The Impact of a Mindfulness Based Cognitive Therapy Group for Depression in People with Dementia attending Memory Clinics: A Feasibility Randomised Controlled Trial

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Thesis declaration form

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:

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Date:

Overview

This thesis focuses on an adapted Mindfulness Based Cognitive Therapy (MBCT) group for depression in people with dementia (PWD) in memory clinics.

Part I is a systematic literature review, including meta-analyses, examining the effectiveness of psychosocial interventions for depression and anxiety in people with dementia (PWD) or mild cognitive impairment (MCI), who are experiencing clinical symptoms of depression or anxiety. Seven randomised controlled trials (RCTs) are included in the review.

Part II is a feasibility randomised controlled trial (RCT) that assessed whether an adapted MBCT group in memory clinics would lead to greater improvements in symptoms of depression, and anxiety, in PWD who were experiencing symptoms depression, as compared to treatment as usual. This is a joint project completed with Jacob Payne (JP). Measures of depression, anxiety, quality of life (QOL) and cognition were assessed at baseline and follow-up. JP reports on the feasibility of the intervention and measures of QOL and cognition. Measures of depression and anxiety are reported here.

Part III is a critical appraisal, I will reflect on conducting the empirical study and my experience of facilitating a Mindfulness Based Cognitive Therapy (MBCT) group. Firstly, I will share how my background influenced my choice of research. Secondly, I will discuss the recruitment challenges and my experiences of facilitating the adapted MBCT group. Finally, I will consider the findings of the empirical paper, based on my experience of facilitating the group and the discussions I had with participants and carers.

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Part I: Literature Review

Psychosocial Interventions for Depression and Anxiety in People with Dementia and Mild Cognitive Impairment: A Systematic Review and Meta-analyses

Abstract

Aims: To assess the effectiveness of psychosocial interventions for symptoms of depression and anxiety in people with dementia (PWD) or mild cognitive impairment (MCI), who are depressed or anxious.

Methods: OvidMedline, PsycInfo and Embase were searched for studies, meeting the inclusion criteria, on the 17th October 2016. Cochrane Risk of Bias Tool rated the quality of studies. The efficacy of the studies was estimated using meta-analyses.

Results: Seven randomised controlled trials (RCTs) were included. No RCTs were identified for people with MCI. Three RCTs found that psychosocial interventions (multicomponent intervention, Mahjong/Tai Chi and exercise/walking) were effective at reducing symptoms of depression in PWD who were depressed. One study (Mahjong/Tai Chi) found that these reductions were no longer evident at six month follow up. Another study, not included in the meta-analyses, found that pleasant events behaviour therapy and problem solving behaviour therapy were effective at improving depression symptoms at the end of treatment; and this effect remained significant at follow up. Three RCTs found that psychosocial interventions (music therapy and cognitive behavioural therapy (CBT)) were effective at reducing symptoms of anxiety in PWD who were anxious. Evidence from two of these RCTs (music therapy and CBT) showed that these improvements were evident at three to six month follow-up.

Conclusions: The identified psychosocial interventions are effective at reducing symptoms of depression or anxiety in PWD experiencing these symptoms. This review is limited by the quality of studies, small sample sizes and the heterogeneity of the interventions, therefore high quality studies with larger sample sizes are required to test the efficacy of specific interventions such as CBT.

Introduction

An increase in life expectancy has resulted in an aging population, with estimates suggesting that the proportion of older adults will rise from 10% to 20% by 2050 (UN Department of Economic and Social Affairs, 2013). Therefore, interventions for age-related health conditions, such as mild cognitive impairment (MCI) and dementia, are becoming a focus of clinical practice and research (Kaplan & Berkman, 2011).

Mild Cognitive Impairment

MCI is an intermediary phase of cognitive impairment that lies between typical aging and dementia (Petersen et al., 1999). Diagnostic criteria include: subjective changes in cognitive ability, objective impairment in at least one cognition domain (e.g. memory, executive function, attention, language or visuospatial skills), preserved functional abilities and no impairment in social functioning (Albert et al., 2011). The prevalence is estimated to be between 6% and 12% for individuals aged over 60 (Sachdev et al., 2015), with the prevalence increasing with age (O'Bryant et al., 2013; Sachdev et al., 2015). There is an increased risk of people with MCI developing dementia, with between 15% and 41% of cases developing a form of dementia every year (Gauthier et al., 2006; Geslani, Tierney, Herrmann, & Szalai, 2005).

Dementia

Dementia is characterised by the progressive decline in cognitive functioning (e.g. memory, executive function, attention, language or visuospatial skills) and activities of daily living (e.g. self-care, financial independence) (Albert et al., 2011;

WHO, 2016). It is estimated that between 5% and 7% of the global population has dementia (Prince et al., 2013). There are approximately 850,000 people with dementia (PWD) in the United Kingdom (UK) (Prince et al., 2014) and this number is expected to rise to 1,000,000 by 2021 (Heap, 2012).

Depression and Anxiety

Neuropsychiatric disorders, such as depression and anxiety, are common in PWD and MCI (Kane & Terry, 2015; Lyketsos et al., 2002; Monastero, Mangialasche, Camarda, Ercolani, & Camarda, 2009). The prevalence of depression is between 10% and 62% for PWD (Barca, Engedal, & Selbaek, 2010; Knapskog, Barca, & Engedal, 2011) and 16% and 25% for MCI (Feldman et al., 2004; Van Der Mussele et al., 2013). The prevalence of anxiety is between 5% and 21% in PWD (Ferretti, McCurry, Logsdon, Gibbons, & Teri, 2001; Starkstein, Jorge, Petracca, & Robinson, 2007) and between 10% and 45% in MCI (Forsell, Palmer, & Fratiglioni, 2003).

Depression and anxiety increase the risk of dementia in people with MCI (Cooper, Sommerlad, Lyketsos, & Livingston, 2015). They are also linked with poorer outcomes, such as reduced quality of life, worsened cognition, increased functional impairment, behavioural disturbance and mortality rates (Kales, Chen, Blow, Welsh, & Mellow, 2005; McCurry, Gibbons, Logsdon, & Teri, 2004; Rapp et al., 2011; Shin, Carter, Masterman, Fairbanks, & Cummings, 2005; Starkstein et al., 2007). In addition to the health implications, the incidence of depression and anxiety in PWD and MCI are placing financial pressures on the National Health Service, with an increased demand on inpatient beds (Kunik et al., 2003). Therefore, evidenced based treatments for depression and anxiety are required for this

population.

Psychotropic medication, such as antidepressants, are associated with adverse side effects (Stomski, Morrison, & Meyer, 2016); and their effectiveness for depression and/or anxiety in PWD and MCI are not demonstrated (Devanand et al., 2003; Leong, 2014; Moretti, Torre, Antonello, & Pizzolato, 2006; Sepehry, Lee, Hsiung, Beattie, & Jacova, 2012). Therefore, depression and anxiety have been identified as a specific target for non-pharmacological interventions (Cooper et al., 2015).

Systematic Reviews

A meta-analysis, consisting of three randomised controlled trials (RCTs), found that non-pharmacological therapies did not show a significant effect on depression scores in PWD (Olazarán et al., 2010). This could be the result of low baseline depression scores, or that the interventions were targeting cognition as opposed to depression. Nevertheless, evidence from two of these RCTs (Chapman, Weiner, Rackley, Hynan, & Zientz, 2004; Olazarán et al., 2004) found that group cognitive stimulation, combined with acetylcholinesterase inhibitors, was found to significantly improve symptoms of depression in PWD after one year of treatment, as compared to those treated with acetylcholinesterase inhibitors alone.

In a systematic review, psychosocial interventions were found to improve depression in PWD, in seven out of the eleven studies reviewed (Teri, McKenzie, & LaFazia, 2005). A recent Cochrane review, including meta-analyses, found that psychological treatments reduced symptoms of depression and anxiety in PWD. However, there were no available RCTs including MCI (Orgeta, Qazi, Spector, & Orrell, 2014) and a large proportion of the studies included in this review did not

require the participants to meet criteria for anxiety or depression at baseline.

A systematic review, consisting of seven RCTs and eight pre–post studies of psychological interventions, showed positive effects on depression scores in people with early dementia (Regan & Varanelli, 2013). This review also highlighted three RCTs and one pre-post study whose inclusion criteria stipulated that participants met criteria for depression at baseline; and these studies showed symptoms of depression improved for PWD that were experiencing depression.

Aims of Review

The current review extends previous reviews by completing a systematic review, with meta-analyses, to compare psychosocial interventions for PWD or MCI who meet clinical criteria for depression or anxiety at baseline.

Methods

Inclusion and Exclusion Criteria

The PICOS framework (Petticrew & Roberts, 2006) was used to select studies.

Inclusion criteria.

Population: Participants that: (a) met criteria for dementia (including all types and stages), or (b) met criteria for MCI. They also met criteria for either depression or anxiety on a standardised outcome measure or a clinical interview on the baseline assessment, which was stipulated as an inclusion criterion in the study. Participants could be recruited from any setting.

Intervention: Psychosocial interventions that intended to reduce depression or anxiety. Psychosocial interventions were defined as interventions that focused on psychological or social factors (such as psychotherapy or an activity group), as opposed to a pharmacological intervention (Forsman, Schierenbeck, & Wahlbeck,

2011; Frederiksen, Farver-Vestergaard, Skovgard, Ingerslev, & Zachariae, 2015). Interventions could include caregivers or family members. Interventions for caregivers alone were not included. Interventions were included if they used a structured time-limited intervention between a participant and a facilitator, such as a weekly one-hour psychotherapy session that ran for eight weeks. The intervention could be delivered to individuals or groups.

Comparator: The intervention would be compared to a control group; including treatment as usual (TAU), waitlist controls or a comparison intervention that could act as a control for the intervention under investigation.

Outcomes: Studies were included if they reported at least one standardised measure of either depression (e.g. Cornell Scale for Depression in Dementia,) or anxiety (e.g. Rating of Anxiety in Dementia Scale).

Study design: RCTs that collected outcome measures at baseline and post treatment. There was no restriction in the sample size used in studies.

Publication characteristics: Published in peer-reviewed journals, in English at any time prior to the 17th October 2016.

Exclusion Criteria.

- Quasi-experimental studies, case studies and qualitative research.
- Pharmacological interventions.
- Conference/poster presentations.
- If more than one article presents the same data, only one article will be presented in the review. The original article was used in these instances.

Selection of Studies

Relevant studies were identified using three search strategies.

(1) A systematic search was conducted using bibliographic databases: Embase (1980-2016), OvidMEDLINE (1946 – 2016) and PsycINFO (1806 – 2016). The search terms were composed of three concepts: 'cognitive impairments', 'depression or anxiety' and 'psychosocial intervention' (See Appendix A). Search strategies have been published for each database (Eady, Wilczynski, & Haynes, 2008; Higgins & Green, 2011; Wong, Wilczynski, & Haynes, 2006) and are used in Cochrane reviews. These were used in the search to facilitate the identification of studies using a randomised design.

(2) Systematic reviews were identified during the systematic search; and they were checked for studies that met the inclusion criteria.

(3) References in the identified studies were reviewed to find any further studies.

Quality Rating of Studies

Cochrane's Risk of Bias tool, used to rate the quality of studies, was completed using Review Manager (Revman) Version 5.3. The studies were rated as low, unclear or high risk of bias in areas such as: selection bias, performance bias, outcome bias, detection bias, attrition bias, reporting bias and other sources of bias. Low risk of bias suggests that the biases were unlikely to have an impact on the study results. Unclear risk of bias infers that there was not adequate information provided to evaluate all potential biases; therefore, it could raise questions about the reliability of the study results. High risk of bias infers that biases may have reduced the confidence in the study's results (Higgins & Green, 2011). The results are illustrated in the 'Risk of Bias' graph and 'Risk of Bias' summary. The risk of bias

informed the interpretation of the meta-analyses.

Heterogeneity

A statistical test (chi squared) measured the heterogeneity between the studies' results (Deeks, Higgins, & Altman, 2008), with a low p-value indicating heterogeneity. The chi square test has been found to be poor at detecting true heterogeneity, especially when the meta-analysis includes a small number studies or when the overall sample size is small. A p value of less than 0.10 was used to determine if the studies were heterogeneous. However, heterogeneity is expected in meta-analyses due to variations in methodologies and clinical samples (Higgins, Thompson, Deeks, & Altman, 2003). Therefore, the heterogeneity was quantified using an I^2 statistic. Approximate guidelines for interpreting heterogeneity suggest that heterogeneity around 25% is low, medium heterogeneity is around 50%, substantial heterogeneity is around 75% (Higgins, Thompson, Deeks, & Altman, 2003).

Data Synthesis

Revman was used to complete the meta-analyses. A random-effects model was used to present the overall estimated effect on depression and anxiety. As the studies under investigation used a range of scales, the analyses used the standardised mean difference scores, as opposed to the mean difference. Effects were weighted by the inverse of the variance of the effect estimate. This gives more weight to studies with larger sample sizes because they have smaller standard errors. This reduces the imprecision of the pooled effect estimate.

Results

A total of 2991 articles were extracted from the literature search, and the abstracts and titles of these articles were read. From these abstracts 48 were identified as possibly relevant to the search criteria. The full-length articles were checked against the inclusion and exclusion criteria. These were read in full and judged against the inclusion criteria. This resulted in seven articles selected for narrative synthesis and six of these were included in the meta-analyses (See Figure 1).

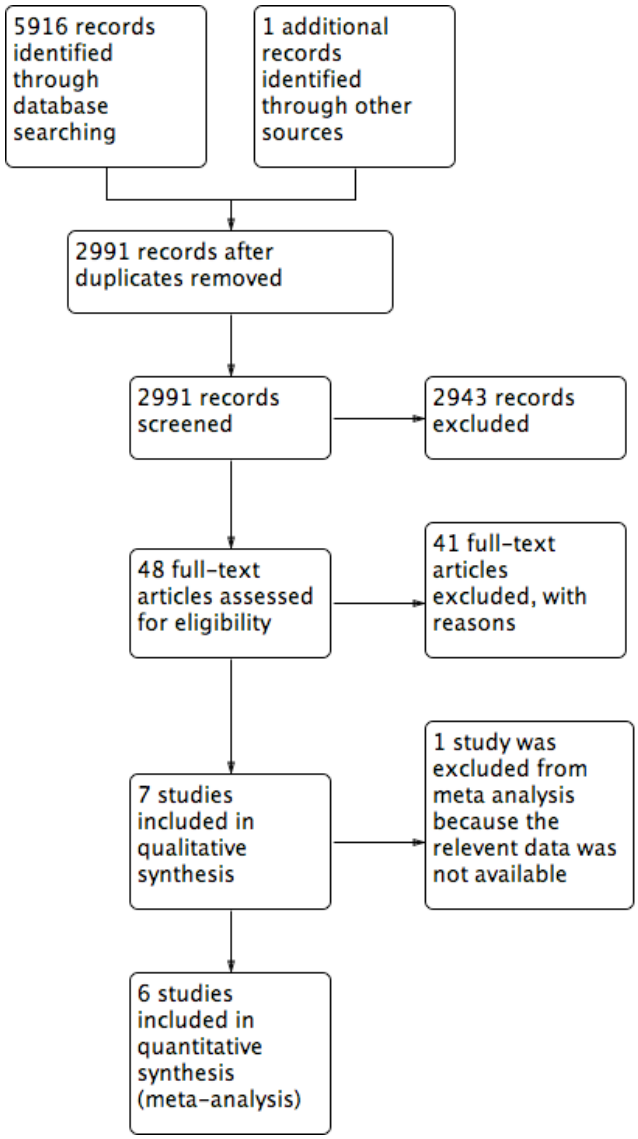


Figure 1: Study Flow Diagram

Excluded Studies

Forty-one studies were excluded: five studies did not use a randomised design; 21 studies did not have inclusion criteria about participants meeting criteria for anxiety or depression at baseline; ten studies did not have inclusion criteria about participants meeting criteria for dementia or MCI; four studies were not testing a psychosocial intervention; one study did not use standardised measure of anxiety or depression; and one study assessed an intervention offered to carers.

Table 1: Summary of the studies' demographic information, design features, outcomes and risk of bias.

Study	Design	Treatment (N) and control (N) intervention Frequency/Duration	Manual/ Integrity Checks. Intention to treat	Population: inclusion criteria, research setting, mean age and gender	Attrition	Outcomes Measures for Depression and Anxiety	Outcomes	Study risk of bias
Depression								
Bailey et al, 2016	RCT (2 arm); pre-post; no follow up	Treatment (group intervention): Multi-component intervention (26) Control: Treatment as Usual (25) Two 30 minute sessions week for 6 weeks	Manualised QAR-Depression Treatment Adherence checks within acceptable limits Intention to treat analysis used	People with dementia (>60 years) with mild to moderate cognitive impairment and symptoms of depression. Nursing home in USA. M = 84.14 years (SD = 8.45) N = 55 (46 female, 9 male).	8%	Depression (CSDD, GDS)	Reduction in depression compared to controls using the CSDD ($p<.05$) but no using GDS.	High
Cheng et al, 2012	Cluster RCT (3 arm); Pre-post; 6 month follow up	Treatment (group interventions): Mahjong and Tai Chi (24) Control Handicrafts (12) One hour three times a week for 12 weeks	Manual guides and integrity checks were not detailed. Intention to treat analysis was not used	People with dementia with mild to moderate cognitive impairment (Clinical Dementia Rating score = 0.5 of 1) and symptoms of depression (GDS score ≥ 6). Nursing home in Hong Kong. M = 81.8 years (SD = 6.54). N = 37 (24 female, 12 male).	0%	Depression (GDS)	Reduction in depression in Mahjong and Tai Chi groups compared to controls ($p< .006$) at one week follow up. This was no longer significant at 6 month follow up	Unclear
Williams & Tappen, 2008	RCT (3 arm); pre-post	Treatment (individual intervention): Exercise and walking (30) Control: Conversation group (15) 12 sessions	The interventions were not manualised and there were no fidelity checks Intention to treat analysis was not used	People with Alzheimer's Disease with symptoms of depression (CSDD score ≥ 7). Nursing homes in USA. M = 87.9 years (SD = 5.95). N = 45 (40 Female, 5 Male).	20%	Depression (CSDD, DMAS, AMS, OAS, MADRS)	The depression group mean scores reduced on the CSDD, from baseline to follow-up, in the treatment and control groups.	High
Teri et al, 1997	RCT (4 arm); pre-post; 6 month follow up	Treatment (individual intervention): 1. Pleasant Events Behavior Therapy (23); 2.Problem-solving behaviour therapy (15) Control: 1. Treatment as usual (10) and 2. waitlist control (20) Nine weekly 60-minute sessions	The intervention was manualised No evidence of fidelity checks. Intention to treat analysis was not used	People with probable Alzheimers and meet criteria for major or minor depressive disorder. Community research centre in the USA M = 76.4 (SD = 8.2) years. N = 72 (34 female and 38 male)	25%	Depression (HDRS, CSDD, BDI)	Reduction in depression scores in treatment groups as compared to controls on the HDRS ($p<.001$), CSDD ($p<.001$) and BDI ($p<.01$) at one week follow up. The significant effect was maintained on the HDRS ($p<.001$) and CSDD ($p<.001$)	High
Anxiety								
Guetin et al, 2009	RCT (2 arm); Pre-post; 6 month follow up	Treatment (individual intervention): Music Therapy (12) Control: Reading sessions (14) 16 sessions, duration not reported	There is some evidence that the music therapy was manualised, although it is not clear. Fidelity checks were not detailed. Intention to treat analysis was used	People with Alzheimer's Disease (70-95 years) with mild to moderate cognitive impairment (MMSE score 12-25) and symptoms of Anxiety (HAS score ≥ 12); receiving a stable dose of anticholinergic treatment for 6 months. Nursing home in France. M = 86.05 years (SD = 5.68). N = 30 (22 female, 8 male) 73.3% female.	20%	Depression (GDS) Anxiety (HAM-A)	<u>One week follow up</u> Reduction in anxiety ($p<.001$) and depression ($p<.001$) compared to controls <u>Six month follow up</u> Reduction in anxiety ($p<.002$) and depression ($p<.006$) compared to controls	Low
Spector et al, 2015	RCT (2 arm); Baseline, week 15 and 6 months	Treatment (individual intervention): Cognitive Behavioural Therapy (21) Control: Treatment As Usual (18) Ten weekly 60-minute sessions	The intervention was manualised (Charlesworth et al, 2014) Fidelity checks were within acceptable limits. Intention to treat analysis was used	People with dementia with mild to moderate cognitive impairment (DSM-IV and score of 0.5, 1 or 2 on CDR) and symptoms of anxiety (RAID score ≥ 11) that has carer willing to participate in therapy Secondary care outpatient NHS services in UK M = 78.5 (SD = 7.02) years N = 50 (30 female, 20 male)	22%	Anxiety (RAID) Depression (CSDD) Anxiety and Depression (HADS)	<u>One week follow up</u> Reduction in anxiety ($p<.05$) on RAID and depression on CDSS ($p<.05$) compared to controls <u>Six month follow up</u> Reduction in anxiety ($p<.05$) and depression ($p<.05$) compared to controls	Low

Stanley et al 2013	RCT (2 arm); pre-post; 6 month follow up	Treatment (individual intervention): Cognitive Behavioural Therapy (16) Control: Treatment As Usual (16) 12 sessions in first 3 months, duration not reported. Up to 8 brief telephone booster appointments during 3-6 months.	The intervention was manualised Fidelity to the model: the therapy sessions were audio recorded and rated. They showed adequate and competency Intention to treat analysis was used	People with a diagnosis of dementia with mild-to-moderate cognitive impairment and symptoms of anxiety (NPI score ≥ 4) Older adult outpatient services in the USA M = 78.6 (SD = 9.68) years N = 32 (13 Male, 19 Female) 5	4%	Depression (GDS) Anxiety (NPI-Anxiety, RAID, GAI)	<u>One week follow up</u> Reduction in anxiety compared to controls ($p<.05$) using the RAID. No significant effect on anxiety using the NPI <u>Three month follow up</u> Reduction in anxiety compared to controls ($p<.05$) No significant effect on anxiety using the NPI Anxiety at 6 months	Unclear

AMS = Alzheimer's Mood Scale, BDI = Beck Depression Inventory, CSDD = Cornell Scale for Depression in Dementia, DMAS = Dementia Mood Assessment Scale, GAI = Geriatric Anxiety Inventory, GDS = Geriatric Depression Scale, HAM-A = Hamilton Anxiety Rating Scale, HDRS = Hamilton Rating Scale for Depression, NPI-A = Neuropsychiatric Inventory-Anxiety, OAS = Observed Affect Scale, MADRS = Montgomery-Asberg Rating Scale, RAID= Rating Anxiety in Dementia Scale.

Description of Studies

Participants were selected from populations in the USA, UK, Hong Kong and France. They were recruited from nursing homes, research centres and outpatient services. Seven studies recruited participants with dementia; five of these studies specified mild to moderate cognitive impairment in their inclusion criteria. No study met criteria for MCI. Participants ranged from 73 to 88 years and the proportion of females in each study ranged from 47% to 89%. Table 1 outlines the demographic details of the included studies.

All studies used a randomised control design. One study was not described as an RCT but it met criteria for being an RCT and was included in the review (Williams & Tappen, 2008). Interventions tested in the studies included cognitive behavioural therapy (Spector et al., 2015; Stanley et al., 2013), pleasant events behaviour therapy and problem solving behaviour therapy (Teri, Logsdon, Uomoto, & McCurry, 1997), music therapy (Guétin et al., 2009), Tai-Chi, Mahjong[1] (Cheng, Chow, Yu, & Chan, 2012), exercise (Williams & Tappen, 2008) and a

[1] Mahjong is a table-top game using tiles.

multicomponent intervention which incorporated CBT techniques, reminiscence, question asking reading, environmental supports and behavioural activity programs (Bailey, Stevens, LaRocca, & Scogin, 2016). Five studies tested an individual intervention and two studies tested a group intervention. The length of intervention ranged from bi-weekly sessions for six-weeks to 16 weekly sessions. Four studies used a wait list control or TAU and three studies used an active treatment condition such as reading sessions, conversation session and handicrafts. Six studies detailed the training or profession of the therapist, however one study did not provide this information (Guétin et al., 2009).

Depression was measured using the 15 item Geriatric Depression Scale (GDS) (Yesavage & Sheikh, 1986), the 24-item Hamilton Rating Scale for Depression (HRSD) (Hamilton, 1960), the 30-item GDS scale (Yesavage et al., 1982) and the 19- item Cornell Scale for Depression in Dementia (CSDD) (Alexopoulos, Abrams, Young, & Shamoian, 1988). Larger scores indicate greater levels of depression. Cheng and colleagues (2012) used the GDS as their primary measure of depression. However, the GDS is not a valid tool for assessing depression in PWD (Kørner et al., 2006). Secondary measures of depression were used in two studies (Teri et al., 1997; Williams & Tappen, 2008) but they were not included in the review. These were the Beck Depression Inventory (Beck, Steer, & Carbin, 1988) and Dementia Mood Assessment Scale (Sunderland & Minichiello, 1996).

Anxiety was measured using the 18-item clinician rated Rating Anxiety in Dementia (RAID) scale (Shankar, Walker, Frost, & Orrell, 1999) and the 14-item Hamilton Anxiety Rating Scale (HAM-A)(Hamilton, 1959). Higher scores on these scales indicate higher levels of anxiety. Secondary measures of anxiety were used in

two studies but they were not included in the review. Stanley and colleagues (2013) also used the anxiety subscale of the Neuropsychiatric Inventory Questionnaire (Cummings et al., 1994), Penn-State Worry Questionnaire (Meyer, Miller, Metzger, & Borkovec, 1990) and the Geriatric Anxiety Inventory (Pachana et al., 2007). Spector and colleagues (2015) used the Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983).

Quality Assessment and Risk of Bias

The Cochrane's Risk of Bias tool was used to rate the quality of each study.

Risk of Bias Items. The 'risk of bias graph' illustrates, in percentages, each risk of bias item for all the included studies (see Figure 2).

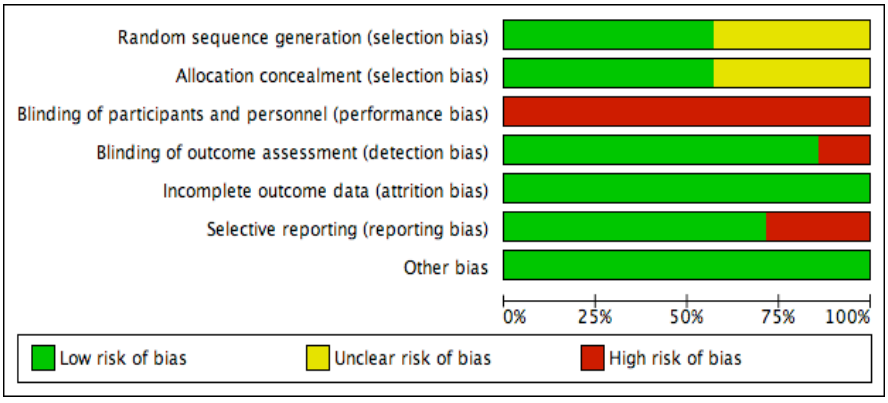


Figure 2: Risk of bias graph

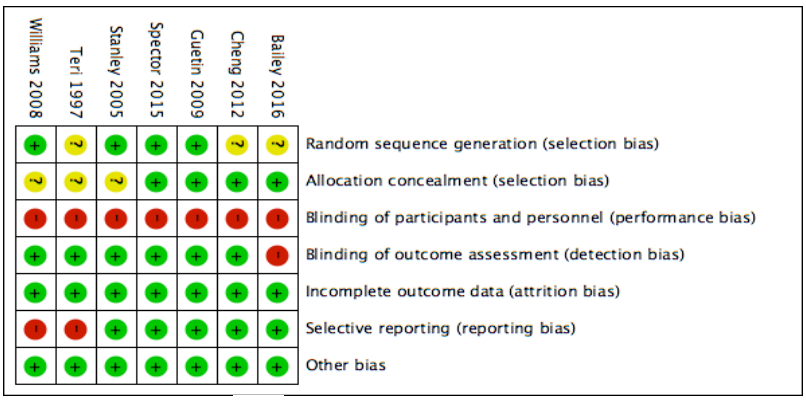
Overall, 43% (n=3) of the studies did not report sufficient detail to determine the bias for both random sequence generation and allocation concealment. All the studies (n=7) were unable to blind participants from the treatment conditions, due to the nature of the interventions. Most of the studies (86%, n=6) provided details that the assessors, completing baseline and follow-up assessments, were blinded to treatment allocation; and were deemed to have a low risk of detection bias. All the studies were considered to have a low risk of bias for outcome data being

incomplete and over 50% (n=4) reported intention-to-treat (ITT) data. Most of the studies (71%, n = 5) were deemed to have a low risk of selective reporting because they reported all pre-specified outcomes; whilst two studies did not report the results of one or more pre-specified outcomes. There were no other biases identified for the seven studies.

Risk of Bias Summary. The 'risk of bias' summary graph details the assigned risk of bias for each item for each included study (see Figure 3).

Studies were deemed as having a high risk of bias if they were rated as high risk of bias in any area, except for the blinding of participants. Studies that were deemed to have unclear risk in one or more areas, were assessed as having an unclear risk of bias. Studies that rated all risk of bias domains as low risk, apart from the blinding of participants, were classified as low risk of bias.

Two studies were judged as having a low risk of bias in all domains apart from the blinding of participants (Guétin et al., 2009; Spector et al., 2015). Two studies were classified as unclear risk of bias, due to limitation such as uncertainties about allocation concealment (Stanley et al., 2013) and random sequence generation (Cheng et al., 2012). Three studies were classified as high risk of bias, due to selective reporting (Teri et al., 1997; Williams & Tappen, 2008) and not blinding the outcome assessment (Bailey et al., 2016).



= low risk of bias, = unclear risk of bias, = high risk of bias

Figure 3: Risk of bias Summary

Meta-Analyses

Interventions for Depression. Four studies compared depression outcomes for psychosocial interventions and control interventions, within one week of completing treatment. These included group interventions (Bailey et al., 2016; Cheng et al., 2012) and an individual intervention (Williams & Tappen, 2008). The data from studies using a three-arm design (Cheng et al., 2012; Williams & Tappen, 2008) were adapted to be used in the meta-analysis. There were similarities in the intervention arms for the studies that used a three-arm design; therefore, the intervention arms were pooled together for the meta-analyses. For instance, the intervention arms were walking and exercise in Williams and colleagues (2008) and Mahjong and Tai Chi were both leisure activities in Cheng and colleagues (2012). One study did not provide enough information to be included in the meta-analysis and will be discussed separately (Teri et al., 1997).

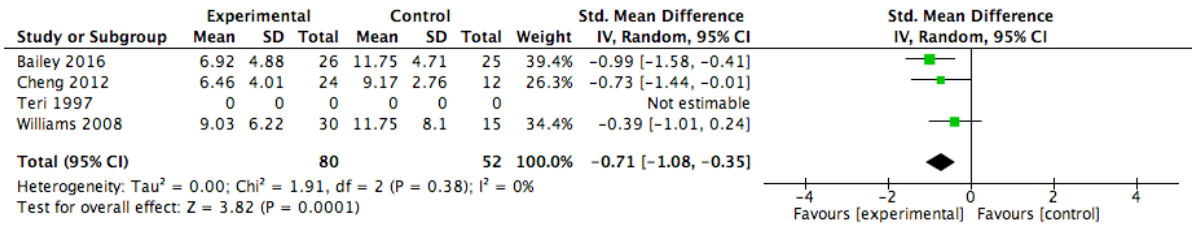


Figure 4: Forest plot of comparison: Depression outcomes one-week post intervention.

The total effect size, using a random-effects model, for the three data sets with 132 participants, was 0.71; (95% confidence interval (CI), -1.08 to -0.35). This indicated a significant ($p <. 0001$) medium to large effect for psychosocial interventions reducing symptoms of depression in PWD, within one week of completing treatment. Cheng and colleagues' (2012) reported a medium to large between groups effect size favoring Tai-Chi/Mahjong, as compared to an active control intervention (handicrafts) (SMD = -0.73, 95% CI: -1.44 to -0.01). Bailey and colleagues (2016) had a large between group effect size favoring a multicomponent intervention, as compared to treatment as usual, using the CSDD to measure depression (SMD = -.99, 95% CI: -1.58 to -.41). However, there was no significant effect when the GDS was used to measure depression. There was a medium between groups effect size when the GDS was used in the analysis. However, the analysis using CSDD was used because it is validated measure of depression in PWD. One study (Williams & Tappen, 2008) reported that exercise and walking was neither superior nor inferior to an active control intervention (conversation). There was no heterogeneity between studies ($I^2 = 0\%$), which suggests that the effect is accurate and can be trusted (see Figure 4). Teri and colleagues (1997), the study not included in the meta-analysis, found a significant reduction in depression scores in the treatment groups (pleasant events behaviour therapy and problem solving behaviour therapy), as compared to the control groups, on the HRSD ($p < .001$) and CSDD ($p < .001$).

Six-month follow up depression data was gathered for two studies (Cheng et al., 2012; Teri et al., 1997), although only one study provided adequate information to be included in the meta-analysis (Cheng et al., 2012). Cheng and colleagues (2012) reported that Tai-Chi/Mahjong was neither superior not inferior to the control

intervention. Teri and colleagues (1997) found that the significant effect was maintained on the HRSD ($p < .001$) and CSDD ($p < .001$).

Interventions on Anxiety.

End of Treatment. Three studies compared the anxiety outcomes for psychosocial interventions and control interventions, within one week of completing treatment. These were all individual interventions (Guétin et al., 2009; Spector et al., 2015; Stanley et al., 2013).

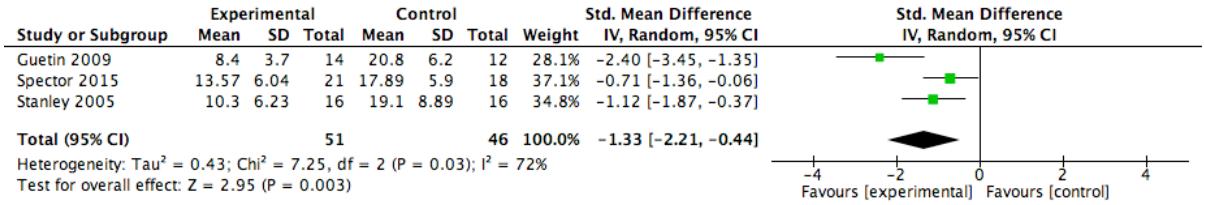


Figure 5: Forest plot of comparison: Anxiety outcomes one week post intervention.

The overall effect size, using a random-effects model, of the three data sets with 97 participants, was -1.33; (95% confidence interval CI, -2.21 to -0.44). This indicated a large significant effect ($p < .005$) for psychosocial interventions for reducing symptoms of anxiety for PWD, within one week of completing the intervention. Two studies had a large between groups effect size favoring psychosocial interventions (CBT and music therapy), as compared to a control intervention (Guétin et al., 2009; Stanley et al., 2013). One study reported a medium to large between group effect size favoring a psychosocial intervention (CBT), as compared to a control intervention (Spector et al., 2015). There was a high amount of heterogeneity between studies ($I^2 = 72\%$) (see Figure 5), which suggests that the effect may not be accurate and should be interpreted with caution.

Six-Month Follow Up. Two studies compared the anxiety outcomes for psychosocial interventions and control interventions, at 3 and 6 month follow up. These were both group interventions (Guétin et al., 2009; Stanley et al., 2013).

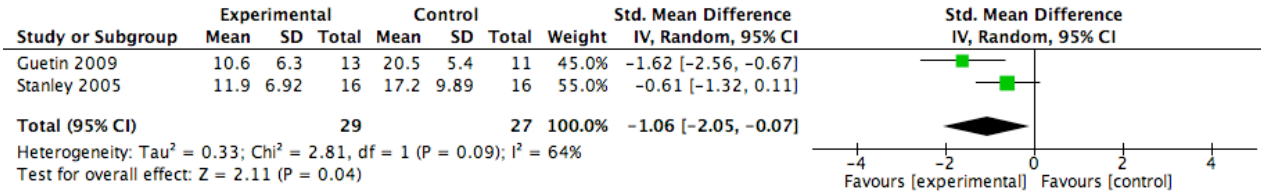


Figure 6: Forest plot of comparison: Anxiety outcome at six month follow up.

The overall effect size of the two data sets with 56 participants, was -1.06 (95% CI, -1.32 to -0.67), indicating that there was a significant large effect ($p < .05$) for psychosocial interventions reducing symptoms of anxiety for PWD. There was a medium to high amount of heterogeneity between studies ($I^2 = 64\%$), which suggests that the effect should be interpreted with caution (see Figure 6).

Discussion

Summary of Results

This review compared the effectiveness of psychosocial interventions for depression and anxiety in PWD or MCI, who were depressed or anxious. Seven RCTs (4 for depression, 3 for anxiety) were selected for narrative review and six of these studies (3 for depression, 3 for anxiety) were included in the meta-analyses.

Depression. A meta-analysis, from three RCTs, suggests that certain psychosocial interventions (Mahjong/Tai Chi, an exercise/walking intervention and a multicomponent intervention) are effective at improving depression symptoms in PWD, over the course of treatment. However, only one of these studies collected follow-up data (Cheng et al., 2012) and the treatment gains were not maintained (Cheng et al., 2012). The studies included in these meta-analyses only recruited participants from nursing homes. One study (Teri et al., 1997), not included in the meta-analysis, recruited participants from a community sample. It found that pleasant events behaviour therapy and problem solving behaviour therapy were

effective at improving depression symptoms at the end of treatment; and this effect was maintained at follow up.

Anxiety. The meta-analysis from three RCTs, suggests that psychosocial interventions (music therapy and CBT) are effective at reducing anxiety symptoms in PWD at the end of treatment (Guétin et al., 2009; Spector et al., 2015; Stanley et al., 2013). These three studies were also individually effective at improving anxiety symptoms at the end of treatment. The meta-analysis, from two RCTs (music therapy and CBT), showed that treatment gains were maintained at follow-up (Guétin et al., 2009; Stanley et al., 2013). More specifically, music therapy maintained the effect (Guétin et al., 2009) and CBT did not (Stanley et al., 2013).

Strengths and Limitations

There was variation in the included studies, in terms of the quality of studies, population studied, the nature, intensity and frequency of the psychosocial intervention, which limited the conclusions made about specific type of interventions for specific populations. There was limited heterogeneity detected between study effects for the meta-analyses for depression. There was a large amount of heterogeneity between study effects for the meta-analyses for anxiety, which suggests that the effect should be interpreted with care. However, the statistic that quantifies heterogeneity (I^2) can be imprecise and biased when used in small meta-analyses, and should be interpreted with caution (Von Hippel, 2015).

The quality of the studies' methodology and reporting is consistent with the findings of previous reviews (Orgeta et al., 2014), which suggested that the quality of evidence is mixed, as a large proportion of the included studies were rated as being unclear or low quality. The quality of the studies, for depression interventions,

was rated as poor, with two studies having a high risk of bias and one having an unclear risk of bias. The quality of studies, for anxiety interventions, was rated as good. The risk of bias was rated as low for two studies and unclear for one study; and all studies used intention to treat analysis. Future RCTs are recommended to use a rigorous methodology and report the relevant information, as detailed in the Consolidated Standards of Reporting Trials (CONSORT).

Around half of the studies did not provide details of fidelity checks (57%, n = 4); therefore, it is difficult to determine if facilitators adhered to the intervention protocol. Three studies did not detail information about power calculations therefore it was unclear if the sample size was sufficient to detect an effect (Bailey et al., 2016; Teri et al., 1997; Williams & Tappen, 2008). The sample sizes in the study were small, ranging from 25 to 68 participants. Therefore, future research needs to recruit larger sample sizes. A large proportion of the studies (57%, n=4) used a "treatment as usual" or "waitlist" control group, as compared to an active control group. It would be beneficial for future research to use an active control group to control for the placebo effect (Boot, Simons, Stothart, & Stutts, 2013).

One study did not describe itself as an RCT, although it met criteria for being an RCT and was included in the review (Williams & Tappen, 2008). It was also unclear whether this individual intervention (exercise and walking) met criteria for being a psychosocial intervention. However, the aim of the intervention was to reduce symptoms of depression using exercise and walking, similar to behavioural activation (Veale, 2007), therefore it was deemed to be a psychosocial intervention. Nevertheless, the data was reanalysed without this study and it did not change the overall results. It was the only intervention for depression that did not significantly improve symptoms of depression, one-week post intervention.

Highly sensitive search strategies for identifying RCTs were used to identify studies (Eady et al., 2008; Higgins & Green, 2011; Wong et al., 2006). To minimise bias, it is recommended that two people complete the literature searches, the extraction of suitable studies and the assessment of risk of bias. However, due to limited resources, the student completing the review completed these tasks, with final studies agreed with her research supervisor.

Implications for Future Research

Depression. There is some evidence to suggest that psychosocial interventions can reduce symptoms of depression in PWD who are depressed. These findings are similar to other reviews (Orgeta et al., 2014; Regan & Varanelli, 2013; Teri et al., 2005). However, these findings cannot be generalised to all PWD because the studies, in the meta-analysis for depression, only recruited participants from nursing homes. Therefore, research is required on interventions for depression for PWD in community samples.

Most of the studies included in the meta-analyses for depression did not measure depression symptoms in participants several months after the intervention; and the one study that did, found that the improvements were not maintained. Therefore, future research should aim to collect longitudinal data to inform the longer-term benefits of interventions for PWD. The only study that continued to show beneficial effect, a considerable amount of time after the end of the intervention, was the pleasant events behaviour therapy and problem solving behaviour therapy (Teri et al., 1997), which was not included in the meta-analysis. This study recruited participants from a community sample and their mean age was younger than the studies included in the meta-analysis; potentially suggesting that

the benefits of interventions on depression symptoms may be better maintained in younger PWD in community samples, a potential focus for future research.

Group interventions (multicomponent intervention, Mahjong/Tai Chi), were found to be effective at improving depression symptoms (Bailey et al., 2016; Cheng et al., 2012), although the individual intervention (exercise/walking) (Williams & Tappen, 2008) was not. Research suggests that individual interventions for depression are superior to group interventions in working ages adults (Huntley, Araya, & Salisbury, 2012), however these results suggest that there may be different trends in a dementia population. In a qualitative study, nursing home residents preferred that treatments for depression focused on reducing isolation, as opposed to individual psychotherapy (Choi, Ransom, & Wyllie, 2008). Only one of the studies (Cheng et al., 2012) compared the group treatment condition (Mahjong/Tai Chi) to a group control condition (handicrafts). While this study did find a benefit of the intervention immediately after treatment, this effect was not present at six-months follow up. Future research should control for the benefits of social contact when testing group interventions.

Anxiety. All the included studies had a medium-to-large (Spector et al., 2015) or large effect size (Guétin et al., 2009; Stanley et al., 2013). Therefore, music therapy and CBT interventions for PWD with anxiety should be prioritised for research. The evidence for music therapy is perhaps particularly strong as it used an active control group (reading group) and it was also found to maintain its large effect at six month follow up (Guétin et al., 2009). This maybe the result of participants being offered more sessions (16 sessions), as compared to CBT (10-12 sessions) (Spector et al., 2015; Stanley et al., 2013). Therefore, it may be beneficial for future research to investigate if interventions that provide more sessions to PWD

are more effective than those that provide fewer sessions.

Implications for Practice

Depression. The multicomponent intervention (Bailey et al., 2016) had the largest effect size for depression interventions, despite using intention to treat analysis. However, the study was rated as having a high risk of bias. This intervention incorporated CBT techniques, reminiscence, environmental supports and a behavioural activity programs. This intervention may be beneficial for PWD residing in nursing homes. Future research should identify which component of this intervention was the agent for change.

Half of the interventions (multicomponent intervention, Mahjong/Tai Chi) had low attrition rates (Bailey et al., 2016; Cheng et al., 2012), which is positive for practice. However, attrition rates in RCTs may not be comparable to attrition rates in normal practice therefore it is recommended that the implementation of these interventions are tested in services.

Anxiety. Music therapy (Guétin et al., 2009) was found to improve anxiety for PWD residing in nursing homes, with a large effect size. Whereas, CBT was found to improve anxiety for PWD from a community setting, with a medium-to-large (Spector et al., 2015) and large (Stanley et al., 2013) effect size. Music therapy and CBT interventions for PWD with anxiety should be prioritised for practice. These interventions may be particularly effective because they focus on thoughts and emotions. CBT is specifically designed to understand emotions, thinking styles and behaviours associated with anxiety (Beck et al., 1963). Music therapy encourages emotional expression to help develop an understanding of one's emotions (Guétin et al., 2009).

Completeness of Evidence

Most of the included studies recruited participants with mild to moderate dementia. The review did not identify any RCTs that were aimed at people with MCI. There were four potential studies that were identified; although they recruited participants with cognitive impairment which did not meet the established criteria for MCI (Alexopoulos et al., 2011; Areán et al., 2010; Kiosses et al., 2015a; Kiosses, Arean, Teri, & Alexopoulos, 2010). As depression and anxiety have been found to increase the risk of dementia in people with MCI (Cooper et al., 2015), it is important that psychosocial interventions for depression and anxiety are available in this population. One study (Kiosses et al., 2015b) was excluded because the sample consisted of participants with definite or probable dementia, and it did not specify the proportion of participants with probable dementia.

Seven studies, that tested psychosocial intervention for PWD, were identified. The depression outcomes for three studies and the anxiety outcomes for three studies were pooled together. However, data from one study failed to be obtained despite contacting the author (Teri et al., 1997). Therefore, the study could only be included in the narrative review.

Conclusion

This systematic review with meta-analyses was distinctive because it aimed to compare the efficacy of psychosocial interventions on symptoms of depression and anxiety in PWD or MCI who were depressed and/or anxious. The review did not identify any RCTs that were aimed at people with MCI therefore this population should be targeted for future research. Preliminary evidence suggests that certain psychosocial interventions are effective at improving depression and anxiety symptoms in PWD over the course of treatment. The quality of evidence was good

for the interventions targeting anxiety, whereas it was poor for the interventions targeting depression. However, it was recommended that music therapy and CBT interventions for PWD and anxiety should be prioritised for research and practice. The psychosocial interventions included in the review did not report any adverse events, which suggest that the observed effect is beneficial to PWD. Future research would be improved with carefully targeted interventions, adequately powered samples and active control groups.

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Part II: Empirical Paper

The Impact of a Mindfulness Based Cognitive Therapy (MBCT) Group for Depression in People with Dementia attending Memory Clinics: A Feasibility Randomised Controlled Trial

Abstract

Aims: Depression and anxiety have been identified as specific targets for psychosocial interventions for people with dementia (PWD). This feasibility study aimed to do exploratory analysis on whether an adapted Mindfulness Based Cognitive Therapy (MBCT) group would lead to greater reductions in symptoms of depression and anxiety, in PWD who are depressed, as compared to treatment as usual (TAU).

Method: A feasibility randomised controlled trial (RCT) was used. PWD that were experiencing depression were recruited from memory clinics. Twenty participants were randomised to either an adapted MBCT group (n=10) or TAU (n=10). This is a joint project completed with Jacob Payne (JP). Measures of depression, anxiety, quality of life (QOL) and cognition were assessed at baseline and follow-up. Measures of depression and anxiety are analysed and reported here. JP reports on the feasibility of the intervention and measures of QOL and cognition.

Results: The MBCT group did not show significant reductions in depression or anxiety at follow-up, as compared to TAU.

Conclusions: There is inadequate evidence to recommend this adapted MBCT intervention for PWD in memory clinics. The MBCT intervention needs redevelopment and piloting before further testing in an RCT.

Introduction

Dementia

Dementia is a neurodegenerative syndrome characterised by the progressive deterioration of cognitive functioning and activities of daily living (Albert et al., 2011; WHO, 2016). The global prevalence of dementia was approximately 46.8 million in 2015; and this is predicted to double by 2050 (Prince et al., 2015).

Depression and Anxiety

Depression and anxiety are common in PWD (Lyketsos et al., 2002); with the prevalence estimated to be between 20% and 30% for depression (Enache, Winblad, & Aarsland, 2011) and between 5% and 21% for anxiety (Ferretti, McCurry, Logsdon, Gibbons, & Teri, 2001; Savva et al., 2009; Starkstein, Jorge, Petracca, & Robinson, 2007). In PWD, depression and anxiety are linked with negative outcomes, such as reduced quality of life, worsened cognition, increased functional impairment, behavioural disturbance and mortality rates (Banerjee et al., 2011; Butters et al., 2008; Kales, Chen, Blow, Welsh, & Mellow, 2005; McCurry, Gibbons, Logsdon, & Teri, 2004; Rapp et al., 2011; Starkstein et al., 2007).

Interventions for Depression and Anxiety

Psychiatric medications, that are prescribed to treat depression and anxiety, are associated with adverse side effects (Stomski, Morrison, & Meyer, 2016); and there has been limited support for their effectiveness in PWD (Leong, 2014; Moretti, Torre, Antonello, & Pizzolato, 2006; Sepehry, Lee, Hsiung, Beattie, & Jacova, 2012). Non-pharmacological interventions for depression and anxiety, in PWD, have been identified as a potential areas for development (Cooper, Sommerlad, Lyketsos, & Livingston, 2015), with the government promising to improve access to evidence based therapies (Department of Health 2011). There are currently limited evidenced

based non-pharmacological treatments currently available for PWD who are depressed.

Non-pharmacological Interventions. A Cochrane review, including a meta-analysis, found that psychological treatments were effective at improving depression symptoms in PWD (Orgeta, Qazi, Spector, & Orrell, 2014). The studies included in this review did not require the participants to meet criteria for depression at baseline. The challenge of designing psychosocial interventions for PWD is making the appropriate adaptations for a range of possible cognitive impairments, such as memory, comprehension, learning capacity, orientation, attention and language.

Mindfulness with Older Adults. Mindfulness involves deliberately holding one's attention on the present moment, without passing judgment (Kabat-Zinn, 2006). Mindfulness has been incorporated into structured group programmes such as Mindfulness Based Cognitive Therapy (MBCT) (Segal, Williams, & Teasdale, 2002) and Mindfulness Based Stress Reduction (MBSR) (Kabat-Zinn, 2013). Mindfulness has been found to improve depression symptoms in older adults without a recognised cognitive decline (Gallegos, Hoerger, Talbot, Moynihan, & Duberstein, 2013; Moss et al., 2015).

Mindfulness with PWD. In a quasi-experimental study, an adapted MBSR intervention significantly reduced depressive symptoms in people with progressive cognitive decline (dementia, mild cognitive impairment and memory loss) living in the community (Paller et al., 2015). In a feasibility RCT for PWD in care homes, a mindfulness based intervention (MBI) improved quality of life and was deemed a feasible intervention for PWD (Churcher Clarke, Chan, Stott, Royan, & Spector, 2017). There were no significant changes in depressive symptoms, although there

may have been less scope for change because it did not recruit PWD who were depressed. A third of participants who met criteria for depression in the MBI group were no longer in the clinical range at follow-up; whereas this change was not evident in the TAU group. Based on this, the authors suggested that interventions could be designed for PWD and depression. The residential sample in this study was more impaired than community samples; therefore, the participants may have not understood some of the mindfulness techniques. This population was more dependent on support and they typically had no carers available to support them. Therefore, the intervention may be more suitable for a higher functioning community sample. It recommended that future research should investigate the feasibility of running a mindfulness group for PWD, with milder cognitive impairment, in a community setting.

Community Services

There are currently no clear guidelines about which services (e.g. Increasing Access to Psychological Therapies (IAPT) or memory clinics) should see people with mild dementia, whose primary concern is depression. Memory clinics are the specialist outpatient services that offer assessment, early diagnosis, treatment and advice to people with memory disorders such as dementia (Lindesay, Marudkar, van Diepen, & Wilcock, 2002). They focus on providing interventions for cognition, as opposed to psychological interventions for depression. However, memory clinics offer a unique opportunity to recruit people with mild dementia and depression in a community setting. Research in this population could inform primary care services, whose main aim is to provide psychological interventions (e.g. IAPT), about evidenced based interventions for depression in PWD.

Current Study

Joint Project and Joint Aims. This feasibility study was part of a joint D.Clin.Psy. project completed with Jacob Payne (JP). The primary aim of this study is to establish the feasibility of doing an RCT for an adapted MBCT programme (e.g. acceptability, recruitment, retention, adherence), which is reported by JP. The secondary aim is to assess whether an adapted MBCT group intervention will lead to greater reductions in symptoms of depression, anxiety, quality of life (QOL) and cognition in PWD who are depressed, as compared to treatment as usual (TAU). Measures of depression, anxiety, quality of life (QOL) and cognition were assessed at baseline and follow-up. JP reports on the measures of quality of life and cognition. Deirdre Noone (DN) reports on the impact of the intervention on depression and anxiety. Appendix C details JP and DN's contributions to the feasibility RCT.

Aims/Hypotheses. As this is a feasibility study, it is expected that the study will be insufficiently powered to detect an effect. The aim of this section of the study is to do an exploratory analysis to assess whether an adapted MBCT group intervention will lead to greater reductions in symptoms of depression and anxiety in PWD who are depressed, as compared to treatment as usual (TAU).

Methods

Design

A single-blind, multicentre, feasibility RCT of an adapted MBCT group versus TAU for PWD who are depressed. The research protocol has been published (Aguirre et al., 2017).

Participants

The study selected participants from two memory clinics in Greater London between June 2016 and April 2017. These memory clinics were chosen based on professional contacts within the research team.

Participant inclusion criteria. Participants were considered for inclusion in the study if they:

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

(b) were in the mild stages of dementia, as indicated by a score of 18 or above on the Mini Mental State Examination (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, to engage in the group, physically able to attend group, able to concentrate in a 90-minute session), which was based on judgement of care coordinator and blind assessor.

Participant exclusion criteria. Participants were excluded if they:

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

(b) presented with suicidal intent that needed immediate intervention;

(c) had a diagnosis of a learning disability;

(d) were involved in other psychosocial intervention research;

(e) had a diagnosis of psychosis;

(f) were within two months of a bereavement.

Procedure

Recruitment of Participants. The principal researchers attended regular memory clinic team meetings, where they provided the team with details about the study, such as information about the intervention and inclusion criteria. The staff identified and discussed the study with suitable patients; and provided them with an information sheet (Appendix D1). If they were interested, they met with a researcher to establish whether they would like to participate, and if so obtained informed consent (Appendix D2). The participant was asked if they would like to invite a carer to complete some questionnaires. The carer was provided with an information sheet (Appendix D3); and informed consent (Appendix D4) was obtained the day of the assessment. The information sheets and consent forms from a previous study (Churcher Clarke et al., 2017) were adapted for the purposes of this study.

An assessor, independent from the group facilitators, met participants for an assessment within two weeks of the group starting and finishing. The initial assessment collected information on demographics, cognitive functioning (as measured by the MMSE) and levels of depression (as measured by the Patient Health Questionnaire). A full assessment was completed for those participants who met the inclusion criteria. The assessor was blind to which group the participant was allocated.

Randomisation. An independent researcher created a randomisation sequence for the study using online software sealedenvelop.com. The independent researcher allocated participants to treatment conditions via email. The assessors, that completed the outcomes measures with participants, were blind to the randomisation sequence and allocation of participants until data analysis was completed. Participants were randomised using a one-to-one ratio.

Intervention and Control Arms

MBCT Group. Participants were invited to attend a weekly MBCT group for eight weeks, which included skills training and in-class practice. The sessions were 90 minutes long. A psycho-education session about MBCT was offered to participants and their carers before the start of the group.

The MBCT for the prevention relapse in recurrent depression (Segal et al., 2002) was adapted for PWD. It was guided by: (1) MBCT literature (Bartley, 2011; Segal et al., 2002; Teasdale, Williams, & Segal, 2014; Williams & Penman, 2012) and consultation with MBCT facilitators from the Oxford Mindfulness Centre (OMC) and senior professionals working with PWD. The structure of the sessions included the use of regular summaries. Participants were encouraged to talk about their cognitive difficulties and symptoms of depression. Shorter meditations (10-20 minutes) were also used, as compared to the original protocol (25-40 minutes). There were summaries provided at the beginning and end of sessions to help consolidate learning, which was informed by literature on CBT for older adults (Simon, Cordás, & Bottino, 2015; Spector et al., 2015; Stanley et al., 2013).

The mindfulness exercises used in the sessions included: body scan, mindful eating, mindful stretching, and mindfulness exercises that had a specific focus (breath, body, sounds, emotions, thoughts). Home practice involved 'formal' practices (listening to the audio recording of mindfulness exercises) and 'informal' practices (incorporating mindfulness into routine daily experiences, such as eating, walking and brushing teeth). Participants were asked to complete a formal practice five times a week; and informal practice for an additional 10–15 minutes a day. Participants were asked to use homework logs to record information about their

formal and informal practice; such as the audio-recording they used and the length of practice. Each participant was contacted each week by a facilitator to support home practice. The protocol is detailed in Appendix B.

Control Group. The TAU group received usual appointments with their health care professionals.

Facilitators' Experience

There was an MBCT group running at each of the two memory clinics. Each of the groups were facilitated by two appropriately trained facilitators. There were two level two trained MBCT facilitators leading one group. There was one level one MBCT trained facilitator leading the other group. The latter group was assisted by a Trainee Clinical Psychologist (author) that had completed the 8-week MBCT programme. In addition to peer supervision, an associate teacher from the Oxford Mindfulness Centre (OMC) provided regular supervision.

Measures

Outcome measures were completed at baseline (within two weeks before the intervention) and follow up (within two weeks after the intervention). Demographic details were collected, such as age, gender, ethnicity, marital status, education and dementia type. Outcome measures were used to assess cognitive function, depression and anxiety. There were two outcome measures used for both depression and anxiety. Some measures were included because they are used clinically in primary care services (e.g. IAPT) and other dementia specific measures were used because they are the 'gold standard' for assessing depression and anxiety in PWD.

Cognitive function. The Mini Mental State Exam (MMSE) (Folstein et al., 1975) involves the participant doing 11 tasks (orientation to time and place, attention, recall, language and visual construction), with scores ranging from 0-30.

Cognitive impairment was categorised as severe for scores between 0-17, mild for scores between 18-24 and not present for scores between 24-30 (Tombaugh & McIntyre., 1992). The MMSE is an widely used tool for assessing cognition in dementia; and the reliability and validity are satisfactory (Woodford & George., 2007). It was used as a screening tool for inclusion. Participants were eligible if they scored 18 and above.

Depression.

Patient Health Questionnaire. Patient Health Questionnaire (PHQ-9) (Kroenke et al., 2001) is a nine-item questionnaire based on the DSM-IV depression diagnostic criteria, with each item rated 0–3 (0=not at all, 1 = several days, 2 = more than half the day, 3 = nearly every day), with scores ranging from 0-27. The severity of depression in indicated by the score (0–4, minimal depression; 5–9, mild depression;10–14, moderate depression; 15–19, moderately severe depression; 20–27, severe depression). The PHQ-9 has been shown to be acceptable to service users in memory clinics, alongside being brief and easy to complete (Hancock & Larner, 2009). It was used as a screening tool for inclusion. The PHQ-9 is commonly used in primary care services (e.g. IAPT).

Cornell Scale for Depression in Dementia. The Cornell Scale for Depression in Dementia (CSDD) (Alexopoulos, Abrams, Young, & Shamoian, 1988) is a 19 item clinician-administered outcome measure used to assess depression. Information was gathered from interviews with the participant and an informant (e.g. family member) and this information is used to rate five areas of depression (mood-related signs, behavioural disturbance, physical signs, biological functions and ideational disturbance). Each item had a three-point scale (0=absent, 1 = mild or intermittent, 2 = severe) with a maximum score of

57. Significant depressive symptoms are indicated as a score of 8 and above (Alexopoulos et al., 1988; Burns, 2002). The CSDD is deemed to be the 'gold standard' for assessing depressive symptoms in PWD (Kørner et al., 2006; Sheehan, 2012).

Anxiety.

Rating Anxiety in Dementia scale (RAID). RAID (Shankar, Walker, Frost, & Orrell, 1999) is an 18-item clinician-administered outcome measure. Information is gathered from interviews with the participant and an informant (e.g. family member) and this information is used to rate four areas of anxiety (worry, apprehension, vigilance, motor tension, autonomic hypersensitivity). Each item is rated on a four-point scale (0=absent, 1 = mild or intermittent, 2 = moderate, 3= severe) with a maximum score of 54. A score of 11 and above was the cut off for clinical anxiety (Shankar et al., 1999). The RAID is deemed to be the best measure for measuring anxiety in this population (Seignourel, Kunik, Snow, Wilson, & Stanley, 2008).

Generalized Anxiety Disorder 7-item scale (GAD-7). GAD-7 is a seven-item questionnaire that assesses anxiety. Each item is rated 0–3 (0=not at all, 1 = several days, 2 = more than half the day, 3 = nearly every day) with scores ranging from 0-21. Scores of 5, 10 and 15 are taken as the clinical cut off for mild, moderate and severe anxiety respectively. This measure has not been validated in PWD. The GAD-7 is commonly used in primary care services (e.g. IAPT).

Data Analysis

Statistical Package for Social Sciences (version 24) was used to analyse the data. Intention to treat analysis was used, which involves analysing the data of all

participants that were randomised, to control for non-compliance and missing data. This provides an unbiased estimate of the treatment effect and improves the quality and validity of the results (Yelland et al., 2015).

Due to the small sample size in this study, an exploratory analysis on outcomes measures was completed. A Mixed Between-Within Subjects Analysis of Variance (ANOVA) was used to compare the outcomes of the MBCT group to TAU. All data was checked to see if it met the assumptions of normality and the appropriate parametric/non-parametric tests were used. The between subject factors was the treatment condition (MBCT group, TAU) and the within subject factor was the time (change scores on the CSDD, PHQ-9, RAID and GAD7). *Post hoc* adjustments were not used to control for multiple comparisons because the study was underpowered (Kim, 2015).

Power Analysis

As this is a feasibility study, it was expected that it would be insufficiently powered. There has been limited high-quality research on the effects of MBCT for depression for PWD, which made it challenging to estimate the effect size for this study. People with traumatic brain injury (TBI) have similarities with this population. Therefore a community based MBCT intervention for TBI with depression, which found a significant medium effect size for depression (Bédard et al., 2014), was used to estimate the sample size.

G*Power 3 software was used to calculate the sample size. Based on an A Priori analysis, a sample size of 34 was required to detect a medium effect size of .25 (Cohen's f), when alpha is set at .05 and power at 0.80, for a Mixed Between-Within Subjects ANOVA.

Ethics and Funding

Ethical approval was granted by City and East Research Ethics Committee in London (Ref: 16/LO/0578, Appendix E) and the local Research and Development departments (Appendix F). The study was insured by the Joint Research Office at University College London (Appendix G). One site obtained funding, from the Oxford Mindfulness Centre, to help run the study.

CONSORT Checklist

A CONSORT checklist was used to guide the inclusion of information about the RCT. This is detailed in Appendix H.

Results

Participants

The CONSORT participant flow diagram is detailed in Figure 1. Twenty participants were assessed at baseline (10 MBCT, 10 TAU) and nineteen participants at follow up (9 MBCT, 10 TAU). One participant was excluded prior to randomisation because physical health difficulties would have prevented her attending the MBCT group.

The mean attendance for both groups was 7.3 (SD=2.63) sessions, with a range of two to nine sessions. Eighty percent of participants attended seven or more sessions. Two participants dropped out of the MBCT intervention. One participant dropped out because of ill health, but completed the follow-up assessment. The other participant decided to drop out because she was not enjoying the intervention and she did not think she had depression; she did not complete the follow up assessment. The last measurement forward technique (LMFT) (Molnar, Hutton, & Fergusson,

2008) was used for this participant, which involved the participant's baseline scores being entered as follow up scores; and included in the intention to treat analysis.

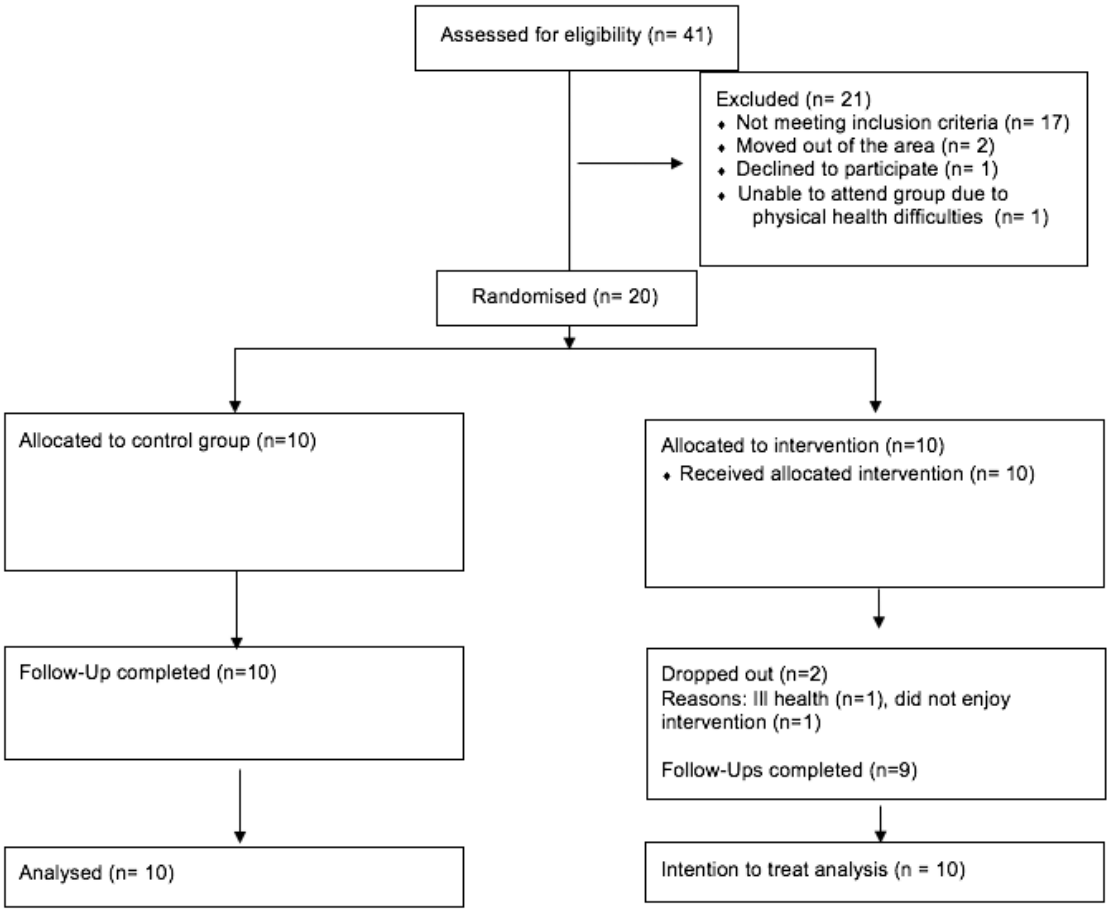

Figure 1: CONSORT participant flow diagram

Missing Data Analysis

There was missing data for ten percent (n = 2) of participants on the PHQ-9, after using LMFT for another participant. The missing items ranged from one item (n = 1, 5%) to nine items (n = 1). Littles's MCAR test was non-significant ($\chi 2$ = 27.22, df = 26, p = .40), which suggests that the PHQ-9 data was missing completely at random. The baseline and follow up PHQ-9 data was imputed using Expectation Maximization (EM) algorithm. This allowed the data from an extra two participants to be used, one at baseline and one at follow up, being included in the analysis for PHQ-9. The imputed and non-imputed data is reported.

Sixty-five percent (n=13) of participants did not have an informant/carer available to complete the CSDD and RAID assessment; with reasons including living alone with limited family contact or refusing consent to contact a family member. Of the available seven carers, there was missing carer data for two participants on the CSDD and one participant on the RAID. One carer was unavailable to complete the follow up assessment; and there was one missing item for the baseline CSDD measure. From the overall sample, there was only 25% (n = 5) of complete CSDD carer data and 30% (n = 6) complete RAID carer data available. Carer data was excluded from the analysis because there was insufficient data.

Descriptive Statistics

The demographic details of the participants are shown in Table 1. At baseline, there were no significant differences between the groups in terms of age, ethnicity, marital status, gender, cognitive functioning, depression and anxiety.

Analyses

All data met the assumptions for homogeneity of variance and assumptions of normality, required for the ANOVAs. Table 2 shows the mean profiles, mean change scores and ANOVA interaction effects for depression and anxiety.

Exploratory Analyses for Outcome Measures.

Depression. At baseline, thirteen participants (seven in intervention group, six in control group) were in the clinical range for depression on the CSDD. One participant from both groups moved outside the clinical range at post-test. In a Mixed Between-Within Subjects ANOVAs, there were no significant interactions between time and group found on measures of depression, as assessed by the CSDD ($F(1,17) = .06$, $p = .80$) and PHQ-9 ($F(1,18) = 2.45$, $p = .14$). There was no significant main effect of group, as assessed by the CSDD ($F(1,17) = 0.54$, $p = .47$) and PHQ-9 ($F(1,18)= 1.47$, $p = .24$). There was no significant main effect of time, as assessed by the CSDD ($F(1,17) = 3.60$, $p = 0.80$). However, depressive symptoms, as assessed by the PHQ-9, reduced for both the intervention and TAU groups from pre-to-post intervention. The significant main effect of time on depressive symptoms (PHQ-9) was detected ($F(1,18) = 8.68$, $p = .009$), with a very large effect size ($\eta_p^2 = .33$)[2] (See Table 2). The imputed data for the PHQ-9 was reported. The non-imputed data is reported in Table 2 and the results were largely similar.

Anxiety. In a Mixed Between-Within Subjects ANOVAs, there were no significant interactions between time and group found on measures of anxiety, as assessed by the RAID ($F(1,17) = .27$, $p = .61$) and GAD-7 ($F(1,17) = .69$, $p = .42$). There was no significant main effect of group using the RAID ($F(1,17) = .18$, $p = .68$) and GAD-7 ($F(1,17)= .027$, $p = .87$). There was no significant main effect of

[2] Effect size (η_p^2)*:* small ≥ .01, medium ≥ .06, large ≥ .13

time using the RAID ($F(1,17) = .04$ $p = .84$) and the GAD-7 ($F(1,17) = .83$, $p = .38$) (See Table 2).

Table 1: Demographics

Characteristics	*Intervention Group (n=10)*	*Control Group (n=10)*	*All participants (n=20)*
Age (years)			
Mean (SD)	77.80 (10.63)	76.80 (4.96)	77.30 (8.09)
Range	62-93	69-86	62-93
Gender			
Male (%)	1 (10)	4 (40.0)	5 (25)
Female (%)	9 (90)	6 (60.0)	15 (75)
MMSE score			
Mean (SD)	25.50 (3.17)	23.50 (3.50)	24.50 (3.41)
Range	21-29	18-28	18-29
Dementia diagnosis			
Alzheimer's Disease	6	4	10
Vascular Dementia	1	2	3
Mixed Dementia	1	4	5
Dementia unspecified type	2	0	2
Anti-dementia medication			
Prescribed	4	5	9
Not-prescribed	3	2	5
Unknown	3	3	6
Average years of formal education (SD)	11.40 (2.50)	12.1 (2.52)	11.74 (2.47)
Ethnicity			
White British (%)	8	9	17
White European (%)	1	0	1
Asian (%)	0	1	1
Black Caribbean (%)	1	0	1
Marital status			
Widowed	2	5	7
Married	5	5	10
Single	1	0	1
Divorced	2	0	2

Table 2: Mean profiles, mean change scores and ANOVA interaction effects for CSDD, PHQ-9, RAID and GAD-7.

Variable	n	Baseline Mean (SD)	Follow-up Mean (SD)	Change from baseline (SD)	ANOVA	F	df	P	Effect Size η_p^2
CSDD^									
Treatment	10	11.90 (5.38)	10.20 (5.34)	+1.70 (4.42)	Time	3.60	1,17	.80	.18
Control	10	13.6 (4.06)	11.33 (3.64)	+2.22 (4.57)	Group	.54		.47	.03
					TxG	.06		.80	.004
PHQ-9 without imputations									
Treatment	9	14.00 (3.57)	10.67 (4.94)	+3.33 (4.58)	Time	15.15	1,16	.001*	.49
Control	9	17.00 (5.36)	11.56 (4.95)	+5.44 (4.97)	Group	1.01		.33	.06
					TxG	0.88		.36	.05
PHQ-9 with imputations									
Treatment	10	13.17 (4.26)	11.40 (5.21)	+1.77 (6.56)	Time	8.68	1,18	.009*	.33
Control	10	17.3 (5.14)	11.49 (4.67)	+5.81 (4.84)	Group	1.47		.24	.08
					TxG	2.45		.14	.12
RAID^									
Treatment	10	12.1 (5.2)	12.67 (7.62)	-.56 (9.29)	Time	.044	1,17	.84	.003
Control	10	14.3 (9.26)	13.0 (7.32)	+1.3 (5.96)	Group	.18		.68	.01
					TxG	.27		.61	.02
GAD-7									
Treatment	10	8.70 (8.23)	8.60 (6.53)	+.1 (6.38)	Time	.83	1,17	.38	.046
Control	10	9.22 (6.28)	7.11 (6.49)	+1.30 (5.96)	Group	.027		.87	.002
					TxG	.69		.42	.039

(+) = an improvement, (-) = a deterioration, (*) = significance, (^) = only participant data is used in the CSDD and RAID. Effect size (η_p^2 *):* small ≥ .01, medium ≥ .06, large ≥ .13.

Discussion

Summary of Results

Although one measure (PHQ-9) suggested an overall improvement in depression over time across both groups, the MBCT group did not show significant reductions in depression or anxiety at follow-up, as compared to TAU. Only one participant moved outside the clinical range for depression (a measured by the CSDD) in both the intervention and control group. Therefore, the null hypotheses could not be rejected. The mean change scores may suggest that there were greater reductions in depression and anxiety in the TAU group, as compared to the MBCT group, although these changes were not significant. This may be explained by natural variability, the Hawthorne Effect or it may suggest a problem with the MBCT protocol. Also, there were no significant improvements in quality of life and cognition (Payne, 2017).

Interpretations of Findings

In a feasibility RCT (Churcher Clarke et al., 2017) that tested a mindfulness based intervention (MBI) for PWD in care homes, symptoms of depression or anxiety were not found to reduce significantly; although a third of the participants receiving the intervention moved out of the clinical range of depression. Therefore, it was hypothesised that PWD in the clinical range of depression would be receptive to treatment (Churcher Clarke et al., 2017), which was not supported in this study. However, the mindfulness intervention was more frequent and the duration of sessions shorter, with ten hour-long sessions twice weekly (Churcher Clarke et al., 2017), as compared to eight weekly 90 minute sessions in the protocol used in this study. A quasi-experimental study found that an adapted MBSR programme, for people with mild cognitive symptoms, significantly improved symptoms of

depression (Paller et al., 2015). Eighty percent of these participants had a carer that attended the intervention and supported home practice. In contrast, carers did not attend the MBCT group in the current study; and only a small proportion of participants had a carer or family member (35%) involved in the process.

Strengths and Limitations

The feasibility study was underpowered because it was unable to recruit the desired number of participants, which increased the likelihood of a type II error. The greater mean improvements in the TAU group, as compared to the MBCT group, suggests that a greater sample size might have shown that the intervention was harmful. However, it is possible that the sample was not representative and another random sample may have responded differently, which highlights the importance of future studies being sufficiently powered. An alternative explanation is that the intervention did not address the needs of this population, such as wider contextual issues that impact upon their mental health.

There were 41 participants assessed for eligibility, however only 21 met inclusion criteria. There are several potential reasons for these recruitment challenges. The recruitment process relied on clinicians identifying and contacting potential participants. This additional work may have reduced their motivation to recruit participants. Clinicians may have had difficulties identifying patients with mild depression, because older adults may be less inclined to admit depression symptoms due to the associated stigma (Overend et al., 2015). In addition, the inclusion criteria may have been too narrow.

Adherence to the adapted MBCT protocol was not formally measured, although it was assumed to be poor because there was insufficient time to complete

all the tasks in each session. This was a consequence of not field-testing the intervention. The session content was prioritised by informal discussions with the facilitators and the MBCT supervisor. The validity and reliability of estimating treatment fidelity would be improved using a standardised adherence tool, such as the MBCT assessment scale (Prowse, Nagel, & Meadows, 2015).

The evidence base suggests that home practice is a key component of mindfulness based interventions (Segal et al., 2002); with more formal home practices, such as meditations guided by an audio CD, being associated with greater improvement on depression measures (Crane et al., 2014; Hawley et al., 2014; Perich, Manicavasagar, Mitchell, & Ball, 2013). Cognitive impairments in this population may have meant that participants did not remember to do home practice; and there was a large proportion of the participants that did not have a carer available to support them. Therefore, the lack of support may have undermined the effectiveness of the intervention. Qualitative feedback from facilitators suggests that just three participants regularly completed formal home practices.

The CSDD and RAID involved interviewing PWD and an informant/carer. As a large proportion of participants did not have an available informant/carer to provide collateral information, the results are based on the participant data on the CSDD and RAID, which may have compromised the validity of the measures. It appeared that participants could make an informed evaluation on their mood and anxiety, as they only had mild cognitive impairment. Therefore, measures that rely on collateral information from carers may not be the most appropriate measures for people with mild dementia living in the community. Future research in this population should use validated outcome measures that do not rely heavily on collateral information from an informant/carer, such as the Montgomery-Asberg

Depression Rating Scale (Montgomery & Asberg, 2006). The validity of measures may be reduced by a lack of collateral information, although it would facilitate depression research for people with mild dementia that do not have an available carer.

There were several variables that had insufficient data to report, such as the use of anti-depressant medication, pre-morbid depression and time since diagnosis. This information should be collected consistently in future research.

Implications in Care Practice and Future Research

There is inadequate evidence to recommend this adapted MBCT intervention for PWD in memory clinics. The MBCT intervention needs redevelopment and piloting before further testing in an RCT. It is recommended that evidenced based mindfulness interventions are field tested in this population before making assumptions about suitable adaptations, such as the original MBCT (Segal et al., 2002) and MBSR (Kabat-Zinn, 2013) programmes or the MBI protocol for PWD in care homes (Churcher Clarke et al., 2017). A case series design may help with the development of the intervention and the selection of the most appropriate outcome measures for depression and anxiety.

Future research on MBIs should provide participants with an audio player that records the number of hours of formal home practice (e.g. listening to CD tracks). MBCT protocols should also consider way of supporting home practice for PWD that do not have the support of carers. Participant rating forms would be beneficial to identify the participants preferences for exercises, which has been used in previous mindfulness research (Churcher Clarke et al., 2017). Qualitative research is currently being done by an MSc Student, which will inform the development of future interventions.

Conclusion

This feasibility RCT found that an adapted MBCT group intervention, for PWD who were depressed, did not lead to changes to depression or anxiety, as compared to TAU. This may be the result of the study being insufficiently powered or it may suggest a problem with the intervention. The MBCT protocol will need to be redeveloped and field-tested with PWD.

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Part III: Critical Review

Introduction

In the critical appraisal, I will reflect on conducting the empirical study and my experience of facilitating a Mindfulness Based Cognitive Therapy (MBCT) group. Firstly, I will discuss how my background influenced my choice of research. Secondly, I will discuss the recruitment challenges and my experiences of facilitating the adapted MBCT group. Finally, I will consider the findings from the empirical paper, based on my experience of facilitating the group and the discussions I had with participants and carers.

My Background

Prior to starting the Doctorate in Clinical Psychology, I worked as an Assistant Psychologist (AP) in a memory clinic. Through my clinical practice, I noticed a lack of evidenced based treatments for psychological difficulties, such as depression and anxiety, in people with dementia (PWD). This informed my literature review and empirical paper. The literature review found that certain psychosocial interventions are effective at reducing symptoms of depression and anxiety in PWD who are depressed or anxious. Most of the studies that tested intervention for depression recruited PWD, with mild to moderate cognitive impairment, residing in nursing homes. This suggested that further research was required to test psychosocial interventions, for PWD with depression, in the community. The empirical paper tested an MBCT intervention for depression in PWD attending memory clinics.

Recruitment Challenges

There were unexpected challenges that led to delays in starting the MBCT group. We obtained ethical approval four month later than expected, which resulted in delays completing eligibility assessments and starting the groups. We relied on

clinicians to identify and contact potential participants, which added to their workload and potentially reduced their motivation to recruit. Clinicians were also under pressure to reduce waiting times, in line with the Prime Minister's Challenge on Dementia (Department of Health, 2015). In addition, memory clinics focus on the cause and treatment of memory impairments and there appeared to be limited scope to assess psychological difficulties such as symptoms of depression. Only a small proportion of men were referred to the group and I was curious about the reasons for this.

Older adults, especially men, may have been reluctant to admit that they were experiencing depressive symptoms, due to the associated stigma (Overend et al., 2015). There may also have been a stigma about asking for help in general. It would have been useful if the service used a routine outcome measure to identify those with depression. The team managers reported that they tended to refer PWD with psychological difficulties to third sector organisations (e.g. charities). Therefore, if I were to do research in this population again, I would recruit participants from a range of services, such as General Practitioners (GP), third sector organisations and memory clinics.

Participants were recruited in memory clinics from two trusts, named Site One and Site Two. Each site brought with them recruitment challenges. In Site One, we recruited 12 participants in four months and started running the MBCT group in September 2016. We were going to postpone the group until January 2017 to enable further recruitment; however, we were unable to do this because the second facilitator was due to retire. Recruitment may have been somewhat easier in Site One because I had worked there as an AP, and I had built good relationships with the management team. The team managers incorporated short mindfulness

meditations at the end of team meetings, which helped clinicians appreciate the benefits of mindfulness and encourage them to refer. Site One also had a free training route for clinicians that wanted to become MBCT practitioners; therefore, there was an appreciation and value to using MBCT.

Recruitment was particularly difficult in Site Two. There were several research studies that were running simultaneously, which may have contributed to research fatigue in the memory clinic staff. In addition, it appeared that staff did not see the value in mindfulness. We speculated that clinicians were struggling to retain the information about the different studies, which in turn limited their ability to refer people to the group. Therefore, the MBCT group was delayed until January 2017. Despite seven months of recruitment, there were only nine participants recruited from this site.

Facilitating the MBCT Group

I was one of the facilitators, for the MBCT intervention, in Site One. I completed an MBCT course and I continued my mindfulness practice prior to and during the group. However, I had not completed the MBCT teacher training. I facilitated the group with an internal member of staff (BM). He was an art therapist who practiced meditation for several decades and had recently qualified as a Level One trained MBCT practitioner. Due to BM's experience of using mindfulness, he facilitated most of the meditations and enquiries. However, I facilitated Cognitive Behavioural Therapy (CBT) exercises because I had more experience in this area. I found it difficult to facilitate the enquiry for mindfulness practices and this is likely due to my lack of experience. Therefore, I agree with the literature that suggests that MBCT facilitators are required to partake in their own mindfulness meditation practice (Segal, Williams, & Teasdale, 2002), to ensure the integrity of the MBCT

intervention (Crane et al., 2014). As this was our first experience of running an MBCT group, the guidance we received from our supervisor, an Oxford Mindfulness Centre facilitator, was essential.

Findings of Empirical Paper

The MBCT group did not show significant improvements in depression and anxiety, as compared to treatment as usual (TAU). The TAU group presented with greater improvements, as compared to the treatment group. I was surprised about these results because the mean attendance was high (7.3 sessions), attrition was low (10%) and the qualitative feedback was positive, which suggested that the MBCT intervention had a high level of acceptability. These findings maybe the result of natural variability. However, it may indicate that there were wider issues that needed to be addressed. To make sense of these findings, I reflected on my experiences of running the group and the discussions I had with participants and carers in Site One. These discussions took place during the group or during phone calls in between sessions.

MBCT Protocol

Practical Issues with the Protocol. The MBCT protocol was not field tested therefore several problems emerged. There was too much material to be covered in the allocated time. This meant that either the sessions were rushed or some of the material was not delivered. Therefore, it is unlikely that both groups got exactly the same intervention. The session content was prioritised by informal discussions with the facilitators and the MBCT supervisor. To improve treatment fidelity, a standardised adherence tool should be used to monitor adherence.

Participants' Response to Mindfulness. The group had a mixed response to mindfulness. The participant that dropped out of the group, after session two, said that the mindfulness exercises were 'weird' and 'cult-like'. One participant said that he did not believe in the benefits of mindfulness. However, he admitted that he found the group relaxing and he started using deep breathing, outside the group, to help him calm down when he was angry. Another participant said that she preferred a Cognitive Stimulation Therapy (CST) group that she attended because it involved doing fun activities. She said that she enjoyed doing the mindfulness exercises in a group environment because it was relaxing and it generated discussion. However, she did not see the benefits of doing these exercises at home because she found it less enjoyable and harder to concentrate. Likewise, one participant appreciated doing the mindfulness exercises in the group but she disliked listening to the CD. She said she enjoyed the questions that were asked after the mindfulness exercise [the enquiry] because she felt positive about being able to participate in the discussion. A similar finding, about the importance of being able to participate in discussions, has been reported in other groups for PWD (Spector et al., 2011). In contrast, one participant preferred listening to the CD. There were two reasons for this; firstly, her hearing aid broke after the second session therefore she had difficulty hearing the exercises, despite sitting next to the facilitators. Secondly, the exercises provided structure to her day because she would complete the exercises before getting up in the morning, before lunch and before going to bed. She reported that this benefited her mood.

Specific Exercises. Dementia is associated with difficulties with abstract thinking (Amieva, 2005); thus, it understandable that participants had difficulties with the more abstract exercises, such as the 'raison exercise' and the story about

'the king and his three sons'. It was evident that the participants found the 'raison exercise' confusing and they became distracted by what other participants were doing. Also, the exercise called 'the king and his three sons' represents the disadvantages of pushing away your problems. The group had difficulties inferring this meaning from this story. Instead the story evoked feelings of rejection from their childhood. These exercises either need to be removed or adapted for this population. The group appeared to prefer the more concrete mindfulness exercises such as mindful listening, mindful stretching and grounding exercises.

The mindful walking exercise was not appropriate for the participants in Site one due to mobility issues, therefore it may need to be adapted for future groups. We tried to limit mindfulness exercises to ten minutes because participants started to lose their concentration after this time. There were two occasions when the exercises were approximately 15 minutes long and it was noticed that the participants were becoming restless. Future research should use participant rating forms to identify the participants preferences for exercises, which has been used in previous mindfulness research (Churcher Clarke et al., 2017).

A poem, that was connected to the theme of the session, was read at the end of every session. However, some participants had difficulties with their working memory and abstract thinking, which impaired their ability to infer meaning from the poem. I included the poem in their homework packs to allow them to read it at home. However, the poetry did not appear to add anything beneficial to the intervention. On reflection, we should have consulted with service users before using the poems in the sessions.

There will be challenges associated with developing an MBCT protocol for PWD because it needs to cater for various combinations of physical and cognitive

impairments. I think that the facilitators should have experiences of working with PWD, because they will have experience of adapting to the needs of each group.

Home Practice. Home practice, a key component of mindfulness based interventions (Segal et al., 2002) involved 'formal' practices (listening to the audio recording of mindfulness exercises) and 'informal' practices (incorporating mindfulness into routine daily experiences, such as eating, walking and brushing teeth). Participants were asked to complete formal practice five times a week; and informal practice for an additional 10–15 minutes a day. Each participant was provided with a folder that detailed the content of each session and the home practice they needed to complete. The feedback from participants and carers, was that they did not use the folder in between sessions because the content was difficult to understand. In addition, there was one participant that was unable to read. These folders need to be reconsidered in future groups.

In MBCT, participants are asked to reflect on their home practice at the beginning of each session (Segal et al., 2002). In my experience of running the group, it was very difficult for participants to reflect on their home practice. This was partly due to participants not doing the home practice or not remembering the home practice they completed. Therefore, we decided that it was more beneficial to reflect on the mindfulness practices done in the sessions. In addition, participants were more likely to complete the formal practices, as opposed to the informal practices. I think the participants struggled to understand the informal practices because of their abstract nature. Therefore, I think there should be a greater emphasis on the formal practice, as opposed to informal practice, to support understanding, which is also indicated in the literature (Crane et al., 2014; Hawley et al., 2014; Perich, Manicavasagar, Mitchell, & Ball, 2013). In my opinion, home

practice needs to be simplified and it may be more beneficial to have one or two core meditations that carry across the sessions.

Support with Home Practice. I believe that the participants would have needed support to do home practice. The majority of participants did not have a carer to support them, which is not uncommon in this population. Therefore, interventions for depression need to be developed for PWD that do not have the support of a carer.

The carers, that were available for two participants in site one, reported that they were not sure how to provide support because they did not have a clear understanding of mindfulness. These carers attended a psycho-education session about the format of the mindfulness sessions, which also involved doing some brief mindfulness exercises. It was noticed that they were not participating in these exercises. I was not able to discuss the reasons why they did not participate, but it may have been due to embarrassment. The carers may need more preparation for this session. Also, it might be beneficial to also provide carers with the mindfulness intervention. I think it would be best to have a separate group for carers because the PWD said that they appreciated having their own space; for instance, one participant reported that they became frustrated when her husband would talk on her behalf.

We rang participants in between sessions to see if they had any questions about their mindfulness practice. This aimed to act as a reminder for participants to do their home practice. This call was appreciated in Site One and I think that it helped with the engagement of participants and reduced potential dropouts. However, Site Two reported that the mid-week call confused participants and they stopped doing it after several weeks. I speculated that participants in Site One were more isolated therefore they appreciated the mid-week call more than those in Site

Two. Therefore, the benefits of a mid-week call may need to be discussed further in service user consultations.

Group Experience

A Sense of Belonging. The participants reported that they enjoyed taking part in the group and they looked forward to meeting every week. The group bonded over their shared experience of having mild dementia and symptoms of depression. It was reported that this provided them with a sense of belonging because they felt that the group understood the difficulties they were going through. The group said that they appreciated the opportunity to share their experiences and frustrations. In a qualitative study, people with mild Alzheimer's reported that they value sharing their experiences and receiving support from other people experiencing similar difficulties (Sørensen, Waldorff, & Waldemar, 2008).

Two participants discussed their experiences of other groups for PWD. They shared that they did not enjoy groups that catered for all severities of dementia (mild, moderate, severe), because they did not identify with people with more severe dementia. This made me reflect that services may label people with dementia, without thinking about the differing needs at different stage of the disease. This suggests that there needs to be a range of interventions for different severities.

Participants also reported that they enjoyed listening to the other people's struggles and providing advice if required. For instance, some participants shared memory strategies with each other and one participant said that it felt good to be able to help others. The value of listening to others has also been identified by PWD attending a Cognitive Stimulation Therapy group (CST; Spector, Gardner, & Orrell, 2011). Participants said that they were disappointed that the group was only for nine

weeks and they wished the group was continuing, which has been reported in other time-limited groups for PWD (Spector et al., 2011).

I speculate that the progress made during the group may have been underestimated because some of the follow-up assessments were completed two weeks after the intervention. The participants reported negative feelings about the loss of social contact from the group, which may have increased their depression and anxiety scores. To understand changes throughout the intervention, we intended to collect outcome measures (PHQ-9 and GAD-7) after every session. This was not possible due to time-constraints, because each participant needed support completing each questionnaire. On reflection, it may have more appropriate to complete these questionnaires during the phone call in between sessions.

Isolation and Inactivity. Participants explicitly spoke about isolation and the limited resources available to them. They spoke about wanting more social groups to meet people, which they suggested would improve their mood. This is consistent with a qualitative study for PWD that suggested that nursing home residents preferred interventions that reduced isolation, as opposed to group or individual psychotherapy (Choi, Ransom, & Wyllie, 2008). Some participants discussed that the group gave them a purpose to get up in the morning. They reported that dementia had prevented them doing activities that used to give them pleasure (e.g. working, driving, visiting people) and they did not know what they could do instead.

Reflection on Group Experience. The group provided participants with mindfulness strategies to cope with symptoms of depression. In my opinion, this was merely hiding the larger socio-political issues; such as the reduction of charity sector services and the limited resources in the National Health Service (NHS). I believe

that interventions to reduce isolation are a priority in this population. I was curious if participants were attending the group for the social interaction or for the MBCT intervention. Therefore, if I were to test a group intervention in this population again, I would compare it with another group intervention for example, a conversation group.

Conclusion

The empirical paper has provided me with a clearer understanding of the processes required to produce good quality research. This experience has taught me about the challenges of recruiting patients in the NHS and the importance of good relationships to facilitate this process. I have learned that new interventions require a robust development phase with service user consultation. I also started my journey to become a mindfulness practitioner and I have become aware of the importance of developing my own regular mindfulness practice. I have learned some of the complexities of doing research with people with mild dementia, such as the lack of carer involvement and the wider contextual issues that impact upon their mental health.

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Appendices

Appendix A: Systematic Search Filter

Database	Cognitive impairment filter	Depression or anxiety filter	Psychosocial intervention filter	Randomised trial filter
Psychinfo	dementia.ti,ab OR cog* impair*.ti,ab OR mild cog*.ti,ab OR Alzheimer*.ti,ab OR 'vascular dementia'.ti,ab OR frontotemporal.ti,ab OR pick* dis*.ti,ab OR multi infarct.ti,ab OR ((cognit* or memory) adj3 (declin* or impair* or los* or deteriorat* or degenerat* or complain* or disturb* or disorder*)).ti,ab	depress*.ti,ab OR dysthymi*.ti,ab OR adjustment disorder*.ti,ab OR mood disorder*.ti,ab OR mood.ti,ab OR affective disorder*.ti,ab OR affective symptom*.ti,ab OR anxiety.ti,ab OR anxious.ti,ab OR overanx*.ti,ab OR anxiety disorder.ti,ab OR anx*.ti,ab OR acute stress disorder.ti,ab OR general* anxiety disorder.ti,ab OR panic disorder.ti,ab OR panic attack*.ti,ab OR post traumatic stress disorder.ti,ab OR obsessive compulsive disorder.ti,ab OR ?phobi*.ti,ab OR panic disorder.ti,ab	psychotherap*.ti,ab OR psychosocial*.ti,ab OR psychoeducational.ti,ab OR behavio$r therapy.ti,ab OR intervention.ti,ab OR counselling.ti,ab OR counsel*.ti,ab OR cognitive therapy.ti,ab OR CBT.ti,ab OR family therapy.ti,ab OR stress management.ti,ab OR coping skill*.ti,ab OR social support.ti,ab OR relaxation techniques.ti,ab OR music .ti,ab OR exercise.ti,ab OR doll therapy.ti,ab OR reminiscence.ti,ab OR foot massage.ti,ab OR Sonas.ti,ab OR aerobic*.ti,ab OR exercise.ti,ab OR Mindful*.ti,ab OR MBCT.ti,ab OR MBSR.ti,ab OR group.ti,ab	"double-blind" OR "random* assigned" OR control OR randomi?ed controlled trial.pt
Embase	dementia.ti,ab OR cog* impair*.ti,ab OR mild cog*.ti,ab OR Alzheimer*.ti,ab OR 'vascular dementia'.ti,ab OR frontotemporal.ti,ab OR pick* dis*.ti,ab OR multi infarct.ti,ab OR ((cognit* or memory) adj3 (declin* or impair* or los* or deteriorat* or degenerat* or complain* or disturb* or disorder*)).ti,ab	depress*.ti,ab OR dysthymi*.ti,ab OR adjustment disorder*.ti,ab OR mood disorder*.ti,ab OR mood.ti,ab OR affective disorder*.ti,ab OR affective symptom*.ti,ab OR anxiety.ti,ab OR anxious.ti,ab OR overanx*.ti,ab OR anxiety disorder.ti,ab OR anx*.ti,ab OR acute stress disorder.ti,ab OR general* anxiety disorder.ti,ab OR panic disorder.ti,ab OR panic attack*.ti,ab OR post traumatic stress disorder.ti,ab OR obsessive compulsive disorder.ti,ab OR ?phobi*.ti,ab OR panic disorder.ti,ab	psychotherap*.ti,ab OR psychosocial*.ti,ab OR OR psychoeducational.ti,ab OR behavio$r therapy.ti,ab OR intervention.ti,ab OR counselling.ti,ab OR counsel*.ti,ab OR cognitive therapy.ti,ab OR CBT.ti,ab OR family therapy.ti,ab OR stress management.ti,ab OR coping skill*.ti,ab OR social support.ti,ab OR relaxation techniques.ti,ab OR music .ti,ab OR exercise.ti,ab OR doll therapy.ti,ab OR reminiscence.ti,ab OR foot massage.ti,ab OR Sonas.ti,ab OR aerobic*.ti,ab OR exercise.ti,ab OR Mindful*.ti,ab OR MBCT.ti,ab OR MBSR.ti,ab OR group.ti,ab	random$ OR factorial$ OR crossover$ OR cross over$ OR cross-over$ OR placebo$ OR doubl$ adj blind$ OR singl$ adj blind$ OR assign$ OR allocat$
Ovid Medline	dementia.ti,ab OR cog* impair*.ti,ab OR mild cog*.ti,ab OR Alzheimer*.ti,ab OR 'vascular dementia'.ti,ab OR frontotemporal.ti,ab OR pick* dis*.ti,ab OR multi infarct.ti,ab OR ((cognit* or memory) adj3 (declin* or impair* or los* or deteriorat* or degenerat* or complain* or disturb*	depress*.ti,ab OR dysthymi*.ti,ab OR adjustment disorder*.ti,ab OR mood disorder*.ti,ab OR mood.ti,ab OR affective disorder*.ti,ab OR affective symptom*.ti,ab OR anxiety.ti,ab OR anxious.ti,ab OR overanx*.ti,ab OR anxiety disorder.ti,ab OR anx*.ti,ab OR acute stress disorder.ti,ab	psychotherap*.ti,ab OR psychosocial*.ti,ab OR OR psychoeducational.ti,ab OR behavio$r therapy.ti,ab OR intervention.ti,ab OR counselling.ti,ab OR counsel*.ti,ab OR cognitive therapy.ti,ab OR CBT.ti,ab OR family therapy.ti,ab OR stress management.ti,ab OR coping skill*.ti,ab OR social support.ti,ab OR relaxation techniques.ti,ab	(randomi?ed controlled trial OR controlled clinical trial OR randomi?ed .ti,ab OR placebo.ti,ab OR clinical trials as topic OR randomly.ti,ab OR trial)

	or disorder*)).ti,ab	OR general* anxiety disorder.ti,ab OR panic disorder.ti,ab OR panic attack*.ti,ab OR post traumatic stress disorder.ti,ab OR obsessive compulsive disorder.ti,ab OR ?phobi*.ti,ab OR panic disorder.ti,ab	OR music .ti,ab OR exercise.ti,ab OR doll therapy.ti,ab OR reminiscence.ti,ab OR foot massage.ti,ab OR Sonas.ti,ab OR aerobic*.ti,ab OR exercise.ti,ab OR Mindful*.ti,ab OR MBCT.ti,ab OR MBSR.ti,ab OR group.ti,ab	

Appendix B: Session Plans

Session 1: Awareness and Automatic Pilot

FOFBOC – on arrival – use as grounding practice.
Ground rules
Overview of Course
Expectations: ask group members to briefly share expectations. ‘’what would you like to take away from the course’’.
PRACTISE 1: Raisin Exercise
PRACTISE: ‘taking your seat’ followed by 10 minute Body scan using similar language to CD. Rationale: 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. Feedback and Enquiry
Reflection on Theme: Connecting practice to session theme. Overview of automatic pilot.
Home Practice: discuss and consider barriers and challenges to undertaking practice. Formal: brief body scan (CD 1 -track 1), Mindfulness of a routine activity Habit releaser – spend a moment reflecting on something you might do differently. One Mindful moment or one mindful mouthful.
Review/session summary Breath focus – one minute breathing space leading into poem – ‘If I had my life to live over’

Session 2: Living in Our Head

Grounding Practice
Recap material from week one
PRACTISE 1: Body Scan – See facilitators guide: the process of Inquiry
Home practice Review : See facilitators guide: the process of Inquiry
Teaching/ACTIVITY : Thoughts and feeling exercise: “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.
PRACTISE: 10 minute sitting – The Breath
Handout: distribute handouts. Review contents briefly.
Home Practice: Discuss and consider barriers and challenges to undertaking practice. Formal: brief body scan, Mindfulness of a routine activity. Pleasant experiences Calendar- only one example daily) Habit releaser – (check who does this already and if so remember to add a habit releasing instruction) going for a walk (instruction: stress releaser, mood booster intentionally– pay attention to the detail. Stop and look around, walk a new path, explore something different, is this different way of ‘walking than you would normally do?). One Mindful moment (Pause to Appreciate) or one mindful mouthful.
Review/session summary

Session 3: Gathering The Scattered Mind

Grounding practice: Five-minute seeing (or hearing) exercises
Recap material from week two and introduce theme of week three
PRACTISE: 2 Three step breathing space and review.
PRACTISE: 3 Mindful Stretching
Teaching - Reflection on Theme: The Scattered Mind
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.
Handout: distribute handouts. Review contents briefly.
Home Practice: Discuss and consider barriers and challenges to undertaking practice. Formal: mindful movement meditation followed by Breath a body meditation 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. One Mindful moment or one mindful mouthful.
Review/session summary
Breath focus – one minute breathing space leading into poem: The breath or the river bank

Session 4: Recognising Aversion

Grounding exercise: Five-minute seeing or hearing exercise.
SCAFFOLD/RECAP: summary /key points poster or power point from session 3.
PRACTISE 1: 15 minutes meditation – awareness of breath and body Following seamlessly into reading a poem such as wild geese See facilitators guide: the process of Inquiry
Home practice Review: See facilitators guide: the process of Inquiry
Reflection on Theme: Connecting practice to session theme – recognizing aversion 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 facilitators guide: the process of Inquiry
Home Practice: Formal: – breath and body meditation and sounds and thought meditation. 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.
Review/session summary:
Three step breathing space. leading into poem – just for now by Danna Faulds

Session 5: Allowing and Letting be

Grounding practice - Short standing Meditation
SCAFFOLD/RECAP: Summarise session 4 and introduce the session theme for week 5.
PRACTISE 1: 10 minutes sitting practice awareness of breath body and thoughts
Home practice Review
Story of the King and his three Son's (see script and guidance on reflection)
Reflection on Theme: Connecting practice to session theme. Some reflection on 'DEMENTIA' again is possibly also required here
Reading Rumi's poem The Guest house
PRACTISE: Breathing space extended. See facilitators guide: the process of Inquiry
Handout: distribute handouts. Review contents briefly.
Home Practice: breath and body meditation,three step breathing space- regular and responsive Mindfulness of a routine activity, habit releaser, habit releaser
Review/session summary:
Breath focus – one minute breathing space leading into poem 'reply to Rumi'

Session 6: Thoughts are not facts

Grounding practice - Short standing Meditation (mountain)
PRACTISE 1: Sitting meditation: See facilitators guide: the process of Inquiry
Home practice review: See facilitators guide: the process of Inquiry
ACTIVITY: see facilitators notes for instructions: 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.
Reflection on Theme: Connecting practice to session theme. When you suffer from depression or anxiety the associated thoughts have 'psychological', 'biological' and 'social' consequences. Exercise: think with the group about the different levels of impact of these thoughts. See week 6 activities sheet.
PRACTISE: The befriending meditation. 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'.
Handout: distribute handouts. Review contents briefly.
Home Practice: 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). Mindfulness of a routine activity – different to previous week. Habit releaser – spend a moment reflecting on something you might do differently. Random act of kindness. One Mindful moment or one mindful mouthful.
PRACTICE: Breathing space and review. - Discuss breathing space as the first step before taking a wider view of thoughts.
Review/session summary: What will you take away from today? Parachute (group and individual).

Session 7: How Best to Take Care of Myself

Grounding practice - Short standing Meditation
SCAFFOLD/RECAP: Summarise session week 6 and introduce theme for session 7
PRACTISE 1: befriending meditation. See facilitators guide: the process of Inquiry
Home practice review
PRACTISE 2: Guided meditation Mountain (resilience). 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 Poem: if you would grow
Planning for the future: 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.
Handout: distribute handouts. Review contents briefly.
Home Practice: discuss and consider barriers and challenges to undertaking practice. Formal: choosing a selection of favoured practices this week 1 or 2 a day. Mindfulness of a routine activity – different to previous week. Habit releaser – spend a moment reflecting on something you might do differently. One Mindful moment or one mindful mouthful.
Review/session summary:
Breath focus – one minute breathing space leading into poem – Summers Day (Mary Oliver)

Session 8: Maintaining and Extending New Learning

Grounding practice body focused practice coming full circle
SCAFFOLD/RECAP: Summarise week 7 and introduce theme for week 8.
PRACTISE: body focused meditation
Home practice review and general discussion and reflections on role of practice. How to take this forward and what to do with the struggle.
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.
Reflection on Theme. Summary of course.
BREAK
Handout: distribute handouts. Review contents briefly.
Review/session summary: What will you take away from the course? – review tree of life. ‘’Endings’’ ‘’taking this forward’’ 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. Closing sentiments – what I would like to give is… Handout tokens
Breath focus – one minute breathing space leading into poem ‘A Slow Dance’ - Anon

Appendix C: Contributions to the Research Project

Task	Contributor
Design of the research study	DN and JP
Ethics	DN and JP
Attending team meetings	DN and JP
Recruitment	DN (Memory Clinic 1) JP (Memory Clinic 2)
Contacting clients for assessments	DN (Memory Clinic 1) JP (Memory Clinic 2)
Booking transport	Deirdre (Memory Clinic 1), research manager at site two (Memory Clinic 2)
Assessments	Deirdre, Jacob, PhD Student, research assistant
Making packs/CDs for the group	Deirdre and research assistant
Group sessions	Deirdre and Facilitator from site two
Mid-week call from group facilitators	Deirdre and research manager at site two
Data entry	DN and JP

Appendix D: Information Sheets and Consent Forms

RESEARCH DEPARTMENT OF CLINICAL, EDUCATIONAL AND HEALTH PSYCHOLOGY

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 Noone 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 Noone and Jacob Payne
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Dr Josh Stott
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Educational and Health Psychology
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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: [redacted]

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]

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

Appendix D2: Participant Consent Form

RESEARCH DEPARTMENT OF CLINICAL, EDUCATIONAL AND HEALTH PSYCHOLOGY

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 Boxes

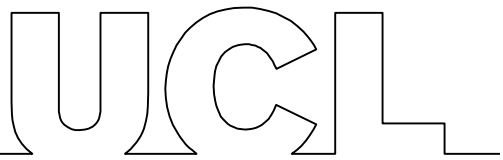
I confirm that I have read and understand the information sheet dated [insert date, insert version] for the above study, have had the opportunity to ask questions and have had these answered acceptably.	
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
I understand that 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 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	

Name of participant	Date	Signature
Name of person taking consent (if different from the principal researcher)	Date	Signature
Principal researcher	Date	Signature

Appendix D3: Carer Information Sheet

RESEARCH DEPARTMENT OF CLINICAL, EDUCATIONAL AND HEALTH PSYCHOLOGY



INFORMATION SHEET FOR CARER or FAMILY MEMBER

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 D4: Carer Consent Form

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 Noone 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	

Please Initial Boxes

Name of participant	Date	Signature
Name of person taking consent (if different from the principal researcher)	Date	Signature
Principal researcher	Date	Signature

Appendix E: Ethical Approval

NHS
Health Research Authority
London - City & East Research Ethics Committee
Bristol Research Ethics Committee Centre
Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT

Telephone: 02071048033/53

06 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).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

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:

Document	*Version*	*Date*
Covering letter on headed paper [Covering letter on headed paper]	1	29 January 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UCL Insurance Certificate]	1	29 January 2016
GP/consultant information sheets or letters [GP information sheet]	1	29 January 2016
Interview schedules or topic guides for participants [Interview Schedule]	1	21 December 2015
Letter from funder [Letter from funder]	1	24 December 2015
Letter from sponsor	1	24 December 2015
Letters of invitation to participant [Participant Information Sheet]	1	29 January 2016
Non-validated questionnaire	1	21 December 2015
Other [Student Summary CV - Deirdre Noone]	1	29 January 2016
Other [Summary CV for supervisor - Lindsay Royan]	1	30 January 2016
Other [Summary CV for supervisor - Elisa Aguirre]	1	30 January 2016
Other [Consent form for Interview]	1	29 January 2016
Other [Carer consent form]	1	29 January 2016
Other [PHQ9 - Validated questionnaire]	1	21 December 2015
Other [GAD7 - validated questionnaire]	1	23 December 2015
Other [Participant rating form - non-validated questionnaire]	1	20 December 2015
Other [CV for Local Researcher]	1	29 January 2016
Other [Local researcher CV mina Patel]	1	29 January 2016
Other [Laura Dickens Local researcher]	1	29 January 2016
Other [Local researcher CV Brian McCombe]	1	29 January 2016
Other [M Maroney CV Local researcher]	1	29 January 2016
Other [Susan Laut's CV]	1	29 January 2016
Other [Participant Information Sheet track changes]	2	22 April 2016
Other [research Protocol track changes V2]	2	22 April 2016
Other [Carer Information Sheet track changes V2]	2	22 April 2016
Other [Poster to advertise research at Oxleas Site]	1	22 April 2016
Other [Response to REC]	2	22 April 2016
Participant consent form [Participant Consent form]	1	29 January 2016
Participant information sheet (PIS) [1]	2	22 April 2016
REC Application Form [REC_Form_01042016]		01 April 2016
REC Application Form [REC_Form_29042016]		29 April 2016
Referee's report or other scientific critique report [Referee's report]	1	30 January 2016
Research protocol or project proposal [Research Protocol]	1	22 April 2016
Summary CV for Chief Investigator (CI) [Summary CV for Chief Investigator]	1	29 January 2016

Appendix F: Local Research and Development Approval

improving lives

Oxleas NHS
NHS Foundation Trust

Oxleas NHS Foundation Trust
Research and Development Office
Memorial Hospital
Shooters Hill
London
SE18 3RG
0203 260 5117

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

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 Aimee 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 #* *197549/967603/6/349/310190/348012*
- *IRAS NHS R&D Form #* *197549/941046/14/929*
- *NHS REC Favourable Opinion* *16/LO/0578 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

[redacted]

Anthony Davis
Research and knowledge manager
[redacted]

cc:

Ms Deirdre Noone, PhD student and co-investigator [redacted]
Mr Jacob Payne, PhD student and co-investigator
Dr Naomi Wynne-Morgan, Local Collaborator
Ms Suzanne Emerton, Sponsor Representativ

NELFT NHS
NHS Foundation Trust

Research and Development Office
North East London NHS Foundation Trust,
1st Floor Maggie Lilley Suite,
Goodmayes Hospital,
Barley Lane,
Goodmayes,
Essex, IG3 8XJ

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,

[redacted]

Sandeep Toot

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

Document	Version	Date
Research Protocol	2	22 April 2016
Participant Information Sheet track changes	2	23 April 2016
Carer Information Sheet track changes	2	22 April 2016
Consent Form for interview	1	29 January 2016
Participant Consent Form	1	29 January 2016
Participant Information Sheet	2	23 April 2016
Peer review		04 December 2015
Peer review		22 January 2016
NHS R&D Form	197549/941046/14/929	11 March 2016
NHS SSI Form	197549/949904/6/560/310 188/346830	30 March 2016
Participant Information Sheet	1	29 January 2016
UCL Insurance Certificate		13 July 2015
GP Information Sheet	1	29 January 2016
Interview Schedule	1	29 January 2016
Letter from Funder		
Letter from Sponsor		
Carer Consent Form	1	29 January 2016
Participant Rating Form	1	20 December 2015
Chief Investigator CV – Dr Aimee Spector	1	29 January 2016
CV – Jacob Payne	1	29 January 2016
CV – Dierdre Noone	1	29 January 2016
PHQ9 – Validated Questionnaire	1	29 January 2016
GAD7– Validated Questionnaire	1	23 December 2015
MMSE – Validated Questionnaire	1	29 January 2016
RAID – Validated Questionnaire	1	29 January 2016
CSDD – Validated Questionnaire	1	29 January 2016
BTFQ – Validated Questionnaire	1	29 January 2016
CAMS-R – Validated Questionnaire	1	29 January 2016

Appendix G: Insurance

University College London Hospitals NHS
NHS Foundation Trust

UCL

UCL/UCLH Joint Research Office

Office Location:
1st Floor Maple House
149 Tottenham Court Road
London W1T 7DN

Postal Address:
UCL,
Gower Street
London WC1E 6BT

Email david.wilson@ucl.ac.uk : Tel No. 020 3447 5199
Web-sites: www.uclh.nhs.uk; www.ucl.ac.uk/jro

25/01/2016

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

Dear Miss Noone,

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. **16/0015**

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 A76 for both your NHS REC and, where applicable, NHS R&D applications submitted via the Integrated Research Application System (IRAS).

/Continued

The UCL insurance policy is renewed annually, but studies included in the UCL insurance portfolio will be automatically rolled over into subsequent insurance period(s) until the study terminates. Indemnity and insurance arrangements for any participating sites will be detailed in individual Site Agreements.

Please keep a copy of this letter for your records. Feel free to contact me if you have any queries concerning the insurance cover.

Yours sincerely,

[redacted]

DAVID WILSON
Database & Information Officer

Appendix H: CONSORT Checklist

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	46
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	47
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	46-50
	2b	Specific objectives or hypotheses	51
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	52-53
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	52-53
	4b	Settings and locations where the data were collected	52
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were administered	98-101
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	55-57
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	58
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	53-54
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	53-54
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	53-54
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	53-54
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	53-54

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	46
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	47
Introduction			
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	2b	Specific objectives or hypotheses	51
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	52-53
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	52-53
	4b	Settings and locations where the data were collected	52
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were administered	98-101
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	55-57
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	58
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	53-54
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	53-54
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	53-54
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	53-54
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	53-54