Mindfulness Based Cognitive Therapy for People with Mild Dementia and Depression: A Feasibility Pilot Randomised Controlled Trial examining changes in Quality of Life and Cognition

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DClinPsy Thesis (Volume 1), 2017
University College London
I confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signature:

Name: Jacob Payne

Date: 6th October 2017
Overview

Part one of this major research project is a systematic literature review which examines the effectiveness of psychosocial group interventions for improving the quality of life of people with dementia. Eleven studies met the criteria for review. There was considerable heterogeneity across studies which varied in their content, treatment intensity, delivery, acceptability and level of caregiver involvement which made it difficult to draw robust conclusions. However, there was evidence that biweekly group Cognitive Stimulation Therapy (CST) and some self-management interventions improved the quality of life of people with dementia.

Part two reports the findings from a pilot Randomised Controlled Trial (RCT) which examined whether an adapted Mindfulness Based Cognitive Therapy (MBCT) intervention for people with mild dementia and depression was feasible and whether it significantly improved their quality of life and cognition. A range of clinical outcome measures were administered at baseline and within two weeks post-intervention. This study is part of a joint research project conducted with Deirdre Noone, who reports measures of depression and anxiety separately. The feasibility of the intervention and the statistical analysis of measures of quality of life and cognition are reported here.

Part three is a critical appraisal which reflects on the process of undertaking the research project outlined in part two. This includes a reflection on some of the challenges and strengths associated with the study, with a focus on its design, feasibility, the assessment process, and a consideration of the personal and professional journey through research.
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Thank you to the many people with dementia, their family carers, and all the memory clinic staff who helped make this research possible. Special thanks go to my fantastic co-researcher, Deirdre Noone, for your valued support throughout the project and to my research supervisor, Dr Josh Stott, for your thoughtful guidance and encouragement. Many thanks to the expertise and advice of Dr Aimee Spector and Dr Elisa Aguirre, to Dr Mina Patel for your creative effort through developing the intervention protocol, and to the Oxford Mindfulness Centre for the provision of external funding for this research. Last but by no means least – huge thanks extend to Éanna Henratty, Charlotte Stoner, and Catriona Craig for all your greatly appreciated time and help with the project.
Part One: Literature Review

Psychosocial group interventions to improve the Quality of Life of People with Dementia: A systematic review
Abstract

**Aims:** This review aimed to evaluate the effectiveness of psychosocial group interventions to improve the quality of life of people with dementia.

**Method:** A systematic review of the research literature was conducted. The PsycINFO, PubMed and Web of Science databases were searched for all papers published up until November 2016.

**Results:** Eleven RCTs met the inclusion criteria for review. There was considerable heterogeneity across studies which varied in their content, treatment intensity, delivery, quality, acceptability and level of caregiver involvement. It was therefore difficult to synthesise findings and draw robust, meaningful conclusions as to which specific components of the interventions improved quality of life. There was, however, evidence that biweekly CST groups and one self-management intervention improved the quality of life of people with dementia.

**Conclusion:** The review adds to the existing research literature with a more specific focus on group psychosocial interventions for people with dementia. Areas of further research are discussed.
**Introduction**

Improving the quality of life of people with dementia is a primary treatment goal in dementia research. The World Health Organisation has defined quality of life as “individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns...incorporating in a complex way individuals’ physical health, psychological state, level of independence, social relationships, personal beliefs and their relationships to salient features of the environment” (WHOQOL Group, 1995, p. 1405). It is increasingly understood that dementia affects an individual’s quality of life in a number of ways and research has suggested that people with dementia report lower quality of life than those living without the disease (Cooper, Bebbington, Katona & Livingston, 2009; Logsdon, McCurry, & Teri, 2007).

Given that quality of life has been defined in this way as a broad, multifaceted construct, this poses a number of difficulties for its evaluation within psychosocial intervention research for people with dementia. Psychosocial interventions in dementia have been defined as purposeful, facilitated activities which enable a person with dementia to live well now (Oyebode & Parveen, 2016). This definition encompasses a diverse range of both individual and group-based interventions, which Scott and Clare (2003) have categorised into four key groups: methods to improve memory and cognition; early approaches to enhance wellbeing; psychotherapy; and support groups. Across these four categories, there is clearly a great deal of heterogeneity in the psychosocial interventions available to support people with dementia. Therefore, a particular challenge relates to the differences between different types of psychosocial interventions and whether a particular intervention addresses the full spectrum of quality of life or instead only specific components. For
example, a psychosocial group-based intervention (e.g. support group) may lead to improvements in one aspect of an individual’s quality of life (e.g. social relationships) whereas not necessarily lead to improvements in other aspects of the construct (e.g. physical health). For psychosocial intervention research to fully address quality of life it needs to consider the multidimensionality of the construct however its complexity means that achieving this is a significant challenge.

There are also a number of challenges associated with measuring quality of life in people with dementia. There are three common ways in which quality of life is measured: self-report; proxy-rating (family carer or staff) or direct observation (e.g. Dementia Care Mapping; DCM; Kitwood & Bredin, 1992). Although a limitation of self-report measures may be that deficits in verbal communication, insight and memory of the person with dementia affects the reliability of the assessment, it is now widely understood that even those with severe dementia are able to report their quality of life (Banerjee et al., 2009; Spector & Orrell, 2006; Thorgrimsen et al., 2003). Furthermore, proxy-ratings of quality of life often differ from those of the person with dementia in which family caregivers may underestimate quality of life (Addington-Hall & Kalra, 2001; Orgeta, Edwards, Hounsome, Orrell, & Woods, 2015). In light of this, and given the subjective nature of the construct which, by its very definition, focuses on an individual’s perception, it has been recommended that where possible, self-report of the person with dementia should be prioritised (Ettema et al., 2005; Thorgrimsen et al., 2003; Woods et al., 2014).

A number of measures exist to monitor quality of life in people with dementia. The most widely used of these is the Quality of Life–Alzheimer’s Disease (QoL-AD; Logsdon Gibbons, McCurry & Teri, 1999) which has been identified in a systematic review as the quality of life outcome measure of choice for dementia research (Moniz-Cook et al., 2008) and been shown to have good internal consistency, construct validity.
and reliability (Thorgrimsen et al., 2003). The QoL-AD has an advantage of being both disease specific (e.g. a question asks specifically about an individual’s memory), whilst also tapping into many of the different components inherent to the construct of quality of life, such as one’s physical health, mood, and social relationships with family and friends. Other common disease-specific measures include the DEMQOL (Smith et al., 2005) and the Alzheimer’s Disease Quality-Related Life Scale (ADQRL; Rabins, Kasper, Kleinman, Black & Patrick, 1999). There are also measures for use specifically with older adult populations (e.g. ICECAP-O; Coast, Peters, Natarajan, Sproston, & Flynn, 2008) as well as more generic measures of quality of life (e.g. EQ-5D-3L; The EuroQol group, 1990; WHOQOL-BREF; Skevington, Lofty & O’Connell, 2004). Whilst an advantage of some of the more generic, non-disease-specific measures may be that they enable the comparison of quality of life across different clinical populations, they are also considered to be relatively broad, and they may lack the sensitivity to detect changes in some of the more specific symptoms associated with dementia, such as impairments in cognition which disease-specific measures (e.g. QoL-AD) include (Ready & Ott, 2003).

Previous systematic reviews have highlighted a lack of research which evaluates whether psychosocial interventions improve the quality of life in people with dementia. There have been previous systematic reviews which have examined only specific types of psychosocial intervention, for example, social support groups (e.g. Leung, Orrell & Orgeta, 2015; Toms, Clare, Nixon & Quinn, 2015) or individual and group psychotherapy (e.g. Cheston & Ivaneka, 2017). The methodological quality of the studies included in these reviews varied considerably, with only the review by Leung et al., (2015) focusing exclusively on RCTs. These studies also examined a broad range of outcomes rather than a specific focus on quality of life, and only a limited number of the studies included in these reviews measured this construct. A systematic
review by Olazaran et al., (2010) reviewed non-pharmacological interventions for people with dementia and highlighted a lack of high quality psychosocial intervention research evaluating quality of life, with only two of a total of 179 studies identified included a quality of life outcome measure.

A later review by Cooper et al., (2012) specifically examined 20 RCTs of non-pharmacological interventions and their effectiveness for improving the quality of life of people with dementia. This review provided evidence that some family carer interventions and group Cognitive Stimulation Therapy (CST; Spector et al., 2003) improved the quality of life in this population. A strength of this review is that evaluated a range of different non-pharmacological psychosocial interventions, rather than a narrow focus on only one, which is therefore useful for delineating which interventions improve quality of life better than others. However, a limitation of this review may be that as it included a broad range of individual and group-based psychosocial interventions developed for people with dementia, family carers, or staff it is therefore difficult to synthesise these findings to draw meaningful conclusions related to group-based interventions. A more specific focus on psychosocial group-based interventions is important in the literature, as this may enable the teasing out of issues specific to group interventions that Cooper et al., (2012) were unable to do because of their broader remit. A review which focuses specifically on group interventions also has some important clinical implications, since quality of life is now a key focus of dementia research and groups are commonly used in clinical practice as they are seen as cost-effective (Olazaran et al., 2010) and they may also provide other benefits such as improved cognition (Spector et al., 2003), social support (Dugmore, Spector & Orrell, 2015; Mason, Clare & Pistrang, 2005) and increased understanding of living and coping with dementia (Dugmore, Orrell & Spector, 2015; Lawrence, Fossey, Ballard, Moniz-Cook & Murray, 2012; Logsdon et al., 2010).
In order to keep the review question focused and to make meaningful conclusions, only talking-based group psychosocial interventions were included and therefore individual or other group interventions such as art, music, drama or exercise therapy were excluded from the review. The review also takes a narrower focus than the previous review by Cooper et al., (2012) by focusing only on outcome measures which monitor quality of life and therefore studies which use indirect observational methods to assess quality of life were not included. This review does not attempt to provide an exhaustive list of all available psychosocial interventions for people with dementia, but instead a more specific focus on psychosocial talking-based group interventions commonly used in clinical practice.

This systematic review examines the following research question:

Are psychosocial group interventions effective in improving the quality of life in people with dementia.

**Methods**

**Search strategy**

A systematic literature search was conducted. The PsycINFO, PubMed and Web of Science databases were searched from any date until November 2016 using the keywords ("Dementia" or "Alzheimer") and ("Quality of Life" or "wellbeing") and ("treatment" or "intervention"). Titles and abstracts were reviewed in accordance with the specified inclusion criteria. Reference sections of included papers were reviewed for any additional relevant studies.
**Inclusion criteria**

- Studies evaluating psychosocial group interventions for people with dementia.
- Randomised controlled trials (RCTs).
- Studies which included a measure of quality of life for people with dementia.
- Studies must be published in English as full-text, peer reviewed articles before November 2016.

**Exclusion criteria**

- Interventions designed for family carers or staff.
- Studies evaluating pharmacological interventions.
- Studies which used observational methods to rate quality of life.
- Studies that only used a quality of life measure subscale (e.g. physical health) and not overall quality of life.
- Studies evaluating art, music, drama, exercise therapy or open-ended support groups.

**Study selection**

The electronic search of the three databases produced a total of 2273 results. After duplicates were removed this left 2061 results. Titles and abstracts were reviewed which resulted in the exclusion of 2031 studies. The remaining 30 full-text articles were then read in full, and under further examination, 19 more studies were excluded. Eleven RCTs therefore met the criteria for review. The study selection process and reasons for exclusion of studies is shown in Figure 1.
Figure 1. Flowchart detailing the inclusion of studies for review.

Data extraction

Key data on intervention details, participant characteristics, quality of life measures, setting and main findings were extracted. The quality of the eleven studies included in the review was assessed according to the same criteria as specified in the previous systematic review by Cooper et al., (2012) which adapted criteria for evaluating RCTs from the Critical Appraisal Skills Programme (Critical Appraisal Skills Programme, 2017: RCT checklist) to give each study a rating of quality (out of six).
One point allocated was therefore allocated for a positive response to each of the following six questions:

1. Were participants appropriately randomised by an independent person?
2. Were participants, staff, and study personnel as far as possible “blind” to study group?
3. Were all those who entered the trial accounted for at its conclusion, and was an intention to treat analysis used?
4. Was the measure of quality of life valid and reliable?
5. Were the participants in all groups followed up and data collected in the same way?
6. Was sufficient power (> 80%) to detect a significant difference in the outcome of quality of life demonstrated?

Table 1 summarises the characteristics of the studies included.
<table>
<thead>
<tr>
<th>Study, setting and brief intervention details</th>
<th>Participants included</th>
<th>Intervention (n)</th>
<th>Control Group (n)</th>
<th>Mean MMSE scores at baseline (SD)</th>
<th>Quality of Life measure (who completed)</th>
<th>Follow up</th>
<th>Main findings on the measure of quality of life</th>
<th>Total Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Amieva et al. (2016)</td>
<td>Probable AD diagnosis (NINCDS-ADRDA criteria); MMSE between 16 to 26; GDS score between 2 to 5; living in the community with a family carer</td>
<td>Cognitive Training (170)</td>
<td>Usual care (154)</td>
<td>Cognitive Training 21.5 (3.2)</td>
<td>QoL-AD (patient)</td>
<td>PI 6/12/18 month follow-ups</td>
<td>No significant change in quality of life between the intervention and control groups</td>
<td>6</td>
</tr>
<tr>
<td>Community (France)</td>
<td>12 weekly 90-minute sessions then one maintenance session every six weeks for 6 months</td>
<td>Reminiscence Therapy group (172)</td>
<td>Individualised cognitive rehabilitation group (157)</td>
<td>Reminiscence Therapy group 21.1 (3.2)</td>
<td></td>
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<tr>
<td></td>
<td>Probable AD diagnosis (NINCDS-ADRDA criteria); MMSE between 16 to 26; GDS score between 2 to 5; living in the community with a family carer</td>
<td>Reminiscence Therapy group (44)</td>
<td>Casual discussion groups (active control, 44)</td>
<td>Reminiscence Therapy group 13.2 (1.2)</td>
<td>SRQoL (patient)</td>
<td>PI 6 month follow-up</td>
<td>A significant improvement in SRQoL scores was identified for those participants in the Reminiscence Therapy group</td>
<td>4</td>
</tr>
<tr>
<td>2. Azcurra (2012)</td>
<td>Probable AD diagnosis according to DSM-IV criteria; able to communicate with Holden Communication Score ≥ 10; MMSE ≥ 10</td>
<td>Reminiscence Therapy group (44)</td>
<td>Casual discussion groups (active control, 44)</td>
<td>Reminiscence Therapy group 14.1 (1.4)</td>
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<tr>
<td>Residential care (Argentina)</td>
<td>24 bi-weekly 60-minute sessions over 12 weeks</td>
<td>Casual discussion groups (active control, 44)</td>
<td>Waiting list control (passive control, 44)</td>
<td>Casual discussion groups 14.1 (1.4)</td>
<td></td>
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</table>
### 3. Charlesworth et al. (2016)

**Community (UK)**

12 weekly 120-minute RYCT sessions then monthly sessions for 7 months

| Diagnosis of dementia (DSM-IV criteria); has a family carer willing to participate; living in the community | Group reminiscence therapy (Remembering Yesterday Caring Today, RYCT) | Treatment as usual (47) | RYCT | 16.3 (7.0) | CSP | 16.3 (6.3) | CSP-RYCT | 17.5 (6.4) | TAU | 19.7 (5.4) | QoL-AD (patient and carer) | PI | 12-month follow-up | No significant improvements in quality of life across all groups | Y | Y | Y | Y | Y | 6 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Group reminiscence therapy and carer support combined (CSP-RYCT) | | | | | | | | | | | | | | |

**Individual Carer Supporter Programme (CSP) (48)**

### 4. Cove et al. (2014)

**Community (UK)**

14 weekly 45-minute CST sessions. Carer training of one hour at beginning and three hours at end of intervention

<table>
<thead>
<tr>
<th>Dementia diagnosis (DSM-IV criteria); MMSE between 18 to 30; able to communicate and understand English; living in the community; has a carer willing to participate</th>
<th>Group Cognitive Stimulation Therapy group (24)</th>
<th>Waiting list control (24)</th>
<th>CST</th>
<th>22.7 (3.8)</th>
<th>CST with additional carer training 22.3 (3.5)</th>
<th>Waiting list control 22.9 (3.0)</th>
<th>QoL-AD (patient)</th>
<th>PI</th>
<th>No significant improvements in quality of life across the all groups</th>
<th>Y</th>
<th>Y</th>
<th>Y</th>
<th>Y</th>
<th>N</th>
<th>5</th>
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<tr>
<td>Group CST with additional carer training (24)</td>
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**Waiting list control (24)**
<table>
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<tr>
<th></th>
<th>Study</th>
<th>Country</th>
<th>Duration</th>
<th>Setting</th>
<th>Eligibility Criteria</th>
<th>Intervention</th>
<th>Outcome Measure</th>
<th>PI</th>
<th>Comments</th>
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<tr>
<td>5.</td>
<td>Laakonen et al., (2016)</td>
<td>Community (Finland)</td>
<td>8 weekly 4 hour sessions. The intervention was based on a psychosocial group rehabilitation model which involves psychoeducation and self-management skills to build self-efficacy in managing dementia</td>
<td>Dementia diagnosis; Finnish-speaking; people with dementia and spouses living at same address</td>
<td>Self-management group for people with dementia and their spouses (67)</td>
<td>Treatment as usual (69)</td>
<td>Self-management group 19.9 (5.7) TAU control group 21.7 (3.7)</td>
<td>15D (patient)</td>
<td>9-month follow-up</td>
</tr>
<tr>
<td>6.</td>
<td>Logsdon et al., (2010)</td>
<td>Community (USA)</td>
<td>9 weekly 90-minute sessions. These provided psychoeducation about dementia and memory loss and group discussions about ways to self-manage. The Early Stage Memory Loss Protocol is manualised</td>
<td>Dementia diagnosis, MMSE score ≥ 18, with family carer; aware of memory loss; able to communicate verbally; able to participate independently in a group setting (without carers present)</td>
<td>Education and discussion groups for people with dementia and carers – Early Stage Memory Loss (ESML) groups (96)</td>
<td>Waiting list control (46)</td>
<td>Education and discussion group 23.2 (4.7) Waiting list control 24.0 (3.8)</td>
<td>QoL-AD (patient and carer)</td>
<td>A significant improvement in quality of life for participants in the education and discussion intervention group compared to control</td>
</tr>
<tr>
<td>7. Marshall et al., (2015)</td>
<td>Diagnosis of either probable AD according to the NINDS-AIREN criteria or probable vascular dementia according to the NINDS-AIREN criteria; MMSE score ≥ 18, participant acknowledged that they have a memory problem</td>
<td>‘Living Well with Dementia’ (LivDem) psycho-educational support group (28)</td>
<td>Waiting list control (30)</td>
<td>‘Living Well with Dementia’ (LivDem) psycho-educational support group 23.6 (4.3)</td>
<td>QoL-AD (patient and carer)</td>
<td>PI 10-week follow-up</td>
<td>No significant improvement in quality of life and the study lacked sufficient power to produce significant findings. However, there was some evidence of improvement in quality of life for those participants in the LivDem group</td>
<td>Y Y Y Y N 5</td>
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<tr>
<td>Community (UK)</td>
<td>10 weekly 75-minute sessions. LivDem incorporates elements of psychotherapy (e.g. sharing feelings associated with the diagnosis) as well as providing psycho-education to help manage dementia</td>
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<td>8. Orrell et al., (2014)</td>
<td>DSM-IV criteria for dementia: able to communicate and see and hear well enough to participate in the group; no major physical illness or disability; or diagnosed intellectual disability</td>
<td>Maintenance CST programme (123)</td>
<td>Treatment as usual (113)</td>
<td>Maintenance CST group 17.7 (5.6)</td>
<td>QoL-AD (patient and carer)</td>
<td>PI and 6-month follow-up</td>
<td>Significant improvements in self-rated quality of life for participants who attended the Maintenance CST program</td>
<td>Y Y Y Y Y 6</td>
<td></td>
</tr>
<tr>
<td>Residential care and community (UK)</td>
<td>24 weekly 45-minute maintenance CST sessions. All participants received standard CST program consisting of 14 biweekly 45-minute sessions delivered over 7 weeks, before the maintenance CST sessions</td>
<td></td>
<td></td>
<td>Treatment as usual 17.8 (5.4)</td>
<td>DEMQOL (patient and carer)</td>
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<tr>
<td></td>
<td>Study</td>
<td>Design</td>
<td>Target Population</td>
<td>Intervention Details</td>
<td>Control Details</td>
<td>Outcome Measures</td>
<td>Study Findings</td>
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<td>9.</td>
<td>Quinn et al., (2016)</td>
<td>Community (UK)</td>
<td>8 weekly 90-minute sessions. Sessions involved providing psycho-education about dementia and develop skills in problem-solving, goal-setting, and mindfulness-based relaxation</td>
<td>ICD-10 diagnosis of AD: vascular dementia, or mixed AD and vascular dementia; Early stages of dementia, with MMSE ≥ 20, having a caregiver who will be willing to participate</td>
<td>Self-management group</td>
<td>Treatment as usual</td>
<td>Self-management group intervention 23.5 (1.9) Treatment as usual 23.8 (2.5)</td>
<td>No significant improvement in quality of life and the study lacked sufficient power to produce significant findings. However, participants in the intervention condition had some improvement on the ICECAP-O and the EQ-5D-3L measures</td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Spector et al., (2003)</td>
<td>Residential care and community (UK)</td>
<td>14 biweekly 45-minute group CST sessions delivered over 7-weeks</td>
<td>DSM-IV dementia; recruited from UK residential homes and day centres; MMSE 10-24; able to communicate enough to participate</td>
<td>Manualised Group Cognitive Stimulation Therapy</td>
<td>Usual activities</td>
<td>Manualised Group Cognitive Stimulation Therapy 23.0 (2.5)</td>
<td>A significant improvement in quality of life was identified for those participants in the CST group compared to the control group</td>
<td></td>
</tr>
<tr>
<td>Woods et al., (2016)</td>
<td>11. Woods et al. (2016)</td>
<td>Community (UK)</td>
<td>RYCT intervention of 12 weekly 120-minute sessions then monthly sessions for 7 months</td>
<td>DSM-IV criteria for mild/moderate dementia; able to communicate and understand communication; be able to engage in a group activity; live in the community, have a relative or carer who could act as an informant</td>
<td>Joint reminiscence therapy groups with people with dementia and their family carers (268)</td>
<td>Treatment as usual (220)</td>
<td>MMSE data not collected</td>
<td>QoL-AD (patient and carer)</td>
<td>PI 10 month follow-up</td>
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**Key:**
QoL-AD = Quality of Life-Alzheimer’s Disease; MMSE = Mini Mental State Examination; SRQoL = Self-reported Quality of Life scale; 15D = 15 Dimensional DSM-IV = Diagnostic and Statistical Manual of Mental Disorders; Fourth Edition; ICD-10 = International Statistical Classification of Diseases and Related Health Problems (ICD), Tenth revision (WHO, 1992).
PI = Post Intervention
Sample characteristics

Most studies provided information on participants’ cognition with mean scores on the Mini Mental State Examination (MMSE; Folstein, Folstein & McHugh, 1975). This provides an index of severity of cognitive impairment, indicating: mild (scores 20-25); moderate (scores 10-20); and severe dementia (scores ≤10). Woods et al. (2016) was the only study which did not use the MMSE however only participants with mild to moderate dementia were included. Mean MMSE scores varied across studies, ranging from 13.2 in the Azcurra (2012) study, which recruited people with dementia living in a care home, to 23.4 in the Logsdon et al. (2010) study. The majority of studies reported mean MMSE scores which fell between a narrow range of 21-24 (Amieva et al., 2016; Cove et al., 2014; Logsdon et al., 2010; Marshall et al., 2015; Quinn et al., 2016). This is in line with a mild dementia sample (NICE, 2006).

The majority of participants were white British (Charlesworth et al., 2016; Cove et al., 2014; Marshall et al., 2015; Orrell et al., 2014; Spector et al., 2003; Quinn et al., 2016) or white American (Logsdon et al., 2010). Although information on participants’ ethnicity was not provided in the other studies they were conducted across a range of populations, including Finland (Laakkonen et al., 2016), Argentina (Azcurra, 2012) and France (Amieva et al., 2016).

Most studies recruited participants living in the community (Amieva et al., 2016; Charlesworth et al., 2016; Cove et al., 2014; Logsdon et al., 2010; Marshall et al., 2015; Woods et al., 2016). Two studies recruited participants from both residential and community settings (Orrell et al., 2014; Spector et al., 2003) and only one study recruited participants exclusively from a residential care home setting (Azcurra, 2012).
In all except one study (Quinn et al., 2016) the majority of participants were female. The mean age of participants ranged from 75.2 (SD = 8.7) in the Quinn et al. (2016) study to 86.4 (SD = 4.9) in the study by Azcurra (2012). For those studies which reported it (Amieva et al., 2016; Azcurra, 2012; Charlesworth et al., 2016; Laakonen et al., 2016; Logsdon et al., 2010; Marshall et al., 2015; Quinn et al., 2016) participants were generally highly educated, with on average over nine years of formal education, and in two studies the majority of participants had been educated to college or university level (Marshall et al., 2015; Quinn et al., 2016).

There was considerable variation in the number of participants prescribed medication for dementia. In some studies this was over 80% (Amieva et al., 2016; Laakonen et al., 2016; Marshall et al., 2015) whereas in most studies prescription rates were much lower, and in one study no participants were prescribed dementia medication (Spector et al., 2003). Only two studies reported the length of time since being diagnosed with dementia (Charlesworth et al., 2016; Quinn et al., 2016); for the majority of participants this was over two years. Two studies only recruited participants with Alzheimer’s disease (Amieva et al., 2016; Azcurra, 2012). The other studies recruited participants with dementia of any subtype, however, across all studies, the most common diagnosis was Alzheimer’s disease.

There were no observed relationships or patterns between different participant characteristics and significant improvements in quality of life.

**Study risk of bias and quality assessment**

The risk of bias for the eleven studies was assessed using the criteria as outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al., 2011). Risk of bias was assessed by grading each potential source of bias
(random allocation concealment, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data and attrition, selective outcome reporting and other biases) as either ‘high’, ‘low’ or ‘unclear’. Quotes from each study and justifications for each judgement are shown in the Risk of Bias tables (Appendix 1). A summary of the risk of bias assessment is shown in Figure 2.

As can be seen in Figure 2, the studies were generally found to be at low risk of bias. The Logsdon et al., (2010) and the Spector et al., (2003) studies did not use the most robust methods to randomise participants, and these studies were therefore judged to be at high risk of section bias. Azcurra, (2012) did not provide sufficient detail on the randomisation of participants and therefore this study was rated as unclear risk of risk of selection bias. Logsdon et al., (2010) did not specify whether the outcome assessments were conducted by someone blinded to which treatment group participants had been allocated and it was therefore also rated as high risk of detection bias. There were high levels of attrition found in the Woods et al., (2016) study and it was therefore judged to be at high risk of attrition bias.

The quality of the 11 studies was assessed in relation to the same six quality used in the Cooper et al., (2012) study. The quality assessment can be seen in Table 1. The studies were generally found to be high quality, with five of the eleven studies given the highest quality rating of six (from a total score of six). The Logsdon et al., (2010) study was also judged to be the lowest quality study with a score of three. Both Spector et al., (2003) and Azcurra et al, (2012) also had quality ratings of four out of six and these studies may therefore be judged lower quality, in addition to greater risk of bias.

Inter-rater reliability was conducted for both the risk of bias assessment and the quality rating of studies. Deirdre Noone (DN, Trainee Clinical Psychologist) was
the second-rater who rated the studies independently. For the risk of bias assessment, there was 96.7% inter-rater reliability between the authors and second rater’s judgments. The second rater (DN) judged that both the Logsdon et al., (2010) and the Spector et al., (2003) studies were at high risk of selection bias. The difference in these ratings were discussed with the research supervisor and following this it was agreed that the ratings for selection bias for both of these studies would be changed from low to a high risk of bias. Inter-rater reliability was also performed for the quality assessment ratings of the 11 studies included in the review. There was 100% inter-rater reliability between the first (author, Jacob Payne) and the second-rater’s (DN) assessment of the quality of the eleven studies. This was also discussed and agreed with the research supervisor.
Figure 2. Risk of Bias Summary.

Measures used

A range of quality of life outcome measures were used, either rated by the person with dementia, their carer, or both. The most common outcome measure was the QoL-AD (Logsdon et al., 1999) which was used in eight studies (Amieva et al., 2016; Charlesworth et al., 2016; Cove et al., 2014; Logsdon et al., 2010; Marshall et al., 2015; Orrell et al., 2014; Spector et al., 2003; Woods et al., 2016). Charlesworth
et al. (2016) and Orrell et al., (2014) also included the DEMQOL (Smith et al., 2005) as another dementia-specific measure of quality of life. Generic quality of life instruments were also used, including: the 15D (Laakonen et al., 2016); the EQ-5D-3L (Quinn et al., 2016; Charlesworth et al., 2016); and the SRQoL (Azcurra, 2012). One study (Quinn et al., 2016) used a measure of quality of life designed specifically for use with an older adult population (ICECAP-O; Coast, Peters, Natarajan, Sproston & Flynn, 2008).

**Primary and secondary outcomes**

In three studies quality of life was the only primary outcome measure (Charlesworth et al., 2016; Logsdon et al., 2016; Marshall et al., 2015). Three studies reported significant improvements on other primary outcomes of social engagement (Azcurra, 2012), cognition (Laakonen et al., 2016; Orrell et al., 2014; Spector et al., 2003) and self-efficacy (Quinn et al., 2016). Significant effects were found on other secondary outcomes, including: family communication (Logsdon et al., 2010); the quality of relationship between the carer and person with dementia (Charlesworth et al., 2016; Logsdon et al., 2010); depression (Logsdon et al., 2010; Quinn et al., 2016); self-efficacy (Logsdon et al., 2010) and Activities of Daily Living (Orrell et al., 2014).

**Overview of the Interventions**

Of the eleven studies included in this review, three used Cognitive Stimulation Therapy (Cove et al., 2014; Orrell et al., 2014; Spector et al., 2003), three used Reminiscence Therapy (Azcurra, 2012; Charlesworth et al., 2016; Woods et al., 2016) and four were identified as self-management programs (Laakonen et al., 2016;
Logsdon et al., 2010; Marshall et al., 2015; Quinn et al., 2016). One study (Amieva et al., 2016) included an evaluation of group reminiscence therapy and cognitive training within the same RCT design.

The number of sessions provided across studies varied, ranging from 8 (Laakkonen et al., 2016; Quinn et al., 2016) to 24 (Laakkonen et al., 2016). The duration and treatment intensity of sessions also varied, ranging from 45-minutes twice a week (Orrell et al., 2014; Spector et al., 2003) to 4-hours once a week (Laakkonen et al., 2016). Most studies provided information on the level of expertise of group facilitators, who tended to have experience in working with older adults from a range of different professions.

The amount of training provided for group facilitators ranged from 5 x 30-minute sessions (Quinn et al., 2016) to 10 full working days (Laakkonen et al., 2016). Some studies briefly outlined how treatment fidelity was monitored, for example, by completing adherence checklists at the end of each session (Woods et al., 2016; Charlesworth et al., 2016; Orrell et al., 2014) and through audio-recording (Marshall et al., 2015; Azcurra, 2012) and live observation of sessions (Laakkonen et al., 2016). Most studies reported that group facilitators received regular supervision whilst delivering the groups.

**Caregiver involvement**

The extent to which carers were involved varied across studies. Some studies did not involve carers (Azcurra, 2012; Orrell et al. 2014; Spector et al., 2003) whereas in the Woods et al., (2016) study, carers were invited to attend all sessions together with people with dementia. In some studies carers took part in a concurrent carers support group which ran alongside the group for people with dementia (Amieva et
al., 2016; Laakkonen et al., 2016). In the Cove at al., (2014) study, carers allocated to the ‘CST plus carer training’ group attended two separate sessions for carers at the beginning and end of the intervention. In the Logsdon et al., (2010) study carers and people with dementia had separate sessions however they met together at the end of each session. In two studies (Marshall et al., 2015; Quinn et al., 2016) carers attended the first and final sessions together with people with dementia. Charlesworth et al., (2016) evaluated two interventions and both of these involved carers; a peer support programme which carers attended separately (Carer Support Programme; CSP) and joint reminiscence therapy sessions.

Follow-ups

Three studies (Cove et al., 2014; Logsdon et al., 2010; Spector et al., 2003) only included post-intervention assessments and did not include a follow-up. The length of follow-ups in the other studies varied, ranging from 10-weeks (Marshall et al., 2015) to 18-months (Amieva et al., 2016).

Acceptability of the interventions

Many studies did not report the attendance of sessions. However, for those that did, attendance to the groups was generally high, with participants attending over 75% of sessions (Cove at al., 2014; Orrell et al., 2014; Quinn et al., 2016; Spector et al., 2013). The highest reported attendance was by Marshall et al., (2015) in which participants attended 83% of sessions. The lowest attendance was in the Woods et al., (2016) study, whereby only 57% of participants attended over half of the sessions.

The level of attrition across studies was generally low and in four studies attrition between baseline and follow-up assessments was below 4% (Azcurra, 2012;
Laakonen et al., 2016; Logsdon et al., 2010; Quinn et al., 2016). The highest level of attrition was in the Woods et al., (2016) study, with an overall level of attrition at 10-month follow-up of 24% in the intervention group and 34% in the control group. Some studies analysed the demographic characteristics of drop-outs compared to participants who completed the intervention and no significant differences between groups were reported (Charlesworth et al., 2016; Cove et al., 2014). Woods et al., (2016) found that participants who dropped out from the control group had a lower level of dementia severity.

There were no observed relationships between attendance to the intervention or caregiver involvement and significant improvements in quality of life.

**Quality of life outcomes grouped by Types of Interventions**

**Cognitive Stimulation Therapy**

Three studies evaluated group Cognitive Stimulation Therapy (CST) (Cove et al., 2014; Orrell et al., 2016; Spector et al., 2003). Group CST is a manualised 14-session intervention for people with dementia which is typically delivered through biweekly sessions (Spector et al., 2003). Sessions focus on a particular theme (e.g. childhood, music, money) and follow a consistent structure, including a warm-up activity, the use of a reality orientation (RO) board (e.g. date, location, group session details) and other cognitively stimulating activities, such as singing a ‘theme song’ as a group.

Both Spector et al., (2003) and Orrell et al., (2014) reported significant improvements in measures of quality of life, the Cove et al., (2014) study did not,

The main difference in the Cove et al., (2014) study was that sessions were delivered weekly instead of fortnightly. Therefore, these results might suggest that group CST leads to improvements in quality of life when delivered biweekly, with these findings maintained over time.

**Reminiscence Therapy**

Three studies evaluated improvements in quality of life through a reminiscence therapy intervention (Azcurra, 2012; Charlesworth et al., 2016; Woods et al., 2016). Group reminiscence therapy is typically delivered weekly, and sessions involve the discussion of memories, activities, and experiences from the past with music, everyday items and photographs used as cues to help elicit group discussion (Woods et al., 2005).

Two recent large scale, multisite RCTs (Charlesworth et al., 2016; Woods et al., 2016) did not find any significant improvements in a measure of quality of life when they compared a manualised 12-session ‘Remembering Yesterday Caring Today’ (RYCT) reminiscence therapy intervention with a treatment as usual control group. Both studies used self- and carer-rated quality of life scores. One study conducted in a residential setting (Azcurra, 2012) delivered 24 biweekly sessions of reminiscence therapy over 12-weeks and found that it significantly improved self-reported quality of life compared to a control group. This might suggest that more frequent sessions
of reminiscence therapy, and with more impaired people with dementia, is more beneficial. However, the intervention was not manualised and it used a generic, non-disease specific measure of quality of life. It also only included a brief summary of the intervention and was found to be at greater risk of bias.

One study (Amieva et al., 2016) conducted a multicentre (40 clinical sites) RCT to compare groups of cognitive training and reminiscence therapy with an individualised cognitive rehabilitation program and a treatment as usual control group. No significant improvements in self-reported quality of life were found for both group interventions (cognitive training and reminiscence therapy).

Self-management support groups

Four studies were identified as self-management support groups (Laakkonen et al., 2016; Logsdon et al., 2010; Marshall et al., 2014; Quinn et al., 2016). Self-management support groups focus on helping the person with dementia to develop the necessary skills and knowledge to manage their condition. This typically involves psychoeducation about coping with memory problems, its impact on mood and daily activities as well as providing a space for people to reflect on their experience of memory loss (Logsdon, et al., 2010; Quinn et al., 2016).

One study (Logsdon et al., 2010) demonstrated that a time-limited self-management support group led to significant improvements in quality of life however this study was found to be lower quality and at greater risk of bias. Logsdon et al., (2010) also demonstrated significant improvements in a measure of self-efficacy. Two studies (Marshall et al., 2014; Quinn et al., 2016) found improvements in quality of life however due to low sample sizes they were not sufficiently powered to produce
significant differences. Laakkonen et al., (2016) did not find any significant improvements in quality of life for participants who attended an 8-week self-management intervention however this study included a heterogeneous group of participants with mild, moderate and severe dementia who may present with different needs. The other three studies (Logsdon et al., 2010; Marshall et al., 2015; Quinn et al., 2016) were only for people with mild to moderate dementia. There was variable reporting of the intervention content and protocol across these studies.

Discussion

The aim of this systematic review was to evaluate whether psychosocial group interventions improved the quality of life of people with dementia.

Summary of the main findings

Eleven RCTs met the inclusion criteria for review. There was considerable heterogeneity across studies which varied in their content, treatment intensity, delivery, acceptability and level of caregiver involvement. It was therefore difficult to synthesise findings and draw robust, meaningful conclusions as to which specific components of the interventions improved quality of life. There was, however, evidence that biweekly group CST may improve the quality of life of people with dementia. The self-management intervention by Logsdon et al., 2010 also identified significant improvements in quality of life, however this study was identified as being of lower quality and greater risk of bias.

There was a lack of research evidence that reminiscence therapy improved participants’ quality of life, with non-significant findings in two large-scale, multisite RCTs, although one study (Azcurra, 2012) delivered in a residential care home setting,
and identified as being at greater risk of bias and lower quality did lead to significant improvements. Overall, the quality of the studies was generally good and the risk of bias low, and therefore results are more likely to be valid.

**Interpretation of findings and connection to previous literature**

The finding that group CST led to significant improvements in quality of life when delivered biweekly rather than weekly is in accordance with NICE guidelines for dementia (NICE, 2006). Cove et al., (2014) did not identify any significant improvements in quality of life through weekly CST sessions, however, this was an underpowered pilot RCT and both Spector et al., (2003) and Orrell et al., (2014) were full RCTs which were adequately powered. As Cove et al., (2014) highlights, in clinical practice the delivery of weekly CST may be more common as this reduces some of the potential burden to staff time and resources and may also be more feasible for people with dementia to attend.

The finding that CST improved quality of life was not demonstrated in a recent RCT which examined an individualised iCST intervention (Orrell et al., 2017) delivered by family carers at home over 75, 30-minute sessions. Despite significant improvements in carer’s quality of life there were no such benefits identified for the person with dementia. This suggests that group CST may provide participants with additional benefits beyond the content of the intervention.

Indeed, it is difficult to ascertain whether some of the reported improvements in quality of life identified in this review are attributed to components of the intervention or non-specific factors instead, such as fostering greater social support or identity, which qualitative research has identified as important aspects of psychosocial groups in dementia (Dugmore et al., 2015; Mason, et al., 2005). Qualitative research has also indicated that groups help to build ones understanding
about living and coping well with dementia (Dugmore et al., 2015; Lawrence et al., 2012). The improvements in quality of life reported in the self-management intervention by Logsdon et al., (2010) highlights the value of groups in helping people with dementia to develop the knowledge and skills to manage their condition and improve their self-efficacy. However this study was also rated as having the lowest quality and also being of greater risk of bias so these findings should be interpreted with caution.

Despite the significant improvements in quality of life reported by Azcurra (2012), the non-significant findings from two large-scale, multisite RCTs of a manualised ‘Remembering Yesterday Caring Today’ joint reminiscence intervention indicates that as yet, there is a lack of research evidence that reminiscence therapy improves the quality of life of people with dementia (Charlesworth et al., 2016; Woods et al., 2016). However, it is important to acknowledge that the current systematic review only focused specifically upon quality of life, and therefore benefits in other clinical outcomes would not have been captured through this review’s narrow inclusion criteria. For example, a systematic review of reminiscence therapy by Woods et al. (2005) highlighted some of the beneficial effects of reminiscence therapy on clinical outcomes such as cognition, caregiver strain, and functional ability.

**Strengths and Limitations**

A strength of this review is that it examined RCTs therefore limiting bias. The risk of bias and quality of the studies was overall good which increases the validity of the results. A challenge was that the terms ‘psychosocial’ and ‘quality of life’ are relatively broad and all-encompassing, so the review attempted address this through having a more specific focus on group interventions in the hope that this would enable
the teasing out issues specific to psychosocial group interventions for people with dementia.

However, there are a number of limitations associated with this review. Although the studies included participants from a range of countries, participants included across studies were predominantly of white ethnicity, which may limit the extent to which findings may be generalised to people with dementia from different ethnic and cultural groups. The review only included studies published in English and it did not include any unpublished grey literature. By taking a narrow focus on quality of life and only examining talking-based group interventions for people with dementia, a number of other potentially valuable interventions such as art, exercise, music, drama therapy and individual interventions were excluded from the review. A further limitation is that this systematic review included a stricter inclusion criteria than the previous review in this area by Cooper et al., (2012). The present review did not include studies which used indirect observational methods of quality of life (e.g. Lai, Chi, & Kayser-Jones, 2004) and furthermore, some potentially relevant studies included in the Cooper et al., (2012) review (e.g. Chapman, Weiner, Rackley, Hynan & Zientz, 2004; Meguro et al., 2008) were not identified by the author in the literature search. The present review was not an update of the Cooper et al., (2012) review, and therefore the inclusion and exclusion criteria were adapted to include a more specific focus on group-based interventions and outcome measures of quality life for people with dementia rather than more indirect observational methods. However, the non-inclusion of these potentially relevant studies and the adoption of the relatively strict inclusion criteria may be considered limitations of the present systematic review. Future reviews in this area may benefit from adopting more inclusive eligibility criteria and performing inter-rater reliability on the full literature search.
Another more general limitation associated with this review relates to the construct of quality of life which is relatively broad and difficult to clearly define. The majority of studies used the QoL-AD outcome measure which covers 13-domains of quality of life, including physical health, mood, energy, relationships with family and friends, memory, fun and self as a whole. As Ready and Ott (2003) highlight, generic measures of quality of life such as the QoL-AD may not be the most sensitive to detecting change. Some measures of quality of life may also be more psychometrically sound than others, and a recent study highlighted that the EQ-5D outcome measure may offer advantages over the QoL-AD, particularly in terms of reliability between self-report and proxy-rated scores (Aguirre, Kang, Hoare, Edwards & Orrell, 2016). However, further research in this area is needed.

**Future research**

This review highlights the need for more RCTs to examine whether psychosocial group interventions improve the quality of life in people with dementia. In particular, there were a lack of RCTs identified for people with dementia living in residential care homes with more severe cognitive impairments, and only one study (Azcurra, 2012) identified in this review recruited exclusively from this setting. This finding is supported from evidence from a recent systematic review which identified that the majority of dementia research conducted in residential settings tends to focus on the management of ‘challenging behaviour’ rather than improving the quality of life of people with dementia (Oyebode & Parveen, 2016).

It is also of note that the eligibility criteria for a number of studies in this review meant that many interventions were only able to be accessed by people with dementia with a family carer. Therefore, it is recommended that where possible, future research does not automatically exclude these people with dementia from an
opportunity to engage with research. A more inclusive sample, with the inclusion of participants with and without carers, may also be more representative of the diversity of clients seen in NHS clinical settings.

The mixed findings identified highlights the need for future research to examine the specific mechanisms of change associated with different psychosocial group interventions for people with dementia. Future research would therefore benefit from embedding qualitative methods into the design of future RCTs through the use of mixed method designs, to further delineate which specific factors contributed to an intervention being more, or less helpful. This would further help towards adapting psychosocial interventions to individual needs (Olazaran et al., 2010). In addition, given the vast number of quality of life measures available, research may benefit from a more in depth focus on the psychometric properties of different measures and triangulating more than one quality of life measure within the same research design.

A final important area for future research would be to provide sufficient detail on the treatment fidelity procedures used to evaluate the intervention given that many studies included in this review did not sufficiently report this.

**Implications to clinical practice**

The review provides evidence that biweekly group CST and some self-management interventions may improve the quality of life of people with dementia. This preliminary evidence might suggest that in clinical practice these interventions will help to improve quality of life of people with dementia, particularly those people in the early stages of the disease. However, it is important to interpret these findings with caution, as this review only examines quality of life to the exclusion of others of in other clinical outcomes, and it takes a narrow focus on psychosocial interventions,
and excludes other individual or group psychosocial interventions (e.g. art, music, drama and exercise therapy), which was beyond the scope and remit of this review.

**Conclusions**

This systematic review examined the effectiveness of psychosocial group interventions to improve the quality of life of people with dementia. It is promising to see that there has been much research conducted since the previous review in this field by Cooper et al., (2012). The heterogeneity across studies made it difficult to synthesise findings and draw robust, meaningful conclusions as to which specific components of the interventions improved quality of life. There was, however, evidence that biweekly CST groups and self-management interventions may improve the quality of life of people with dementia. Further research in this field is needed, particularly adequately powered RCTs which clearly specify attempts made to enhance treatment fidelity and incorporate qualitative methodologies through mixed method designs. This will help towards advancing our understanding of the personal characteristics of participants and the specific components of psychosocial interventions which make them more, or less, effective.


Part Two: Empirical Paper

Mindfulness Based Cognitive Therapy for People with Mild Dementia and Depression: A Feasibility Pilot Randomised Controlled Trial examining changes in Quality of Life and Cognition
Abstract

Aims: This pilot RCT aimed to establish whether an adapted Mindfulness Based Cognitive Therapy (MBCT) intervention for people with mild dementia and depression was feasible and whether it led to improvements in their quality of life and cognition.

Method: An adapted MBCT intervention for people with mild dementia and depression was evaluated through a single-blind, multisite, pilot RCT. Participants were recruited via memory clinics and randomly assigned to one of two treatment conditions: an eight-week adapted MBCT intervention or a treatment as usual (TAU) control group. A range of clinical outcome measures were administered at baseline and within two weeks post-intervention. This study is part of a joint research project conducted with Deirdre Noone\(^1\). The feasibility of the intervention and the statistical analysis of measures of quality of life and cognition are reported here.

Results: The intervention was feasible in terms of high attendance to the intervention and low levels of attrition. It was not judged to be feasible to recruit enough participants within the recruitment time-frame. No significant improvements in the measures of quality of life and cognition were found for participants in the adapted MBCT intervention compared to TAU control.

Conclusion: Although the adapted MBCT intervention was feasible, there is currently a lack of robust research evidence to recommend this intervention for people with mild dementia and depression.

\(^1\) Deirdre Noone reported the analysis of measures of anxiety and depression separately.
Introduction

Research has indicated that psychosocial group interventions (e.g. Cognitive Stimulation Therapy; CST; Spector et al., 2003) may improve the quality of life and cognition of people with dementia (Aguirre, Woods, Spector & Orrell, 2013; Cooper et al., 2012). There is also evidence to suggest that psychosocial groups may reduce symptoms of depression in this population (Logsdon et al., 2010; Quinn et al., 2016). This is important, given the high prevalence of depression in people with dementia and its association with a number of negative health outcomes, including impaired cognition and reduced quality of life (Enache, Winblad & Aarsland, 2011; Hoe, Hancock, Livingston & Orrell, 2006).

Mindfulness interventions, such as mindfulness-based stress reduction (MBSR; Kabat-Zinn, 1990, 2003) and mindfulness-based cognitive therapy (MBCT; Segal, Williams, & Teasdale, 2002) are two structured group programmes typically delivered over eight weeks. Both interventions incorporate mindfulness exercises to cultivate the non-judgemental awareness of present moment experience (Kabat-Zinn et al., 1998). MBCT was originally adapted from MBSR as a treatment for prevention relapse in depression (Teasdale, et al., 2000). There is now extensive research evidence which suggests that mindfulness interventions offer a range of benefits in both clinical and non-clinical populations and for the management of psychological distress associated with long-term physical health conditions, including cancer, HIV, and diabetes (Bohlmeijer, Prenger, Taal, & Cuijpers, 2010; Hofmann, Sawyer, Witt & Oh, 2010; Riley & Kalichman, 2014). There is also evidence that people with dementia are able to actively engage with mindfulness techniques (Bousfield, 2015; unpublished doctoral thesis; Litherland et al., 2013) and it has also been argued that mindfulness may help to slow the progression from mild cognitive impairment to dementia and reduce cognitive decline or possibly even have a neuro-protective effect against
developing the disease (Hu, Prakash & Chaudhury, 2011; Xiong, 2009; Quintana-Hernandez et al., 2016).

Preliminary research evidence has highlighted some of the potential benefits of mindfulness interventions for people with dementia. In a care home setting, a MBSR-based intervention significantly reduced levels of staff-rated agitated behaviour of people with dementia (Lantz, Buchalter, & McBee, 1997). More recently, a quasi-experimental study by Paller et al., (2015) evaluated an MBSR-adapted intervention for people with early-stage cognitive difficulties, which included a heterogeneous group of participants with Alzheimer’s disease, mild cognitive impairment and memory loss without a clinical diagnosis. Participants and their carers were recruited from a community setting and carers helped to support with the engagement to home mindfulness practice. The mindfulness intervention led to significant improvements in participant quality of life, mood, and subjective sleep quality. However, limitations of this study include the diagnostic heterogeneity of the participants recruited and its low quality, quasi-experimental design. The researchers concluded that there was a need for RCT research to evaluate mindfulness interventions for people with dementia.

A recent pilot RCT (Churcher Clarke, Chan, Stott, Royan, & Spector, 2017) evaluated a 10-session, adapted MBSR intervention delivered biweekly for people with dementia living in care homes. Findings indicated that the intervention was feasible and that it led to significant improvements in quality of life. No significant improvements were found in the other outcome measures however a third of participants who attended the MBSR intervention moved out of the clinical range on a measure of depression whereas no participants in the control group did. These findings, along with the consistent finding that MBCT has been shown to be effective in reducing symptoms of depression and is a NICE recommended intervention for
preventing the future relapse of depression in people without dementia (Kuyken et al., 2016, NICE, 2009), provides a rationale for delivering a MBCT intervention instead of MBSR, and specifically recruiting people with comorbid depression and dementia.

Previous research into mindfulness interventions for people with dementia has tended to focus on MBSR-based interventions (e.g. Paller et al., 2014, Churcher Clarke et al., 2017), and there is a need to determine whether MBCT may also offer potential benefits for this population. MBCT, and its focus on building one’s non-judgemental awareness of ruminative thinking patterns associated with depression may be particularly beneficial for use with this clinical population. Furthermore, there are also a number of differences associated with delivering interventions for people with dementia living in the community rather than a care home setting. For example, these people with dementia are likely to be less cognitively impaired and perhaps having increased cognitive skills may enable people with dementia living in the community to engage with mindfulness techniques differently. People with dementia living in the community may also have greater access to family caregiver support who are able to assist with home mindfulness practice, as highlighted in the Paller et al., (2014) study. There may also be additional challenges associated with recruitment and attendance to groups delivered in a community rather than in care homes, for example, participants willingness to travel to groups may affect group attendance. There is a need to evaluate the feasibility of delivering a mindfulness intervention in a community setting.

The present study therefore attempts to add to the existing research literature by evaluating an adapted MBCT intervention for people with comorbid depression and dementia living in a community setting. This study evaluates whether the adapted MBCT intervention was feasible, including an assessment of recruitment, attendance, attrition and adherence to the adapted MBCT protocol, which was developed by a
clinician working within one of the memory clinics (Mina Patel, Appendix B). Change was assessed using a range of clinical outcome measures and the present study focuses specifically on two of these which examine quality of life and cognition. It is anticipated that the findings from this current study, including an evaluation of its feasibility, will help to inform the design and sample size of a future full RCT.

**Aims**

1. To examine how feasible it is to deliver a MBCT intervention for people with mild dementia and depression from memory clinics, in terms of recruitment, attendance, attrition and adherence to the adapted MBCT protocol.

2. To preliminary investigate whether a MBCT intervention has any beneficial effects on the quality of life and cognition of people with mild dementia.

**Hypotheses**

- The adapted MBCT intervention will be feasible, as measured by the recruitment, attendance, attrition and adherence to the adapted MBCT intervention.

- There will be improvements in the quality of life and cognition of participants who attended the adapted MBCT intervention compared to those participants in the TAU control.
Joint project

This research study was conducted as part of a joint DClinPsy research project conducted with Deirdre Noone. Deirdre Noone reports the effectiveness of an adapted MBCT intervention for people with dementia on measures of depression and anxiety. Sarah Douglas, an MSc student, conducted qualitative interviews with people with dementia who attended the MBCT intervention to explore their experience of attending the group and their engagement with mindfulness practice.

The present study outlines the effectiveness of an adapted MBCT intervention for people with dementia on outcome measures of quality of life and cognition. The feasibility of the intervention is also reported, in terms of recruitment, retention, attrition and adherence to the adapted MBCT intervention protocol.

Appendix C outlines the relative contribution of each trainee to the research.

Method

Design

This is a single-blind, multisite, pilot RCT. Participants were randomly assigned to one of two treatment conditions: an eight-week adapted MBCT intervention or a TAU control group. A number of clinical outcome measures were assessed by a researcher blind to the treatment group at baseline and within two weeks post-intervention. Caregivers were also invited to attend an introductory session prior to the first session of the group along with people with dementia. The full clinical trial protocol is registered online (ISRCTN16382776; Aguirre et al., 2017).
Participant inclusion criteria
Participants were included in the study if they:

a) met the DSM-IV criteria for dementia (American Psychiatric Association, 2000);

b) were in the mild to moderate stage of dementia, as indicated by a score of 18 or above on the Mini Mental State Exam (MMSE; Folstein, Folstein & McHugh, 1975);

c) met criteria for depression, as indicated by a score of 9 or above on the Patient Health Questionnaire (Kroenke, Spitzer & Williams, 2001);

d) were functionally able to attend and participate in the group (i.e. able to communicate in English, were able to see and hear well enough to engage in the group, were physically able to attend the group, were able to concentrate in a 90-minute session), based on the judgement of the care coordinator and blind assessor.

Participant exclusion criteria
Participants were excluded from the study if they:

a) did not have the capacity to consent for themselves;

b) presented with severe depression or at high risk of self-harm (e.g. suicidal intent) which required urgent attention;

c) had a diagnosis of a learning disability;

d) were involved in any other psychosocial intervention research;

e) had a diagnosis of psychosis;

f) were within two months of a bereavement.
Procedure

The primary researchers (Deirdre Noone and Jacob Payne) contacted the managers of the memory clinics to discuss the study (e.g. rationale; inclusion and exclusion criteria etc.). The feasibility of running the group was also discussed (e.g. available transport, expected level of attrition for groups etc.). If the managers agreed to take part, the researchers attended MDT meetings at the memory clinic to present details about the study. Staff were asked to identify potential participants based on the specified inclusion and exclusion criteria. Staff then briefly discussed the study with potential participants and provided them with a participant information sheet (Appendix D). If they were interested in taking part, staff sought verbal consent for the potential participant to be contacted by a member of the research team. The researchers then contacted the participant and arranged to meet with them either at their own home or at a memory clinic.

The researchers met with the potential participant to discuss the study and their decision as to whether to take part. Informed consent was assessed by a trainee clinical psychologist with training in the mental capacity act (Department of Health, 2005). The initial screening assessed for eligibility was based on the measures of depression (score of 9 or above on the PHQ-9) and cognitive functioning (score of 18 or above on MMSE). Only those participants who met the inclusion criteria completed a full assessment.

The assessments were conducted at baseline and within two weeks post-intervention. The assessor was blind as to which treatment group participants had been allocated.

Participants were randomised to one of two treatment conditions: an MBCT intervention or a TAU control. Randomisation was conducted remotely by an
independent researcher using the online software sealedenvelop.com.

**Intervention**

The intervention protocol was based on the original MBCT protocol for the prevention of depression relapse (Segal et al., 2002). Adaptations were made to the protocol, which included a reduced length of meditation exercises and space within sessions to reflect on distress associated with having memory problems. The adapted MBCT intervention consisted of eight, weekly, 90-minute sessions. Carers were invited to an introductory psycho-education session on MBCT prior to the first session of the group. This included practicing mindfulness exercises with people with dementia and a discussion of the importance of home practice between sessions. Carers were also made aware that participants would receive a support call from the course facilitators to help support with the mindfulness practice between group sessions. The full detailed content of the adapted MBCT protocol is shown in Appendix B. An overview of the content of the sessions is presented in Table 1.

The MBCT intervention incorporated daily assignments of ‘formal’ home practice of mindfulness techniques (using 15–20 minute audio-recordings) as well as ‘informal’ exercises to incorporate mindfulness practice into everyday experience (e.g. whilst eating, walking, showering, brushing teeth etc.). Participants were encouraged to practice both formal and informal mindfulness exercises for approximately 25–40 minutes each day. Participants also received a weekly telephone call from a course facilitator to discuss any difficulties associated with home mindfulness practice or challenges experienced through attending the group.
Group Facilitators

Two clinicians facilitated the MBCT group. To enhance treatment fidelity it was ensured that at least one group facilitator was Level 1 mindfulness trained. The facilitators had experience of working with older adults and people with dementia. Deirdre Noone facilitated the MBCT group in memory clinic 1 along with a member of staff from the memory clinic. In memory clinic 2 the MBCT group was facilitated by two internal members of staff. The facilitators received weekly supervision throughout the delivery of the intervention.
<table>
<thead>
<tr>
<th>Session Number</th>
<th>Session Title</th>
<th>Session content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-session</td>
<td>Introductory session with carers</td>
<td>Introduction to the mindfulness programme</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clapping exercise</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Breathing exercise (balloon exercise)</td>
</tr>
<tr>
<td>1</td>
<td>Awareness and Automatic Pilot</td>
<td>Introduction to the mindfulness programme</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Raisin exercise</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Body scan (10 minutes, track 1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discussion of home practice and potential barriers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Breath focus – one minute breathing space</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Poem</td>
</tr>
<tr>
<td>2</td>
<td>Living in Our Head</td>
<td>Grounding Practice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Body scan (10 minutes, track 1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thoughts and feeling exercise</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 minute sitting – The Breath</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Breath focus – one minute breathing space</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Poem</td>
</tr>
<tr>
<td>3</td>
<td>Gathering The Scattered Mind</td>
<td>Grounding Practice (5 minutes)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sitting meditation (10-15 minutes)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thoughts and feeling exercise</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Three step breathing space</td>
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<tr>
<td></td>
<td></td>
<td>Mindful Stretching</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discussion of home practice and potential barriers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Breath focus – one minute breathing space</td>
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<td></td>
<td></td>
<td>Poem</td>
</tr>
<tr>
<td>4</td>
<td>Recognising Aversion</td>
<td>Grounding Practice (5 minutes)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sitting meditation (15 minutes)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mindful walking</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3-minute breathing space</td>
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<tr>
<td></td>
<td></td>
<td>Poem</td>
</tr>
<tr>
<td>5</td>
<td>Allowing – letting be</td>
<td>Grounding practice (5 minutes)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sitting meditation (10 minutes)</td>
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<td></td>
<td>Discussion of memory problems and impact</td>
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<td></td>
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<td>Breathing space extended practice</td>
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<td>Discussion of home practice and potential barriers</td>
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<td>Poem</td>
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<td>6</td>
<td>Thoughts are not facts</td>
<td>Grounding practice (5 minutes)</td>
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<td></td>
<td></td>
<td>Sitting meditation (10 minutes)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thoughts – fact or fiction exercise</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Befriending meditation (10 minutes)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>One minute-breathing space</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Poem</td>
</tr>
<tr>
<td>7</td>
<td>How best to take care of myself</td>
<td>Befriending/sitting meditation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mountain meditation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Activity – rebalancing your life (values)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>One minute-breathing space</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Poem</td>
</tr>
<tr>
<td>8</td>
<td>Maintaining and Extending New Learning</td>
<td>Grounding Practice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Body scan (10 minutes, track 1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discussion of ‘endings’</td>
</tr>
<tr>
<td></td>
<td></td>
<td>One minute-breathing space</td>
</tr>
</tbody>
</table>

Table 1. Overview of the MBCT intervention.
**Demographics**

Demographic information was collected, which included participants’ age, gender, ethnicity, marital status, prescribed medication, dementia diagnosis and stage of dementia (See Table 1).

**Measures**

Deirdre Noone analysed measures of depression using the Cornell Scale for Depression in Dementia (CSDD; Alexopoulos, Abrams, Young & Shamoian, 1988) and the PHQ-9 (Kroenke, Spitzer & Williams, 2001) and measures of anxiety using the Rating Anxiety in Dementia scale (RAID; Shankar, Walker, Frost & Orrell, 1999) and the GAD-7 (Spitzer, Kroenke, Williams & Löwe, 2006).

This thesis focused on the analysis of quality of life and cognition using the following measures:

**Quality of life**

The Quality of Life – Alzheimer’s Disease (QoL-AD; Logsdon, Gibbons, McCurry & Teri, 1999) is a 13-item measure of quality of life which can be completed by either the person with dementia, their carer, or both. It includes 13 domains of quality of life, including physical health, mood, energy, relationships with family and friends, memory, fun and self as a whole. Each item is rated either ‘poor’ (1), ‘fair’ (2), ‘good’ (3) or ‘excellent’ (4) with higher scores indicating better quality of life. The QoL-AD has been shown to have good internal consistency (Crombach’s alpha coefficient of 0.82) and inter-rater reliability (Cohen’s kappa values > 0.70) and a systematic review has identified it as the outcome measure of choice for measuring quality of life in
people with dementia (Logsdon et al., 1999; Moniz-Cook et al., 2008; Thorgrimsen et al., 2003).

**Cognition**

The Mini-Mental State Examination (MMSE; Folstein et al., 1975) is a measure of cognitive functioning which covers domains including orientation, short-term memory, attention, language and visual construction and it is widely used with people with dementia and cognitive impairment. The maximum score obtained on this measure is 30, with scores providing an index of severity of cognitive impairment: mild (scores 20-25); moderate (scores 10-20); and severe dementia (scores ≤10). Evaluation of the psychometric properties of the MMSE indicates that it has satisfactory reliability and construct validity. Tombaugh & McIntyre, (1992) reported satisfactory internal consistency of the MMSE, with Crombach’s alpha coefficients falling between .54 and .96. Mitchell (2009) assessed the accuracy of the MMSE in detecting dementia and mild cognitive impairment, and reported a pooled sensitivity of 79.8% and specificity of 81.3% for the MMSE in memory clinic settings. The MMSE has been recommended as a brief screening tool rather than for use as a diagnostic tool for people dementia (Tombaugh & McIntyre, 1992).

**Assessment of feasibility**

Feasibility of the MBCT intervention was evaluated using data of recruitment, attendance, attrition, reasons for ineligibility and adherence to the adapted MBCT protocol. The course facilitators were also consulted on their experience of running the groups and how they perceived participants’ to experience the adapted MBCT intervention.

Post-intervention assessments were conducted within two weeks of the final
group session. The assessors reminded participants to not disclose their group allocation. The assessor recorded their impression of which treatment group they believed participants were allocated to and their confidence in that prediction. Where possible, the same assessor conducted both the baseline and post-intervention assessments, however for two clients this was not possible due to staff constraints. Details of the recruitment process is shown in the CONSORT participant flow diagram (Figure 1).
Figure 1. CONSORT participant flow diagram of recruitment to the study.

Assessed for consent and eligibility (n= 41)

- Excluded (n= 21)
  - Did not meet inclusion criteria (n= 18)
  - Moved out of the area (n= 2)
  - Declined to participate (n= 1)

Randomised (n=)

Allocated to intervention group (n=10)

- Received MBCT intervention (n= 10)

Lost to follow-up (n= 1)
Reason: Discontinued intervention (did not like the intervention) (n = 1)
Follow-up completed (n=9)

Analysed (n= 10)
Intention to treat analysis

Allocated to control group (n=10)

Lost to follow-up (n= 0)
Follow-up completed (n=10)

Analysed (n= 10)
Excluded from analysis (n= 0)
Power analysis

A statistical power analysis was performed to estimate sample size using G*power software (Faul, Erdfelder, Lang & Butchner, 2007). With $p = .05$, power = .80 and based on the medium effect size ($r = 0.38$) reported in the previous study by Churcher Clarke et al., (2017) a projected sample size of $N = 32$ was calculated to detect a significant effect on the QoL-AD outcome measure.

Data analysis

For aim 1, data analysis was conducted using the Statistical Package for the Social Sciences (SPSS; version 21.0). Outcome data was tested for assumptions of normality. A 2 x 2 mixed Analysis of Variance (ANOVA) was used to analyse change in the outcome measures of quality of life and cognition with group (MBCT intervention and TAU control groups) as the between subject factor and time-point (baseline and post-intervention) as the within subject factor. An intention to treat (ITT) analysis was used and therefore all available data was analysed, including participants who dropped out. For aim 2, descriptive statistics were used to evaluate the feasibility of the study in terms of recruitment, attendance and attrition.

Ethical considerations

Ethical approval was granted by the National Research Ethics Service London - London - City & East Research Ethics Committee (REC; Ref: 16/LO/0578; Appendix H).
Results

Participant characteristics

The demographic and clinical characteristics of participants are shown in Table 2. The majority of participants (90%) were in the mild stages of dementia with the most common diagnosis Alzheimer’s disease (50%). The majority of participants were White British (85%) and female (75%). There were no significant differences (at the \( p < .05 \) level) between the two groups in terms of age, dementia severity, cognitive functioning, prescribed medication, marital status and ethnicity.
Table 2. Baseline clinical and demographic characteristics of participants.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Intervention Group (n=10)</th>
<th>Control Group (n=10)</th>
<th>All participants (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>77.80 (10.63)</td>
<td>76.80 (4.96)</td>
<td>77.30 (8.09)</td>
</tr>
<tr>
<td>Range</td>
<td>62-93</td>
<td>69-86</td>
<td>62-93</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (%)</td>
<td>1 (10)</td>
<td>4 (40.0)</td>
<td>5 (25)</td>
</tr>
<tr>
<td>Female (%)</td>
<td>9 (90)</td>
<td>6 (60.0)</td>
<td>15 (75)</td>
</tr>
<tr>
<td><strong>MMSE score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>25.50 (3.17)</td>
<td>23.50 (3.50)</td>
<td>24.50 (3.41)</td>
</tr>
<tr>
<td>Range</td>
<td>21-29</td>
<td>18-28</td>
<td>18-29</td>
</tr>
<tr>
<td><strong>Stage of Dementia</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild (%)</td>
<td>10 (90)</td>
<td>8 (80)</td>
<td>18 (90)</td>
</tr>
<tr>
<td>Moderate (%)</td>
<td>0</td>
<td>2 (20)</td>
<td>2 (10)</td>
</tr>
<tr>
<td><strong>Dementia diagnosis</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Alzheimer’s Disease (%)</td>
<td>6 (30)</td>
<td>4 (20)</td>
<td>10 (50)</td>
</tr>
<tr>
<td>Vascular Dementia (%)</td>
<td>1 (5)</td>
<td>2 (10)</td>
<td>3 (15)</td>
</tr>
<tr>
<td>Mixed Dementia (%)</td>
<td>0</td>
<td>4 (20)</td>
<td>4 (20)</td>
</tr>
<tr>
<td>Dementia unspecified type (%)</td>
<td>4 (20)</td>
<td>0</td>
<td>4 (20)</td>
</tr>
<tr>
<td><strong>Anti-dementia medication</strong></td>
<td></td>
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</tr>
<tr>
<td>Prescribed (%)</td>
<td>4 (20)</td>
<td>5 (25)</td>
<td>9 (45)</td>
</tr>
<tr>
<td>Not-prescribed (%)</td>
<td>3 (15)</td>
<td>2 (10)</td>
<td>5 (25)</td>
</tr>
<tr>
<td>Unknown (%)</td>
<td>4 (20)</td>
<td>3 (15)</td>
<td>7 (35)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
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<tr>
<td>White British (%)</td>
<td>8 (40)</td>
<td>9 (45)</td>
<td>17 (85)</td>
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<td>White European (%)</td>
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<td>0</td>
<td>1 (5)</td>
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<tr>
<td>Asian (%)</td>
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<td>1 (5)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Black Caribbean (%)</td>
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<td>0</td>
<td>1 (5)</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
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<tr>
<td>Widowed (%)</td>
<td>2 (10)</td>
<td>5 (25)</td>
<td>7 (35)</td>
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<td>Married (%)</td>
<td>5 (25)</td>
<td>5 (25)</td>
<td>10 (50)</td>
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<tr>
<td>Single (%)</td>
<td>1 (5)</td>
<td>0</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Divorced (%)</td>
<td>2 (10)</td>
<td>0</td>
<td>2 (10)</td>
</tr>
</tbody>
</table>
Examining Aim 1

Feasibility

Feasibility was evaluated in accordance with the pre-specified criteria as outlined in the full clinical trial protocol (ISRCTN16382776; Aguirre et al., 2017)

a) Recruitment rate

The CONSORT diagram shown in Figure 1 details the flow of participants recruited to the study and reasons for exclusion. A total of 41 people with dementia were recruited from the two memory clinics. A high proportion of these n = 18 (43.9%) did not reach the inclusion criteria for the study. Nine people (21.9%) had scores that fell below 9 on the PHQ-9 outcome measure. Two participants moved out of the area before the group started and one participant declined to participate as they did not wish to attend a group. The final sample of 20 participants is considerably lower than the proposed recruitment target of 32 participants between the period June 2016 to September 2016. This indicates that it was not feasible to recruit enough participants within this time-frame.

b) Retention rate

The intervention was well attended. All participants allocated to the intervention group attended the pre-session with their carers. The intervention protocol specified an acceptable completion rate would be 55% of participants attending four or more of the eight sessions. Findings indicated retention rates were higher than this, with the mean attendance of the eight intervention sessions of 6.3 (SD = 2.63) and a high proportion of participants (80%) attended six or more sessions. One participant dropped out of the MBCT intervention in each memory
clinic site. One of these decided that they preferred to attend a CST intervention delivered in a memory clinic closer to their home. The other participant reported that they did not like the intervention and they therefore declined to complete the post-intervention assessment. The overall rate of attrition between baseline and post-intervention assessments was low (5%).

c) Incidence of adverse events

There were no adverse events reported throughout the research study.

d) Acceptability of the MBCT programme

The acceptability of the MBCT programme was assessed through qualitative interviews and conducted by an MSc student (Sarah Douglas). These findings are in the process of being analysed and they will be reported separately.

The adherence to mindfulness practice has also been evaluated;

Adherence to mindfulness practice

There were differences in how useful staff experienced the between session support calls across the two memory clinics. In memory clinic 1, all except for one participant were able to be contacted each week. Facilitator feedback indicated that the support calls helped to remind participants to practice the home mindfulness exercises. It was also felt that the support calls managed any anxieties associated with attending the group (e.g. one participant thought they were talking too much) and built rapport with the group facilitators to minimise dropouts. However, in memory clinic 2 staff did not find the weekly support calls to be particularly useful as
they led to any greater adherence to the home mindfulness practice and they were therefore discontinued early on.

Overall, there was low adherence to the home mindfulness practice however this varied across the two memory clinics. In memory clinic 1, it was reported that one participant practiced the formal mindfulness exercises 2-3 times a day and one participant once or twice a week. In memory clinic 2, only one participant practiced the formal mindfulness exercises between group sessions.

Feedback from course facilitators indicated that the more concrete group exercises (e.g. body scans, mindful stretching, and hearing exercises) were more helpful than exercises that were more abstract (e.g. raisin exercise). Although it was anticipated that home practice log sheets would be recorded, in both memory clinics staff reported that they were too challenging for participants to complete and they were therefore discontinued.

e) Acceptability of the outcome measures

The proportion of missing data for the QoL-AD and MMSE was low with 5% of data missing. The proportion of missing data for the measures of depression and anxiety reported by Noone (2017) was also low (10%). Carer data was not available for a high proportion of participants (65%) due to participants either living alone without caregiver support available to take part or in some instances carers declined to participate.

Blinding of Assessors

It was intended that assessors would be blinded as to which treatment group participants had been allocated. However, inevitably some participants disclosed this information at the post-intervention assessment. From a total of 20 assessments, the
assessors became unblinded in a high proportion of these n = 8 (40%) and were possibly unblinded in 30% of assessments.

Examining Aim 2 – Quality of life and Cognition

Analysis of outcome measures

Data from the QoL-AD and the MMSE outcome measures were analysed for the presence of outliers and to determine whether scores were normally distributed. No outliers were detected and the data met all assumptions of normality, homogeneity of variance and sphericity. A 2 x 2 mixed design ANOVA was used to analyse measures of quality of life and cognition with group (adapted MBCT intervention and TAU control) as the between-subject factor and time (baseline and post-intervention) as the within-subject factor. A summary of these results is shown in Table 3.

Missing data

There was missing data for one participant (5%) on items of the QoL-AD and MMSE outcome measure. Little’s (1988) MCAR test was non-significant for both the QoL-AD ($\chi^2 = 16.91$, df = 17, p = .46) and MMSE ($\chi^2 = 19.00$, df = 17, p = .27) which indicates that there was no pattern to the missing data and it was missing completely at random. Missing data was imputed using the expectation-maximisation (EM) algorithm. Due to the low achieved sample size both imputed and non-imputed scores are reported.
Quality of Life

For the analysis of quality of life without data imputations, the main effect of time was not significant, $F(1, 17) = .44, p = .52$, $\eta^2_p = .03$. The main effect of treatment group was not significant, $F(1, 17) = 4.48, p = .05$, $\eta^2_p = .21$. There was no significant interaction between time and group, $F(1, 17) = 0.11, p = .74$, $\eta^2_p = 0.01$.

For the analysis of quality of life with data imputations, the main effect of time was not significant, $F(1, 17) = .38, p = .55$, $\eta^2_p = .02$. The main effect of treatment group was significant, $F(1, 17) = 5.77, p = .03$, $\eta^2_p = .24$. There was no significant interaction between time and group, $F(1, 17) = 0.75, p = .39$, $\eta^2_p = .04$.

There were no significant improvements in the quality of life of participants who attended the adapted MBCT intervention for both non-imputed and imputed data. Hypothesis 1, that there would be a significant improvement in the quality of life of participants who attended the MBCT intervention compared to those participants in the TAU control group was not supported.

Cognition

For the analysis of cognition without data imputations, the main effect of time was not significant, $F(1, 17) = 1.81, p = .20$, $\eta^2_p = .09$. The main effect of treatment group was not significant, $F(1, 17) = 2.70, p = .12$, $\eta^2_p = .13$. There was no significant interaction between time and group, $F(1, 17) = .80, p = .38$, $\eta^2_p = .04$.

For imputed MMSE scores, the main effect of time was not significant, $F(1, 17) = .15, p = .70$, $\eta^2_p = .01$. The main effect of treatment group was not significant, $F(1, 17) = 2.48, p = .13$, $\eta^2_p = .12$. There was no significant interaction between time and group, $F(1, 17) = 1.26, p = .28$, $\eta^2_p = .07$. 
There were no significant improvements in cognition of those participants who attended the adapted MBCT intervention for both non-imputed and imputed data. Hypothesis 1, that there would also be significant improvements to the cognition of participants who attended the MBCT intervention compared to the TAU control group was therefore not supported.
### Table 3. Changes in quality of life and cognition over time.

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Baseline scores Mean (SD)</th>
<th>Post-intervention scores Mean (SD)</th>
<th>Change from baseline</th>
<th>ANOVA</th>
<th>( F )</th>
<th>( P )</th>
<th>Effect size</th>
<th>( \eta^2 )</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>QoL-AD (+)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without imputations</td>
<td></td>
<td></td>
<td></td>
<td>Time</td>
<td>.44</td>
<td>.52</td>
<td>.03</td>
<td></td>
</tr>
<tr>
<td>MBCT Intervention</td>
<td>33.89 (6.29)</td>
<td>34.22 (6.24)</td>
<td>+0.33</td>
<td>Group</td>
<td>4.48</td>
<td>.05</td>
<td>.21</td>
<td></td>
</tr>
<tr>
<td>Control Group</td>
<td>29.10 (4.38)</td>
<td>30.10 (2.88)</td>
<td>+1.00</td>
<td>Interaction (Time x Group)</td>
<td>.11</td>
<td>.74</td>
<td>.01</td>
<td></td>
</tr>
<tr>
<td>With imputations</td>
<td></td>
<td></td>
<td></td>
<td>Time</td>
<td>.38</td>
<td>.55</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>MBCT Intervention</td>
<td>35.01 (6.92)</td>
<td>34.00 (5.93)</td>
<td>-1.01</td>
<td>Group</td>
<td>5.77</td>
<td>.03*</td>
<td>.24</td>
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</tr>
<tr>
<td>Control Group</td>
<td>29.10 (4.38)</td>
<td>30.10 (2.88)</td>
<td>+1.00</td>
<td>Interaction (Time x Group)</td>
<td>.75</td>
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<tr>
<td><strong>MMSE (+)</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without imputations</td>
<td></td>
<td></td>
<td></td>
<td>Time</td>
<td>1.81</td>
<td>.20</td>
<td>.09</td>
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<tr>
<td>MBCT Intervention</td>
<td>25.50 (3.17)</td>
<td>26.50 (2.55)</td>
<td>+1.00</td>
<td>Group</td>
<td>2.70</td>
<td>.12</td>
<td>.13</td>
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</tr>
<tr>
<td>Control Group</td>
<td>23.50 (3.50)</td>
<td>23.70 (4.22)</td>
<td>+0.20</td>
<td>Interaction (Time x Group)</td>
<td>.80</td>
<td>.38</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>With imputations</td>
<td></td>
<td></td>
<td></td>
<td>Time</td>
<td>.15</td>
<td>.70</td>
<td>.01</td>
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</tr>
<tr>
<td>MBCT Intervention</td>
<td>25.50 (3.17)</td>
<td>26.50 (2.55)</td>
<td>+1.00</td>
<td>Group</td>
<td>2.48</td>
<td>.13</td>
<td>.12</td>
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</tr>
<tr>
<td>Control Group</td>
<td>24.18 (2.93)</td>
<td>23.70 (4.22)</td>
<td>-0.48</td>
<td>Interaction (Time x Group)</td>
<td>1.26</td>
<td>.28</td>
<td>.07</td>
<td></td>
</tr>
</tbody>
</table>

* significant at \( p < .05 \) level  
(+): improvement is based on higher scores  
QoL-AD = Quality Life-Alzheimer’s Disease; MMSE = Mini Mental State Examination
**Discussion**

**Summary of the main findings**

The present study demonstrates that an adapted MBCT intervention for people with mild dementia was feasible in terms of high attendance to the intervention and low levels of attrition. It was not feasible to recruit enough participants within the recruitment time-frame. No significant improvements in measures of quality of life and cognition were identified and there is currently a lack of research evidence to recommend this MBCT intervention for people with dementia.

**Interpretation of findings and connection to previous literature**

These findings may reflect a true lack of difference between groups in the measures of cognition and quality of life. However, the low sample size meant that the study was underpowered which might have affected the results. The low sample size may be attributed to some of the challenges associated with recruiting participants from memory clinics in the community, and many participants were also excluded because they did not reach inclusion criteria on the PHQ-9. However, given the small effect size for both measures, the results suggest that a very large sample would be needed in order to achieve significance. In addition, as this was a feasibility pilot and not a full-scale RCT, it was not necessarily anticipated that this study would be adequately powered.

Assuming that these results do indeed reflect a true lack of difference between groups there are some possible explanations for this. It may be that the amount of mindfulness practice was too infrequent due to the low reported compliance with home practice and through having weekly, instead of biweekly sessions. An optimum treatment ‘dose’ may be the delivery of biweekly mindfulness sessions in accordance with the previous research by Churcher Clarke et al., (2017) which demonstrated
significant improvements in quality of life. Research from the wider literature has also
highlighted that biweekly CST led to significant improvements in quality of life
whereas weekly CST did not (Cove et al., 2014; Spector et al., 2003). However, as
Cove et al., (2015) highlights, it would not have been feasible to deliver biweekly
sessions in the current study, and given the current demands on staff resources within
the NHS, it is unlikely that this would be feasible in clinical practice either.

There are further explanations for the non-significant findings. There was a
significant difference between groups for imputed quality of life scores and also what
appears to be slightly higher levels of cognition for participants in the MBCT group.
This may have affected results through regression to the mean, as it may have been
more difficult to achieve significant changes in the measures of quality of life and
cognition when participants in the MBCT group had higher scores at baseline (Barnett,
van der Pols & Dobson, 2005).

It is also worth considering whether the measures selected were sensitive
enough to detect potential benefits from the MBCT intervention. In terms of the
MMSE, it might be argued that as this MBCT intervention was not designed to exercise
cognitive skills, as with other psychosocial interventions in dementia (e.g. CST;
Spector et al., 2003), we would not necessarily expect to see improvements in
cognitive functioning. Furthermore, although the QoL-AD has been identified as the
outcome measure of choice for assessing quality of life in dementia (Moniz-cook et
al., 2008), a systematic review of quality of life measures used in dementia has
highlighted that it is not very sensitive to change (Ready & Ott, 2003), and perhaps
this measure did not capture some subtle improvements in other discrete areas of
functioning (e.g. social relationships).

In the absence of qualitative findings, it remains unclear whether people with
dementia found the MBCT intervention acceptable. Furthermore, the lack of
significant improvements in measures of quality of life and cognition is similar to findings from previous RCTs examining psychosocial group interventions for people with dementia (e.g. Charlesworth et al., 2016; Cove et al., 2015) and systematic reviews in this field have also indicated mixed findings (Cooper et al., 2012; Olazaran et al., 2010; Payne, 2017).

**Strengths and Limitations**

There are some key strengths associated with this study. The study used a rigorous RCT design to evaluate a new, adapted MBCT intervention for people with mild dementia and depression. It is, to our knowledge, the first RCT evaluation of a MBCT intervention adapted for people with dementia. The intervention was well attended with low levels of attrition and no adverse events were reported over the course of the intervention. The high levels of control provided through the RCT design increased the internal validity of the study. However, the relatively homogenous group of participants recruited, who were almost exclusively white British, and in the early stages of dementia, may limit the generalisability of findings. The recruitment target was also not met and the study was therefore underpowered.

It is possible that a lack of carer support may have contributed to the low compliance with home mindfulness practice. Previous research into mindfulness interventions for people with dementia (e.g. Paller et al., 2015) has highlighted some of the benefits of mindfulness for person with dementia and their carers, and carers also helped to support people to learn and practice mindfulness skills. Whilst we hoped that carers would support participants with home mindfulness practice, many participants did not have a carer available to take part. However, the inclusion of people with dementia without carers is also a strength of this study, as this population are often excluded from research into psychosocial interventions in dementia (e.g.
Charlesworth et al., 2016; Cove et al., 2015; Laakkonen et al., 2016; Quinn et al., 2016). Our less restrictive inclusion criteria, in which both participants with and without carers were able to take part, may also be more representative of the diversity of the clients seen in clinical practice.

It remains unclear which specific components of the MBCT intervention people with dementia found more, or less, beneficial. It is possible that some of the more subtle benefits of the MBCT intervention, such as increased social support, were not detected through the RCT design (Dugmore, Orrell & Spector, 2015; Lawrence, Fossey, Ballard, Moniz-Cook & Murray, 2012; Mason, Clare & Pistrang, 2005). Personal characteristics of participants may also act as mediators as to whether or not psychosocial interventions are beneficial (Orrell et al., 2017).

Except for external supervision, this study did not include other ways to monitor treatment fidelity, such as live observation, audio-recording sessions or the use of standardised adherence checklists (e.g. Mindfulness-Based Interventions Teaching Assessment Criteria; Crane et al., 2013). Furthermore, although we would expect natural variations across sites in practice based research, it is important to again highlight that there were key differences in the intervention delivery between the two memory clinics, particularly in terms of the use of staff support calls. It is possible that these slight differences in the intervention delivery may have impacted in some way upon the effectiveness of the intervention (Breitenstein et al., 2010; Vernooij-Dassen & Moniz-Cook, 2014).

A further limitation of these findings relates to differences in the baseline quality of life scores between the two groups which were not taken account for in the statistical analyses. For example, perhaps stratification or minimisation could have been performed in order to achieve greater balance in quality of life at baseline in light of the higher quality of life found in the intervention group. Furthermore, in the
statistical analysis perhaps an ANCOVA could have been performed to take account for these differences. These are important considerations for future full RCT research in this area.

Clinical implications and areas of further research

There is as yet a lack of research evidence to recommend this adapted MBCT intervention for people with mild dementia. It is recommended that an adequately powered, full RCT is conducted and that further adaptations are made to the MBCT protocol through ongoing consultation with people with dementia and the group facilitators. It is recommended that further ways to monitor the treatment fidelity (live observation, audio-recording sessions and standardised adherence checklists) are used in further research. Furthermore, although feasibility was reported in this present study in accordance with pre specified criteria as outlined in the trial protocol, external criteria could have also been used to assess feasibility, for example, a CONSORT checklist which focuses specifically on feasibility and pilot studies (e.g. Eldridge et al., 2016). This is an important consideration for future research.

It is hoped that the qualitative findings of the MSc student Sarah Douglas, in which interviews were conducted with people with dementia who attended the MBCT group may help to further delineate which personal characteristics of participants and other factors act as mediators for the mindfulness intervention being more, or less, helpful. This will help towards further adaptations to the mindfulness intervention protocol.

Conclusions

This is the first pilot RCT of an adapted MBCT intervention for people with mild dementia and depression. Although the intervention was feasible in terms of
attendance to the intervention and levels of attrition, there is currently a lack of research evidence to recommend this adapted MBCT intervention for people with dementia. Future RCTs should be adequately powered with a more explicit focus on the specific components of mindfulness intervention or the personal characteristics of people with dementia which relate to enhanced or diminished efficacy.
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internal medicine, 16*, 606-613.


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Part Three: Critical Appraisal
**Introduction**

This critical appraisal reflects on the process of undertaking the research project outlined in part two. This includes a reflection on some of the challenges and strengths associated with the study, with a particular focus on its design, feasibility, the assessment process, and the personal and professional journey through research.

**Research design**

It was initially proposed that part two of the thesis would report a mixed methods design to evaluate the adapted MBCT intervention, to incorporate both the thematic analysis of interviews conducted with people with dementia and the quantitative analysis of measures of quality of life and cognition. However, due to some delays with the start of the MBCT groups, through ongoing discussion during supervision it was decided that it was no longer feasible to conduct and analyse interviews within the allocated time-frame. Part two therefore only reports the quantitative findings of measures of quality of life and cognition, and qualitative interviews were conducted and reported separately, by an MSc student (Sarah Douglas).

Despite these changes, I believe that my initial vision for the project was somewhat ambitious. The scale of this project, as a pilot RCT, at times felt quite challenging. I learnt that a slight delay in one aspect of the project, for example, gaining ethical approval, or challenges associated with recruitment, significantly impacted when the MBCT groups were able to be delivered and consequently what was feasible within the allocated time-frame for a DClinPsy research project.

At the same time, whilst the level of control provided through a more rigorous RCT design was in many ways a strength of the research, and it afforded high levels of control and therefore increased internal validity, I wonder whether some more of
the subtle benefits of the intervention may not have been detected through this research design. Perhaps the use of a different research methodology, such as a case series design, or qualitative interviews, may have allowed a closer examination of some of the specific components of the MBCT intervention that people with dementia found more, or less, helpful, and would have furthered our understanding of the mechanisms as to ‘how’ and ‘why’ the intervention did, or did not, ‘work’ (Kazdin, 2007).

**Recruitment**

The most challenging aspect of this research project was recruitment. Despite being prepared in advance by our research supervisors that recruitment within a community setting may be difficult, it was much slower, and more arduous, than we initially anticipated, and the study therefore did not reach its initial recruitment target of thirty-two participants. The research study was consequently underpowered, which was disappointing. The recruitment process involved visiting MDT meetings at memory clinics and liaising with staff individually, via email or over the phone, to discuss the suitability of potential referrals. I was left frustrated that despite these efforts, and the time-spent travelling often long travel distances between different community sites, recruitment to the study remained low. The level of interest and enthusiasm which staff expressed during MDT meetings was not necessarily reflected in any increase in referrals to the study. I was mindful that following these meetings I found myself checking emails to see whether there were any new referrals to the group.

I wonder whether for some staff it might have been difficult to hold recruitment to our study in mind, given other ongoing service pressures and demands around the time of recruitment. For example, one memory clinic
relocated site, which staff acknowledged was, understandably, ‘disruptive’. There were of course other research projects to recruit to within the NHS Trust around the same time in addition to staff balancing the clinical demands, pressures, and responsibilities inherent to their everyday job role. With hindsight, I wonder whether visiting MDT meetings was the most effective way of recruiting participants. There were times when I presented details of the study towards the end of MDT meetings which often involved the team discussing complex clients, including issues of risk and safeguarding. I wondered whether recruitment to the group may have felt like some additional burden to staff.

Perhaps one way in which recruitment might be increased for future research in this area would be to offer mindfulness taster sessions for staff. In addition to providing another opportunity to discuss recruitment and the rationale for the study, research has also indicated some of the potential benefits of mindfulness for staff working within mental health settings, such as helping to protect against staff burnout (e.g. Baker et al., 2015). It is also possible that some staff may not have fully understood the relatively abstract concept of mindfulness, or been fully invested with the rationale to refer participants to the study, without having had the opportunity to engage and connect with it through their own personal mindfulness practice. Furthermore, research has highlighted the importance of building strong relationships with clinicians to aid recruitment (Patel, Doku, & Tennakoon, 2003). I believe that whilst in some ways this was achieved, perhaps having another opportunity to meet with staff, outside of the context of the MDT meeting may have helped to foster stronger relationships with staff and possibly improved recruitment too.

A challenge associated with recruiting via memory clinics is that people with dementia are often signposted to other services after they receive a
diagnosis. Recruitment may therefore have been enhanced through an ethical amendment to recruit directly via third sector organisations (e.g. Alzheimer’s UK), or perhaps by liaising with local GP surgeries or CMHTs. However, as this was a pilot feasibility RCT, our aim was to determine how feasible it was to recruit people from memory clinics in the early stages of dementia soon after receiving a diagnosis. Therefore, whilst recruiting through these other services may have possibly increased referrals, it was outside the remit and of the current study.

The successful recruitment of clients from psychiatric populations is also largely dependent on building effective therapeutic relationships and rapport with participants (Patterson, Duhig, Connell & Scott, 2014). I found this more of a challenge through being situated as an external researcher and not being employed full-time within a memory clinic. Later in the course of this research project I found myself working on clinical placement within an older adult service, and again placed in a familiar position of recruiting to different community groups being delivered within the service. Although I acknowledge that there are many differences and additional barriers associated with recruiting to a major research project and running groups within a clinical setting, I observed first-hand the great benefit of being embedded full-time within a service and the positive impact this had on recruitment. I also recognised that my experience of recruiting to this major research project, and the many lessons learned from this experience, was now helping to inform my clinical practice.

**Assessments**

There was some delay to the start of the MBCT group in memory clinic 2 and as a result, some participants who were referred had to wait a long time for
their initial baseline assessment. Through discussion during supervision, I
scheduled for fortnightly calls with participants as a way of building rapport,
engagement, and their retainment to the study. For these reasons, I found these
calls to be helpful.

There were a number of questionnaires for participants to complete as part of
the assessment and the assessment process was therefore quite long. To reduce
some of this potential impact and burden to people with dementia I made an effort
to ensure that participants felt comfortable and respected during the assessment and
we spent time discussing when they may like to take a break. I became aware that,
particularly with some of the more cognitively impaired or talkative participants,
assessments seemed to take much longer than I had initially planned. I maintained a
warm, empathic questioning style and gathered information in a person-centred,
collaborative way to ensure that the assessment did not feel rushed.

Although participants were reminded at the post-intervention assessments to
not disclose which treatment group they had been allocated to, for many participants
this proved a significant challenge and many participants were keen to speak about
their experience of attending the group. We monitored for this bias by recording our
judgements as to which treatment group we believed (or knew) participants had been
allocated and these findings indicated that staff became unblinded in 40% of
assessments and possibly unblinded in 30% of assessments. This highlights the
difficulty in remaining blinded as to which treatment group participants had been
allocated, and I imagine that this may be a particular challenge whilst conducting
research with people with dementia, who may find it more difficult to retain this
instruction at the start of the assessment.

I hoped that participants would not disclose which group they had been
allocated, though at the same time I was also inevitably curious and intrigued to hear
about their experience of the group when they did so. I noticed a dilemma between not wanting to close this conversation down too quickly, as I did not want participants to experience any shame through having forgotten this prior instruction, yet at the same time I did not want to open up the conversation up too much. I was reminded of this with one participant in particular, who, during her baseline assessment told me that that her main reason for wanting to attend the group was to be able to meet and socialise with other people with memory problems who were in a similar position to her. With much excitement, at the post-intervention assessment she told me that she had attended the group and got on well with one participant in particular. Unfortunately, as I had also previously assessed this participant, this was another participant that I had now become unblinded to which treatment group they were allocated, though I was also pleased that she had found the group helpful.

**Multiple perspectives**

I was aware that the scale of the project expanded throughout the course of the research, with multiple perspectives involved including people with dementia, their carers, research supervisors, memory clinic staff, the wider research team and external members of staff from the Oxford Mindfulness Centre (OMC). Early on in the research process we received external funding through OMC. I witnessed that whilst in many ways this funding was a great positive for the study, and it provided funding for participant transport which would otherwise have not been available, it also introduced a number of changes to the project, for example, the transition from an MBSR to an MBCT intervention.

Given that it is rare that research is conducted by a single person, I greatly appreciated this opportunity to work within a wider research team and the experience of undertaking this as a joint research project together with Deirdre
Noone. There was great value to moral support such as whilst attending the NHS REC meeting, which at the time was a daunting experience.

One of the key learning points for me throughout this research was the importance of close communication between all staff members within the research team. I experienced challenges with a lack of time during the assessments, particularly with more cognitively impaired clients, and for some participants it was not possible to complete all ten outcome measures. With some participants, even some very brief outcome measures, such as the PHQ-9, took a very long time to complete. Unfortunately, as a result of some questionnaires not being able to be completed, this led to some loss of potential data. There were some sub-projects within the research design, including gathering data for a PhD student, and this missing data impacted on us gathering less data than we had initially planned and hoped. I recognise that with hindsight, I should have communicated some of these challenges in terms of a lack of time experienced during the assessments with all members of the research team much sooner, as we may have been able to problem-solved together as a research team it there were ways to address this, for example, additional support with the data collection, if this was available.

**Outcome measures**

I witnessed a conflict between the MBCT intervention being shown to be feasible and well attended, whilst at the same time the intervention demonstrating a lack of significant improvements in outcome measures of quality of life and cognition. I had also heard some positive feedback of the group through post-intervention assessments and by speaking with the course facilitators. This left
me wondering whether perhaps some of the potential benefits of the intervention may not have been fully captured through the choice of outcome measures selected for the study and whether they were the most appropriate for detecting clinical change. Indeed, this may be a challenge associated with mindfulness intervention research more generally, as the cultivation of mindfulness skills in itself does not necessarily focus on achieving certain goals or outcomes, and it may be that some of the potential benefits of mindfulness are in fact unquantifiable (Crane, 2009).

Both the QoL-AD (Logsdon Gibbons, McCurry & Teri, 1999) and the MMSE (Folstein et al., 1975) were selected as measures to assess the quality of life and cognitive functioning of participants. This decision was based on the measures selected for use in the previous research by Churcher Clarke et al., (2017) and through discussion with our research supervisors. However, it might be argued that because the mindfulness intervention was not particularly exercising cognitive skills, as with other psychosocial interventions in dementia such as CST (Spector et al., 2003) we would not necessarily expect to see any change in cognitive functioning. Furthermore, as Ready and Ott (2003) highlight, generic measures of quality of life such as the QoL-AD may not be the most sensitive to detect change.

There may have been other measures which would have been useful to report in the analysis, such as a mindfulness specific measure or a measure to monitor some of the wider systemic benefits of the intervention. For example, previous psychosocial intervention research (e.g. Charlesworth et al., 2016) has included a measure to assess change in the quality of the relationship between the person with dementia and the caregiver (e.g. Quality of Caregiver and Patient Relationship; QCPR; Spruytte, Van Audenhove, Lammertyn & Storms; 2002) and
demonstrated improvements in this areas. However, incorporating this measure
would also have some limitations too, as the recruited sample may also be less
inclusive, with only participants with carers eligible to take part.

**Journey through research with people with dementia**

I was initially drawn to this research project through my experience of being
with my grandmother who had dementia 15 years ago. I remember the many times
that I visited her care home and whilst staff on the ward were warm and supportive,
they seemed to lack the time and resources to deliver group activities on the ward.
The quality of life of my grandmother and the other people with dementia living in
the care home seemed to me, subjectively at least, to be quite poor. Within the family,
around the time we had conversations about the sense of the loss of my grandmother
and a grieving for the person that she used to be. Through some of my observations
with my grandmother on the care home, and this narrative of dementia within the
family, I recognise that I too was filled with a certain degree of hopelessness and
despondency about dementia.

My motivation to conduct research with people with dementia was captivated
through some of the dementia teaching and older adult lectures on the DClinPsy
course. I was captivated to hear about some of the benefits of psychosocial group
interventions (e.g. CST; Spector et al., 2003) for people with dementia and this,
together with an awareness of some of the potential benefits of mindfulness in a care
home setting through the previous research by Churcher Clarke et al., (2017), shifted
some of my early preconceptions and stereotypes that I perhaps held about dementia.
Along with some personal interest in mindfulness, and an awareness of the knowledge
and dementia expertise at UCL, drew me to this opportunity to learn more about
dementia and possibly another way of helping people with dementia.
During my literature review, I was particularly struck by the distinct lack of research which evaluated mindfulness interventions in people with dementia. My initial database searching highlighted that there was a proliferation of interventions aimed specifically at improving the quality of carers or staff of people with dementia, or what seemed to me to be an overreliance of proxy-ratings of quality of life rather than the direct involvement of people with dementia. I was reminded of the work of Kitwood (1997) and what he describes as ‘malignant social psychology’, a loss of personhood and invisibility for the person with dementia. I was motivated to conduct research to involve people with dementia, and to learn about some other ways of being with and supporting people with dementia through this research project.

**Conclusions**

I have been incredibly moved throughout this research journey by the many inspiring people with dementia that I have met. I recognise that in a number of ways, both personally and professionally, I have developed throughout this major research project, and I have enjoyed many aspects of the research despite some inevitable challenges along the way. There have been a number of learning points from my engagement with this research. Firstly, I have learnt about some of the challenges associated with recruitment, particularly to groups within a community setting, and I have reflected on some of the different ways in which recruitment may be enhanced in future research. Secondly, I have learnt first-hand the great value and importance of close communication with many different colleagues, and the value of undertaking research whilst being situated within a wider research team. Finally, at the end of this research I recognise that my understanding of conducting research and my knowledge of dementia has developed immensely. I hope to take forward into my future clinical work as a clinical psychologist working with people with dementia.
References


### Appendices

**Appendix A**

**Risk of Bias Tables**

**Amieva et al. (2016)**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
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<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>“Participants were randomly assigned through an independent and remote telephone randomisation service”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No allocation concealment procedures were described</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Of the 653 patients, 586 were followed up at three month visit (89.7%) 25 withdrawn, 42 missed assessment. Attrition rates similar across groups. Low risk due to low attrition.</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Protocol is referenced in the paper however trial protocol registration is not specified.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>“Participants and clinical staff were aware of the trial arm to which the study participants were allocated”</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>“all assessment interviews were done by physicians and psychologists blinded to allocation status.”</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No other potential bias reported</td>
</tr>
</tbody>
</table>

**Azcurra (2012)**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Participants were “randomly assigned”. No details of how random sequence was generated.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No allocation concealment procedures were described.</td>
</tr>
</tbody>
</table>
Incomplete outcome data (attrition bias)
All outcomes
Low risk
5 participants (out of 145) dropped out. Attrition rates were similar across groups. Low risk due to low attrition.

Selective reporting (reporting bias)
Unclear risk
No trial protocol reported. All stated outcomes were discussed.

Blinding of participants and personnel (performance bias)
All outcomes
High risk
Participants and personnel would have been aware of their condition.

Blinding of outcome assessment (detection bias)
All outcomes
Low risk
“the investigators remained ‘blind’ to the participants’ exposure to the intervention”

Other bias
Low risk
No other potential bias reported

---

Charlesworth et al., (2016)

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>“The SHIELD administrator enters participants’ variables into a remote web-based randomisation, which then allocates them in equal proportions between CSP or TAU on an individual basis.”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No allocation concealment procedures were described.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Retained 83% of participants at 12 months. We used Fisher’s exact tests and Mann-Whitney U-tests to compare baseline characteristics of those 241 pairs who completed the final follow-up and those 50 who withdrew before then. There were no significant differences in any demographic variable between groups”</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>Trial registered ISRCTN37956201. All outcomes specified in the paper were reported.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>“The nature of the interventions prevented us from blinding participants and providers to their allocated group”</td>
</tr>
<tr>
<td>Bias</td>
<td>Authors’ judgement</td>
<td>Support for judgement</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>--------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>“We blinded research interviewers by providing interventions independently of their assessments”</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No other potential bias reported</td>
</tr>
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<td></td>
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<tr>
<td><strong>Cove et al., (2014)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bias</strong></td>
<td><strong>Authors’ judgement</strong></td>
<td><strong>Support for judgement</strong></td>
</tr>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>“Participants were randomised using the block method to achieve equal group sizes and using Random Allocation Software version 1”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No allocation concealment procedures were described.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>9 dropped out (out of 68). “There were no significant differences in the proportion of completers and non-completers across the three conditions, and groups were well matched in baseline characteristics (age, sex, diagnosis etc.).” All outcomes specified in the paper were reported.</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Trial registration not reported in paper. All stated outcomes discussed.</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Participants and personnel would have been aware of their condition.</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>“assessors were blinded to treatment allocation”</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No other potential bias reported</td>
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<td></td>
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<tr>
<td><strong>Laakkonen et al., (2016)</strong></td>
<td></td>
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</tr>
<tr>
<td>Bias</td>
<td>Risk</td>
<td>Support for judgement</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
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<td>----------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Random sequence generation (selection bias)</strong></td>
<td>Low risk</td>
<td>“couples were randomised in blocks of 20. A person unrelated to the intervention telephoned a person at a randomisation centre...couples were randomly allocated using computer-generated random numbers’</td>
</tr>
<tr>
<td><strong>Allocation concealment (selection bias)</strong></td>
<td>Unclear risk</td>
<td>No allocation concealment procedures were described.</td>
</tr>
<tr>
<td><strong>Incomplete outcome data (attrition bias)</strong></td>
<td>Low risk</td>
<td>Total study attrition at 9 months was 5 couples (4%) – all in the control group. Low bias due to low attrition. All outcomes specified in the paper were reported.</td>
</tr>
<tr>
<td><strong>Selective reporting (reporting bias)</strong></td>
<td>Low risk</td>
<td>Study protocol 340/13/03/01/10. All outcomes specified in the paper were reported.</td>
</tr>
<tr>
<td><strong>Blinding of participants and personnel (performance bias)</strong></td>
<td>High risk</td>
<td>Participants and personnel would have been aware of their condition.</td>
</tr>
<tr>
<td><strong>Blinding of outcome assessment (detection bias)</strong></td>
<td>Low risk</td>
<td>Staff conducting the assessments were blinded to which treatment group participants had been allocated to. However, 'participants were eager to share their experiences. Thus...could not be kept entirely blinded”</td>
</tr>
<tr>
<td><strong>Other bias</strong></td>
<td>Low risk</td>
<td>No other potential bias reported</td>
</tr>
</tbody>
</table>

Logsdon et al., (2010)

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>High risk</td>
<td>“treatment condition was randomised in advance by assigning to start with either ESML or wait-list (WL) at the outset and then to alternate between conditions”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No allocation concealment procedures were described.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Of the 142 dyads who began the study, 136 (96%) completed follow-up. All outcomes specified in the paper were reported. “</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>No study protocol. All outcomes stated in paper were discussed.</td>
</tr>
<tr>
<td>Bias</td>
<td>Authors’ judgement</td>
<td>Support for judgement</td>
</tr>
<tr>
<td>---------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Participants and personnel would have been aware of their condition.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) All outcomes</td>
<td>High risk</td>
<td>Outcome measures conducted post intervention described as &quot;objective&quot;, however it is not clearly specified in the paper that blinding of outcome assessment occurred.</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No other potential bias reported</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>“Randomisation was made using an online secure system”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No allocation concealment procedures were described.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>6 out of 58 dropped out (all in control group)</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>Study protocol registration ISRCTN25079950. All outcomes specified in the paper were reported.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Participants and personnel would have been aware of their condition.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) All outcomes</td>
<td>Low risk</td>
<td>“data was gathered by a researcher who was independent from the clinical work and blind to which arm the participant had entered”</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No other potential bias reported</td>
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</tbody>
</table>

**Orrell et al., (2014)**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
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<tr>
<td>Bias</td>
<td>Low risk</td>
<td>Support for judgement</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>----------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Random sequence generation (selection bias)</td>
<td></td>
<td>“The random allocation sequence was computer generated and in the ratio of 1:1.”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No allocation concealment procedures were described.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>“followed up 218 participants (92% of 236; 96% of those still alive) at 3 months and 199 (84% of those still alive at 6 months”</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>Trial protocol registered ISRCTN26286067. All outcomes specified in the paper were reported.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Participants and personnel would have been aware of their condition.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>“masked researchers conducted initial and subsequent interviews…the statistician conducting the data analysis was also masked to group assignment”</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No other potential bias reported.</td>
</tr>
</tbody>
</table>

Quinn et al., (2016)

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>“Participants were randomised by an independent organisation (NWORTH: North Wales Organisation for Randomised Trials in Health) using a computer based algorithm.”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No allocation concealment procedures were described.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>One person with dementia dropped out between baseline assessment and follow-up. Low risk due to low attrition.</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>Trial protocol registered ISRCTN02023181. All outcomes specified in the paper were reported.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Participants and personnel would have been aware of their condition.</td>
</tr>
<tr>
<td>Bias</td>
<td>Authors’ judgement</td>
<td>Support for judgement</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>--------------------</td>
<td>----------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>High risk</td>
<td>“Participants were randomly allocated into treatment and control groups. The assessor ordered the names of the selected participants for each centre alphabetically and allocated numbers in sequence according to the total number to be randomised”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No allocation concealment procedures were described.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>97 (of 115) participants were assessed at follow-up.</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Trail registration not specified in paper. All stated outcomes in the paper were reported.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Participants and personnel would have been aware of their condition.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>“full assessments were conducted in the week prior to, and the week following, the intervention by the researcher masked to group membership”</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No other potential bias reported</td>
</tr>
<tr>
<td>Bias</td>
<td>Authors’ judgement</td>
<td>Support for judgement</td>
</tr>
<tr>
<td>-------------------------------------------</td>
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<td>-----------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>“Randomisation was carried out remotely by the NWORTH accredited Clinical Trial Unit”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No allocation concealment procedures were described.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>High risk</td>
<td>395 of 488 followed up at 3 months, 350 of 488 followed up at 10 month assessment. High attrition (over 20%). “Attrition was higher in the control group”</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td>Trial registration: ISRCTN42430123. All outcomes specified in the paper were reported.</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td></td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Participants and personnel would have been aware of their condition.</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>“Assessments, blind to treatment allocation, were carried out at baseline, three months and 10-months”</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No other potential bias reported</td>
</tr>
</tbody>
</table>
Appendix B

Adapted MBCT Protocol

MINDFULNESS BASED COGNITIVE THERAPY FOR DEPRESSION IN DEMENTIA

Introductory session

<table>
<thead>
<tr>
<th>Assign</th>
<th>Part 1 – Session with both participants and carers Music in background when they arrive – offer name tags</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Welcome and introductions * where are the toilets/fire exit.</td>
</tr>
<tr>
<td></td>
<td>Brief overview of the session - opportunity to get to know each other and ask any questions. Give you an idea of what we will be doing in the group.</td>
</tr>
<tr>
<td><strong>Ice breaker</strong></td>
<td>- Make a line in the room 1. make a line in the room - organise yourselves in order to how close you live to the building. 2. make a line with your experience of breathing exercises, meditation, mindfulness, yoga. *it doesn’t matter where you are in the line e.g. beginners mind - everything is new regardless of experience - every moment we have is new.</td>
</tr>
<tr>
<td></td>
<td>Ground Rules: e.g. confidentiality, phone off, being on time (if running late - still come - rather arrive late than not at all)</td>
</tr>
<tr>
<td></td>
<td>Be organised before you come in e.g. bring glasses if you need them.</td>
</tr>
<tr>
<td><strong>Mindfulness</strong></td>
<td>Mindfulness found to help people who feel low.</td>
</tr>
<tr>
<td></td>
<td>- When we have low mood – we may find that our mind is racing (we may thinking about the past or worrying about the future) – this can make us sad. Mindfulness is a way of managing that. We will be exploring this over the course of the group.</td>
</tr>
<tr>
<td></td>
<td>Clapping exercise: Clap your hands 4 times and hold them upright. Notice the sensations – how long do the sensations last? Are the sensations changing? Where are the sensations – fingers, palm, wrist, arm? Is the sensation tingly or like pins and needles. - tell them they can stop</td>
</tr>
</tbody>
</table>
- explain that the time they were focused on the present moment was mindfulness. They were focused on the present moment by focusing on the sensations in their hands.
- When they drifted off thinking about other things (e.g. dinner, going home), they were not mindful.

Explore responses to exercise.

Questions and answers about the material so far.

Break – rearrange chairs in two circle

FOFBOC
Enquiry about FOFBOC

Practicalities

- The backbone of mindfulness is the practice.
- Each week we will give you exercises to do at home during the week. These exercises will be on a CD? The tracks will be about 10 minutes long.
- Challenges – difficulties motivating yourself to do the practice. That is okay – we all have those thoughts e.g. ‘I can’t be bothered’. (Compare to running).
- What could help you do your daily practice? E.g. a time of the day (after breakfast), do you have a CD player? are you comfortable using it?
- Sharing the experience – joint practise
- Personal benefits – How mindfulness can help you. Help cope with stress, anxiety and low mood.
- Phone calls to support practice.
- It is a personal journey – everyone will find some sessions more useful than others.

Any questions?
*Any questions or comments from those starting the course next week?
*Any questions or comments from family members?

Carers
- If they would like to practice – the mindful way workbook.
- How can carers support with this process?

End with breathing exercise (balloon exercise).

Part 3 – Summary and close

Closing message and thanks
MINDFULNESS BASED CONGITIVE THERAPY FOR DEPRESSION IN DEMENTIA

Session 1
Awareness and Automatic Pilot

Title and Theme: ‘Waking up to this moment

On automatic pilot, it is easy to drift unawares into ‘doing mode’ and the ruminative thought patterns that can take us back into depression. Habitual doing mode also robs us of our potential for living life more fully. We can transform our experience by ‘intentionally’ paying attention to it in particular ways. We put into practice stepping out of automatic pilot by paying attention intentionally, mindfully. To eating, to the sensations of the body, and to aspects of everyday experience.

Taken from Mindfulness Based Cognitive Therapy for Depression (2012)

Pre-class preparation for facilitator: See teacher guidance and detailed session notes. (in lead up to start of group practice the meditations that will be led in this session)

List of materials:
- Flip chart, pens
- Plain paper, pens (box with materials for use each week)
- Folder, hand-outs
- Posters if using – parachute,
- CD’s for distribution
- CD player. Projector if required

Agenda and guidance for facilitators

<table>
<thead>
<tr>
<th>Assign</th>
<th>Description</th>
<th>Time allocated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Welcome – name tags – housekeeping</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FOFBOC – on arrival – use as grounding practice.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ground rules – respect, confidentiality, timeliness, keeping us informed, taking care of yourself. No expectation to speak. can speak to us separately if required. Write on flip chart.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Introductions: in pairs and then in group.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overview of Course (review) – format, what to expect.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expectations: ask group members to briefly share expectations. ‘’what would you like to take away from the course’’. Note on flip chart and keep for review towards end of course. Expectations of participants - commitment to group. Importance of home practice.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
You could ask each member to tell the group “one thing that you would like to get out of this experience that would make it worthwhile for you?” (Follow with folding flip chart of individual papers to illustrate suspension of expectations, allowing opportunity to link to beginner mind).

Weaving your parachute – share JKZ words and relate to course and practice “Make sure you weave your parachute every day, rather than leave it to the time you have to jump out of the plane.”

**Concept of SCAFFOLD** – Explain to group that each week will add to the learning, a process of building as we go. Use of recaps and summaries will help consolidate learning. Scaffolding in this way will allow for greater freedom to explore experience in confidence of being held together.

Week 1 – the beginning (the first glimpse, looking through the window: understanding the mechanisms at play (autopilot: minds tendency to chatter): sowing the seed and starting the process of building capacity for mindful attention.

**PRACTISE 1: Raisin Exercise** (provide only limited introduction/information). See script.

**Rationale:** see handout ‘the humble raisin’ – what the raisin practice teaches us.

**Feedback** – split into groups of 2/3. Share experience of practice. Encourage to consider the layers of experience e.g. ‘what did you notice (body, thoughts and emotions)’. Share with larger group. Consider use of one word feedback if group not forthcoming. What is felt, seen, smelled, heard and tasted

See facilitators guide: the process of Inquiry - but in week one you are simply beginning the process and so any inquiry is likely to be relatively simple.

**Break**
<table>
<thead>
<tr>
<th><strong>PRACTISE:</strong> ‘taking your seat’ followed by 10 minute Body scan using similar language to CD.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rationale:</strong> see handout ‘learning that comes from body scan’. Keep simple and short for this group as too much too soon could cause aversive reaction. Issues re: attention/concentration also need to be considered.</td>
</tr>
<tr>
<td><strong>Feedback</strong> – split into groups of 2/3. Share experience of practice. Encourage to consider the layers of experience e.g. ‘what did you notice (body, thoughts and emotions)’. Share with larger group. Consider use of one word feedback if group not forthcoming.</td>
</tr>
<tr>
<td><strong>Reflection on Theme:</strong> Connecting practice to session theme. Overview of automatic pilot. Relationship between automatic pilot and mood. Learning that comes from both practices undertaken in session (raisin and body focus). Possible videos (cited on Palouse meditation website with permission to download and view). Joshua bell plays violin. <a href="https://www.youtube.com/watch?v=9gti4JFwP_o&amp;index=2&amp;list=PLbiVpU59JkValOIEIo2Y65mBopHCjKvBo">https://www.youtube.com/watch?v=9gti4JFwP_o&amp;index=2&amp;list=PLbiVpU59JkValOIEIo2Y65mBopHCjKvBo</a> Reflect on how cultivating present moment awareness through mindful practice can help wake us up from auto pilot and thus release us from habits that hinder and/or harm our well-being.</td>
</tr>
<tr>
<td><strong>Handout:</strong> distribute handouts. Review contents briefly.</td>
</tr>
</tbody>
</table>
**Home Practice:** discuss and consider barriers and challenges to undertaking practise.

‘What may stop you from practicing?’

‘What can you do to make space and time to undertake practise?’

‘Do you have any questions or concerns?’

- Formal: brief body scan (CD 1 -track 1). 6 out 7 days if possible.
- Mindfulness of a routine activity – Instruction: ask participants to turn to person next to them and pick an activity that they are going to engage in mindfully.
- Habit releaser – spend a moment reflecting on something you might do differently.

One Mindful moment or one mindful mouthful.

Remind participants that this is not compulsory but evidence highlights importance of practice to promote change. Consider creative ways to overcome barriers or design practice around them. May require individual discussion immediately after session. Consider/discuss use of reminders e.g. phone calls, text messages to patient or carer.

‘weaving your parachute’

No right or wrong

No success or failure ‘just sowing the seeds’

**Review/session summary:** What will you take away from today? First opportunity to present the ‘parachute’.

Breath focus – one minute breathing space leading into poem – ‘If I had my life to live over’ – by Nadine Stair

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**MINDFULNESS BASED COGNITIVE THERAPY FOR DEPRESSION IN DEMENTIA**

**Session 2**

**Living in Our Head**

**Theme: Befriending the body**

In doing mode we "know about" our experience only indirectly, conceptually, through thought. This means that we can easily get lost in rumination and worry. Mindfulness of the body provides an opportunity to explore a new way of knowing directly, intuitively – "experientially". Experiential knowing is a way to be aware of and pleasant experiences without getting lost in ruminative thought. Already,
most participants will be experiencing some difficulties in their practice. These difficulties offer precious opportunities to practice letting go of thinking and to connect with direct awareness of the body.

Taken from Mindfulness Based Cognitive Therapy for Depression (2012)

Pre-class preparation for facilitator: See teacher guidance and detailed session notes. (as before follow the home practise guidance along with rest of group and in addition Practice the meditations that will be led in this session)

List of materials:
- Flip chart, pens
- Plain paper, pens
- Hand-outs
- Posters – body outline; scenario written out: walking across the street
- CD player

Agenda and guidance for facilitators

<table>
<thead>
<tr>
<th>Assign</th>
<th>Description</th>
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<tbody>
<tr>
<td>Grounding Practice: Standing or sitting (dependent on group) ‘allowing yourself to arrive.</td>
<td></td>
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<tr>
<td>(SCAFFOLD) - RECAP: use summary sheet from week 1: last week we started our journey: it began with a glimpse of the workings of our mind (autopilot: minds tendency to chatter): sowing the seed and starting the process of building capacity for mindful attention. How easily we miss things because we are in ‘doing mode’ in autopilot. Prop: put in view summary poster with key themes: STONE SOUP – demonstrates how it takes a ‘process’ for something to evolve. Allowing things to emerge rather than forcing them.</td>
<td></td>
</tr>
<tr>
<td>PRACTISE 1: body Scan as on CD</td>
<td></td>
</tr>
<tr>
<td>Rationale: see handout</td>
<td></td>
</tr>
<tr>
<td>Feedback – split into groups of 2/3. Share experience of practice. Encourage to consider the layers of experience e.g. ‘what did you notice (body, thoughts and emotions)’. Share with larger group. Consider use of one word feedback if group not forthcoming.</td>
<td></td>
</tr>
<tr>
<td>You could use an outline of the body to log people’s experience, poster? See facilitators guide: the process of Inquiry</td>
<td></td>
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<tr>
<td>Home practice Review : if people are struggling illustrate how struggle is human, necessary and not harmful to process. Use: STONE SOUP – demonstrates how it takes a ‘process’ for</td>
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<thead>
<tr>
<th>Time allocated</th>
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<td>5</td>
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</tbody>
</table>
something to evolve. Allowing things to emerge rather than forcing them.

See facilitators guide: the process of Inquiry

<table>
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<tr>
<th>Break</th>
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</table>

**Teaching/ACTIVITY** : Thoughts and feeling exercise:  
Either role play, read or use poster of the following scenario:

“You’re walking down the street and coming toward you, on the other side of the street you see someone you know. You smile and wave but the person doesn’t seem to notice and walks on by. What thoughts pop into your head? What emotions and what body sensations?” (draw on relationship between situation, thoughts, feelings).

See script and outline for details on feedback.

**Reflection on Theme**: Connecting practice to session theme.  
Practice: the body scan helps reveal the doing mode: the body holds and expresses emotions. We can feel through our body, the body reacts to the mind it also feedbacks to the brain which can fuel our worries fears etc.

As we learn to focus on the body, the clearer we are able to see the chatter of the mind.

Illustrate feedback loop (use cognitive triangle)  
Reflect on Stress response  
Consider use of Body Map (link back to picture of body where body holds emotion)

head nodding study example if time permits

‘to cultivate mindfulness truly, we need to become fully integrated with our body once more’ (Frantic world pg: 95)

<table>
<thead>
<tr>
<th>PRACTISE: 10 minute sitting – The Breath</th>
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</table>

**Rationale**: see handout

**Feedback** – split into groups of 2/3. Share experience of practice. Encourage to consider the layers of experience e.g. ‘what did you notice (body, thoughts and emotions)’. Share with larger group. Consider use of one word feedback if group not forthcoming.

**Handout**: distribute handouts. Review contents briefly.

**Home Practice**: Discuss and consider barriers and challenges to undertaking practice.  
‘What may stop you from practicing?’  
‘What can you do to make space and time to undertake practice?’ |

20 mins
MINDFULNESS BASED COGNITIVE THERAPY FOR DEPRESSION IN DEMENTIA

Session 3
Gathering the Scattered Mind

Theme: befriending the breath (MBCT – Ca)

The mind is often scattered and lost in thought because it is working away in the background to complete unfinished tasks and strive for future goals. Instead, we
need to find a way to intentionally “come back” to the here and now. The breath and body offer an ever present focus on which we can reconnect with mindful presence, gather and settle the mind and ease ourselves from doing into being.

Taken from Mindfulness Based Cognitive Therapy for Depression (2012)

**Pre-class preparation for facilitator:** See teacher guidance and detailed session notes. (as before follow the home practise guidance along with rest of group and in addition Practice the meditations that will be led in this session)

- List of materials:
  - Flip chart, pens
  - Plain paper, pens
  - hand-outs
  - Posters -
  - CD player

**Agenda and guidance for facilitators**

<table>
<thead>
<tr>
<th>Assign</th>
<th>Description</th>
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<tbody>
<tr>
<td>Grounding practice: replaced with Five-minute seeing (or hearing) exercise and review (popcorn)</td>
<td></td>
<td>7</td>
</tr>
<tr>
<td>SCAFFOLD/RECAP: Session summary from week 2. key points poster or power point: Introducing the session theme for week 3.</td>
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<td>5</td>
</tr>
<tr>
<td>PRACTISE 1: 10-15 minute sitting meditation (awareness of breath and body; how to respond to intense physical sensations)</td>
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<td>10 + 15 (25)</td>
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</table>

**Rationale:** deliberately bringing awareness to the body in this way works on a number of levels: learning to sustain attention, introducing flexibility, noticing the connection between mind and body. By coming out of our head and into our body we are able to ground ourselves. Starting with the breath and then expanding that awareness to the rest of the body.

**Feedback** – split into groups of 2/3. Share experience of practice. Encourage to consider the layers of experience e.g. “what did you notice (body, thoughts and emotions)” Share with larger group. Consider use of one word feedback if group not forthcoming.

See facilitators guide: the process of Inquiry

**Home practice review:** including body scan; mindfulness of the breath; routine activity habit releaser and pleasant experiences calendar; | | 10 |
See facilitators guide: the process of Inquiry

<table>
<thead>
<tr>
<th>Break</th>
<th>10</th>
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<tbody>
<tr>
<td>PRACTISE: 2 Three step breathing space and review</td>
<td>5</td>
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</tbody>
</table>
| PRACTISE: 3 Mindful Stretching  
Rationale:  
Feedback – brief feedback in large group | 10 |
| **TEACHING - Reflection on Theme:** Connecting practice to session theme.  
As we continue our journey, our practise begins to reveal the busyness of the mind. We begin to see how it is scattered here and there. We come once again to the breath – intentionally, as it offers us the opportunity to be focused and gather our scattered mind.  
Analogy of the ‘rumour mill’ the minds running commentary is just like this. Might be true, might not but it continues to get passed on, round and round. (see frantic world page 136)  
Analogy of ‘windmill of the mind’ – play song? Use image? | |
| **Handout:** distribute handouts. Review contents briefly.  
Setting up unpleasant experiences calendar | |
| **Home Practice:**  
Discuss and consider barriers and challenges to undertaking practice.  
‘What might stop you from practicing?’  
‘What can you do to make space and time to undertake practice?’  
‘Do you have any questions or concerns?’ | |
| • Formal: mindful movement meditation (8 minutes) followed by Breath a body meditation (8 minutes) | |
| • Unpleasant experiences calendar - a different experience each day; | |
| • three-step breathing space three times daily | |
| • Mindfulness of a routine activity – different to previous week. | |
| • Habit releaser – valuing your entertainment – rather than doing it as you usually would. See instruction sheet. | |
MINDFULNESS BASED COGNITIVE THERAPY FOR DEPRESSION IN DEMENTIA

Session 4
Recognising Aversion

Theme: Staying Present: (becoming aware)

The skill of “coming back” needs to be complemented by seeing more clearly what “takes us away” into doing, rumination, mind wandering, and worry. We begin the experiential investigation of “aversion”, the mind’s habitual reaction to unpleasant feelings and sensations, driven by the need not to have these experiences, which is at the root of emotional suffering. Mindfulness offers a way of staying present by giving another way to view things: it helps us take a wider perspective and relate differently to experience.

Taken from Mindfulness Based Cognitive Therapy for Depression (2012)
Agenda and guidance for facilitators

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<th>Assign</th>
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<tr>
<td></td>
<td>Five-minute seeing or hearing exercise.</td>
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<td><strong>SCAFFOLD/RECAP:</strong> summary/key points poster or power point from session 3:</td>
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<td></td>
<td>Introducing the session theme for week 4.</td>
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<td><strong>PRACTISE 1:</strong> 15 minutes meditation – awareness of breath, body, sounds, then thoughts and choiceless awareness (opening up to whatever comes up/to experience)</td>
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<td>See script. Following seamlessly into reading a poem such as wild geese</td>
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<td><strong>Rationale:</strong> to be able to come back to the present we need to observe the processes that take us away. In this meditation we begin with the breath but we then expand our awareness to the body, to sounds and our thoughts. Noticing them, observing/staying with them and allowing them to just be as they are. At this stage in the course we are beginning to expose the ‘rumour mill’. Helps us to begin to recognise the processes that take us away from this moment and possibly help us to stop the spiraling.</td>
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<td></td>
<td>Read Wild Geese and link to idea of ‘spacious awareness’ and opening up to experience.</td>
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<tr>
<td></td>
<td><strong>Feedback</strong> – split into groups of 2/3. Share experience of practice. Encourage to consider the layers of experience e.g. ‘what did you notice (body, thoughts and emotions)’. Share with larger group. Consider use of one word feedback if group not forthcoming.</td>
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<td></td>
<td>See facilitators guide: the process of Inquiry</td>
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<tr>
<td></td>
<td><strong>Home practice Review:</strong> including mindful movement, sitting meditation, unpleasant experiences calendar, and three-step breathing space.</td>
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<tr>
<td></td>
<td>See facilitators guide: the process of Inquiry</td>
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<td></td>
<td><strong>Break</strong></td>
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</tbody>
</table>
**Reflection on Theme**: Connecting practice to session theme. Learning to respond rather than react.

**Teaching**: we are learning to relate differently to our experience. Sometimes this may mean staying with experience that we don’t like and not avoiding it like we have done or tend to do. The body helps us to do this, by grounding us, offering a resting place for our attention and by enabling us to be with the experience differently.

Defining the territory of depression and the role of automatic thoughts. Beginning the process of naming, understanding ‘symptoms’ and the way they manifest.

Brief reflection on depression criteria (although not likely to be as helpful with our group but use judgement and be creative) ask the group: What does this tell us? What do you notice or see?

Some reflection on ‘DEMENTIA’ is possibly also required here – how their response may be linked to their diagnosis, the existential issues and the uncertainty that it brings.

**PRACTISE: Mindful walking (see script)**

**Rationale**: formal meditation. Not all meditation has to be static.

**Feedback** – split into groups of 2/3. Share experience of practice. Encourage to consider the layers of experience e.g. ‘what did you notice (body, thoughts and emotions)’. Share with larger group. Consider use of one word feedback if group not forthcoming.

See facilitators guide: the process of Inquiry

**Checking in**: How is it going? – short group exercise to check in more generally. Use a physical exercise e.g.

Check the flower/tree – how is it going.

Do this in small groups or as larger group depending on time and energy level.

**Handout**: distribute handouts. Review contents briefly.

**Home Practice**: discuss and consider barriers and challenges to undertaking practice.

‘What might stop you from practicing?’

‘What can you do to make space and time to undertake practice?’

‘Do you have any questions or concerns?’

Formal: – breath and body meditation (track 4 - 8 minutes) and sounds and thought meditation (track 5 - 8 minutes) Three step breathing space- regular (three times a day)
Three step breathing space – responsive (whenever you notice unpleasant feelings). (track 8)

- Mindfulness of a routine activity – different to previous week.
- Habit releaser – pop out at a set time of day but without planning the activity itself. See what takes your fancy. People with dementia might struggle with this so may require adapting further depending on group.

One Mindful moment or one mindful mouthful.

Remind participants that this is not compulsory but evidence highlights importance of practice to promote change. Consider creative ways to overcome barriers or design practice around them. May require individual discussion immediately after session. Consider/discuss use of reminders e.g. phone calls, text messages to patient or carer.

‘weaving your parachute’
No right or wrong
No success or failure

<table>
<thead>
<tr>
<th>Review/session summary: What will you take away from today?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Three step breathing space. leading into poem – just for now by Danna Faulds</td>
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<tr>
<td><strong>Thanks and close session</strong></td>
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</table>

**MINDFULNESS BASED CONGITIVE THERAPY FOR DEPRESSION IN DEMENTIA**

**Session 5**
**Allowing – letting be**

**Theme: Allowing – letting be**

*Relating differently to an unpleasant feelings and sensations – allowing things to be as they already are.* We can disempower version by intentionally bringing to all experience a sense of ‘allowing’ it to be, just as it is, without judging it or trying to make it different. Such an attitude of acceptance embodies a basic attitude of kindness to experience. From this clear seeing we can choose what if anything, needs to change.

**Taken from Mindfulness Based Cognitive Therapy for Depression (2012)**
Pre-class preparation for facilitator: See teacher guidance and detailed session notes. (as before follow the home practise guidance along with rest of group and in addition Practice the meditations that will be led in this session)

List of materials:
- Flip chart, pens
- Plain paper, pens
- hand-outs
- Posters
- CD player

Agenda and guidance for facilitators

<table>
<thead>
<tr>
<th>Assign</th>
<th>Description</th>
<th>Time allocated</th>
</tr>
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<tbody>
<tr>
<td>Grounding practice - Short standing Meditation (mountain)</td>
<td>SCAFFOLD/RECAP: key points poster or power point, summary from session 4. Introducing the session theme for week 5. Up to this point emphasis has been on learning how notice, being aware of where the mind wanders and then bringing it back to the here and now. Using the breath to anchor but also as vehicle to move attention around. This has allowed a form of scaffold to be in place. Time to venture into broader territory?</td>
<td>5</td>
</tr>
<tr>
<td>PRACTISE 1: 10 minutes sitting practice awareness of breath body and thoughts; See script.</td>
<td>Rationale: allowing the exploration of and noticing the reactions we have to whatever thoughts, feelings, body sensations that arise introducing a difficulty within the practice and noting its effect on the body and reactions to it.</td>
<td></td>
</tr>
<tr>
<td>Feedback – split into groups of 2/3. Share experience of practice. Encourage to consider the layers of experience e.g. ‘‘what did you notice (body, thoughts and emotions)’’. Share with larger group. Consider use of one word feedback if group not forthcoming.</td>
<td>See facilitators guide: the process of Inquiry</td>
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<tr>
<td>Break</td>
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</table>
**Story of the King and his three Son’s** (see script and guidance on reflection) see page 291 of main text ‘end note’. Use questions listed there to support process of inquiry or teaching. ‘the ambiguous ending invites curiosity. Qu:Which of these possible attitudes was more likely to bring about lasting peace? Resignation or a welcoming/acceptance?

**Reflection on Theme**: Connecting practice to session theme. Learning to be with experience without judging or trying to change it any way. Cultivating such an attitude of acceptance is an important part of taking care and an important step towards seeing the need for change more clearly.

Some reflection on ‘DEMENTIA’ again is possibly also required here – link to discussion last week (how depression may be a reaction (an aversive one to the diagnosis) but there is a different place to stand – emphasising that Acceptance is not resignation.

Reading Rumi’s poem The Guest house – Discuss in pairs and then come to group. reflections

**PRACTISE**: Breathing space extended and review (see script and guidance)

**Rationale**: Until now we have used breathing space meditation on a regular and as needed basis. With the extended instruction, the aim is to see this as the thing to turn to whenever you feel troubled. Introducing the idea of acceptance and compassion.

**Linking to idea of Primary and secondary suffering. Concept of looking through a different lens? It’s not so much ‘what happens to you…but how you respond to what happens to you’.

**Feedback** – review in whole group.

See facilitators guide: the process of Inquiry

**Handout**: distribute handouts. Review contents briefly.

**Home Practice**: discuss and consider barriers and challenges to undertaking practice.

‘What might stop you from practicing?’
‘What can you do to make space and time to undertake practice?’
‘Do you have any questions or concerns?’

- Formal: breath and body meditation (track 4 - 8 minutes); OR
  Sounds and thought meditation (track 5 - 8 minutes)
  OR Exploring difficulty meditation (track 6 – 10

| 128 |
minutes). Two of the three options depending on group.
Three step breathing space - regular (three times a day)
Three step breathing space – responsive (whenever you notice unpleasant feelings). (track 8)

- Mindfulness of a routine activity – different to previous week.
- Habit releaser – taking time to sow some seeds or nurture a plant. Do this mindfully. This could also be the weeks routine activity. (Ellen Langer study – Harvard university. Increased well-being in elderly residents who were asked to care for something).

One Mindful moment or one mindful mouthful.

Remind participants that this is not compulsory but evidence highlights importance of practice to promote change. Consider creative ways to overcome barriers or design practice around them. May require individual discussion immediately after session.

‘weaving your parachute’
No right or wrong
No success or failure

Review/session summary: What will you take away from today? – (parachute group and individual) could use serenity prayer to summarise the theme.

Breath focus – one minute breathing space leading into poem ‘reply to Rumi’

Thanks and close session

MINDFULNESS BASED CONGITIVE THERAPY FOR DEPRESSION IN DEMENTIA

Session 6
Thoughts are not facts

Theme: Thoughts are not facts – don’t believe everything you think
Relating differently to thoughts. We free ourselves from the ruminative doing mode when we clearly see negative moods as passing states of mind, and negative thinking as distorted products of those mind states. It is enormously liberating to
realise that our thoughts are merely thoughts, even the ones that say they are not, and to recognise the context out of which they are born.

**Taken from Mindfulness Based Cognitive Therapy for Depression (2012)**

List of materials:
- Flip chart, pens
- Plain paper, pens
- hand-outs
- Posters : waterfall
- Tool box worksheet : list of things that I can do/use etc.
- CD player

**Agenda and guidance for facilitators**

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<tr>
<th>Assign</th>
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<tbody>
<tr>
<td>Grounding practice - Short standing Meditation (mountain)</td>
<td>5</td>
<td></td>
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<tr>
<td>SCAFFOLD/RECAP: key points poster or power point summary session 5: Introducing the session theme for week 6.</td>
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<tr>
<td>PRACTISE 1: Sitting meditation: Awareness of breath, body, sounds, and thoughts and feelings, noticing how it relates to any thoughts that arise. See script.</td>
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<tr>
<td>Rationale: turning towards the difficult starts with recognising the nature of it. This meditation enables us to make a connection between our breath, body, sounds, thoughts and feelings.</td>
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<tr>
<td>Feedback – split into groups of 2/3. Share experience of practice. Encourage to consider the layers of experience e.g. ‘what did you notice (body, thoughts and emotions)’. Share with larger group. Consider use of one word feedback if group not forthcoming. Nuggets of knowledge.</td>
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<tr>
<td>See facilitators guide: the process of Inquiry</td>
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<tr>
<td>See facilitators guide: the process of Inquiry</td>
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<tr>
<td>Mention preparation for end of course</td>
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<tr>
<td>Break</td>
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<tr>
<td>ACTIVITY: see facilitators notes for instructions:</td>
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</table>
**John was on his way to school**  
*He was worried about the math lesson  
He was not sure he could control the class again today.  
It is not part of a janitors duty.*

Lead onto FACT or Fiction exercise. Getting group to come up some thoughts and then deciding where they should go. Use visual aids, large A4 sheets and place on floor.

Train of associations: use role play.

Mood thoughts and alternative viewpoints exercise: scenarios in the office- see instructions.

ACT based diffusion exercises should also be considered as they could work very well with this group.

‘just because you think it, doesn’t mean it’s true’

Poem: Two kinds of intelligence

<table>
<thead>
<tr>
<th><strong>Reflection on Theme:</strong> Connecting practice to session theme. Following on from ‘John’ exercise - Separating events from their interpretation can be liberating.</th>
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</thead>
<tbody>
<tr>
<td>When you suffer from depression or anxiety the associated thoughts have ‘psychological’, ‘biological’ and ‘social’ consequences.</td>
</tr>
<tr>
<td>Exercise: think with the group about the different levels of impact of these thoughts. See week 6 activities sheet.</td>
</tr>
<tr>
<td>Learning to recognise our thoughts for what they are will help us to learn to distance ourselves from them.</td>
</tr>
<tr>
<td>Inviting an attitude of investigation, curiosity, and kindness allows the cultivation of a different relationship to these thoughts.</td>
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<tr>
<td>Analogy of the waterfall – use poster to illustrate this.</td>
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<table>
<thead>
<tr>
<th><strong>PRACTISE: The befriending meditation</strong></th>
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<tbody>
<tr>
<td><strong>Rationale:</strong> Introducing compassion in this week’s meditation which will be continued in week 7.</td>
</tr>
<tr>
<td><strong>Feedback</strong> – split into groups of 2/3. Share experience of practice. Encourage to consider the layers of experience e.g. ‘what did you notice (body, thoughts and emotions)’. Share with larger group. Consider use of one word feedback if group not forthcoming.</td>
</tr>
</tbody>
</table>
See facilitators guide: the process of Inquiry

Start thinking with the group about preparation for the end of the course. Brief discussion. ‘what will you put in your tool box?’ use Tool box worksheet to start list making: working wisely, treading lightly: my tool box (name can be changed to suit group.

**Here we are not doing the usual relapse signature/prevention work. Linking to idea of ‘keeping well’**.

<table>
<thead>
<tr>
<th>Handout: distribute handouts. Review contents briefly.</th>
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<tbody>
<tr>
<td><strong>Home Practice</strong>: discuss and consider barriers and challenges to undertaking practice.</td>
</tr>
<tr>
<td>‘What might stop you from practicing?’</td>
</tr>
<tr>
<td>‘What can you do to make space and time to undertake practice?’</td>
</tr>
<tr>
<td>‘Do you have any questions or concerns?’</td>
</tr>
<tr>
<td>- Formal: Befriending Meditation (track 7, 10 minutes), 6 out of 7 days. Aim to sit quietly for a few minutes before you do this meditation or use tracks 1 or 4 from the CD to help you. Three minute breathing space (responsive as you need it).</td>
</tr>
<tr>
<td>- Mindfulness of a routine activity – different to previous week.</td>
</tr>
<tr>
<td>One Mindful moment or one mindful mouthful.</td>
</tr>
</tbody>
</table>

Remind participants that this is not compulsory but evidence highlights importance of practice to promote change. Consider creative ways to overcome barriers or design practice around them.

‘weaving your parachute’
No right or wrong
No success or failure

<table>
<thead>
<tr>
<th>PRACTICE: Breathing space and review. - Discuss breathing space as the first step before taking a wider view of thoughts. BS helps to stand behind the waterfall.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Review/session summary</strong>: What will you take away from today? Parachute (group and individual).</td>
</tr>
<tr>
<td><strong>Thanks and close session</strong> – end with poem.</td>
</tr>
</tbody>
</table>

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132
MINDFULNESS BASED CONGITIVE THERAPY FOR DEPRESSION IN DEMENTIA

Session 7
How Best to take care of myself

Theme: Taking time to take care –

*Using skilful action to take care of ourselves in the face of lowering mood.* We can lift depressed mood by intentional skilful action. We can respond more promptly and effectively to lowering mood by learning to recognise our personal pattern of warning signs. After taking a breathing space, we kindly take care of ourselves by acts that give pleasure or a sense of mastery, or provide a clear focus for mindfulness.

Taken from Mindfulness Based Cognitive Therapy for Depression (2012)

Pre-class preparation for facilitator: See teacher guidance and detailed session notes. (as before follow the home practise guidance along with rest of group and in addition Practice the meditations that will be led in this session)

List of materials:
- Flip chart, pens
- Plain paper, pens
- hand-outs
- Posters – mountain,
- My manifesto or my pledge worksheet
- CD player

Agenda and guidance for facilitators

<table>
<thead>
<tr>
<th>Assign</th>
<th>Description</th>
<th>Time allocated</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Grounding practice - Short standing Meditation (mountain)</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td><strong>SCAFFOLD/RECAP:</strong> key points poster or power point. Session summary from week 6: Introducing the session theme for week 5.</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>PRACTISE 1:</strong> befriending meditation – or Sitting meditation awareness of breath and body; noticing how we relate to our</td>
<td></td>
</tr>
</tbody>
</table>
experience to the reactions we have two what are the thoughts feelings and sensations that arise especially when difficulties arise within the practice and just noticing reactions to them on our body.  
See script.  
Rationale: option for either. This week is about cultivating kindness, developing resilience and nourishing the mind

**Feedback** – split into groups of 2/3. Share experience of practice. Encourage to consider the layers of experience e.g. ‘‘what did you notice (body, thoughts and emotions)’’. Share with larger group. Consider use of one word feedback if group not forthcoming.

See facilitators guide: the process of Inquiry

**Home practice review:** connected to review of the previous meditation so will be some overlap in discussion. Also discuss breathing space, habit releaser and mindfulness of routine activity.

See facilitators guide: the process of Inquiry

**Break**

**PRACTISE 2: Guided meditation Mountain (resilience)**

**Rationale:** starting with a short breath focus and moving into the mountain meditation- This mediation works on a number of levels (internal visual, auditory) helps to cultivate a sense of groundedness, stability, strength and resilience. Can be further aided using visual stimuli (picture of mountain).

**Feedback** – split into groups of 2/3. Share experience of practice. Encourage to consider the layers of experience e.g. ‘‘what did you notice (body, thoughts and emotions)’’. Share with larger group. Consider use of one word feedback if group not forthcoming.

Ask group to generate list of words that capture the message of the mountain. These can be collated and distributed as a handout the following week.

See facilitators guide: the process of Inquiry

**ACTIVITY – rebalancing your life:**  
Nourishing and depleting exercise (see guide)  
Generating list of pleasure and mastery activities (see guide)

**Reflection on Theme:** Connecting practice to session theme. Mindfulness, Resilience and compassion. What do we need to maintain well-being. ‘‘How to best take care of myself when depression threatens to overwhelm me?’’  
Activity: get participants to brainstorm
<table>
<thead>
<tr>
<th>Poem: if you would grow</th>
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<tbody>
<tr>
<td><strong>Planning for the future:</strong> Exercise to explore links between activity and mood plan how best to schedule activities for when mood threatens to overwhelm. Consider an action plan. Identifying actions to deal with the threat of recurrence. What I will do? Handout template: My Manifesto/my pledge worksheet: How to keep well. How to take care. What to look out for. Spend some time working through this. See guidance.</td>
</tr>
<tr>
<td><strong>Handout:</strong> distribute handouts. Review contents briefly.</td>
</tr>
<tr>
<td><strong>Home Practice:</strong> discuss and consider barriers and challenges to undertaking practice. ‘What might stop you from practicing?’ ‘What can you do to make space and time to undertake practice?’ ‘Do you have any questions or concerns?’</td>
</tr>
<tr>
<td>• Formal: choosing a selection of favoured practices this week 1 or 2 a day.</td>
</tr>
<tr>
<td>• Mindfulness of a routine activity – different to previous week.</td>
</tr>
<tr>
<td>• Habit releaser – spend a moment reflecting on something you might do differently.</td>
</tr>
<tr>
<td>One Mindful moment or one mindful mouthful.</td>
</tr>
<tr>
<td>Remind participants that this is not compulsory but evidence highlights importance of practice to promote change. Consider creative ways to overcome barriers or design practice around them.</td>
</tr>
<tr>
<td>‘weaving your parachute’</td>
</tr>
<tr>
<td>No right or wrong</td>
</tr>
<tr>
<td>No success or failure</td>
</tr>
<tr>
<td><strong>Review/session summary:</strong> What will you take away from today? Parachute – group and indv. Preparing for end of group: brief reflections</td>
</tr>
<tr>
<td>Breath focus – one minute breathing space leading into poem – Summers Day (Mary Oliver)</td>
</tr>
<tr>
<td>Thanks and close session</td>
</tr>
</tbody>
</table>
MINDFULNESS BASED CONGITIVE THERAPY FOR DEPRESSION IN DEMENTIA

Session 8
Maintaining and Extending New Learning

Theme: Moving forward – The Rest of your life.

Planning for a new way of living. Maintaining and extending a more mindful and caring way of being requires clear intention and planning. It is helpful to link intentions for regular mindfulness practice to a personally significant value or positive reason for taking care of oneself.

Taken from Mindfulness Based Cognitive Therapy for Depression (2012)

List of materials:
- Flip chart, pens
- Plain paper, pens
- hand-outs
- Letter to myself worksheet
- Poster – large laminated parachute from week 1, hour glass and door
- Prompt (Words Of Wisdom – WOW) cards/blanks or prewritten
- Expectations from week 1
- Take away tokens
- CD player

Agenda and guidance for facilitators

<table>
<thead>
<tr>
<th>Assign</th>
<th>Description</th>
<th>Time allocated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grounding practice body focused practice coming full circle</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>SCAFFOLD/RECAP: key points poster or power point. Session summary from week 7. End of group: start of the rest of your life</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>PRACTISE: body focused meditation</td>
<td>10+ 10</td>
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</tbody>
</table>

Rationale: see handout ‘learning that comes from body scan’. We arrive full circle to where we started. The body, our friend a new connection.

Feedback – split into groups of 2/3. Share experience of practise. Encourage to consider the layers of experience e.g. ‘’what did you notice (body, thoughts and emotions)’’. Share with larger group. Consider use of one word feedback if group not forthcoming. See facilitators guide: the process of Inquiry

Home practice review and general discussion and reflections on role of practice. How to take this forward and what to do with the struggle. | 10 |
<table>
<thead>
<tr>
<th>REVIEW OF EXPECTATIONS: ask group members to briefly share expectations. ‘what would you likely to take away from the course’’. Note on flip chart and keep for review towards end of course. Expectations of participants - commitment to group. Importance of home practice.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weaving your parachute – HOW IS YOUR PARACHUTE COMING ON? weave your parachute every day, rather than leave it to the time you have to jump out of the plane.” Ask people to think about how they will complete their parachute. Write down the last thing. Leaving one blank piece for ‘the rest of your life’.</td>
</tr>
<tr>
<td>REFLECTION ON THEME. Summary of course. FULL CIRCLE Arriving here and now – letter to myself. To be sent or handed to participants at a later, agreed time.</td>
</tr>
<tr>
<td>BREAK</td>
</tr>
<tr>
<td>Handout: distribute handouts. Review contents briefly.</td>
</tr>
<tr>
<td>Review/session summary: What will you take away from the course? – review tree of life. ‘Endings’ ‘taking this forward’</td>
</tr>
<tr>
<td>Maybe sit or stand in circle. Opportunity to give something to rest of group. Gift in form of word or something that allows a nice ending.</td>
</tr>
<tr>
<td>Closing sentiments – what I would like to give is… Handout tokens</td>
</tr>
<tr>
<td>Breath focus – one minute breathing space leading into poem ‘A Slow Dance’ - Anon</td>
</tr>
<tr>
<td>Thanks and Goodbye</td>
</tr>
</tbody>
</table>
Appendix C

Contribution of each trainee to the research project.

<table>
<thead>
<tr>
<th>Task</th>
<th>Contributor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design of the research study</td>
<td>Deirdre and Jacob</td>
</tr>
<tr>
<td>Ethics</td>
<td>Deirdre and Jacob</td>
</tr>
<tr>
<td>Attending team meetings</td>
<td>Deirdre and Jacob</td>
</tr>
<tr>
<td>Recruitment</td>
<td>Deirdre (Memory Clinic 1), Jacob (Memory Clinic 2)</td>
</tr>
<tr>
<td>Retention phone calls for participants whilst waiting for assessments in Memory Clinic 2</td>
<td>Jacob</td>
</tr>
<tr>
<td>Contacting clients for assessments</td>
<td>Deirdre (Memory Clinic 1), Jacob (Memory Clinic 2)</td>
</tr>
<tr>
<td>Booking transport</td>
<td>Deirdre (Memory Clinic 1), Elisa (Memory Clinic 2)</td>
</tr>
<tr>
<td>Assessments</td>
<td>Deirdre, Jacob, Charlotte and Eanna</td>
</tr>
<tr>
<td>Making packs/CDs for the group</td>
<td>Deirdre and Eanna</td>
</tr>
<tr>
<td>Group sessions</td>
<td>Deirdre and Mina</td>
</tr>
<tr>
<td>Mid week call from a group facilitator</td>
<td>Deirdre and Elisa</td>
</tr>
<tr>
<td>Data entry</td>
<td>Deirdre and Jacob</td>
</tr>
</tbody>
</table>
Appendix D

PARTICIPANT INFORMATION SHEET

Study Title: A Mindfulness-Based Cognitive Therapy (MBCT) Group for People with Memory Problems and Low Mood (Student Research Project)

Invitation to participate in a research study

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Thank you for reading this information sheet.

What is the purpose of the study?

This study aims to find out whether mindfulness training can help improve the mood, anxiety and quality of life of people experiencing memory problems and low mood.

Who is organising and funding the research?

The research is being organised by University College London and funded by the Oxford Mindfulness Centre. The study will be conducted by Deirdre Noon and Jacob Payne. They work as Trainee Clinical Psychologists, and the study will form part of an educational qualification for both researchers (Doctorate in Clinical Psychology) at University College London (UCL). They are being supervised by Dr. Aimee Spector and Dr. Josh Stott, who are both Clinical Psychologists based at UCL.

What is mindfulness training?

Mindfulness is a way of training our attention to focus on the present moment, and to be kinder towards ourselves. Much of the time our minds are lost in thoughts about the past or the future. Living more in the ‘here and now’ may change our relationship with stress and worry.

Research has shown mindfulness training to be helpful for many different kinds of people experiencing a range of difficulties, and there has been some limited research that suggests mindfulness may be beneficial for people with memory problems. Therefore, this study is designed to find out if people with memory problems attending mindfulness training
experience improvements in their: mood, anxiety, quality of life and thinking.

We want to see if mindfulness training is better than usual care that people receive in services such as memory clinics and Improving Access to Psychological Therapies (IAPT) services. To do this, we will use a randomized controlled trial design, whereby half of the people that take part in the study will attend mindfulness sessions and half will receive usual care. The fairest way to decide whether or not people have the opportunity to attend the mindfulness sessions is by chance. The allocation will be done using an independent computer that will not contain any personal information about you.

If you attend the mindfulness sessions you will be invited to attend an interview after the group. This will give you the opportunity to discuss your experience of attending the group.

This study is a ‘pilot’. This means it is a small-scale study that will be used to prepare for a larger study. This pilot will help test out and improve the way future studies in this area are conducted.

**What happens in mindfulness training?**

Mindfulness training is a free eight-week course, and sessions take place once a week, lasting for about 60 minutes each time. The sessions will involve a group of about 5-10 people with low mood and memory problems. During the sessions you will do activities like: gentle breathing and learning to focus on your body.

**Why have I been invited to take part?**

You have been invited to take part because you are considered to be experiencing difficulties with your memory and mood.

**Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form.

If you decide to take part, you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

**What will happen to me if I take part?**

Following discussion of any questions you may have with a researcher, and signing the consent form, all participants will be asked to:

- Meet with a researcher for around one hour to answer questions about your attention, mood, anxiety, quality of life and thinking. The time stated to complete the interviews and questionnaires is an estimate; you may take as many breaks as you want or feel necessary, and if you prefer we can meet for more sessions to finish these.
- Either attend eight-weekly mindfulness training sessions OR receive your usual care for eight weeks.
- Meet with a researcher again to answer the same questions as before. In order to complete the assessment, the researcher may ask to meet a family member or
your clinician to complete some questionnaires. The mindfulness training sessions will be audio recorded and will be kept password protected.
>
> If you attend the eight-weekly mindfulness training sessions, you will be invited to attend an interview to discuss your experience of attending the group.

**What do I have to do?**

You can carry on your everyday activities as normal while participating in the study. All we ask is that if you are allocated to the mindfulness group, you try to attend all 8 sessions. We understand there may be times when you are unwell and therefore unable to attend a session.

**What are the possible disadvantages and risks of taking part?**

We appreciate that when you are experiencing memory problems, it may be hard to talk about things like your mood and quality of life. The researcher carrying out the assessments and interviews is someone who has clinical experience and is working under supervision.

You will be encouraged but never forced to take part in a particular activity during the sessions. Overall the risks of taking part in this study are minimal. However, if being involved in this research really does not suit you, for example if you find it distressing, you are free to withdraw at any point.

**What are the possible benefits of taking part?**

There are no proven benefits for the participants to take part in this study. Although we hope that attending the sessions is a helpful and enjoyable experience, we cannot promise this. Previous research into mindfulness suggests that people can experience greater awareness, acceptance, control, improved coping and enjoyment. If you decide to take part in the interview after the mindfulness training, we hope that you may find having the opportunity to talk about the group an interesting experience. For all participants, the information we get from this study may help us to support people with memory problems better in the future.

**Will my taking part in the study be kept confidential?**

We will ask for your permission to send your GP a letter explaining that you will be taking part in the study. All information collected about you over the course of the study will be kept private unless we became aware of something which made us worry about you or someone around you, in which case we will discuss the issue with you. For example, if we had some concern that you were at risk to yourself or other people, we may need to disclose this information with those involved in your care (e.g. your GP). All documents that leave the memory clinic will have your name removed with the exception of a consent form. The interviews will be recorded and transcribed. Any quotes from interviews that are used for publication will be anonymised. Once the study has finished, University College London will keep the study data in a secure location. The MBCT group sessions maybe recorded for supervision purposes. This is to ensure that the facilitators are providing the optimum intervention. These recordings will be deleted after the facilitators have received feedback about the group.
What will happen if I don’t want to carry on with the study?

You will be free to withdraw from the study at any time, without giving a reason. Withdrawing from the study will not affect the standard of care you receive. We will need to use all data collected in the study, up to the point of withdrawal.

What if something goes wrong?

Every care will be taken in the course of this study. However, in the unlikely event that you are injured by taking part, compensation may be available.

If you suspect that the injury is the result of the Sponsor’s (University College London) or the memory clinic’s negligence then you may be able to claim compensation. After discussing with the researcher, please make the claim in writing to Dr. Aimee Spector who is the Chief Investigator for the research and is based at University College London. Her details are provided at the end of this form. The Chief Investigator will then pass the claim to the Sponsor’s Insurers, via the Sponsor’s office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this study or if you are unhappy with anything about your participation, you can contact Dr Aimee Spector.

If you have private medical insurance, you should inform your insurance company that you are intending to take part in this study.

Is the research insured?

The research study is covered by UCL policy which provides insurance for negligent harm.

What will happen to the results of the research?

The results will be published in health journals. No participants will be identified in any publication. Once the study has ended, you can meet with a researcher to find out about the results. The researchers will also present the study findings to people at your care home.

Who has reviewed the study?

All NHS research is looked at by a group of people, called a Research Ethics Committee to protect your safety, rights, and dignity. This study has been approved by X Research Ethics Committee.

Who can I contact for further information?

For more information about this research, please contact:

Deirdre Noon and Jacob Payne

Department of Clinical,

Educational and Health Psychology
Dr Aimee Spector
Department of Clinical,
Educational and Health Psychology
UCL
Gower Street
WC1E 6BT
Email: a.spector@ucl.ac.uk
Tel: 020 7679 6231

Dr Josh Stott
Department of Clinical,
Educational and Health Psychology
UCL
Gower Street
WC1E 6BT

If you would like seek advice from an independent person who is not associated with the project, please contact:

Dr Will Mandy
Senior Lecturer,
Department of Clinical,
Educational and Health Psychology
UCL
Gower Street
WC1E 6BT
Email: will.mandy@ucl.ac.uk
Or if you have any complaints about this study please contact:

Dr Aimee Spector
Department of Clinical,
Educational and Health Psychology
UCL
Gower Street
WC1E 6BT
Email: [Redacted]
Tel: [Redacted]

Dr Josh Stott
Department of Clinical,
Educational and Health Psychology
UCL
Gower Street
WC1E 6BT
Tel: [Redacted]

Thank you for thinking about taking part in this research study.
Appendix E

Participant Consent Form

Study Title: A Mindfulness-Based Cognitive Therapy (MBCT) Group for People with Memory Problems and Low Mood in Memory Clinic: A Feasibility Pilot Study (Student Research Project).

Participant Number:

Name of Researchers: Deirdre Noone and Jacob Payne

Chief Investigator: Dr. Aimee Spector

Academic Supervisors: Dr. Aimee Spector and Dr. Josh Stott

Please Initial

<table>
<thead>
<tr>
<th>Boxes</th>
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<tbody>
<tr>
<td>I confirm that I have read and understand the information sheet dated [insert date, insert version] for the above study, have had the opportunity to ask questions and have had these answered acceptably.</td>
<td></td>
</tr>
<tr>
<td>I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.</td>
<td></td>
</tr>
<tr>
<td>I understand that sections of any of my medical notes and data collected during the study may be looked at by individuals involved in the study, where it is relevant to my taking part in this</td>
<td></td>
</tr>
</tbody>
</table>
research. I give my permission for these individuals to have access to my records.

I give permission for the MBCT sessions to be recorded for supervision purposes.

I give permission for my GP to be informed of my participation in the study.

I understand that all information given by me or about me will be treated as confidential by the research team.

I agree to take part in the above study.

<table>
<thead>
<tr>
<th>Name of participant</th>
<th>Date</th>
<th>Signature</th>
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<tr>
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<table>
<thead>
<tr>
<th>Name of person taking consent (if different from the principal researcher)</th>
<th>Date</th>
<th>Signature</th>
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<tbody>
<tr>
<td></td>
<td></td>
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</tr>
<tr>
<td>Principal researcher</td>
<td>Date</td>
<td>Signature</td>
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Appendix F

RESEARCH DEPARTMENT OF CLINICAL, EDUCATIONAL AND HEALTH PSYCHOLOGY

UCL

INFORMATION SHEET FOR CARER, FAMILY MEMBER OR CLINICIAN

Study Title: A Mindfulness-Based Cognitive Therapy (MBCT) Group for People with Memory Problems and Low Mood: A Feasibility Pilot Study (Student Research Project).

Invitation to participate in a research study

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Thank you for reading this information sheet.

What is the purpose of the study?

This study aims to find out whether mindfulness training can help improve the mood, anxiety and quality of life of people experiencing memory problems and low mood.

What is mindfulness training?

Mindfulness is a way of training our attention to focus on the present moment, and to be kinder towards ourselves. Much of the time our minds are lost in thoughts about the past or the future. Research has shown mindfulness training to be helpful for many different kinds of people experiencing a range of difficulties, including memory problems and low mood. Therefore, this study is designed to find out if people with memory problems and low mood attending mindfulness training will experience improvements in their mood, anxiety, quality of life and thinking.

We want to see if mindfulness training is better than usual care that people receive in either memory clinics or Improving Access to Psychological Therapies (IAPT) services. To do this, half of the people that take part in the study will attend mindfulness sessions and half will receive usual care. The fairest way to decide whether or not people have the opportunity to attend the mindfulness sessions is by chance. The allocation will be done using an independent computer that will not contain any personal information about you.

If you know a participant that took part in mindfulness training you will be invited to attend an interview after the eight-week course.

This study is a ‘pilot’. This means it is a small-scale study that will be used to prepare for a larger study. This pilot will help test out and improve the way future studies in this area are
conducted.

What happens in mindfulness training?

Mindfulness training is a free eight-week course, and sessions take place once a week, lasting for about 60 minutes each time. The sessions will involve a group of about 5-10 people with low mood and memory problems. During the sessions participants will do activities like: gentle breathing and learning to focus on your body.

Why have I been invited to take part?

You have been invited to take part because you know a participant taking part in study, and therefore could assist the researchers in completing some assessments and answering some questions about the participant.
Appendix G

RESEARCH DEPARTMENT OF CLINICAL, EDUCATIONAL AND HEALTH PSYCHOLOGY

Carer Consent Form

**Study Title:** A Mindfulness-Based Cognitive Therapy (MBCT) Group for People with Memory Problems and Low Mood in Memory Clinic: A Feasibility Pilot Study (Student Research Project).

**Participant Number:**

**Name of Researchers:** Deirdre Noon and Jacob Payne

**Chief Investigator:** Dr. Aimee Spector

**Academic Supervisors:** Dr. Aimee Spector and Dr. Josh Stott

I confirm that I have read and understand the information sheet dated [insert date, insert version] for the above study, have had the opportunity to ask questions and have had these answered acceptably.

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

I understand that all information given by me or about me will be treated as confidential by the research team.

I agree to take part in the above study
<table>
<thead>
<tr>
<th>Name of participant</th>
<th>Date</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of person taking consent (if different from the principal researcher)</td>
<td>Date</td>
<td>Signature</td>
</tr>
<tr>
<td>Principal researcher</td>
<td>Date</td>
<td>Signature</td>
</tr>
</tbody>
</table>
Appendix H

Ethical approval by City and East Research Ethics Committee in London

08 May 2016

Dr Aimee Spector
Department of Clinical, Educational and Health Psychology, UCL
Gower Street
London
WC1E 6BT

Dear Dr Spector,

Study title: Mindfulness-Based Cognitive Therapy for People with Dementia and Depression (Student Study)

REC reference: 16/LO/0578

Protocol number: n/a

IRAS project ID: 197549

Thank you for your letter of 29th April 2016, responding to the Committee’s request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-Committee of the REC. A list of the Sub-Committee members is attached.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Mr Rajat Khullar, nrescommittee.london-cityandeast@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must
confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).


Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.
### Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

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<th>Document</th>
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Appendix I

Permission from local Research and Development departments

18th May 2016

Letter of NHS Permission for Research

Study title: MBCT for People with Memory Problems and Low Mood (Student Study) V1
CSP/IRAS ref: 197549

Dear Dr Amee Spector,

I am pleased to inform you that the above research study has been granted NHS Permission to be undertaken at Oxleas NHS Foundation Trust, effective from the date of this letter. Please note that:

1. NHS permission has been granted following a review of the information provided in the following documents:

   - IRAS NHS SSI Form # 157549/567603/6/349/3105/3/348012
   - IRAS NHS R&D Form # 197549/941046/14/929
   - NHS REC Favourable Opinion 16/10/0978 06 May 2016

2. Permission is granted only for those activities for which a favourable opinion has been given by the Research Ethics Committee and (if applicable) the Medicines and Healthcare products Regulatory Agency, and on the understanding that the study is conducted in accordance with the
Research Governance Framework and (if applicable) ICH Good Clinical Practice, and the Trust’s policies and procedures.

3. The research sponsor or the Chief Investigator, or the local Principal Investigator at a research site, may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety. The R&D office should be notified that such measures have been taken. The notification should also include the reasons why the measures were taken and the plan for further action. The R&D Office should be notified within the same time frame of notifying the REC and any other regulatory bodies. Any amendments (including changes to the local research team) need to be submitted in accordance with IRAS guidance and the R&D Office informed.

4. Principal Investigators must inform the R&D Office of the total number of recruits recruited to this study on a monthly basis and, for NIHR portfolio studies only, also ensure that this information is recorded correctly on the national accrual database.

5. The Trust is required to monitor all research activities to ensure compliance with the Research Governance Framework and other legal and regulatory requirements. This is achieved by random audit, and all required documents must be made available upon request to facilitate this process.

Please note that deviation from any of the five conditions listed above will render this permission void.

Finally, I wish you every success with your study. Please don’t hesitate to contact me should you require any further assistance.

Yours sincerely,

Anthony Davis
Research and knowledge manager
anthony.davis@oxteas.nhs.uk

cc:
Ms Deirdre Noone, PhD student and co-investigator
Mr Jacob Payne, PhD student and co-investigator
Dr Naomi Wynne-Morgan, Local Collaborator
Ms Suzanne Emerton, Sponsor Representative
09 June 2016

Dear Dr Spector,

RE: Mindfulness-Based Cognitive Therapy for People with Dementia and Depression (Student Study)

R&D Ref: 197549

I am pleased to inform you that the above named study has been granted approval and indemnity by North East London NHS Foundation Trust. You must act in accordance with the North East London NHS Foundation Trust’s policies and procedures, which are available to you upon request, and the Research Governance Framework. Should any untoward events occur, it is essential that you contact your Trust supervisor and the Research and Development Office immediately. If patients or staff are involved in an incident, you should also contact the Governance and Assurance department, in Goodmayes Hospital, and complete the Incident and Reporting Form, namely the IR1 form.

You must inform the Research and Development Office if your project is amended and you need to re-submit it to the ethics committee or if your project terminates. This is necessary to ensure that your indemnity cover is valid and also helps the office to maintain up to date records.

You are also required to inform the Research and Development Office of any changes to the research team membership, or any changes in the circumstances of investigators that may have an impact on their suitability to conduct research.

You must inform the Research and Development Office if your project is amended and you need to re-submit it to the ethics committee or if your project terminates. This is necessary to ensure that your indemnity cover is valid and also helps the office to maintain up to date records.

You are also required to inform the Research and Development Office of any changes to the research team membership, or any changes in the circumstances of investigators that may have an impact on their suitability to conduct research.

Yours sincerely,

[Name]

Research and Development Manager, North East London NHS Foundation Trust.
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Appendix J

Insurance provided by the Joint Research Office at University College London

25/01/2016

Miss Deirdre Noonan
Department of Clinical, Educational and Health Psychology
UCL
London
WC1E 6BT

Dear Miss Noonan,

Chief Investigator: Dr Aimee Spector

Study/Trial Title: Mindfulness based cognitive therapy for people with Dementia and Depression

Funder: Oxford Mindfulness Centre, University of Oxford

UCL Project ID No. 160015

Re: Insurance for studies not involving a Clinical Trial of an Investigational Medicinal Product (non-CTIMP) sponsored by UCL

Thank you for completing the UCL Insurance Registration Form dated 20.02.2016. I am pleased to inform you that the above study, as described in the registration form, is now insured under UCL’s policy. A copy of the current insurance summary (Verification of Insurance) is attached to this letter.

The policy provides for the legal liabilities (negligence) of UCL and its employees or agents.

This confirmation letter, together with the attached summary, needs to be submitted to the Research Ethics Committee in support of question A70 for both your NHS REC and, where applicable, NHS R&D applications submitted via the Integrated Research Application System (IRAS).

/Continued

Director Research Support Centre, Director R&D UCLH – Brian Williams
Managing Director Research Support Centre – Dr Nick McNally

UCL Insurance Confirmation Letter
Version 13: 30.07.2015