The Feasibility of a Mindfulness Intervention for Depression in People with Mild Dementia: A Pilot Randomized Controlled Trial.

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Abstract

Objectives: This preliminary study aimed to establish the feasibility of running an adapted Mindfulness Based Cognitive Therapy (MBCT) intervention for people with mild dementia and depression. It also aimed to conduct an exploratory analysis as to whether the MBCT intervention would lead to greater improvements in measures of depression, anxiety, quality of life and cognition, as compared to treatment as usual (TAU).

Methods: A single-blind, multisite, feasibility randomized controlled trail was used. People with dementia and depression were recruited from participating memory services. Twenty participants were randomized to either an adapted MBCT and TAU group (n=10) or TAU (n=10). Measures of depression, anxiety, quality of life (QOL) and cognition were assessed at baseline and follow-up.

Results: The intervention was feasible in terms of high attendance and low levels of attrition. It was not judged feasible to recruit enough participants within the recruitment time-frame. The MBCT group did not show significant improvements in depression, anxiety, QOL and cognition at follow-up, as compared to TAU.

Conclusion: There is currently inadequate evidence to recommend this adapted MBCT intervention for people with dementia for the treatment of depression within memory services. The MBCT intervention needs redevelopment and piloting before further testing in an RCT.

Introduction

Depression and anxiety are common in people with dementia (PWD) (Kuring et al, 2018); with the prevalence estimated to be between 20% and 30% for depression (Enache et al, 2011) and between 5% and 21% for anxiety (Lyketsos et al., 2002; Kuring et al, 2018; Savva et al., 2009). In people with dementia, depression and anxiety are linked with negative outcomes such as reduced quality of life and worsened cognition (Rapp et al., 2011; Winter et al , 2011). Psychiatric medications, that are prescribed to treat depression and anxiety, are associated with adverse side effects (Stomski et al., 2016); and there has been limited support for their effectiveness in PWD (Dudas et al., 2018; Orgeta et al., 2017). Non-pharmacological interventions for depression and anxiety, in PWD, have been identified as potential areas for development (Cooper et al., 2015); and a recent meta-analysis has found that psychosocial interventions are effective at reducing symptoms of depression and anxiety in this population (Noone et al., 2019).

Mindfulness Based Interventions (MBI) have been found to improve depression symptoms in older adults without cognitive decline (Gallegos et al., 2013; Moss et al., 2015); however there is limited evidence for their effectiveness in people with recognized cognitive decline. However, an adapted Mindfulness Based Stress Reduction (MBSR) intervention was found to significantly reduce depressive symptoms in people with progressive cognitive decline (i.e. dementia, mild cognitive impairment and memory loss) living in the community (Paller et al., 2015). More specifically, a feasibility RCT (Churcher Clarke et al., 2017) evaluated a 10-session, adapted MBSR intervention delivered biweekly for people with dementia living in care homes. The intervention was feasible and it led to significant improvements in quality of life. There were no significant changes in depressive symptoms. However, a third of the participants receiving the intervention moved out of the clinical range of depression, whereas this change was not evident in the treatment as usual (TAU) group. Based on this, the authors

suggested that people with dementia with comorbid depression would be receptive to MBIs. However, the residential sample in this study was more cognitively impaired than community samples and, therefore, it is possible that participant's ability to understand, recall and implement techniques may have affected results (indicated by the lack of improvement on a measure of mindfulness ability). Previous research into MBI for people with dementia has tended to focus on MBSR-based interventions (e.g. Paller et al., 2015, Churcher Clarke et al., 2017), and there is a need to determine whether Mindfulness Based Cognitive Therapy (MBCT) may also offer potential benefits for this population. The goal was to test the MBCT intervention with people whose dementia was less severe. To find this population, we turned to community settings, to investigate the feasibility of running a MBCT for people with dementia with depression and a milder cognitive impairment. UK National Health Service (NHS) Memory services, specialist outpatient services for people with memory disorders, provide a unique opportunity to recruit people with mild dementia and depression in a community setting. In line with the guidance from the medical research council for the feasibility and piloting stage of intervention development (Skivington et al., 2021), the current study was conducted alongside a qualitative study that explored the experiences of the participants, carers, and facilitators (Douglas et al., 2021).

Aims

1. To examine the feasibility of an adapted MBCT for people with dementia in terms of: a) recruitment rates; b) retention rates; c) acceptability of intervention; and d) adherence to MBCT protocol.
2. To use exploratory analysis to assess whether an adapted MBCT group intervention will lead to greater improvements in depression, anxiety, quality of life and cognition in people with dementia who are depressed, compared to TAU.

Methods

Design

A single-blind, multicenter, feasibility RCT of a treatment group (MBCT and TAU) versus TAU, for people with dementia who met the criteria for depression detailed below. As this was a feasibility study, it was expected that the study would be insufficiently powered to detect a significant effect of the intervention on outcome measures. As there was limited research on the effects of MBI in this population, it was difficult to estimate the likely effect size. The aim was to recruit 32 participants as this was considered feasible to the requirements of this pilot trial (Eldridge et al., 2016).

Participants

Participants were selected from two memory clinics between June 2016 and April 2017. Participants were considered for inclusion included 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 able and willing 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.

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

The primary researchers contacted the managers of the memory clinics to discuss the study (e.g. rationale; inclusion and exclusion criteria etc.). The researchers attended team meetings at the memory clinic to present details about the study. Staff were asked to identify potential participants based on the specified inclusion and exclusion criteria. If they were interested in taking part, staff sought verbal consent for the potential participant to be contacted by a member of the research team.

Participants provided written informed consent. A researcher, independent from the group facilitators, met participants, either in their home or at their local memory clinic, for an assessment within two weeks of the group starting and finishing. Lone working policies were followed for both NHS trusts. Following consent procedures, the participants were further screened against the MMSE and PHQ-9 to ensure they met the criteria for inclusion. If met, a full assessment was completed for these participants, with an assessor who was blinded to group allocation. An independent researcher used a randomization sequence (sealedenvelope.com) to allocate participants to treatment conditions using a one-to-one ratio. The assessors who administered the outcome measures with participants were blind to the randomization sequence and allocation of participants until data analysis was completed.

Intervention and Control Arms

Control Group

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

Treatment Group

Participants were invited to attend a weekly MBCT group for eight weeks and received TAU. The sessions were 90-minutes long. A psychoeducation session about MBCT was offered to participants and their carers before the start of the group. Participants were provided with transportation to sessions if required.

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 et al., 2011; Segal et al., 2002; Teasdale et al., 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 et al., 2015; Spector et al., 2015; Stanley et al., 2013). The study protocol has been published (Aguirre et al., 2017). See Appendix 1 for facilitators' experience and training in mindfulness.

Measures

Outcome measures were completed at baseline and post treatment (two weeks before and 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, anxiety and quality of life. There were two measures used for both depression and anxiety. Some measures were included because they are used clinically in primary care services and other dementia specific measures were used because they are the 'gold standard' for assessing depression and anxiety in people with dementia.

Cognitive function

The Mini Mental State Exam (MMSE) (Folstein et al., 1975) is widely used as a screening tool for assessing cognition in dementia; and the reliability and validity are satisfactory (Woodford & George., 2007). The severity of cognitive impairment was indicated by the score (0-17, severe; 18-24, mild; 24-30, not present; Tombaugh & McIntyre., 1991). Participants were eligible if they scored 18 and above.

Depression

Patient Health Questionnaire (PHQ-9) (Kroenke et al., 2001) is a nine-item questionnaire based on the DSM-IV depression diagnostic criteria that has been shown to be acceptable to service users in memory clinics (Hancock & Larner, 2009). The severity of depression was 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 Cornell Scale for Depression in Dementia (CSDD) (Alexopoulos et al., 1988) is a 19-item clinician-administered outcome measure used to assess depression. Information is gathered from interviews with the participant and an informant (caregiver) 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 has a three-point scale with a maximum score of 57. Significant depressive symptoms are indicated as a score of 8 and above (Alexopoulos et al., 1988). The CSDD is deemed to be the 'gold standard' for assessing depressive symptoms in people with dementia (Sheehan, 2012).

Anxiety

Rating Anxiety in Dementia scale (RAID) (Shankar et al., 1999) is an 18-item clinician-administered outcome measure. Information is gathered from interviews with the participant

and an informant 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 with a maximum score of 54. A score of 11 and above is the cut off for clinical anxiety (Shankar et al., 1999). The RAID is deemed to be the best measure for measuring anxiety in PWD (Seignourel et al., 2008).

Generalized Anxiety Disorder 7-item scale (GAD-7) is a seven-item questionnaire that assesses anxiety, 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 people with dementia but it is commonly used in primary care services (e.g. Improving Access to Psychological Therapies Service).

Quality of Life

The Quality of Life – Alzheimer's Disease Scale (QoL-AD; Logsdon et al., 1999) is a 13-item measure of quality of life which can be completed by either the person with dementia, their carer, or both. It includes 13 domains of quality of life, including physical health, mood, energy, relationships with family and friends, memory, fun and self as a whole. Each item is rated either 'poor' (1), 'fair' (2), 'good' (3) or 'excellent' (4) with higher scores indicating better quality of life. QoL-AD as deemed the 'gold-standard' for measuring quality of life in PWD (Moniz-Cook et al., 2008).

Assessment of Feasibility

The assessment of feasibility was based on:

a) Recruitment rates (numbers recruited, including reasons for ineligibility) and retention rates (attendance to the intervention and levels of drop-out.)

b) Acceptability of the MBCT intervention and outcome measures (determined though qualitative interviews, which is being prepared for publication).
c) Adherence to MBCT intervention protocol (determined by feedback from staff on the delivery of different mindfulness exercises used in session and adherence to intersession support calls and home mindfulness practice).
d) Incidence of any adverse events. Adverse event reporting followed established NHS procedures.

Data Analysis

Statistical Package for Social Sciences (version 24) was used to analyse the data. Intention-to-treat analysis was used. Due to the small sample size in this study, an exploratory analysis on outcomes measures was completed. A 2x2 Mixed Between-Within Subjects Analysis of Variance (ANOVA) was used to compare the outcomes of the treatment 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 factor was the treatment condition (treatment group, TAU) and the within subject factor was the time (change scores on the CSDD, PHQ-9, RAID, GAD7, QoL-AD and MMSE).

Results

Participants

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

cognitive functioning, dementia severity, depression and anxiety. Ninety percent of participants were in the mild stages of dementia with the most common diagnosis being Alzheimer's disease (50%). The majority of participants were White British (85%) and female (75%). ***[Table 1 near here]***

Feasibility

Feasibility was evaluated in accordance with the pre-specified criteria as outlined in the full clinical trial protocol.

a) Recruitment rate

The CONSORT diagram shown in Figure 1 details the flow of participants recruited to the study and reasons for ineligibility. A total of 41 people with dementia were recruited. A high proportion of these (n=18, 43.9%) did not reach the study inclusion criteria. The main reason that participants were excluded was due to scores that fell below the threshold nine on the PHQ-9 screening measure for depression (n = 9). Other reasons for exclusion included participants not having capacity to consent for themselves, or being involved in other psychosocial research at the time of recruitment. Two participants moved out of the area before the group started and one participant declined to participate as they did not wish to attend a group intervention. The final sample of 20 participants is lower than the proposed recruitment target of 32 participants.

b) Retention rate

The intervention was well attended. The intervention protocol specified an acceptable completion rate would be 55% of participants attending four or more sessions. Findings indicated mean attendance of the eight sessions of 7.3 (SD = 2.63) and a high proportion of participants (80%) attended seven or more

sessions. One participant dropped out of the MBCT intervention in each memory clinic site. One of these decided to attend a cognitive stimulation therapy (CST) intervention in a memory clinic closer to their home. The other participant reported that they did not like the intervention and they declined to complete the post intervention assessment. The Last Measurement Carried Forward Technique (LMFT) (Molnar et al., 2008) was used for this participant, which involved the participant's baseline scores being entered as post treatment scores; and included in the intention-to-treat analysis. The overall rate of attrition between baseline and post-intervention assessments was low (5%).

c) *Acceptability of the MBCT intervention and outcome measures*

Acceptability of the intervention and outcome measures used was determined through interviews conducted with participants and course facilitators. These findings have been analysed thematically and reported separately (Douglas et al., 2018, in submission).The proportion of missing data for the CSDD, RAID, GAD-7, QoL-AD and MMSE was low with 5% of data missing. The proportion of missing data for the PHQ-9 was also low (10%). Sixty-five percent (n=13) of participants did not have an informant/carer available to complete the CSDD, RAID and QoL-AD 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 post treatment 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 and QoL-AD carer data available. Therefore, only participant data was used in the analysis.

d) Adherence to the MBCT intervention protocol

There were differences in how useful staff experienced the between session support calls across the two memory clinics. In memory clinic one, all except one participant were contacted each week. Facilitator feedback indicated that the support calls helped to remind participants to practice the home mindfulness exercises. It was also felt that the support calls managed any anxieties associated with attending the group (e.g. one participant thought they were talking too much) and built rapport with the group facilitators to minimise dropouts. However, in memory clinic two staff did not find the weekly support calls to be useful as they did not lead to greater adherence to the home mindfulness practice and they were discontinued. Overall, there was low adherence to the home mindfulness practice however this varied across the two memory clinics. In memory clinic one, it was reported that one participant practiced the formal mindfulness exercises 2-3 times a day and one participant once or twice a week. In memory clinic two, only one participant practiced the formal mindfulness exercises between group sessions.

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

Blinding of Assessors

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

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 (1988) 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 post treatment PHQ-9 data was imputed using Expectation Maximization (EM) algorithm. This allowed the data from an extra two participants to be used, at baseline and post treatment, being included in the analysis for PHQ-9. The imputed and non-imputed data is reported.

Clinical Outcomes

All data met the assumptions for homogeneity of variance and assumptions of normality, required for the ANOVAs. Table2 shows the mean profiles, mean change scores and ANOVA interaction effects for depression, anxiety, quality of life and cognition in the exploratory analyses**. [Table 2 near here]**

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 ($\eta_p^2 = .33$)[1] (See Table2). 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 ($F(1,17) = .03$, $p = .87$). There was no significant main effect of time using the RAID ($F(1,17) = .04$ $p = .84$) and the GAD-7 ($F(1,17) = .83$, $p = .38$) (See Table 2).

Other outcomes

In a Mixed Between-Within Subjects ANOVAs, there were no significant interactions between time and group found on the quality of life ($F(1, 17) = 0.11$, $p = .74$) or cognition ($F(1, 17) = 0.80$, $p = .38$) measures. There was no significant main effect of timeon measures of quality of life ($F(1,17) = .44$, $p = .52$) or cognition ($F(1,17) = 1.81$, $p = .20$). There was no significant main effect of treatment group on measures of quality of life ($F(1,17) = 4.48$, $p = .05$) or cognition ($F(1,17) = 2.70$, $p = .12$).

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

Discussion

Summary of Results

The present study demonstrates that an adapted MBCT intervention for people with dementia was feasible in terms of high attendance to the intervention and low levels of attrition. It was not feasible to recruit enough participants within the recruitment time-frame. In terms of clinical outcomes, one measure (PHQ-9) suggested an overall improvement in depression over time across both groups, although the treatment group did not show significant reductions in depression, anxiety, quality of life or cognition at post treatment, as compared to TAU. Therefore, the null hypotheses could not be rejected. The mean change scores may suggest that there were greater improvements in depression, anxiety and quality of life in the TAU group, as compared to the treatment group, although these changes were not significant. This may be explained by natural variability or the outcome was influenced by the timing of the assessment e.g. there may have been an immediate effect that dissipated by the time the post treatment assessment was completed. It also may suggest a problem with the MBCT protocol. This has been explored in the accompanying qualitative research (Douglas et al, 2021) which explored participants, carers, and facilitators' experiences of the intervention. Whilst the interviewees described that the intervention led to positive emotional changes, such as increased ability to focus and to stay in the present moment, and a greater sense of acceptance and self-compassion. They also suggested further modifications for PWD, such as shortening the duration of sessions, simplification of instructions, and supporting participants to practice meditation between sessions (Douglas et al, 2021).

Feasibility

The low levels of attrition and the high attendance may indicate that people with dementia found the MBCT intervention acceptable. However, the low adherence to the home

mindfulness practice also raises questions about the acceptability of the MBCT intervention for people with dementia living in a community setting, particularly given the absence of carer support available to them within the present study. There were also significant challenges associated with the recruitment, which was lower than expected, particularly due to participants not reaching eligibility on the PHQ-9 outcome measure. Clinicians may have also experienced difficulties identifying patients with mild depression, because older adults may be less inclined to admit depression symptoms and therefore under-report due to the associated stigma (Overend et al., 2015).

Outcomes

In a feasibility RCT (Churcher Clarke et al., 2017) that tested a mindfulness based intervention (MBI) for people with dementia in care homes, there was a significant improvement in quality of life, which was not found in this study. 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 hypothesized that this treatment would be effective for people with dementia in the clinical range of depression, 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 treatment 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. Furthermore, participants in the treatment group expressed that they were sad that the group finished and this may have had a negative impact on their outcomes when they completed the post treatment assessment two weeks after the group finished. Future research may benefit from completing additional outcomes on the penultimate week of the group.

The results were limited by the heterogeneity of the MBI (e.g. adherence to home practice, presence or absence of support calls, different facilitators across sites). Adherence to the adapted MBCT protocol was not formally measured therefore, 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 prioritized by informal discussions with the facilitators and the MBCT supervisor. The validity and reliability of estimating treatment fidelity could be improved using a standardized adherence tool, such as the MBCT assessment scale (Prowse et al., 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 meditation guided by an audio CD, being associated with greater improvement on depression measures (Crane et al., 2014). Cognitive impairments in this population may have meant that participants did not remember to do home practice and a large proportion of the participants

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 people with dementia 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 were judged to be in the early stages of dementia, as measured by the MMSE. Measures that rely on collateral information from carers may not be the most appropriate measures for people with mild dementia living in the community. Therefore, self-report measures may hold the most utility for research in this population.

Conclusion

This was the first feasibility RCT of an adapted MBCT intervention for people with mild dementia and depression. Although the intervention was feasible in terms of attendance to the intervention and levels of attrition, the intervention did not lead to changes to depression, anxiety, quality of life and cognition, as compared to TAU. As such, there is currently a lack of research evidence to recommend this adapted MBCT intervention for people with dementia. The non-significant results here may have been the result of insufficient statistical power or it may suggest a problem with the intervention. The MBCT protocol will need to be redeveloped and field-tested with people with dementia.

Clinical Implications

Implications in Care Practice and Future Research

- The MBCT intervention needs redevelopment and piloting before further testing in an RCT. 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.
- MBIs would benefit from making adaptations to homework task such as simplifying home practice logs, providing audio player to record the number of hours of formal home practice; and structured telephone support. MBCT protocols should particularly consider ways of supporting home practice for people with dementia 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).

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Data Availability Statement

The data that support the findings of this study are available from the corresponding author, [DN], upon reasonable request.

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Appendix 1

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.

Table 1: Demographics

Table 1

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

Figure 1: CONSORT participant Flow Diagram

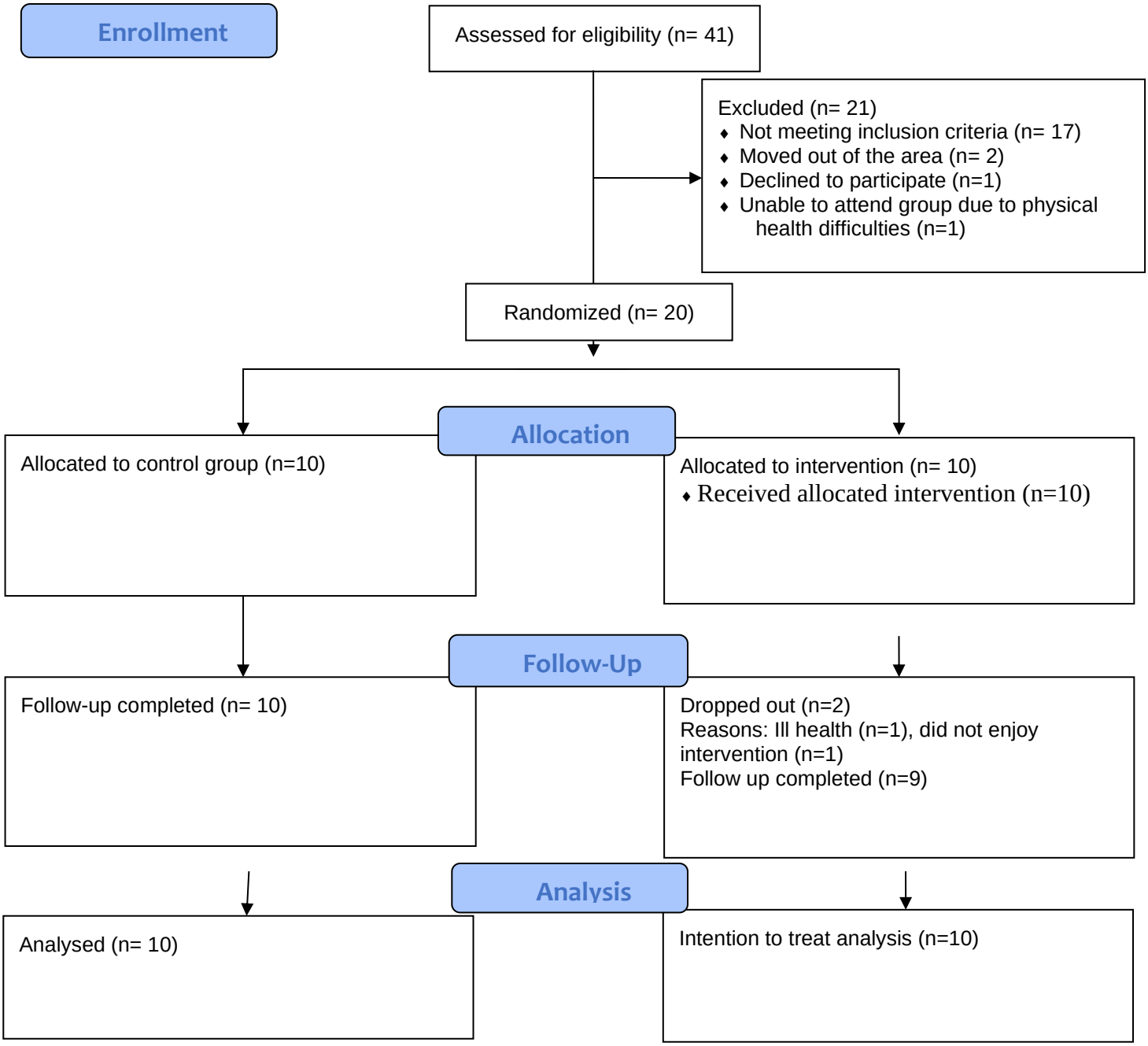

Table 2 : Mean profiles, mean change scores and ANOVA interaction effects for CSDD, PHQ-9, RAID and GAD-7.

Variable	Baseline Mean (SD)	Follow-up Mean (SD)	Change from baseline (SD)	ANOVA	F	P	Effect Size η_p^2
CSDD^							
Treatment	11.90 (5.38)	10.20 (5.34)	+1.70	Time	3.60		.18
Control	13.6 (4.06)	11.33 (3.64)	+2.22	Group	.54	.80	.03
				TxG	.06	.47	.004
						.80	
PHQ-9 without imputations							
Treatment	14.00 (3.57)	10.67 (4.94)	+3.33	Time	15.15	.001*	.49
Control	17.00 (5.36)	11.56 (4.95)	+5.44	Group	1.01	.33	.06
				TxG	0.88	.36	.05
PHQ-9 with imputations							
Treatment	13.17 (4.26)	11.40 (5.21)	+1.77	Time	8.68	.009*	.33
Control	17.3 (5.14)	11.49 (4.67)	+5.81	Group	1.47	.24	.08
				TxG	2.45	.14	.12
RAID^							
Treatment	12.1 (5.2)	12.67 (7.62)	-.56	Time	.044	.84	.003
Control	14.3 (9.26)	13.0 (7.32)	+1.3	Group	.18	.68	.01
				TxG	.27	.61	.02
GAD-7							
Treatment	8.70 (8.23)	8.60 (6.53)	+.1	Time	.83	.38	.046
Control	9.22 (6.28)	7.11 (6.49)	+1.30	Group	.027	.87	.002
				TxG	.69	.42	.039
QoL-AD^							
Treatment	33.89 (6.29)	34.22 (6.24)	+0.33	Time	.44	.52	.03
Control	29.10 (4.38)	30.10 (2.88)	+1.00	Group	4.48	.05	.21
				TxG	.11	.74	.01
MMSE							
Treatment	25.50 (3.17)	26.50 (2.55)	+1.00	Time	1.81	.20	.09
Control	23.50 (3.50	23.70 (4.22)	+0.20	Group	2.70	.12	.13
				TxG	.80	.38	.04

(+) = an improvement, (-) = a deterioration, (*) = significance, (^) = only participant data is used in the CSDD, RAID, QoL-AD

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