occur in the presence of others such as in group reminiscence therapy (Parker, 2006; Tadaka & Kanagawa, 2007; Wang, 2007; Zauszniewski et al., 2004). This highlights the issues surrounding the paucity of agreement in the literature on what exactly reminiscence is and how it benefits those with dementia.

Surrogate terms

Although authors have defined or described reminiscence differently, some use surrogate terms when discussing reminiscence, which assists in analysing the concept. Such terms are:

- Recall of past events (Butler, 1963; Cappeliez, Rivard, & Guidon, 2007; Dochterman & Bulechek, 2003; Kasl-Godley & Gatz, 2000; McCloskey & Bulechek, 2000; Webster, 1997; Woods et al., 2005);
- Thinking and telling (Cappeliez, Lavalle, & Rourke, 2001; Cappeliez, O'Rourke, & Chaudhury, 2005);
- Discussion (Woods et al., 2005);
- Life review (Arakawa-Davies, 1997; Burnside & Haight, 1992; Davis, 2004; Kasl-Godley & Gatz, 2000; Parker, 2006; Serrano, Latorre, Gatz, & Montanes, 2004; Webster & Cappeliez, 1993).

Some authors are more descriptive than others in defining the content of the recalled past, leading to variations and potential for confusion. Webster (1997) is one of a few who suggests that past memories that are personal to the individual are the content of recall. On the other hand, Butler's (1963) definition is quite sparse and does not indicate the content of recall at all. The most common surrogate term identified in the literature is life review, which is often used interchangeably with reminiscence.

Determining the defining attributes

Attributes refer to recurrent characteristics of a concept within the literature which help to differentiate the concept from others. From the literature it was seen that three attributes of reminiscence were identified:

(1) Reminiscence is a process of recall which occurs in stages.

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(2) Reminiscence is an interaction which involves recalling or telling of early events or a memorable early experience which may occur with or without specific purposes.
(3) Reminiscence is an interaction between the person recalling the memory and one or more individuals.

Reminiscence is a process of recall which occurs in stages. Studies highlight reminiscence as a 'process' for recalling the past, indicating that it is structured or organised in approach (Butler, 1963; Cappeliez et al., 2007; Chao, Chen, Liu, & Clark, 2008; Gibson, 2004; Merriman, 1989; Schweitzer & Bruce, 2008). Merriman (1989) discerned four components that constitute the structure and process of reminiscence. The beginning involves the selection of a memory to recall, followed by immersion in that memory and gradual withdrawal from the experience. The process ends with closure, which involves returning to the present. This suggests that recall of the past does not occur in a haphazard way but is a systematic or organised mental process consisting of a beginning, middle and end.

> Similarly, Chao et al. (2008) developed an understanding of the process of reminiscence as a therapeutic intervention in nursing home residents with dementia. Four stages in the process of reminiscence were identified which are entrée, immersion, withdrawal and closure. Entrée involves opening the individual's memories of significant past experiences by stimulating recall of memories using multisensory triggers and themed topics which were relevant to the individual's background. Immersion involves the individual becoming subsumed in the memory or experience after choosing particular events or experiences during the entrée stage. This can lead to a variety of emotions both positive and negative in nature. In the withdrawal phase, individuals return from their memories to the present. This may be triggered by sadness on recollection of certain memories, fatigue or environmental factors such as noise. Finally, during closure, residents share their reminiscences with the nursing staff and with others. While recall occurred in an organised way, the process of reminiscence was not always planned but often occurred spontaneously during routine nursing activities.

Bohlmeijer et al. (2007) offer a four stage process of reminiscence which includes identity-forming and self continuity, enhancing meaning in life and coherence, preserving a sense of mastery and promotion acceptance and reconciliation. Identity forming is an integral function of reminiscence where the individual has an awareness of how they have changed over time. An individual's self identity may be enhanced by telling and retelling the story of their lives. Meaning in life is enhanced by reminiscence by focusing on positive past experiences, acquired values, and past and future plans. Having a sense of mastery and control allows the individual to successfully problem solve, overcome traumatic recollections and age healthily. Those with a positive self identity find reconciliation with past experiences, age successfully, accept death and have a greater sense of well-being as a consequence of reminiscence.

Reminiscence is an interaction which involves recalling or telling of early events or a memorable early experience which may occur with or without specific prompts. Burnside and Haight (1992) suggest that an attribute of reminiscence is that the recollection of memories must not be of recent events or experiences. However, there is a deficit of research to support this notion. An attribute which is supported is that reminiscence is an interaction which involves recalling early events or memorable early experiences which may occur with or without

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specific purposes. Gluck and Bluck (2007) note that people recall a larger number of events from the second and third decades of their life than from other periods and happy or positive events are usually recalled from late adolescent / young adulthood. Accessing some memories will encourage self acceptance while accessing others will actually stimulate self change. Much depends on the aims of the intervention and the techniques used (Coleman, 2005). Engaging in reminiscence of an escapist or obsessive nature often occurs in those suffering from psychological distress. Reminiscing in this manner allows the individual to return to the relative psychological comfort of earlier good days in order to escape from the 'aversive or boring present and an unappealing future' (Cappeliez et al., 2007, p. 154).

Gibson (2006) and Schweitzer and Bruce (2008) purport that from an organisational point of view, prompted or structured reminiscence usually involves group sessions. Prompts or triggers are important in the reminiscence process as often people need visual, tactile, auditory experiences to aid recall. Prompts which stimulate a response include photographs, music, old newspapers, knitting patterns, smells, tastes and old objects. Music is particularly significant in evoking memories. Certain triggers may evoke a 'flash bulb memory' response and it is vital that nurses are aware of what these triggers may be in order to elicit a response from the individual. Personalising the prompts or triggers to the individual may aid reminiscence. Family involvement plays a role in the process as well as adopting a person centred approach to care. How well the nurse knows the individual will have a lot to do with how effective the reminiscence process will be.

Woods et al. (2005) make reference to the triggers that may be used to stimulate the process of recall, namely objects that are familiar to the individual. Due to the progressive cognitive decline associated with dementia (Kasl-Godley & Gatz, 2000), multisensory triggers, personal to the individual and involving all the five senses are used as catalysts to stimulate the process of reminiscence. Familiar tastes, smells, textures, sounds and visual images can stimulate activities or memories associated with childhood, schooldays, worklife or relationships. Linking the past into the present in this way creates a sense of continuity and restores a sense of personal identity, mastery, self esteem and integrity that may be otherwise lost to the person with dementia (Gibson, 2006; Kitwood, 1997; Schweitzer & Bruce, 2008). However, it is important to note that memory prompts should be appropriate to the age and the culture of the individual.

Spontaneous or unstructured reminiscence usually occurs at the individual level. Authors stress that nurses or carers should be prepared to support reminiscence as an essential intervention whenever or wherever it occurs as such an empathetic process requires training with a special focus on fostering excellent staff communication skills.

Reminiscence is an interaction between the person recalling the memory and one or more other individuals. Past experiences which are recalled are meaningful to the person and the memory may have an emotional aspect. Much of the literature (Baillon et al., 2004; Bates et al., 2004; Brooker & Duce, 2000; Egan et al., 2007; Ferri et al., 2005; Lai, Chi, & Kayser-Jones, 2004; Moos & Bjorn, 2006; Parker, 2006; Politis et al., 2004; Wang, 2007; Woods et al., 2005; Yamagami et al., 2007) focuses on reminiscence therapy on individuals with dementia and conclusions suggest that reminiscence as a therapeutic tool is proven to be beneficial, with individuals with dementia sustaining a higher level of well-being during this activity. Interaction is actively encouraged between staff members and reminiscence group members, 'making reminiscence an inclusive, stimulating and sociable activity for both participants and staff' (Brooker & Duce, 2000, p. 357). Reminiscence group therapy

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provides an opportunity for individuals to recall and review past life events and stimulate a positive self attitude. The personal interaction between the individual and the nurse or caregiver or with the reminiscence group may provide a means of precluding social isolation as well as improving psychological well-being and communication skills of these individuals. Gibson (2004) and Parker (2003) maintain that people with dementia can benefit from reminiscence in grounding their present relationships and maintaining warm, caring relationships which may ward off isolation and withdrawal. The Cochrane review of Woods et al. (2005) assessed the effectiveness of reminiscence therapy for older individuals with dementia; it indicated improvements in cognition, mood, and general behaviour as well as a reduction in caregiver strain.

However, McKee et al. (2005) purport that while much research has been conducted on the benefits of group reminiscence therapy, it is clearly important to recognise and evaluate reminiscence as a simple social or solitary non-verbal engagement with one's past life which can also bring huge benefits to psychological health. Cohen and Taylor (1998) highlight that the impact of such 'natural' reminiscence on the psychological well-being of individuals has rarely been evaluated.

Related concepts

Related concepts are 'concepts that bear some relationship to the concept of interest but do not seem to share the same set of attributes' (Rodgers, 2000, p. 92). One concept related to reminiscence is life review.

Life review. The foundation of all reminiscence work is widely attributed to the work of Butler (1963). In his famous paper *The life-review: An interpretation of reminiscence in the aged*, Butler postulated that reminiscence is observed more frequently in older people. He believed the act of recalling the past or reviewing one's life is triggered by the realisation of approaching death (Bohlmeijer et al., 2007). In using both 'life review' and 'reminiscence' in the title of his paper, Butler has caused some ambiguity between the processes of general reminiscence and life review.

Burnside and Haight (1992) purport that life review may have its roots in the church due to the fact that life and conscience examination are scrutinised by the religious. Additionally, Socrates philosophised about life review stating that the unexamined life is not worth living (Hutchins, 1952 in Burnside & Haight, 1992). Life review demands high levels of inner skills (Coleman, 2005) and is therefore not necessarily characteristic of older adults. Coleman (2005) additionally suggests it implies a search for meaning through reflection on one's life experiences and may lead to transformation goals and changed values.

The terms reminiscence and life review are often used interchangeably in the literature but are quite different in their goals, theory base, approach, content, client role, facilitators' roles and short term goals. Many authors are in general agreement that the long term goals such as adaptation, improved quality of life, well-being and mood are potentially the same (Gibson, 2006; Lin et al., 2003; Woods et al., 2005). However, researchers stress the importance of being clear in the type and aims of reminiscence being undertaken as this determines the theoretical framework underpinning the process and having a strong theoretical basis for why a treatment approach is chosen is essential for evidence-based practice (Burnside & Haight, 1992; Coleman, 2005; Haight & Burnside, 1993; Kovach, 1991; Woods et al., 2005).

Burnside and Haight provide a conceptual analysis of reminiscence and life review. In their analysis life review is defined as 'retrospective survey or existence, a critical study of a life, second look at one's life' (Burnside & Haight, 1992, p. 856). It has the specific aim of achieving a state of integrity or a sense of wholeness by resolving past conflicts and unfolding the meaning of life before death (Cappeliez, 2002; Lin et al., 2003; Parker, 2006; Torges, Stewart, & Duncan, 2008). Stemming from Erickson's Human Developmental, it has its roots in psychoanalysis (Kovach, 1991; Parker, 1995). Both recent and remote memories are recalled and are often painful in nature. Molinari (1999) describes life review as a deconstructing of life events into a more positive life narrative. It consists of a one to one, structured evaluation of one's past covering the whole life span in chronological order. It is lead by trained professionals who engage in the principles of counselling to guide the interactions. A time limited approach is adopted, usually over a time period of four to six weeks, depending on the life reviewer's needs. Life review can be used right across the life span but it is most commonly used as a therapeutic intervention for older people, cognitively intact or with depressive symptoms (Bohlmeijer et al., 2007). It can be used 'selectively with people with dementia' (Gibson, 2006. p. 106).

Lin et al. (2003) suggest that short term outcome measures to evaluate the impact of life review should include integrity, increased well-being and decreased depression. Longer term outcome measures should include adaptation, increased life satisfaction and increased quality of life.

Similarities between reminiscence and life review lie in that they both emanate from Butler's work in the early 1960s. They are therapeutic interventions mainly implemented with older people and each involves eliciting memories. Common to both approaches is the construction of life stories (Coleman, 1999) and the associated long term outcomes are adaptation, increased life satisfaction and increased quality of life (Burnside & Haight, 1992; Lin et al., 2003; Woods et al., 2005).

Nostalgia. Nostalgia is described as a longing for things, persons or situations that are not present or a longing for a perceived utopian past (Merchant & Ford, 2008). Nostalgia affects the young as well as the old; however, as individuals age, there is a greater tendency to recall bygone days and this often appears to be a longing for not only the past which has been personally experienced but for a past paradise which was never actually experienced.

Literature suggests that nostalgic reverie often revolves around momentous life events and reflects more positive than negative emotions, contains more desirable than undesirable features and leads to more positive than negative mood (Wildschut, Sedikides, Arndt, & Routledge, 2006). Significant life events such as marriages, the birth of a child and graduations when recalled evoke a stronger, more intense memory and recall is better than with less significant life events. Merchant and Ford (2008) describe two types of nostalgia: personal and vicarious. Personal nostalgia is based on an individual's direct experiences in the search for an idealised past. People engaging in personal nostalgia often remember past events more positively than they actually were and feel a sense of happiness and joy coupled with a bittersweet sense of loss in that the past is not going to return. Personal nostalgia serves as an 'anchor of continuity and identity' especially for the elderly when life circumstances are changing. During these changing life circumstances, insecurities and unsureness are experienced and thus individuals revert to memories of the past for comfort and support amidst fears of an uncertain future. Additionally, personal nostalgia aids those who may experience loneliness and recalls the past when family were present and times were happier.

Nostalgia and reminiscence are similar concepts in that both involve remembering past events, both are primarily conducted by the elderly and both activities when effectively

carried out produce a positive outcome for the person recalling the past event. However, nostalgia has been distinguished from reminiscence, particularly in the case of vicarious nostalgia, whereby actual life events or situations which did occur to the individual are recalled. Reminiscence recollects actual life events in opposition to nostalgia, which often is a longing for a past that never was. Additionally, literature suggests that an antecedent of reminiscence involves verbalising the recollection to another individual, while nostalgia may be a cognisant, silent, solitary experience.

Antecedents. Antecedents refer to situations, events or phenomena that precede the concept (Dowling, 2003). Certain preceding characteristics or patterns must be observed before reminiscence occurs. The antecedents of reminiscence are age, life transitions, attention span, ability to recall, ability to communicate and certain stressful situations.

As an individual experiences the ageing process certain life events, stressful situations, relocation or the threat of maladjustment may be encountered. With increases in the elderly population, reminiscence has become a popular activity when caring for the elderly and much has been written about the effects of reminiscence therapy and reminiscence groups, conducted particularly in residential or day care settings (Baillon et al., 2004; Bohlmeijer et al., 2007; Brooker & Duce, 2000; Cappeliez et al., 2008; Chin, 2007; Tadaka & Kanagawa, 2007; Wang, 2007; Yamagami et al., 2007; Zauskniewski et al., 2004).

In order for reminiscence to occur and to be successful, recall of the past must occur, therefore a certain amount of memory function, attention span and the ability to vocalise is required. Remote memory, within which the reminiscence process occurs, is usually the last system to deteriorate in the elderly (Lin et al., 2003). This type of memory is where an individual has the ability to recall past events, such as childhood events, but not recent ones. According to Lin et al. (2003) stimulating and increasing the use of this remote memory improves general cognitive function. Woods et al. (2005) contend that autobiographical memory, which is memory of a person's middle years, and a good level of communication are key to reminiscence and to an individual's retaining a clear sense of personal identity. However, autobiographical memory is often absent in individuals with dementia, which ultimately disconnects the person's past from the present. Nurses and caregivers play an important role in the practice of reminiscence and therefore need evidence based knowledge about reminiscence and its relation to health promotion for the elderly.

Individuals engaging in reminiscence tend to recall past events that are positive and memorable to the person, especially events which have occurred between the ages of 15 and 30 years (Gluck & Bluck, 2007). In contrast it may be adaptive to selectively forget negative past events (Wilson & Ross, 2003). Often, naturally occurring reminiscences happen as a result of negative emotions. Stressful situations may occur when prompts or triggers are used to elicit reminiscence in individuals with dementia which may evoke unhappy memories. Older people may have encountered pain or loss in their past and recalling certain past events may cause distress to them (Cappeliez et al., 2005).

Consequences. Consequences are events that occur as a result of the concept. There are many documented consequences of reminiscence, some of which are that it aids positive mental health, aids successful adaptation to old age, reaffirms a sense of identity, maintains self esteem, improves communication skills, increases interaction between individuals, facilitates preparation for death, helps to master personal losses experienced in later life, facilitates important decision making, allows for examination of one's conscience, prepares for the

future, and evaluates a past life (Bohlmeijer et al., 2007; Cappeliez et al., 2001, 2005, 2008; Egan et al., 2007; Lai et al., 2004; Schweitzer & Bruce, 2008; Serrano et al., 2004; Swee Hong & Heathcote, 2005; Tadaka & Kanagawa, 2007; Thorgrimsen, Schweitzer, & Orrell, 2002; Woods et al., 2005; Yamagami et al., 2007; Zauszniewski et al., 2004).

> Clinical trials evaluating the impact of reminiscence work in dementia care indicate it is associated with an improvement in cognition (Lai et al., 2004; Thorgrimsen et al., 2002; Tadaka & Kanagawa, 2007; Wang, 2007) and in depressive symptoms (Chiang et al., 2010; Hsieh & Wang, 2003) consistent with Bohlmeijer's (2007) findings on the use of reminiscence with older people without dementia. Positive effects have also been demonstrated on behavioural functioning (Baillon et al., 2004; Politis et al., 2004; Thorgrimsen et al., 2002) as well as caregiver strain and staffs' knowledge of residents' backgrounds (Thorgrimsen et al., 2002). There is also evidence that reminiscence interventions lead to enhanced well-being for participants with dementia (Brooker & Duce, 2000; Cook, 1998; Haslam et al., 2010; Rattenbury & Stone, 1989).

Respecting what individuals say through reminiscence has the potential to raise self esteem, especially for those with dementia, where loss of cognitive function can affect their sense of identity (Heathcote, 2007). Bohlmeijer et al. (2007) purport that many older individuals suffer from reduced psychological well-being and reminiscence has potentially a lot to offer them.

Often researchers relate their views of reminiscence to 'disengagement theory' (Cumming & Henry, 1961 in Lin et al., 2003), which highlights successful ageing as involving a process of withdrawal from social life in preparation for death (Lin et al., 2003). Parker (2006) contends that other studies focus on what Erikson termed 'ego-integrity' whereby when ego-integrity in old age is achieved the person believes his or her life has significance and meaning and fulfilment is achieved, thus they are not fearing death. However, it must be noted that not all the elderly experience the same life events, situations or have similar needs. According to Coleman (2005) reminiscence for death preparation predicts life satisfaction, supporting Erikson's insight into the dynamics of integrity in the final stages of life.

Life transitions and events cause individuals to interpret and make sense of changes and often recall the past. Doing so provides a sense of continuity and facilitated adaptation. Reminiscence can facilitate this by providing a mechanism by which people adapt to life changes (Lin et al., 2003). Occasionally older adults use reminiscence as a means of interacting with others, maintaining social involvement to foster well-being.

Randall and Kenyon (2001) contend that 'restorying' an individual's life is possible so that negative experiences become opportunities for development and acquisition of wisdom. When conducted effectively and in the correct situation, reminiscence has the potential to contribute to psychological adaptation by providing a sense of self fulfilment and self achievement. Additionally it promotes the discovery of the meaning of life, reduces the incidence of depression and overcomes feelings of guilt and conflict related to one's past.

Discussion

Given the seriousness of the impact of dementia on all associated with the illness, the ageing population and the increasing prevalence with age, healthcare policy is focused on improving and maintaining quality of life in dementia from diagnosis to the end of life. The provision of effective, evidence-based care pathways at all stages of the illness, especially within long-stay facilities, is important (O'Shea, 2007). Conversely researchers suggest that residential care

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staff often lack the skills and knowledge required to care for residents with dementia thus impacting negatively on the quality of life of patients (Murphy, O'Shea, & Cooney, 2007).

> Initiatives such as the National Dementia Strategy (Department of Health, 2009) in the UK and the Action Plan for Dementia (APD) in Ireland advocate a person-centred approach to care which will provide for the individual needs of the person with dementia. Such an approach seeks to focus on what people are still able to do, maintaining the individuality of the person with dementia (Kitwood, 1997), and in addition, promoting a sense of well-being by creating a supportive social environment, enabling people to continue to communicate, maintain relationships and be socially included despite their dementia (Kitwood, 1997; Schweitzer & Bruce, 2008). Integrating evidence-based psychosocial approaches to complement medical and neurological models of service delivery is key to the person-centred approach. However, if healthcare professionals are to develop the skills necessary for such an empathic delivery of care, staff training is essential (O'Shea, 2007).

Psychosocial interventions have the potential to improve the quality of life of people with dementia and those who care for them (Brooker, 2007). They also have the potential to support a person-centred approach to dementia care (Keady, Woods, Hahn, & Hill, 2004). Reminiscence therapy (RT) is a psychosocial intervention commonly used in dementia (Wang, 2007). Reminiscence in dementia is an important concept to define as research indicates that reminiscence could improve outcomes for people with dementia and their caregivers (Woods et al., 2005). Part of the appeal of reminiscence in dementia care is that it improves the quality of life of people with dementia, improves mood and well-being and reduces behavioural problems (Moos & Bjorn, 2006; Woods et al., 2005). One factor of its popularity is that it works with early memories, which remain relatively intact for people with dementia (Basso, Bruce, & de Hamsher, 2003), thus drawing on the person's preserved abilities rather than focusing on their levels of impairment (Gibson, 2006; Schweitzer & Bruce, 2008).

Although RT is used extensively in dementia care, little is known about its effectiveness as a care intervention (Moos & Bjorn, 2006). Most studies have employed qualitative, descriptive or observational methods with few robust experimental trials (Finnema, Droes, Ribbe, & Tilburg, 2000; Lin et al., 2003; McKeown, Clarke, & Repper, 2006; Woods et al., 2005). In the most recent Cochrane systematic review on reminiscence therapy in dementia, Woods et al. (2005) argued that there was evidence of an improvement in cognition and in general behaviour in people with dementia as well as a decrease in caregiver strain following reminiscence therapy.

When used appropriately, reminiscence has the ability to help individuals retain a sense of self worth, identity and individuality. Older adults who engage in reminiscence were found to have enhanced psychological morbidity and display greater positive emotion (Swee Hong & Heathcote, 2005). Reminiscence facilitates individuals to problem solve in the present by identifying past strengths and methods of coping with difficult life events, reinforcing a sense of continuity, finding meaning in one's life.

The term life review is used synonymously when discussing reminiscence and while both concepts encapsulate a similar component of recalling the past, they both have distinct theoretical differences. Reminiscence is associated with therapy and change while life review involves the evaluation and re-synthesis of past experiences, usually precipitated by the need to resolve issues, achieving a sense of meaning to one's life prior to death. Lashley (1993) highlights the differences further between the two concepts noting that reminiscence is considered to be a psychosocial intervention focusing on positive memories whereas life review allows the individual to reflect on their life with the purpose of coming to terms

with past guilt and unresolved conflicts, to reconcile relationships, ultimately finding meaning in past experiences.

A frequent concern when using reminiscence is the prompting of unhappy memories. Older people may have encountered loss or pain in their past and recalling certain past events may cause distress to them. A study of naturally occurring reminiscences indicated that 67% of these reminiscences occurred as a result of negative emotions, primarily sadness or nostalgia (Cappeliez et al., 2005). Without appropriate support, an individual may be left with overwhelming feelings evoked by painful remembrances. It has been suggested by Swee Hong and Heathcote (2005) that by adopting a person-centred approach to patient care and having knowledge of the individual, potential problems should be avoided. Likewise stimulating reminiscence can too easily be seen as an easy option to engage the elderly and distracting them from present day concerns – 'it's character escapist rather than constructive' (Coleman, 2005, p. 291).

Nevertheless, variations in outcomes and the diverse forms of RT used in studies made it difficult to provide conclusive evidence of its effectiveness. The implications for future research were clearly indicated. More robust randomised controlled trials with clear treatment protocols are warranted. In addition, reminiscence for the population it is targeting needs to be clearly defined, the type of reminiscence and its aims also need to be explicitly outlined and outcome measures should appropriately reflect both.

Woods and colleagues' (Woods et al., 2005) definition is applicable to individuals with dementia but would benefit from indicating the purpose of undertaking reminiscence and possible outcomes predicted in this population. Taking into consideration the recommendations and key findings in dementia research, we propose that reminiscence in individuals with dementia be defined as:

> 'Reminiscence is the deliberate use of prompts, for example photographs, smells, music and questioning, to promote the recall of pleasant memories. The focus of reminiscence work is to stimulate the person, provide enjoyment and foster a sense of achievement and self-worth. The anticipated outcomes of reminiscence work are enhancement of the person's quality of life, behaviour and mood.'

Conclusion

Successful ageing has been long associated with a process known as reminiscence. Research suggests that reminiscence, especially when conducted by the elderly, is a normal and universal adaptation response to ageing which stimulates personal growth. Reminiscence is a common, effective and purposeful psychosocial intervention used with individuals with dementia which permits intrapersonal self evaluation and fosters interpersonal relationships and self esteem, while additionally reinforcing one's own sense of competence and well-being. While no one definition exists of what reminiscence is, an operational definition is proposed in response to analysing the concept of reminiscence with the purpose of developing the concept of reminiscence in dementia care.

Conflict of interest statement

No conflict of interest has been declared by the authors.

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Andrew Hunter is a qualified mental health nurse and trained cognitive behavioural therapist. He has undertaken research and lectured in Mental Health Nursing at Edinburgh University and The University of Manchester. Since 2008 Andrew has been lecturing and researching at The National University of Ireland, Galway. He specialises in teaching communication and psychosocial interventions to nursing students and has developed experience in grounded theory and RCT methodologies. He has expertise in CAMHS, educational and dementia care research.

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Appendix 2

EPOC study design screening form

EPOC study design screening form

1. Randomised controlled trial (RCT)

Randomised controlled trial (RCT) i.e. a trial in which the participants (or other units) were definitely assigned prospectively to one or two (or more) alternative forms of health care using a process of random allocation (e.g. random number generation, coin flips).

2. Controlled clinical trial (CCT)

Trial in which participants (or other units) were:

a) **Definitely** assigned prospectively to one or two (or more) alternative forms of health care using a quasi-random allocation method (e.g. alternation, date of birth, patient identifier) or;

b) **Possibly** assigned prospectively to one or two (or more) alternative forms of health care using a process of random or quasi-random allocation.

3. Controlled before and after study (CBA)

Study in which intervention and control groups are involved other than by a random process, and inclusion of baseline period of assessment of main outcomes. There are three minimum criteria for inclusion of CBAs:

a) Contemporaneous data collection;

Score **DONE** if pre and post intervention periods for study and control sites are the same.

Score **NOT CLEAR** if it is not clear in the paper, e.g. dates of collection are not mentioned in the text.

Score **NOT DONE** if data collection was not conducted contemporaneously during pre and post intervention periods for study and control sites.

b) Appropriate choice of control site:

Studies using second site as controls:

Score **DONE** if study and control sites are comparable with respect to level of care and, setting of care.

Score **NOT CLEAR** if not clear from paper whether study and control sites are comparable.

Score **NOT DONE** if study and control sites are not comparable.

c) Minimum number of sites:

Score **DONE** if there are a minimum of two intervention sites and two control sites.

Score **NOT DONE** if there are less than two intervention sites and two control sites.

4. Interrupted time series (ITS)

Studies that seek to establish a change in trend attributable to the intervention. There are two minimum criteria for inclusion of ITS designs:

a) Clearly defined point in time when the intervention occurred.

Score **DONE** if reported that intervention occurred at a clearly defined point in time.

Score **NOT CLEAR** if not reported in the paper (will be treated as NOT DONE if information cannot be obtained from the authors).

Score **NOT DONE** if reported that intervention did not occur at a clearly defined point in time.

b) At least three data points before and three after the intervention.

Score **DONE** if 3 or more data points before and 3 or more data points recorded after the intervention.

Score **NOT CLEAR** if not specified in paper e.g. number of discrete data points not mentioned in text or tables.

Score **NOT DONE** if less than 3 data points recorded before and 3 data points recorded after intervention.

If the study is not any of the above designs, it should not be included in the review. If you score NOT DONE for any of the above criteria, the study should not be included in the review. If the reviewer is unsure of the study design, the paper should be discussed with your fellow reviewer before data extraction is undertaken.

Appendix 3
Databases searched by ALOIS

ALOIS search strategies

The following databases are searched monthly:

  a. Medline (Ovid SP)

  b. Embase (Ovid SP)

  c. PsycInfo (Ovid SP)

  d. Cinahl (EBSCOhost)

  e. Lilacs (Bireme)

The following trials registers are searched monthly:

National and international trials registers:

- CentreWatch Clinical Trials Listing Service: www.centrewatch.com
- CENTRAL (The Cochrane Library): http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME?CRETRY=1&SRETRY=0
- ClinicalTrials.gov: www.clinicaltrials.gov
- Current Controlled Trials (mRCT) (covers Action Medical Research; Medical Research Council - UK; National health Service Research and Development Health Technology Assessment Programme; National Institutes of Health; ISRCTN; ClinicalTrials.gov; The Wellcome Trust): www.controlled-trials.com/mrct
- IFPMA Clinical Trials Portal: http://clinicaltrials.ifpma.org/no_cache/en/myportal/index.htm
- ISRCTN Trials Register: www.controlled-trials.com/isrctn
- National Research Register (was searched monthly until archived in September 2007): http://www.nrr.nhs.uk/
- Netherlands Trial Register: www.trialregister.nl/trialreg/index.asp
- NIHR Clinical Research Portfolio Database: http://public.ukcrn.org.uk/search/
- UMIN Japan Trial Register: www.umin.ac.jp/ctr
- UK Clinical Trials Gateway: www.controlled-trials.com/ukctg
- WHO Portal (covers ClinicalTrials.gov; ISRCTN; Australian and New Zealand Clinical Trial Registry; Chinese Clinical Trial Register; India Clinical Trials Registry; German Clinical trials Register; Iranian Registry of Clinical Trials; Sri

Lanka Clinical Trials Registry; The Netherlands National trial Register):
www.who.int/trialsearch

Pharmaceutical industry trials registers:

- AstraZeneca Clinical Trials: www.astrazenecaclinicaltrials.com
- Bristol-Myers Squibb Clinical Trial Registry:
  www.bms.com/clinical_trials/Pages/clinical_trial_registry.aspx
- Daiichi Sankyo: www.daiichisankyo.com
- Eli Lilly and Company Clinical Trials Registry: www.lillytrials.com
- Eisai: www.eisai.com/index.asp
- Forest Clinical Trial Registry:
  http://www.forestclinicaltrials.com/CTR/CTRController/CTRHome
- GlaxoSmithKline Clinical Trial Register: www.gsk-clinicalstudyregister.com
- Lund beck: www.lunbeck.com
- NovartisClinicalTrials.com:
  www.novartisclinicaltrials.com/webapp/etrials/home.do
- Pfizer Clinical Trials:
  http://www.pfizer.co.uk/Research/Clinicaltrials/Pages/Clinicaltrials.aspx
- Roche Clinical Trial Protocol Registry: www.roche-trials.com/registry.html
- Shire: http://www.shirestudyresults.org/Search.aspx
- Wyeth Clinical Trial Listings: www.wyeth.com/ClinicalTrialListings

The following grey literature sources are to be searched monthly from November 2009:

- ISI Conference Proceedings:
  http://isiwebofknowledge.com/products_tools/multidisciplinary/webofscience/cpci/
- Australasian Digital Theses Program: http://adt.caul.edu.au/
- Theses Canada:
  http://www.collectionscanada.gc.ca/thesescanada/index-e.html
- Index to Theses (UK and Ireland): http://www.theses.com/
- DATAD: http://www.aau.org/datad/index.htm

- OPENSIGLE: http://opensigle.inist.fr/
- Dissertation Abstracts Online (US and Canadian): http://library.dialog.com/bluesheets/html/bl0035.html

Appendix 4

Other search strategies for systematic review

Other search strategies for systematic review

Medline via Ovid

1. "dement". ab.ti.
2. "alzheimer*". ab.ti.
3. 1 or 2.
4. "reminis". ab.ti.
5. 3 and 4
6. Remove duplicates from 5.

EMBASE

1. dement*.
2. dement*. ti
3. dement*. ab
4. 2 or 3
5. alzheimer* AND disease.ti
6. alzheimer*. ti
7. alzheimer*. Ab
8. 6 or 7
9. 4 or 8
10. reminisc*. Ti
11. reminisc*. Ab
12. 10 or 11
13. 9 AND 12

CINAHL

1. dement* or alzheimer*
2. reminisc*
3. 1 AND 2.

Appendix 5

Characteristics of excluded studies

Characteristics of Excluded studies

Study	Reason for exclusion
Bass 1996	12 residents participated. Six described as 'reality oriented' and six 'confused'.
Cook 1991	Participants were described as elderly nursing home residents. Diagnosis of dementia not evident in the text.
Cook 1998	Participants were elderly female nursing home residents. Participants were excluded if they had "organic brain impairment" (pg. 113).
Chao et al. 2006	Participants were described as older nursing home residents with MMSE >24.
Chung 2009	Day-care setting.
Chiang et al. 2010	Participants described as institutionalised elderly people. Diagnosis of dementia not evident in the text. Mean MMSE scores 23 in both groups
Gudex et al. 2010	Sample included all residents, not just residents with dementia.
Haight et al. 2006	The intervention is a structured life review.
Haslam et al. 2010	Sample included all residents, not just residents with dementia.
Ito et al. 2007	The intervention incorporated a combination of reminiscence and reality orientation.
Lin, Li-Jung 2010	Intervention is based on a structured life review program.
Youssef 1990	Participants were described as 'elderly women'. No diagnosis of dementia evident in the text.
Yasuda et al. 2009	Community setting.

Appendix 6

Data extraction form

Data extraction form

Reviewers name:		
Reference ID	Date of data extraction:	Year of study publication:
Study title:		
Author:		
Study reference:		

Data extraction form

Study design:

RCT (Patient level)
RCT (Cluster level)
CCT (Quasi-RCT)
CBA
ITS

Study participants:

Setting:

Sample size:

No. randomised to intervention:

No. randomised to control:

Diagnostic criteria:

Mean age: Control-   Experimental-

Inclusion criteria/Exclusion criteria for study participants:

Intervention:

Describe experimental intervention:

Facilitated by:

No. of facilitators:

Describe facilitator training programme:

Frequency/ Intensity/ Duration :

Integrity of the intervention (describe):

Comparison:

Describe control/comparison intervention:

Outcomes:

Primary outcome(s) and measurement scale:
Timing of primary outcome assessment (include frequency and length of follow up for each outcome):
Secondary outcome(s) and measurement scale:
Timing of secondary outcome assessment (include frequency and length of follow up for each outcome):

Assessment of risk of bias for studies with a separate control group (RCTs, CRTs, CCTs, CBAs). Adapted from the Cochrane Handbook Table 8.5d: Criteria for judging risk of bias in the 'Risk of bias' assessment tool adapted using EPOC criteria.

RANDOM SEQUENCE GENERATION	
Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.	
Note: Both CCTs and CBAs will be 'High risk' of bias.	
Criteria for a judgement of 'Low risk' of bias.	Score 'Low risk' if the investigators describe a random sequence generation process. Outlined as: • Referring to a random number table; • Using a computer random number generator; • Coin tossing; • Shuffling cards or envelopes; • Throwing dice;

	• Drawing lots; • Minimisation.
Criteria for a judgement of 'High risk' of bias.	Score 'High risk' if the investigators describe a non-random sequence generation process. Outlined as: • Sequence generated by odd or even date of birth; • Sequence generated by some rule based on date (or day) of admission; • Sequence generated by some rule based on hospital or clinic record number. Other non-random approaches that occur but are not mentioned above: • Allocation by judgement of the clinician; • Allocation by preference of the participant; • Allocation based on the results of a laboratory test or a series of tests; • Allocation by availability of the intervention.
Criteria for a judgement of 'Unclear risk' of bias.	Score 'Unclear' if there is insufficient information provided about the sequence generation process to permit judgement of 'Low risk' or 'High risk'.

Describe:
Judgement:

ALLOCATION CONCEALMENT

Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.

Note: CBAs will be 'High risk' of bias.

Criteria for a judgement of 'Low risk' of bias.	Score 'Low risk' if participants or investigators enrolling participants could not foresee assignments because of the following, or an equivalent method was used to conceal allocation: • Central allocation (including telephone, web-based and pharmacy controlled

	randomisation);
	• Sequentially numbered drug containers of identical appearance;
	• Sequentially numbered, opaque, sealed envelopes.
Criteria for a judgement of 'High risk' of bias.	Score 'High risk' if participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: • Using an open random allocation schedule (e.g. an open list of random numbers); • Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not numbered sequentially); • Alternation or rotation; • Date of birth; • Case record number; • Any other explicitly unconcealed procedure.
Criteria for the judgement of 'Unclear risk' of bias.	Score 'Unclear risk' if insufficient information to permit judgement of 'Low risk' or 'High risk'.

Describe:
Judgement:

BLINDING OF OUTCOME ASSESSMENT
Detection bias due to knowledge of the allocated interventions by outcome assessors.

Criteria for a judgement of 'Low risk' of bias.	• Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.
Criteria for the judgement of 'High risk' of bias.	• No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; • Blinding of outcome assessment, but likely that the blinding could have been broken and the outcome measurement

	are likely to be influenced by lack of blinding.
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information provided about the blinding of outcome assessment process to permit judgement of 'Low risk' or 'High risk'.

Describe:
Judgement:

INCOMPLETE OUTCOME DATA

Attrition bias due to amount, nature or handling of incomplete outcome data.

Criteria for a judgement of 'Low risk' of bias.	Any one of the following: • No missing outcome data; • Missing outcome data balanced in numbers across groups, with similar reasons for missing data across groups.
Criteria for the judgement of 'High risk' of bias.	Any one of the following: • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; • 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization.
Criteria for the judgement of 'Unclear risk' of bias.	Any one of the following: • Insufficient reporting of attrition/exclusions to permit judgement of 'Low risk' or 'High risk'.

Describe:
Judgement:

SELECTIVE REPORTING

Reporting bias due to selective outcome reporting.

Criteria for a judgement of 'Low risk' of bias.	Any of the following: • The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported; • The study protocol is not available but all relevant outcomes in the methods section are reported in the results section.
Criteria for the judgement of 'High risk' of bias.	Any one of the following: • Not all of the study's pre-specified primary outcomes have been reported; • One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; • One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); • One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; • The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'.
Describe: **Judgement:**	
Were baseline outcome measures similar?	
Criteria for a judgement of 'Low risk' of bias.	Score 'Low risk' if participating residents' outcomes were measured prior to the intervention, and no important differences were present across study groups.
Criteria for the judgement of 'High risk' of bias.	Score 'High risk' if important differences in outcome measures were present and not adjusted for in analysis.

Criteria for the judgement of 'Unclear risk' of bias	Insufficient information to permit judgement of 'Low risk' or 'High risk'.

Describe: **Judgement:**	

Were baseline characteristics similar?

Criteria for a judgement of 'Low risk' of bias.	Score 'Low risk' if baseline characteristics of the study and control groups are reported and similar.
Criteria for the judgement of 'High risk' of bias.	Score 'High risk' if there is no report of characteristics in text or tables or if there are differences between control and intervention groups.
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'.

Describe: **Judgement:**	

Was the study adequately protected against contamination?

Criteria for a judgement of 'Low risk' of bias.	Score 'Low risk' if allocation was by long-stay unit and it is unlikely that the control group received the intervention.
Criteria for the judgement of 'High risk' of bias	Score 'High risk' if it is likely that the control group received the intervention.
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'.

Describe: **Judgement:**

OTHER BIAS – Bias that is not addressed in any of the other categories are addressed here: **Bias in the recruitment of participants in cluster designs**

Criteria for a judgement of 'Low risk' of bias.	Those involved in the identification and/or recruitment of the cluster participants did not have knowledge of the group allocation because one of the following, or an equivalent method, was employed: • Cluster participants were recruited prior to randomisation of clusters to groups and the same participants were followed up over time; • Cluster participants were recruited after randomisation of clusters to groups but carried out by a person who was blinded to the group allocation.
Criteria for the judgement of 'High risk' of bias.	• Those involved in the identification and/or recruitment of the cluster participants may have had knowledge of the group allocation; • Cluster participant identification and/or recruitment undertaken post randomisation of clusters to groups by a person who was unblinded and who may have had knowledge of characteristics of the cluster participants.
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'.
Describe: **Judgement:**	

Assessment of risk of bias for ITS: Adapted from Cochrane Handbook Table 8.5d: The Cochrane Collaboration's tool for assessing the risk of bias; adapted using EPOC criteria for ITS

Was the intervention independent of other changes?	
Criteria for a judgement of 'Low risk' of bias.	Score 'Low risk' if there are compelling arguments that the intervention occurred independently of other changes over time and the outcome was not influenced by other confounding variables/historic events during study period. If events/variables identified, note what they are in the description section.
Criteria for the judgement of 'High risk' of bias.	Score 'High risk' if reported that intervention was not independent of other changes in time.
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'.
Describe: **Judgement:**	
Was the shape of the intervention effect pre-specified?	
Criteria for a judgement of 'Low risk' of bias.	Score 'Low risk' if point of analysis is the point of intervention OR a rational explanation for the shape of intervention effect was given by the author(s). Where appropriate, this should include an explanation if the point of analysis is NOT the point of intervention.

Criteria for the judgement of 'High risk' of bias.	Score 'High risk' if it is clear that the condition above is not met.
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'.

Describe:	
Judgement:	

Was the intervention unlikely to affect data collection?	

Criteria for a judgement of 'Low risk' of bias.	Score 'Low risk' if reported that intervention itself was unlikely to affect data collection (for example, sources and methods of data collection were the same before and after the intervention).
Criteria for a judgement of 'High risk' of bias	Score 'High risk' if the intervention itself was likely to affect data collection (for example, any change in source or method of data collection reported)
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'.

Describe:	
Judgement:	

BLINDING OF OUTCOME ASSESSMENT

Detection bias due to knowledge of the allocated interventions by outcome assessors.

Criteria for a judgement of 'Low risk' of bias.	• No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; • Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.
Criteria for the judgement of 'High risk'	• No blinding of outcome assessment, and the outcome

	measurement is likely to be influenced by lack of blinding;
	• Blinding of outcome assessment, but likely that the blinding could have been broken and the outcome measurement is likely to be influenced by lack of blinding.
Criteria for the judgement of 'Unclear risk' of bias.	Any one of the following: • Insufficient information to permit judgement of 'Low risk' or 'High risk'.

Describe:
Judgement:

Were incomplete outcome data addressed adequately?

Criteria for a judgement of 'Low risk' of bias.	Score 'Low risk' if missing outcome measures were unlikely to bias the results (e.g. the proportion of missing data was similar in the pre- and post-intervention periods.
Criteria for the judgement of 'High risk' of bias.	Score 'High risk' if missing outcome data was likely to bias the results.
Criteria for the Judgement of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'.

Describe:
Judgement:

Was the study free from selective outcome reporting?

Criteria for a judgement of 'Low risk' of bias.	Score 'Low risk' if there is no evidence that outcomes were reported selectively (e.g. all relevant outcomes in the methods section are reported in the results section.
Criteria for the judgement of 'High risk' of bias.	Score 'High risk' if some of the important outcomes are subsequently

	omitted from the results.
Criteria for the Judgement of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'.
Describe: **Judgement:**	
Other sources of bias ?	

Additional information requested

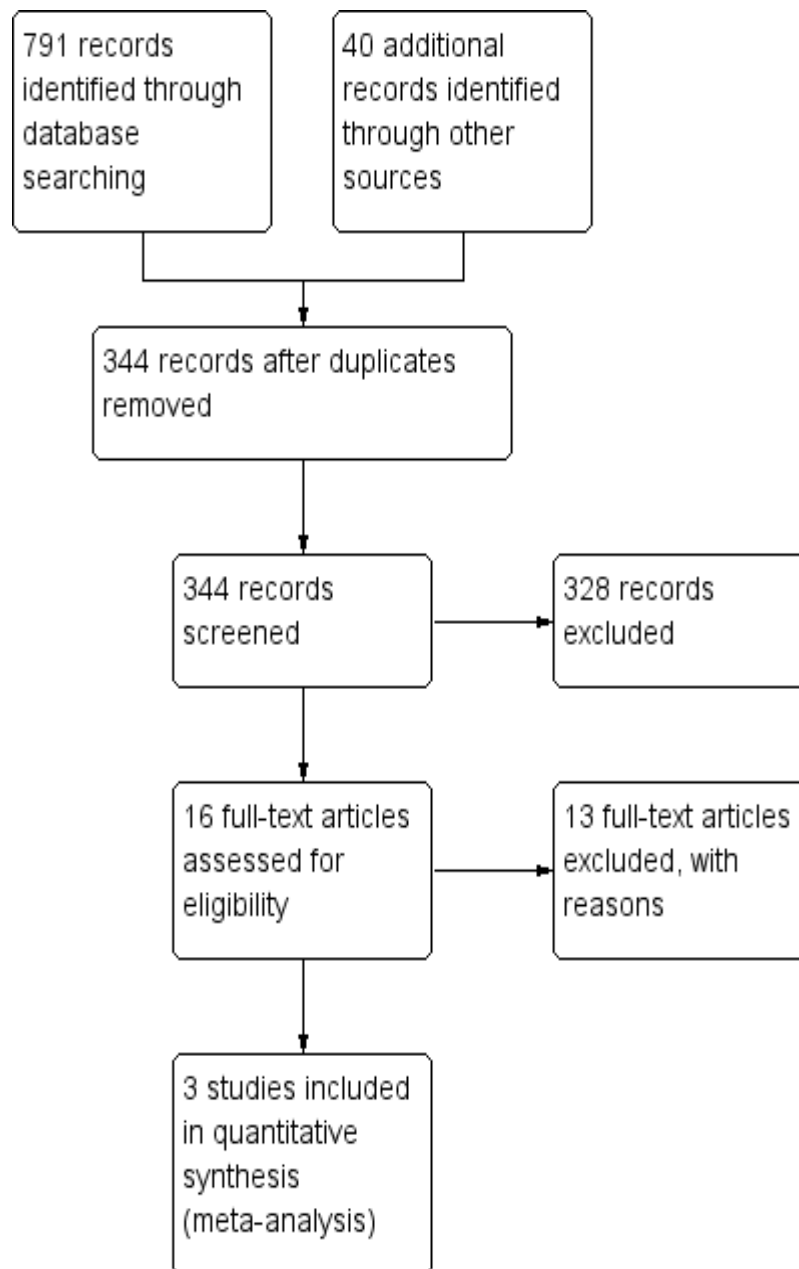| |
|---|
| Contact with the author? Yes/No

If yes, outline details/data obtained: |

Results for continuous data

Outcome	Intervention (n)	Baseline (T1)	Post-intervention (T2)	Change scores1
	Reminiscence (n)	Mean (SD)	Mean (SD)	Mean (SD)[2]
	Usual care (n)	Mean (SD)	Mean (SD)	Mean (SD)[2]

[1]If not detailed in the study, calculate by subtraction T2 mean score from T1 mean score

[2]If SD of change score is not reported, use SD at T2

Appendix 7
Study selection flowchart

Study selection flowchart

791 records identified through database searching

40 additional records identified through other sources

344 records after duplicates removed

344 records screened

328 records excluded

16 full-text articles assessed for eligibility

13 full-text articles excluded, with reasons

3 studies included in quantitative synthesis (meta-analysis)

Appendix 8

Characteristics of included studies

Characteristics of included studies

Hsieh et al. 2010

Methods	**Study design**: RCT
Participants	**Setting:** Two private nursing homes in northern Taiwan. **Diagnostic criteria:** Participants were assessed using a structured protocol which included the following criteria; DSM IV, a review of patient's medical history, laboratory findings and physical examination. All participants had a diagnosis of mild-to-moderate dementia as measured by the Clinical Dementia Rating Scale (CDR). Scores of 1 indicating mild and 2 indicating moderate dementia. **Inclusion criteria** 1. Ability to speak fluently in Chinese or Taiwanese; 2. No severely damaged sensory function e.g. no loss of vision or hearing. **Exclusion criteria for study participants:** 1. Participants were excluded if suffering from delirium. **Mean age/SD**: Control: 77.25 (10.49). Experimental: 77.90 (5.60). **Participants randomised:** 33 randomly allocated to group reminiscence therapy and 33 to control.
Interventions	**Experimental:** The topics of the reminiscence group therapy centred on lifespan issues designed for residents with dementia who were able to share their stories. Sessions were structured and facilitators adhered to clear guidelines. Participants were encouraged to tell their stories and gather old photos or meaningful materials to use when they shared their personal life experiences. Topics discussed included friendships, work experience and other significant life events. The focus during group reminiscence sessions was on having fun. The researchers included 18 activities suitable for people with dementia residing in long-term care. Special attention was given to creating a warm, comfortable environment. To facilitate communication, participants sat in a circle and could leave the group whenever they wished. Facilitators observed for manifestations of agitation and/or anxiety. **Facilitated by:** Research teams specialising in geriatric and psychiatric nursing. **No. of facilitators:** Two/ group, consisting of a leader and co-leader. **Description of facilitator training programme**: No details provided. **Frequency/Intensity/Duration of intervention:** 40-50 minute sessions, once weekly for 12 weeks. **Control**: No details provided.
Outcomes	Outcomes considered in this review and reported in or extracted from the study:

	• **Depression:** As measured by the Geriatric Depression Scale- Short Form (GDS-SF) and the Neuropsychiatric Inventory (NPI), subarea of depression. Outcomes were assessed one week prior and one week post the delivery of the intervention.
Notes	*Abstract states 61 residents were randomly distributed, however main paper states: "There were 33 participants in each group at the beginning of the study but four had withdrawn in the experimental group and one in the control group by the end of the study" (p.75). Baseline demographics and outcome data tables within the text suggest that there were 29 participants in the experimental group and 32 in the control.

Risk of bias table

Item	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk ▾	"We randomly assigned each resident into experimental or control group" (p.73). Insufficient information to permit judgement of 'Low risk' or 'High risk'.
Allocation concealment (selection bias)	Unclear risk ▾	Insufficient information to permit judgement of 'Low risk' or 'High risk'.
Blinding of outcome assessment (detection bias)	Unclear risk ▾	Insufficient information to permit judgement of 'Low risk' or 'High risk'.
Incomplete outcome data (attrition bias)	Unclear risk ▾	Insufficient reporting of attrition/exclusions to permit judgement of 'Low risk' or 'High risk'.
Selective reporting (reporting bias)	Low risk ▾	The study protocol is not available but all relevant outcomes in the methods section are reported in the results section.
Were baseline outcome measurements similar?	Low risk ▾	"At the start of the RGT intervention program, there were no significant differences as measured by t test between the experimental and control groups with regard to demographic characteristics, illness stage, depression and behaviour, such as cognitive and apathy symptoms" (p.75).
Were baseline characteristics similar?	Low risk ▾	"At the start of the RGT intervention program, there were no significant differences as measured by t test between the experimental and control groups with regard to demographic characteristics, illness stage, depression and behaviour, such as cognitive and apathy symptoms" (p.75).
Was the study adequately protected	Unclear risk ▾	Insufficient information to permit judgement of 'Low risk' or 'High risk'.

against contamination?		
Other bias	Low risk ▼	None identified.

Wang 2007

Methods	**Study design:** RCT

Participants	**Setting:** Five elderly care facilities in Taiwan.
	Inclusion criteria:
	    1. 65 years of age or more;
	    2. Having mild to severe dementia according to the Clinical Dementia Rating score of 1-3;
	    3. Absence of any additional psychiatric diagnosis;
	    4. Unimpaired hearing or vision.
	Exclusion criteria:
	    1. Participants who could not complete the Geriatric Depression Scale-Short Form (GDS-SF).
	Mean age/SD: Control: 78.92, (7.64). Experimental: 79.76, (6.29).
	Participants randomised: 51 to experimental and 51 to control.

Interventions	**Experimental:** Six reminiscence groups were conducted sequentially with each group consisting of 8-10 participants. Each group adhered to the same intervention protocol. Sessions were themed: 'First meeting', 'Childhood experiences', 'Older flavours of food', 'Old style music', 'Festivals', 'My family', 'Younger age', and 'My achievements'. Memory triggers used included-photographs, household and other familiar items from the past, old time music and old time food flavour. **Facilitated by:** Nursing staff, all of whom had extensive experience in caring for people with dementia and held a master's degree either in psychiatric or geriatric nursing. **No. of facilitators:** Sessions were led by two facilitators. **Description of facilitator training programme:** All facilitators underwent 32 hours of training in reminiscence therapy and group dynamics. It is not clear who delivered the training programme to the facilitators. **Frequency/Intensity/Duration of intervention:** Each experimental group received eight group sessions, one hour/ week for eight weeks. **Integrity of the intervention (describe):** Each facilitator adhered to a structured intervention protocol. **Control**: No details provided.

Outcomes	Outcomes considered in this review and reported in or extracted from the study:
	    • **Cognition:** As measured by the Chinese version of the Mini-Mental State Examination (MMSE);
	    • **Depression: As measured by the Chinese**

		version of Geriatric Depression Scale-Short Form (GDS-SF) and the Chinese version of the Cornell scale for dementia (CSDD). Outcomes were assessed one week prior and one week post the delivery of the intervention.
Notes		

Risk of bias

Item	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Those who agreed to participate were randomly assigned to either experimental or control groups within each facility based on a table list (subjects with even numbers were assigned to the experimental group and vice versa)" p.1236.
Allocation concealment (selection bias)	Unclear risk	Insufficient information to permit judgement of 'Low risk' or 'High risk'.
Blinding of outcome assessment (detection bias)	Low risk	"The data collectors included two graduate nurses who were blinded to subject assignment" (p.1237).
Incomplete outcome data (attrition bias)	Low risk	Insufficient reporting of attrition/exclusions to permit judgement of 'Low risk' or 'High risk'. Comment: Authors carried out an intention-to-treat analysis. "Table 1 lists the demographic information for the intention to treat sample among the two groups" (p.1238).
Selective reporting (reporting bias)	Low risk	The study protocol is not available but all relevant outcomes in the methods section are reported in the results section.
Were baseline outcome measurements similar?	Low risk	"An independent t-test was used to test the homogeneity of the two groups based on their pre-test scores. The test results demonstrated no statistically significant differences between pre-test scores of the two groups relative to the three dependent variables (t=-0.263, 0.652, 0.222 respectively: $p > 0.05$)" (p.1238).
Were baseline characteristics similar?	Low risk	"No significant differences were found at the baseline in any of the demographic variables besides the length of institutionalisation ($p< 0.01$)" (p.1238).
Was the study adequately protected against contamination?	High risk	"Because each study site comprised of both experimental and control subjects, interaction between subjects from both groups may threaten the study validity" (p.1239).
Other bias	Low risk	No evidence identified.

Wang et al. 2009

Methods	**Study design:** Controlled clinical trial.
Participants	**Setting:** Four care facilities in southern Taiwan. **Inclusion criteria:** 1. 65 years of age or older; 2. Clinical diagnosis of mild to moderate dementia and a Clinical Dementia Rating (CDR) score of 1-2; 3. Able to communicate with the language used in the group (Mandarin or Taiwanese); 4. Ability to function within a group without excessive disruption **Exclusion criteria:** 1. Severe speech or hearing problems; 2. Other psychiatric disorders. **Mean age/SD: Experimental group:** 78.76 (7.60).**Control group:** 79.32 (6.35). **Participants randomised:** 38 to experimental and 39 to control.
Interventions	**Experimental:** Four separate reminiscence therapy groups from four facilities, two in Mandarin and two in Taiwanese. Language selection was based on the characteristics of the facilities. Each group was made up of 8-10 participants and each followed the same intervention protocol. Each group session was based on eight different themes. Themes included: 'first meeting', 'childhood experiences', 'old time flavour of food', 'old time music', 'festival', 'my family', 'when I was young' and 'my award'. Memory triggers used included old photographs, food, music, household and other familiar objects from the past. Facilitators went through each theme and each participant was asked to respond individually. **Facilitated by:** Group leaders who had extensive experience working in geriatric elderly care. **No. of facilitators**: Two. **Description of facilitator training programme:** 32 hours of reminiscence therapy. No details provided on who trained the facilitators. **Frequency/intensity/Duration:** Each intervention group received I hour of reminiscence group therapy/week for a period of eight weeks. **Integrity of the intervention (describe):** Group facilitators adhered to a structured intervention protocol. **Control:** Regular nursing care.
Outcomes	Outcomes considered in this review and reported in or extracted from the study: • **Behaviour competence:** As measured by the Clifton Assessment Procedures for the Elderly Behaviour Rating Scale (CAPE-BRS). Outcomes were assessed one week prior and one week post the

		delivery of the intervention.
Notes		
Risk of bias		
Item	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk ▾	"Subjects were assigned to the intervention (structured group reminiscence therapy) or control group based on a recruitment sequence table list i.e., subjects with even numbers were assigned to the experimental group" (p.228).
Allocation concealment (selection bias)	Unclear risk ▾	Insufficient information to permit judgement of 'Low risk' or 'High risk'.
Blinding of outcome assessment (detection bias)	Low risk ▾	"All measures were administered for both groups via structured face-to-face interviews (demographics) and direct observation (BI, CAPE-BRS) in the week prior to and the week following the intervention by the same researcher, who was masked to group membership" (p.229**).**
Incomplete outcome data (attrition bias)	Low risk ▾	"A total of 77 subjects (38 in the intervention and 39 in the control group) completed all sessions of the study. Nine (10.5%) subjects did not complete the study protocol, five from the intervention group and four from the control group. Reasons for dropout included sickness, schedule conflict with appointment and death" (p.229). Comment: I calculated the dropout rates for each group: experimental = 6% and control= 4.5%.
Selective reporting (reporting bias)	Low risk ▾	The study protocol is not available but all relevant outcomes in the methods section are reported in the results section.
Were baseline outcome measurements similar?	Low risk ▾	"Results demonstrated no statistically significant difference between groups on the pre-test in terms of the overall behavioural competence, physical disability, apathy, communication difficulties, and in social disturbance or in activities of daily living (p > 0.05)" (p.229).
Were baseline characteristics similar?	Low risk ▾	"No significant differences were found at baseline on all the demographic variables or CDR score (dementia staging)" (p.229).
Was the study adequately protected against contamination?	High risk ▾	"Each study site had both intervention and control participants (group assignment was at the individual level), and interaction between participants outside visitors was possible and could threaten internal validity" (p.230).
Other bias	Low risk ▾	None identified.

Appendix 9
DARES study protocol

TRIALS

STUDY PROTOCOL

Open Access

Effectiveness of a structured education reminiscence-based programme for staff on the quality of life of residents with dementia in long-stay units: A study protocol for a cluster randomised trial

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Abstract

Background: Current projections indicate that there will be a significant increase in the number of people with dementia in Ireland, from approximately 40,000 at present to 100,000 by 2036. Psychosocial interventions, such as reminiscence, have the potential to improve the quality of life of people with dementia. However, while reminiscence is used widely in dementia care, its impact on the quality of life of people with dementia remains largely undocumented and there is a need for a robust and fair assessment of its overall effectiveness. The DementiA education programme incorporating REminiscence for Staff study will evaluate the effectiveness of a structured reminiscence-based education programme for care staff on the quality of life of residents with dementia in long-stay units.

Methods/Design: The study is a two-group, single-blind cluster randomised trial conducted in public and private long-stay residential settings in Ireland. Randomisation to control and intervention is at the level of the long-stay residential unit. Sample size calculations suggest that 18 residential units each containing 17 people with dementia are required for randomisation to control and intervention groups to achieve power of at least 80% with alpha levels of 0.05. Each resident in the intervention group is linked with a nurse and care assistant who have taken the structured reminiscence-based education programme. Participants in the control group will receive usual care. The primary outcome is quality of life of residents as measured by the Quality of Life-AD instrument. Secondary outcomes include agitation, depression and carer burden. Blinded outcome assessment is undertaken at baseline and at 18-22 weeks post-randomisation.

Discussion: Trials on reminiscence-based interventions for people with dementia have been scarce and the quality of the information arising from those that have been done has been undermined by methodological problems, particularly in relation to scale and scope. This trial is powered to deliver more credible and durable results. The trial may also convey process utility to a long-stay system in Ireland that has not been geared for education and training, especially in relation to dementia. The results of this trial are applicable to long-stay residential units in Ireland and internationally.

Trial registration: Current Controlled Trials ISRCTN99651465

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Background

Dementia is a chronic progressive debilitating disease that is largely a disorder of old age. It is characterised by widespread impairment of mental functioning, progressive memory loss, language difficulties, confusion and disorientation. These impairments are often accompanied by behavioural and psychological disturbance [1]. The behavioural disturbances associated with dementia are defined as symptoms of disturbed perception, altered thought content, mood and behaviour [2].

Studies on the prevalence of dementia indicate a sharp rise with age, doubling with every 6.3 year increment in age in Western Europe [3]. Current projections indicate that there will be a significant increase in the number of people with dementia in Ireland, from approximately 40,000 at present to 100,000 by 2036 [4]. International estimates suggest that approximately half of those with dementia will be cared for in a residential care setting at some point during the disease [5]. There is limited information on prevalence rates for dementia within long-stay settings, but what is available suggests that the majority of long-stay residents are likely to have dementia. It is estimated, for example, that between 50% and 80% of residents in various types of residential care settings in the UK may have dementia [6]. Recent small-scale estimates for Ireland suggests that a large majority of long-stay residents have cognitive impairment (up to 89%), the majority of whom are likely to have undiagnosed dementia [7]. This data is at variance with official statistics for Ireland, which suggests that only 26% of residents in long-stay care have dementia [8].

The Action Plan for Dementia (APD) for Ireland [9] advocates a person-centred approach to care in both community and long-stay settings that emphasises the individual needs of the person with dementia. Such an approach focuses on what people are still able to do and remember, and on maintaining the individuality of the person with dementia [10]. Promoting a sense of well-being among older people with dementia is enhanced by creating a supportive social environment, thereby enabling people to communicate and connect with family and friends [10,11]. Integrating evidence-based psychosocial approaches with medical and nursing care models of service delivery is key to the person-centred approach. If healthcare professionals are to develop the skills necessary for such an approach to care delivery, education about dementia and staff training in psychosocial treatments are essential [4,9]. Unfortunately, residential care staff in Ireland do not always have the skills and knowledge necessary to respond effectively to the individual needs of residents with dementia [12].

Psychosocial interventions have the potential to improve the quality of life of people with dementia and those who care for them, and a number of systematic reviews have been undertaken [13-15], including Cochrane reviews of specific approaches [16,17]. Reminiscence is a psychosocial intervention commonly used in dementia. It involves the discussion of past activities, events and experiences with another person or group of people, usually with the aid of tangible prompts such as photographs or other familiar items. One factor contributing to the popularity of reminiscence is that it can be used with early memories, which remain relatively intact for people with dementia, thus drawing on the person's preserved abilities rather than focusing on level of impairment induced by the illness. Although used extensively, little is known about the effectiveness of reminiscence as a care intervention for people with dementia [18], [19], [20].

Most studies that have examined the effectiveness of reminiscence have employed qualitative, descriptive or observational designs, with few robust experimental designs having been undertaken [19,21-23]. The most recent Cochrane systematic review of reminiscence therapy in dementia [19] showed that there was evidence of an improvement in cognition and in general behaviour in people with dementia, as well as a decrease in caregiver strain following reminiscence therapy. Five randomised controlled trials were included in this Cochrane review, although only four, with a combined total of 144 participants, had extractable data. The studies were small in scale, incorporating diverse forms of reminiscence therapy, resulting in inconclusive evidence on overall effectiveness. Therefore, the effectiveness of reminiscence on the quality of life of people with dementia remains uncertain, pointing to the need for a more robust and fair assessment of interventions using treatment protocols that set out clearly the type of reminiscence being undertaken, overall objectives, process and outcomes.

Our proposed DementiA education programme incorporating REminiscence for Staff (DARES) intervention is designed to address some of the unanswered questions regarding the effectiveness of reminiscence in the care of people with dementia. The main component of DARES is a structured education reminiscence-based programme for staff which is delivered at the level of the long-stay residential unit to dyad combinations of nursing and care staff who are directly engaged in the care of specified people with dementia.

In this study, we define reminiscence as the deliberate use of prompts, including photographs, smells, music and questioning, to promote the recall of pleasant memories. We view reminiscence as a one-to-one interaction between the person with dementia and a staff member, except where working in a small group is more

appropriate, as determined by the capacity and needs of the individual with dementia. Reminiscence is both planned, i.e. where reminiscence is the specific focus of the interaction with the person with dementia, and spontaneous, i.e. the opportunistic use of reminiscence while providing nursing care. The aim of using reminiscence with people with dementia is to stimulate the person, provide enjoyment and foster a sense of achievement and self-worth. The anticipated outcomes for people with dementia of using reminiscence are improvement in the person's quality of life, behaviour and mood.

Aim

The aim of the DARES study is to evaluate the effectiveness of a structured education reminiscence-based programme for staff on the quality of life of residents with dementia in long-stay residential units. The study has three main objectives:

1. To develop a comprehensive structured education reminiscence-based programme for staff that is specifically orientated toward enabling planned and spontaneous reminiscence to take place as part of the care of people with dementia.
2. To evaluate the impact and effectiveness of the structured education programme within the context of a cluster randomised trial.
3. To understand participants' qualitative perceptions of the education programme, their experience of care following the intervention and its impact on their lives.

Methods/Design

The DARES study is a two-group, single-blind cluster randomised trial conducted in public and private long-stay residential settings in Ireland (see Figure 1). Randomisation to control and intervention is at the level of the long-stay residential unit. Care staff within the long-stay residential units allocated to the intervention group receive the structured education reminiscence-based programme. Trained staff use reminiscence with eligible consenting residents within the intervention long-stay settings. Residents in long-stay settings allocated to the control group receive usual care. Blinded outcome assessment is undertaken at baseline and at 18-22 weeks post randomisation. A comparison of outcomes between the intervention and control sites is made to examine if differences exist, and to what extent, between control and experimental groups. Ethical approval has been granted by the Research Ethics Committee of the National University of Ireland, Galway and from each of the appropriate county/hospital-based ethics committees responsible for the public long-stay units in the trial.

We used methods for standard sample size estimates for trials that randomised at the level of the individual [24] adjusting for clustering by inflating sample size estimates by the design effect given by $1 + (\bar{n}-1)\rho$, $\bar{n}$ where is the average cluster size, and ρ is the estimated intraclass correlation coefficient (ICC) [25]. Sample size estimates are based on the primary outcome of quality of life of people with Alzheimer's disease as measured by the Quality of Life-Alzheimer's disease (QOL-AD) scale. This instrument consists of two versions; one completed by the person with dementia (care recipient) and the other by the caregiver [26,27]. We chose the care recipient version to estimate sample size for the DARES trial, expressed as the mean rate difference between intervention and control groups.

Based on a mean QOL-AD score of 32.5 for people with dementia in residential care homes [28] and an ICC value of 0.1 identified from pilot work on reminiscence groups for people with dementia for the REMCARE Trial [29], a total of 18 residential units are required, each containing 17 people with dementia, to detect a 4 point difference in mean QOL-AD scores between control and experimental groups, for power of at least 80% with alpha levels of 0.05. This calculation allows for a loss to follow-up of 20% of residents and up to 3 residential units. ICC values lower than 0.1 would increase the power of the study.

Participants

Public and private long-stay units across the western half of the Republic of Ireland who meet the eligibility criteria were invited to participate in the DARES study. Units are eligible to participate if they have 17 residents with dementia who agree, either directly or through proxy, to take part in the study. This aggregates to a total of 306 residents in the study. Residents are eligible for participation if they have lived in the residential unit for at least one month and are likely to be there for the duration of the study. Given the reality that formal clinical diagnosis of dementia in residential care is rare in Ireland, diagnosis of dementia in residents is determined in any one, or more, of the following ways:

• A formal diagnosis of dementia determined by the DSM-1V or ICD-10 criteria for dementia [30,31]
• Any other diagnosis of dementia by a medical clinician
• Resident is on anti-Alzheimer's medications, including Aricept (donepezil), Ebixa (memantine) and Exelon (rivastigmine)
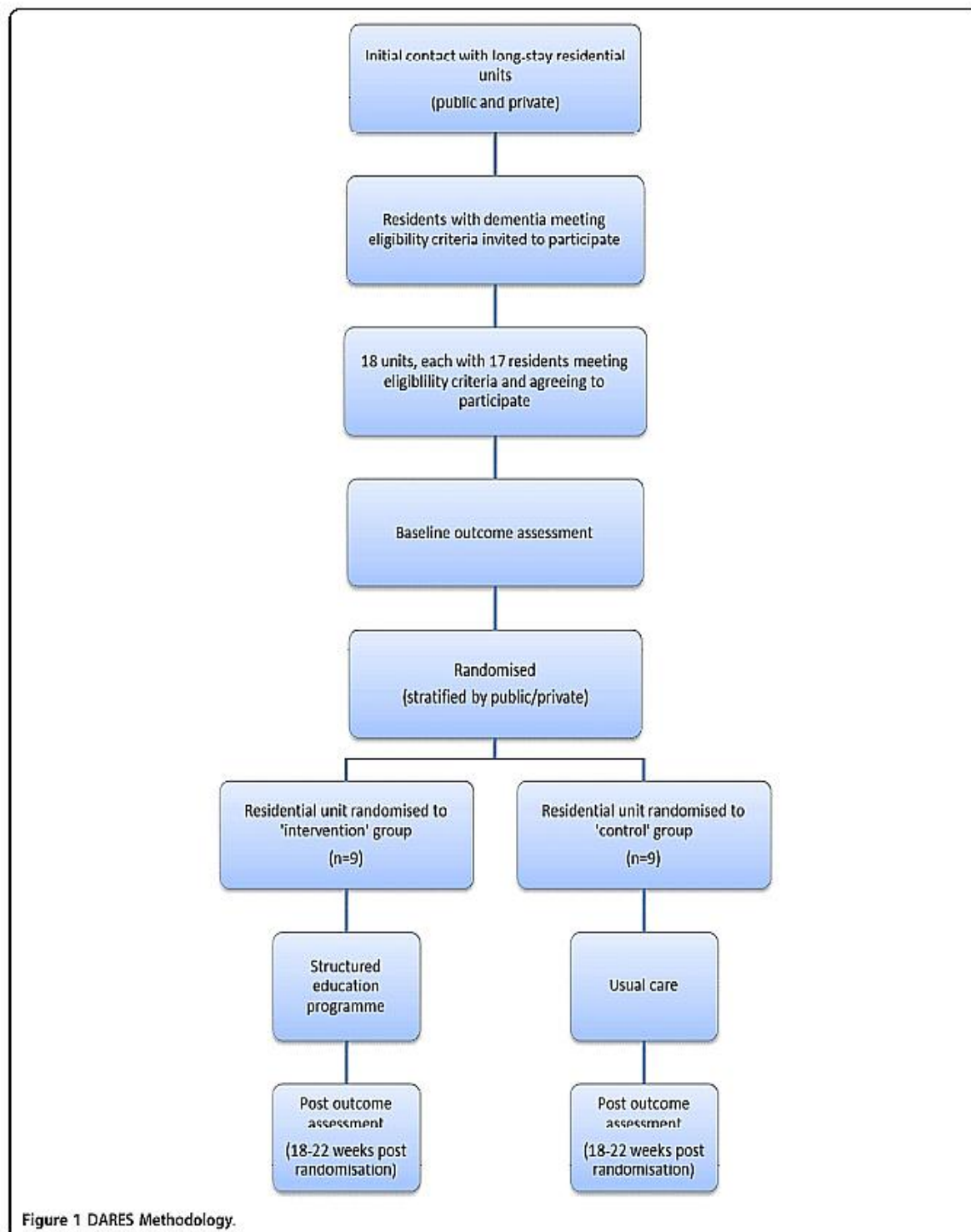• Nurses' judgement and/or nursing records advise that the person has dementia

Figure 1 DARES Methodology.

Residents are excluded from the study if they have a significant sensory impairment or an acute physical illness that, in the judgement of the appropriate nursing staff, impairs their ability to participate.

Each nurse and care assistant participating in the study will usually have worked within the care setting for at least three months and be likely to continue working there for the duration of the trial. Five dyads are required to participate in each unit. Each of the participating dyads are allocated three-four participating residents with dementia with whom they implement reminiscence for the duration of the study.

Randomisation

Randomisation to control and intervention is at the level of the long-stay residential unit. The random allocation sequence is generated using a computer generated random number list (the Mersenne Twister, Stat Direct). Randomisation is 1:1 ratio and is stratified by public and private residential units to ensure an appropriate representation of public and private facilities; a ratio of one third public to two thirds private reflects the overall distribution of beds in the region. Concealment of group allocation is achieved by giving the responsibility for sequence generation and group allocation to a researcher with statistical expertise who is independent of the study and its investigators.

The independent statistical researcher will create a consecutive list of 12 unnamed private units, numbered 1-12, and a separate list of 6 unnamed public units, numbered 1-6. A random allocation sequence is generated and each unnamed unit is assigned a trial allocation based on the sequence. As participatory units agree to enter the trial, the research team will provide the independent statistical researcher with an anonymised list of unit(s) that meet the eligibility criteria. The independent statistical researcher will then document the unique identification code assigned to that unit in the next 'unnamed' position in the randomised public or private list and release the corresponding group allocation for the unit.

Blinding

This is a single-blind cluster randomised trial. Resident and staff participants within each participating unit are recruited, and baseline data collected, prior to the random allocation of units to control and intervention groups. Because of the nature of the intervention, it is not possible to blind participants (residents with dementia or staff working in the units) to group allocation. Outcome assessment is protected by blinding the research nurses involved in data generation and collection to the group allocation of participating units, staff and residents. Data analysis is undertaken by researchers and statisticians blinded to group allocation by providing a database of outcomes identifiable only by number.

Intervention

The structured education programme for staff was developed using input from a number of different sources:
• A review of the relevant literature on reminiscence, psychosocial interventions and care for people with dementia
• A concept analysis of reminiscence, undertaken to identify the key attributes of reminiscence

• Interviews with experts from the fields of dementia, dementia education, psychiatry of old age, occupational therapy within psychiatry of old age, psychology and reminiscence
• Interviews with care staff in public and private long-stay units to establish their training needs and preferences for training modalities
• Interviews with people with dementia and with relatives of people with dementia to establish what they feel is important in the care of people with dementia
• A review of standards, guidelines and examples of international best practice on dementia care and dementia education

The education programme is founded on the DARES programme philosophy of empowerment of staff participants, including identifying what participants perceive to be important and what they feel they need to know. The concepts of learner-centeredness and adult learning are at the core of the programme, and those teaching the programme adopt a facilitator-participant role, as this is considered central to realising the empowerment philosophy. Staff participants are trained to enable them to incorporate reminiscence strategies when developing person-centred care plans.

The curriculum incorporates the following sessions:
• Introduction
• Understanding the person with dementia
• How memory works
• Reminiscence explained
• Communicating with persons with dementia
• Behaviours that challenge
• Using reminiscence in practice
• Person-centred care planning for people with dementia

The structured education programme is facilitated by experienced educators and delivered over three days: two consecutive days at the beginning of the intervention and a third day six weeks later. The DARES research team provide telephone support to staff participants during the study period, as well as conducting one support visit to each unit.

Each resident participant in the long-stay unit in the intervention group is linked with a nurse and care assistant who have attended the education programme. Each staff dyad is responsible for using reminiscence with three to four resident participants and for embedding reminiscence within the resident's care plan. Each staff dyad engages the resident with dementia in reminiscence on at least four occasions per week (i.e. one planned formal session and three spontaneous sessions). Staff in the intervention record formal and informal reminiscence conducted with each resident. Staff also complete a life history in order to provide a foundation for the reminiscence sessions.

Control Group (Usual Care)

Residents in the control group receive usual care where a resident's care is guided by current nursing and medical care plans. This can vary between and within units, but in principle at least, the various elements of care on offer to this group are also available to those in the intervention group. Therefore, the trial examines the additional effects of reminiscence arising from the structured education programme. While the complexity and potential heterogeneity of usual care is acknowledged, every effort is made to describe clearly the components of usual care for residents with dementia through interviews with managers or staff nurses, and through documentary analysis of the residents care plan.

Consent

The Director of Nursing/Nurse in Charge or their nominee identifies all residents fulfilling the trial inclusion criteria, including the residents' likely ability to participate and the potential benefits or stresses for him/her arising from participation. Residents who would be unduly distressed by inclusion in the study are not asked to consider participation.

Care staff introduce the research nurse (RN) to each potential participant. The RN spends time building a rapport with each potential participant, explains the study in simple language, and explores whether the resident is interested in being included in the trial. If the resident indicates that he/she is not interested in participating in the study, the RN will not pursue consent any further. For residents interested in participating, the RN provides written information about the study. Information about the study is also provided to the relevant next of kin of potential participants. The various information sheets inform potential participants and their families of the purpose, process, potential benefits and harms of the trial, data collection procedures, time commitment, voluntary participation, the right to withdraw (without prejudice to care), as well as providing an assurance of confidentiality.

In seeking consent, it is made clear that participation is voluntary and that the resident has the right to withdraw at any point without prejudice. The resident is given opportunities to indicate how they feel about being involved, to ask questions, clarify issues or to withdraw if they so desire. Where a potential participant is willing to engage in the trial and expresses an understanding of the purpose of the study and its voluntary nature, as well as expressing a choice to participate, the RN will finalise the consent process directly with the resident.

In instances where it is not possible to gain consent directly, consent by proxy is used, where the older person's next of kin is asked to give formal written consent on behalf of their relative. The next of kin is asked to make their decision on the basis of their knowledge of the individual's prior attitudes and values [32]. All next of kin are provided with information on the study, including material on benefits and risks. There is growing evidence that there are differences between the views of people with dementia and their proxies [33] so where possible the perspective of the older person with dementia is sought in the first instance.

Assent is assessed throughout the study for all residents irrespective of whether consent has been obtained directly or by proxy. Where assent is not forthcoming at any stage, the resident is withdrawn from the study without consequence.

Adverse Events

Reminiscence is this study is used to assist the resident in recalling positive and happy thoughts that enhance communication and connectivity with self and others, thereby improving their quality of life. The risks and harmful side-effects from participating in DARES are, therefore, likely to be low and no adverse reactions were reported from the two pilot sites or from previous trials in the literature [16]. During the structured education programme, staff are trained to deliver reminiscence training that fosters positive thoughts and happy memories. Staff also learn how to respond to situations where reminiscence results in the recall of negative or upsetting events in the lives of residents. Staff must record any such events on the Reminiscence Record Sheets. The research team ask staff during each point of contact (support visit, support telephone calls) whether any adverse events have occurred and offer support as required. If a resident becomes unduly distressed because of reminiscence, staff will respond to the situation in an appropriate manner and if unresolved will raise the issue with the research team. Prospective participants and their families are fully informed of the potential risks and benefits of the project. The resident has the right to opt out of the study at any stage.

Outcomes

Outcomes are measured for both the control and experimental group at baseline (T_1) (following consent and prior to randomisation and cluster allocation) and again at 18-22 weeks post randomisation (T_2).

Each participating long-stay unit is assigned a RN who is responsible for blinded outcome assessment for all participating residents within that unit. All research nurses undertake a two-day preparation programme consisting of:

  i) Training on the procedures and protocols surrounding the recruitment of participants and

delivery, assessment and recording of all outcome measurements

ii) Simulated completion of all data collection instruments and forms

Primary Outcome

The primary outcome is quality of life of residents as measured by the Quality of Life-AD (QOL-AD) instrument [26]. The QOL-AD covers 13 domains of quality of life. It is designed to provide both a care recipients (CR) report and a caregiver's (CG) report of the resident's QOL. The measure has good internal consistency, validity and reliability and has been recommended by the European consensus group on outcome measures for use in the measurement of psychosocial interventions in dementia [34].

The QOL-AD is administered as a structured interview using standardised instructions. The RN administers the QOL-AD form to the CR, regardless of the severity of dementia. A staff member who is familiar with the CR completes the caregiver proxy version of the QOL-AD. The RN is available to advise the designated staff member on how to complete the proxy version of the QOL-AD form, answering any questions that may arise in the process.

Secondary Outcomes

(a) The level of agitation in resident participants is measured using the Cohen-Mansfield Agitation Inventory (CMAI). The CMAI is a 29-item scale specifically developed to assess the frequency of agitated and disruptive behaviours [35]. The questionnaire has four domains: physical/aggressive, physical/non-aggressive, verbal/aggressive, verbal/non-aggressive. The measure has good validity and reliability [36,37]. The CMAI is administered by the RN, following consultation with relevant staff who are aware of the resident's behaviour over the previous two weeks.

(b) Depression in resident participants is assessed using the Cornell Scale for Depression in Dementia (CSDD) [38]. The scale was specifically developed to assess signs and symptoms of major depression in people with dementia across five broad categories. As some people with dementia may not be able to provide reliable reports, the CSDD uses a comprehensive interviewing approach, through two semi-structured interviews: an interview with a main carer and an interview with the person with dementia. Good validity and reliability have been demonstrated for the scale [38].

(c) Staff care burden is assessed using a modified version of the Zarit Burden Interview [39]. The scale was initially developed to assess carer burden on the relatives of impaired older people. The original questionnaire contains 22 questions rated on a 4-point Likert

scale and was designed to assess the impact of caring on the physical and emotional well-being of carers. The original scale has satisfactory reliability and validity [40]. A modified version of the original scale is used in this study, containing 13 questions selected for their appropriateness and applicability to nursing care staff in residential long-stay units. The modified scale has performed satisfactorily when used to assess burden on nursing staff caring for people with dementia in a Canadian long-stay setting [41].

Analyses
Quantitative Data

The focus is on the long-stay care setting with the resident as the unit of analysis. Analyses is by intention to treat, with all available data included. Quantitative data is analysed, in aggregate, using the Statistical Package for the Social Sciences (SPSS, v17). Data is entered into SPSS, coded and cleaned. Demographic characteristics of staff and of residents are described using percentages, measure of central tendency (means or medians) and measures of variation (standard deviations or ranges). Differences in mean scores are examined using analysis of variance and 2-sample independent t-tests. Relative risks with 95% confidence intervals are calculated with the control group as the reference. Multi-level modelling is used to address the issue of clustering within randomised groups.

Analysis of covariance is used to adjust for baseline differences in outcome variables. Test statistics based on chi-square are divided by the design effect while test statistics based on the t-test or z-tests are divided by the square root of the design effect. Whilst every effort is made to exclude all confounders at the design phase of the study, this may not always be possible. The analysis of data will, therefore, include the search for and control of nuisance variables, for which adjustments had not been made. The change in the primary response variable is modelled across the within subject factors (T_1 and T_2), adjusting for explanatory variables as required.

Qualitative Data

The DARES study includes an embedded qualitative component. This work is done in three parts to:

1) Support the development of the structured education programme. There have been 18 interviews with nurses and health care assistants, 9 interviews with recognised experts in the field of dementia, 3 interviews with people with dementia and 3 interviews with relatives completed.

2) Understand participants' (staff and people with dementia) perceptions of reminiscence, its impact on their lives and their experience of care. There are 9

interviews with nurses, 9 interviews with health care assistants and 9 interviews with people with dementia in the intervention group.

3) Understand and define usual care in the control sites. There are 9 interviews with clinical nurse managers in the control sites.

The primary method of data collection for the qualitative work is in-depth one-to-one interviews, guided by an interview schedule. Contextual data will have already been collected by the RNs during data collection visits to the various sites. This data will help to set the context for the relevant qualitative interviews at these sites. Grounded theory is used to guide the design of the qualitative elements of the study. The constant comparative technique is used to analyse data. Information generated at each data collection point is analysed in full prior to moving to the next stage. This approach enables data analysis to guide ongoing data collection and sampling decisions (theoretical sampling). The qualitative evaluation of residents' experiences of receiving the intervention and their understanding of the intervention will also assist in minimizing threats to fidelity.

Rigour

Threats to treatment fidelity is minimised by providing the structured education programme within the context of a comprehensive, formal curriculum delivered by experienced educators. Strategies will be put in place to assess the level of reminiscence being conducted in the intervention units, along with remedial action plans where it is found that reminiscence is not being conducted as part of normal care within these units. These strategies include:

- Visiting the unit once between the initial two-day training and the delivery of Day 3

- Using day 3 of the training programme to assess adherence to the programme

- Providing dyads with a telephone number to contact with any queries or problems

- Putting a corrective action plan in place if required for any dyad

Data validation is enhanced by having data collection performed by a small number of trained RNs and by adherence to assessment protocols. Errors are logged by the project manager and remedial strategies implemented as required. The central study processes (e.g. eligibility assessment, outcome assessment etc.) are kept under review to add to the rigour of the study. Single data entry into SPSS is used with visual verification of a sample of records from the data set created from the single entry using a continuous sampling plan (CSP-1) [42].

A pilot study has already been conducted with two residential units, one public and one private. This pilot was used to: identify problems with the research design/processes; refine data collection and analysis; assess adequacy of data sources; examine selection and enrolment processes; test instruments; and assess the resident and staff perspectives on participation in a trial of this complexity. Data from the pilot study is not included in the main analyses of the trial.

Discussion

The 2009 World Alzheimer Report [3] contains a beautiful picture of an older woman called Jacqueline taking part in a reminiscence therapy session in Nice, France in 2008. The woman is relaxed and smiling, obviously enjoying whatever happy memories are being evoked during the session. Another picture, in the same publication, shows a woman with dementia, a former mathematics teacher, writing numbers on a blackboard. The latter was purchased by care staff to help the woman feel connected to her past and allow her the opportunity to experience old pleasures. These pictures embody the belief that reminiscence-based care has the potential to enhance the quality of life of people with dementia in a variety of care settings.

The problem is that we know relatively little about the overall effectiveness of reminiscence as a care intervention, with a recent Cochrane review concluding that there was an urgent need for more quality research on the impact of reminiscence-based care on residents with dementia and care staff. Reminiscence itself has diverse roots, ranging from psychotherapy (the life review), involving sometimes painful evaluation of personal memories, to oral history, which has the simpler aim of enhancing communication and connectivity in an enjoyable engaging fashion. Reminiscence, as used in this study, focuses on the latter through discussion of past activities, events and experiences, usually with aid of familiar items from the past to prompt memory, making use of the cognitive strengths of the person with dementia rather than any cognitive weakness. Many older people with dementia suffer from reduced psychological well-being and reminiscence has potentially a lot to offer them, particularly in relation to maintaining identity and a more complete realisation of the self. It also may assist carers in developing a deeper attachment and connection to the person with dementia, thereby enhancing personhood and the whole caring experience.

This study will report on an on-going large trial that will examine the effect of a reminiscence-focused dementia education programme for care staff on quality of life, agitation and depression for people with dementia living in long-stay units in Ireland. Staff attitudes to residents with dementia and perceived care burden among staff are also measured. The study has the potential to shed light on key measurement and

methodological issues that arise when conducting psychosocial trials of this nature on people with dementia in long-stay settings. It will also provide evidence on the usefulness of reminiscence-based education programmes for staff as a means of orienting care practice towards more person-centred care.

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Authors' contributions
EOS, KM, DC, AC, FJ, AH, EM and DD designed the trial protocol and secured funding for the DARES Trial. EOS and DD drafted the manuscript and KM, DC, AC, FJ, AH, EM contributed to the manuscript. All authors read and approved the final manuscript.

Competing interests
The authors declare that they have no competing interests.

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Appendix 10

Study information sheet and agreement

to participate for long-stay units

DARES Information Sheet – Long-Stay Care Facility

Your long-stay care facility is invited to take part in an important research study. Before you decide, it is important that you understand why the research is being done and what it will involve. This information sheet tells you about the purpose, benefits and implications of this research study. If there is anything that you are not clear about, we will be happy to explain it to you. Thank you for reading this information.

Are all long-stay care facilities eligible to take part in DARES?

A long-stay care facility can take part in DARES provided:

- There are 17 residents with dementia in your facility who meet the study criteria and are willing to take part in the study. Previous experience indicates that we will need approximately 20-22 residents with dementia in your facility to ensure that 17 residents are available to participate in the study.
- There are at least 5 nurses and 5 healthcare assistants interested in taking part.
- A dyad (a nurse and healthcare assistant pair) will work together to offer reminiscence, so it must be possible to pair each nurse with a healthcare assistant.
- Each dyad will use reminiscence with 3 or 4 residents with dementia for the duration of the study. This means the dyad needs to work in the same unit as 3 or 4 residents with dementia who have agreed to take part in the study.

Taking part – what it involves for your long-stay care facility

If you agree that your long-stay facility will take part in the DARES study, a research assistant will visit your facility to recruit 17 residents with dementia and 10 staff into the study. The research assistant will collect baseline data from both residents and staff

and will review the care plans of participating residents. The research assistant will also look at their medical records, to see if they are on medication for memory loss.

Long-stay facilities will then be randomised into two groups: a control group, where care continues as usual, and an intervention group. If your facility is randomly selected for the intervention group, then 10 staff from your facility will attend the DARES reminiscence-based dementia education programme, delivered over 3 days in, or at a venue close to, your long-stay care facility.

Each pair of staff will then use reminiscence in the care of 3 or 4 residents with dementia who have agreed to take part in the study. On-going support will be provided to staff in the intervention group. 20-22 weeks after randomisation, post-intervention data will be collected from your facility.

If your facility is randomly selected for the control group, where care continues as usual, then you will not receive the intervention, that is, the structured education programme, but final data will be collected from residents and staff 20-22 weeks after randomisation. All facilities, whether intervention or control, will be given access to the education materials when the study is complete.

How long is the study period?

From the time we first contact you to the end of the study will be approximately 6 months.

What are the benefits of taking part?

The DARES study has the capacity to positively impact both the residents with dementia and the staff in your facility. DARES delivers a reminiscence-based dementia education programme to your staff, free of charge, in, or close to, your facility. Participation in this programme will help to up skill your staff, improve their knowledge and understanding of dementia, and improve the care delivered to residents. It will also demonstrate to the regulatory authorities, e.g. HIQA, and to

potential clients and their families your commitment to training and development for the betterment of both residents and staff. It is anticipated that participation in this programme will reduce the care burden of staff caring for people with dementia.

Reminiscence can help staff to know residents better and supports the delivery of person-centred care. If the DARES intervention is successful, care staff will be able to communicate better with residents with dementia, understand more about their needs and wishes and incorporate this into their care plan.

Taking part – what to do next

If you would like your long-stay facility to take part in the DARES study, please sign the enclosed *Agreement to Participate* form and return it to NUI Galway (see the return address on the next page). If you have questions, please contact the project manager, Edel Murphy on 091- 495938.

DARES

Long-Stay Care Facility Agreement to Participate

Name:	
Title:	
Email address	
Long-stay care facility:	
	I have received and read the *DARES Information Sheet – Long-Stay Care Facility.* **Yes** ☐ **No** ☐ I agree that this long-stay facility will participate in the DARES study. **Signed:** _____

Please return to:

Edel Murphy

DARES Project Manager

Aras Moyola

School of Nursing and Midwifery

NUI Galway

Appendix 11

Resident study information sheet and

consent to participate form

Using reminiscence with older people – an important study begins

My name is _____, from NUI Galway. The nursing staff in this care home think that you might be interested in being part of a research study. Research is a way to test new ideas and helps us to learn new things. Our study, called the DARES study, looks at whether a training programme for staff improves how they look after people with memory problems.

So I am asking you to take part in a research study. It is your choice whether or not you wish to be in this research. You can say yes or no. Whatever you decide is OK.

What is the study about?

We have been asked to look at how the use of reminiscence affects the care of people with memory problems. Reminiscence is about talking about the past, maybe using photographs or music from the old days. We think that reminiscence may help improve the quality of your care but we are not sure and would like your help to look at this.

What will happen during this study?

Long-stay care homes who are taking part in this study will be divided into two groups. This home may be in the group where a nurse and care assistant who care for you will attend a special training programme. They will want to ask you about what matters to you, about your past and what interests you. They will use all this information to plan care that meets your needs. Or this home may be in the group where everything continues exactly as usual.

Being part of the study means that a researcher will ask you some questions and look at your care plan. We will also check your medical records to see what medication you are on. We will not intrude and at any time, you can ask us to leave if you feel uncomfortable with us being there.

At the end of the study, the research team might decide to talk to you about the study, if that is OK with you. They will use a tape recorder to make sure they don't forget what you say. After they have typed up what is on the tape, they will get rid of the tape recording.

What else should I know about the study?

You do not have to answer or do anything if you don't want to.

What will we learn?

We hope to learn more about the best way to look after people with memory problems.

What if I don't want to be in this study?

You do not have to be in the study if you do not want to. If you don't want to be in this study, you will continue to be cared for as normal. Even if you say yes now, you can still change your mind later. You can stop being part of the study at any time. It is up to you.

Who will know I was part of this study?

If you choose to take part, what you tell me or what is observed will be held as strictly confidential. You will not be named and nothing you tell me will be reported in a way that could identify you.

Who should I ask if I have any questions?

Ask me anything you like about the study. I am here over the next few days and will check with you how you are getting on. If you have further questions, you can us call 091-495938. You should also talk to your next of kin or relative(s)/carer(s) about the study.

Site code: **Participant Code**   **Date**   **T1 or T2**

Reminiscence Study Resident Consent Form

The DARES study has been explained to me and I understand what is involved. I know that I can leave the study at any time without having to give a reason.

Participant: …………………………………… Date: ………………

Time: ………..

If the process of signing is too difficult the researcher should document here that the consent has been obtained verbally.

……………………………………………………………………………

If the participant is unable to give consent the following should be recorded:

In my opinion, this participant cannot give consent.

Reason(s):

……………………………………………………………………………

Name of researcher: ………………………………..Date: ………… Time: ………

Seek proxy consent if the person assents to participating in the study.

Appendix 12

Study information sheet for next-of-kin

consent by proxy form

Using reminiscence with older people – an important study begins

NUI Galway is being funded by the Health Research Board to undertake an important study, called DARES, on the impact of a reminiscence-based training programme for staff on the quality of life of people with memory problems.

What is the study about?

The purpose of this research study is to examine whether the use of reminiscence in day-to-day caring within the care home makes a difference to the quality of life and behaviour of residents with memory problems.

Reminiscence involves prompting people to remember and discuss past events, positive experiences and activities from their lives by using materials such as photographs, life history, historical items, music or archival videos. The aim is to increase resident-staff interaction, and to enhance resident's quality of life, including their overall mood and well-being.

Involving your relative

Some residents in this care home are being invited to take part in the study, including your relative. Staff in the care home are very supportive of the study and its potential to improve the quality of life and well-being of residents.

What are we going to do?

Long-stay care homes who are taking part in DARES will be divided at random into two groups. This home might be in the intervention group or in the control group.

If a care home is randomly selected for the **intervention group**, a number of staff from the home will attend a training programme preparing them to use reminiscence. They will then use the knowledge gained from the programme to learn more about the resident's past and their likes and dislikes, and this information will be used to plan their person-centred care. To examine the impact of reminiscence, the research team will also complete some questionnaires with residents at the start and at the end of the study. A small number of residents participating in the study will be interviewed at the end of the study to see what they thought about reminiscence. These interviews will be tape-recorded and then typed up, after which the tapes will be destroyed.

If a care home is randomly selected for the **control group**, where care continues as usual, then the staff will not attend the training programme, but the research team will complete some questionnaires with residents at the start and at the end of the study.

In both groups, the research team will look at the care plans of participating residents and also at their medical records to check if the resident is on medication for memory problems.

The results of this study may lead to new practical approaches to caring for people with memory problems in long-stay care settings. All care homes who take part in the study will be given access to the education materials when the study is complete.

What we guarantee

Residents' privacy and confidentiality will be safeguarded and in no way will your relative be identifiable in this research. Participation is strictly voluntary, and residents can withdraw at any time without any effect on their care.

Who do I contact to find out more?

Should you require any more information or have any queries, please contact the Director of Nursing, in the first instance.

Site code:	**Participant Code**	**Date**	**T1 or T2**

<div style="border:1px solid black; background-color:#d3d3d3; text-align:center; font-weight:bold;">

Reminiscence Study Consent form - Next of Kin

</div>

Staff in the care home have identified your relative/next of kin as a suitable participant for this research study. We are therefore asking you to give consent on behalf of your next of kin to be involved in this study.

What we guarantee

Your next of kin's privacy and confidentiality will be safeguarded and in no way will s/he be identifiable in this research. Participation is strictly voluntary, and you can withdraw consent on behalf of your next of kin at any time without any effect on your next of kin's care.

Who do I contact to find out more?

Should you require any more information or have any queries, please contact the Director of Nursing.

<div style="text-align:center;">

CONSENT

</div>

This study has been explained to me. I have had a chance to ask questions. If I have questions later about the research, I can ask the Director of Nursing in the care home in the first instance.

As the next of kin of _____, I consent on his/her behalf to participate in this study. (*Printed name of participating resident*)

_____
Printed name of next of kin of the resident

_____
Relationship of next of kin to the resident

━━
Signature of next of kin of the resident   **Date**

I have explained the study to _____, and she/he

(P*rinted name of participating resident*) has indicated willingness to participate. We will continue to monitor his/her assent to participate in the study.

Name of researcher: _____ Date: _____ Time: _____

Appendix 13
Staff study information sheet
and staff consent form

The National University of Ireland, Galway is being funded by the Health Research Board to undertake an important study, called DARES, on the impact of a reminiscence-based education programme for staff on the quality of life of people with dementia.

What is the study about?

The purpose of this research study is to examine whether the use of reminiscence in day-to-day caring within the care home makes a difference to the quality of life and behaviour of residents with memory problems and the care burden of staff caring for people with dementia.

Reminiscence involves prompting people to remember and discuss past events, positive experiences and activities from their lives by using materials such as photographs, life history, historical items and music or archival videos. The aim is to increase resident-staff interaction, enhance resident's quality of life, including their overall mood and well-being, and reduce the care burden of staff.

What will the study involve?

When 17 residents with dementia and 10 staff from this care facility agree to take part in the study, a care facility is included in the study. Long-stay facilities in the study will be randomised into two groups: a control group, where care continues as usual, and an intervention group.

If your facility is randomly selected for the intervention group, a number of staff nurses and health care assistants in this care home will attend a three-day training programme preparing them to use reminiscence. Each staff nurse will be paired with a health care assistant and each pair will be caring for 3 or 4 residents with dementia who have agreed to participate in this study. The staff will use the knowledge gained from the programme to learn more about each resident's past and their likes and dislikes, and this information will be used to plan their person-centred care.

To examine the impact of reminiscence, the research team will also complete some questionnaires with residents and staff at the start and at the end of the study and will look at care practices. In addition, the research team will check the medical records of each participating resident, to see if the resident is on medication for memory problems. At the end of the study, the research team will also interview a small number of staff and resident

participants, selected at random, to explore their experience of using reminiscence. These interviews will be recorded and transcribed and then the audio tapes will be destroyed.

If your facility is randomly selected for the control group, where care continues as usual, then you will not receive the intervention, that is, the structured education programme, but the research team will complete some questionnaires with residents and staff at the start and at the end of the study and will look at care practices.

All facilities, whether intervention or control, will be given access to the education materials when the study is complete.

The results of this study may lead to new practical approaches to caring for people with memory problems in long-stay care settings.

What we guarantee
The privacy and confidentiality of staff, residents and the care centre will be safeguarded and in no way will you be identifiable in this research. Participation is strictly voluntary, and staff and residents can withdraw at any time.

Who do I contact to find out more?
Should you require any more information or have any queries, please contact the Director of Nursing, in the first instance.

Site code:	**Participant**	**Date**	**T1 or**
	Code		**T2**

Reminiscence Study Staff Consent Form

The Director of Nursing in the care home has suggested to us that we invite you to take part in this study. We are therefore asking you to consent to be involved in this study.

What we guarantee

Your privacy and confidentiality will be safeguarded and in no way will you be identifiable in this research. Participation is strictly voluntary, and you can withdraw from the study at any time.

Who do I contact to find out more?

Should you require any more information or have any queries, please contact the Director of Nursing.

CONSENT

This study has been explained to me and I am happy to take part.

Printed name of the staff participant

Signature of staff participant   **Date**

Appendix 14
Letters of ethical approval

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

HSE West,
Mid-Western Regional Hospital,
Dooradoyle,
Limerick, Ireland.

Tel: 00353 (0) 61 301111
Fax: 00353 (0) 61 301165
Website: www.hse.ie

20th May, 2010.

Ms. Edel Murphy,
DARES Project Manager,
School of Nursing & Midwifery,
National University of Ireland,
GALWAY.

Re: Protocol Title
        The DARES study: A cluster randomised trial on the effectiveness of a
        structured education reminiscence-based programme for staff on the quality of
        life of residents with dementia in long-stay unit.

Dear Ms. Murphy,

I wish to thank Dr. Declan Devane and Dr. Adeline Cooney for attending the Research Ethics
Committee meeting on the 19th May, 2010 in connection with your study.

I wish to advise that the Committee has now approved your study. However, you should note
that your study cannot commence until you also receive Risk Management approval. This
approval will be issued to you shortly.

You are obliged to inform us as soon as your study is completed or if it terminates early for
any reason.

I wish you every success in your study.

Yours sincerely,

Marie Hickey Dwyer,
Consultant Ophthalmic Surgeon,
Chairperson, Ethics Research Committee.

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Research Ethics Committee
Sligo General Hospital
The Mall
Sligo
Chairman Dr. John Williams
Adm. Mette Jensen Kavanagh

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Prof. Eamonn O'Shea
ICSG
Top Floor
Cairnes Building
NUI Galway
Galway

June 9th 2010

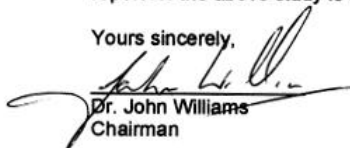**Re. Research Ethics Application**

Dear Prof. O'Shea,

The Research Ethics Committee (REC) at Sligo General Hospital has received the revised submission of the study "*The DARES study: A cluster randomised trial on the effectiveness of a structured education reminiscence-based programme for staff on the quality of life of residents with dementia in long-stay units*", which was first reviewed at the REC meeting May 19th 2010. The revisions / clarifications meet the requirements of the REC and the REC Chairman has given a **favourable ethical opinion** for the above study.

Documents reviewed:
- REC Application Form
- Protocol
- Principal Investigator C.V.
- RCT Staff Information Sheet version 4, June 1 2010
- RCT Staff consent form version 4, June 1 2010
- RCT Long stay facility information sheet version 6, June 1 2010
- RCT Long stay facility consent form version 6, June 1 2010
- Relative information sheet version 4, June 1 2010
- Relative proxy consent form, version 4, June 1 2010
- RCT Resident information sheet, version 4, June 1 2010
- RCT Resident consent/assent form, version 4, June 1 2010
- Letter to REC dated June 3rd 2010
- Insurance Certificate
- Interview guides, staff & residents

The REC requires that approved studies submit an annual report to the REC. The annual report for the above study is due on May 19 2011.

Yours sincerely,

Dr. John Williams
Chairman

cc. Edel Murphy, DARES Project Manager, School of Nursing and Midwifery, NUI Galway

Western Area,
Health Service Executive.
Mayo General Hospital,
Castlebar,
Co. Mayo,
Ireland.

Tel: (094) 9042000
Fax: (094) 9021454

Dictated: 4th July 2010
Typed: 13th July 2010

Ms. Edel Murphy,
DARES Project Manager,
School of Nursing and Midwifery,
National University of Ireland,
Galway.

Re: A cluster randomized trial on the effectiveness of a structured education reminiscence-based programme for staff on the quality of life of residents with dementia in long-stay units.

Dear Ms. Murphy,

This letter will confirm that the DARES research proposal was considered at our Hospital Research Ethics Committee Meeting which took place on Monday, 31st May 2010. I am writing to confirm that our Committee has granted ethical approval for the research study to take place at Mayo General Hospital and affiliated hospitals in County Mayo.

Our Committee felt that it was important that the next of kin should be involved in the consent process where appropriate.

You may wish to correspond therefore with two people in particular. I might suggest Dr. Elaine Walsh, Consultant for Old Age Psychiatry. I also mention the name of Ms. Marian Kilcoyne, Clinical Nurse Manager, Grade 3 who is in charge of St. Ann's Unit at the Sacred Heart Hospital in Castlebar.

If you have any further questions or concerns, please feel free to contact me at Mayo General Hospital.

Many thanks.

Yours sincerely,

Mr. Kevin Barry, MD, F.R.C.S.I. (Gen Surg), F.A.C.S.
Consultant Surgeon.

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Clinical Research Ethics Committee
Unit 4
Merlin Park Hospital
Galway.

23rd July, 2010.

Professor Eamon O'Shea
Director Irish Centre for Social Gerontology
ICSG
Cairnes Building
NUI
Galway.

Ref: 11/10 - *The DARES study: A cluster randomized trial on the effectiveness
of a structured education reminiscence-based programme for staff
on the quality of life of residents with dementia in long-stay units*

Dear Professor O'Shea,

The above project was considered and approved at the Clinical Research Ethics
Committee meeting on Wednesday 21st July, 2010.

Yours sincerely,

Dr. Shaun T. O'Keeffe
Chairman Clinical Research Ethics Committee.

c.c. Ms. Edel Murphy, DARES Research Project Manager, School of Nursing &
Midwifery, National University of Ireland, Galway.

University Hospital Galway, Ospidéal na h-Ollscoile, Gaillimh,
Galway, Ireland. Tel: 00 353 (0)91 524222 / 544544

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10th December 2010   Ref: 051010EOS

Professor Eamon O'Shea
Irish Centre for Social Gerontology
National University of Ireland
University Road
Galway
Co. Galway

Re: DARES study (DementiA Reminiscence-based Education programme for Staff)

Dear Prof. O'Shea,

Thank you for your correspondence in relation to the above research proposal that was received on the 16th of November.

Please accept my apologies in the delay in getting a response to you. The Chairperson has reviewed your clarifications and is now satisfied that all ethical considerations have been met.

Therefore, I am pleased to inform you that research ethical approval has been granted to the above piece of work.

Wishing you all the best with your research.

Yours Sincerely,

Paul Marsden

Paul Marsden
Secretary – Research Ethics Committee
On behalf of
Dr. Una Fallon
Chairperson – Research Ethics Committee

A favourable ethics review from the Research Ethics Committee (REC) is not the same as permission from the relevant HSE manager to proceed with the study. Authorisation from HSE management must be sought separately.

Appendix 15

Master list and summary sheet

Site code:	

Master list

Residents consented and data collection completed

	Name of resident	DARES Code	Dyad number
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			

16			
17			

Staff dyads

Dyad no.	Nurse plus codes	Care assistant plus codes	Resident codes
Dyad 1			
Dyad 2			
Dyad 3			
Dyad 4			
Dyad 5			

Site code:	

Summary sheet

Number of resident participants consented	
Codes assigned to resident participants	
Number of resident participants screened but not included	
Codes assigned to resident participants screened but not included	
Number of nurses consented	
Codes assigned to nurses	
Number of care assistants consented	
Codes assigned to care assistants	

Appendix 16
Context of care form

Contextual Information on Study Setting

Describe where residents *included in the sample* are located, for example, all residents have a single room or resident shares a six bedded room with five other residents. Make clear if residents reside on different units.

Indicate if unit/home has been customised to orientate residents with dementia to the environment, for example, pictures of a toilet on the toilet door, stop signs of exits, bright colours on doorways, pictures residents, safe place to wander etc.

Describe where residents *included in the sample* typically spend their day; for example, spends the majority of the day beside his/her bed or in the day room.

Describe a typical day for residents *included in the sample,* for example, spends the day beside their bed, flicks through the newspaper, paces the corridor etc.

Describe where residents *included in the sample* eat, for example, at the bedside, in the day room or in a separate dining area

Describe the day room (only if residents *included in the sample* spend time there), for example, décor, typically where residents sit etc. Does the resident engage in any activities while in the day room?   Describe these activities? Do staff involve them in activities? How? Give examples where possible?

Identify any off-unit/home facilities that residents *included in the sample* go to e.g. Chapel, garden, day centre etc.

Describe any types of social/recreational activities that residents *included in the sample* engage in, are these activities ad hoc or planned? Who initiates the activity? Is the activity one-to-one or a group activity? Do residents actively participate in the activity?

Any other comments you think is important in 'painting a picture' of life in the facility for residents included in the sample.

Appendix 17
Agent nomination and confidentiality form

Reminiscence Study – Agent Nomination and Confidentiality Form

Name of long-stay care centre: _____

As a member of management staff of the long-stay unit named above, I hereby nominate _____ as an agent of this long-stay unit for the purposes of the Data Protection Acts 1988 and 2003, for the duration of the long-stay unit's involvement in the DARES study. As an agent of the long-stay unit, _____ will be bound by the normal procedures governing resident confidentiality in this unit. Information about individual residents will be treated confidentially and will be used solely for the purpose of the research study.

_____ will remove personal identifiers from the data to ensure that only anonymised data is disclosed from the care centre to the study.

As a researcher working with the DARES Study, _____ agrees to be bound by the normal procedures governing resident confidentiality in this care centre. Information about individual residents will be treated confidentially and will be used solely for the purpose of the research study.

Long-stay   Manager   Signature: _____   Date: _____

Manager Name (block capitals): _____

Researcher's signature: _____ Date: _____

Researcher's name (block capitals): _____