A Mindfulness Programme for People with Dementia in Care Homes: A Feasibility Pilot Study

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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.

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Overview

This thesis focuses on mindfulness-based interventions for people with dementia.

Part 1 of the thesis is a literature review examining the effectiveness of mindfulness-based interventions (MBI) for people with acquired cognitive impairment, and whether any modifications were made for this population. The 11 included papers are presented according to the type of acquired cognitive impairment. The effectiveness of the MBIs is considered for each type of acquired cognitive impairment according to different outcomes. This is followed by a discussion of common themes of modification to the MBIs for this population.

Part 2 is an empirical study which investigated the feasibility and the potential benefits of an adapted mindfulness programme for people with mild to moderate dementia in care homes using a randomised controlled design. The process of intervention development and outcomes for quality of life, stress and cognition are reported. This paper forms part of a joint research study conducted with Churcher Clarke (2015). She will assess the feasibility of the programme and report outcomes for anxiety, depression and mindfulness.

Part 3 is a critical appraisal. It will reflect on the process of conducting the research, including: strengths of the study, my qualitative observations of participants and the care home staff, the main challenges encountered during study design, recruitment, intervention delivery and implementation, and the implications for future research.

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Part 1: Literature Review

The Effectiveness of Mindfulness-Based Interventions for People with Acquired Cognitive Impairments: A Systematic Review

Abstract

Aims: This review evaluated the effectiveness of mindfulness-based interventions (MBIs) for people with acquired cognitive impairments, and whether any modifications were made to the intervention delivery or content for this population.

Method: The PsycINFO, EMBASE, MEDLINE, Web of Science, CINAHL Plus and the Cochrane Library databases were searched for papers published in all years up to January 2015. Study quality was evaluated using a modified version of Downs and Black's (1998) checklist.

Results: Eight acquired brain injury (ABI) studies and three studies in mild cognitive impairments (MCI) or dementia were included in this review. In general, most ABI studies found that depression was reduced following the intervention. No conclusions were possible regarding the effects of MBI for people with MCI or dementia due to the limited number of studies and small sample sizes. Many ABI studies made modifications to address the cognitive difficulties of this population and common themes were identified. The extent of modifications in MCI/dementia studies was too varied to identify any common themes. However, no adverse events were reported.

Conclusion: Although there is some evidence that MBIs reduce symptoms of depression for people with ABI, this is limited by the study quality. Further high quality studies for people with acquired cognitive impairments are required.

Acquired cognitive impairment

Cognitive impairment is common following brain injury and is a feature of neurodegenerative disorders such as dementia. Such cognitive impairments are acquired: there is a decline in cognition compared to premorbid level in domains such as memory, language, attention/executive functioning, and/or visuospatial skills. They are considered distinct from lifelong cognitive impairments such as learning disability. Learning disability refers to a significant impairment of intelligence and social functioning with onset before adulthood, and can include congenital conditions such as Down's Syndrome (British Psychological Society, 2001).

The major types of acquired cognitive impairment include mild cognitive impairment (MCI), dementia and acquired brain injury. In addition to cognitive impairment, it is also common for these populations to experience psychological symptoms, reduced quality of life and difficulties with occupational functioning (Alzheimer's Disease International, 2013; National Audit Office, 2010a; Orgeta, Qazi, Spector, & Orrell, 2014). The diagnostic criteria for MCI include: subjective reports of cognitive changes by the affected individual or observers; objective impairment in one or more cognitive domains; independence in functional abilities with minimal aids/assistance; and absence of dementia (Albert et al., 2011). Prevalence estimates of MCI in older adults vary greatly due to the heterogeneity in classification, but in general prevalence estimates increase with age (Ward, Arrighi, Michels, & Cedarbaum, 2012). People with MCI are at increased risk of developing dementia, with risk estimates between 5-20% (Langa & Levine, 2014).

The key difference between MCI and dementia is that dementia is a progressive neurodegenerative condition, with more severe cognitive deficits that

have a substantial effect on activities of daily living (e.g., personal care, managing finance) (Albert et al., 2011). Around 835,000 people in the United Kingdom have dementia, with the number expecting to double within 30 years. Costs of care are projected to rise from £15.9 billion in 2009 to £34.8 billion by 2026 (Alzheimer's Society, 2014; National Audit Office, 2010a). Psychological symptoms such as anxiety and depression are common in people with both MCI and dementia (Monastero, Mangialasche, Camarda, Ercolani, & Camarda, 2009; Alzheimer's Disease International, 2013). A Cochrane review found some evidence that psychological treatments (i.e., cognitive behavioural therapy, counselling and interpersonal psychodynamic therapy) can reduce depressive symptoms and clinician-rated anxiety symptoms in people with dementia; but they did not find any trials for people with MCI (Orgeta et al., 2014).

Cognitive impairment is also common after acquired brain injury (ABI). According to the Royal College of Physicians and British Society of Rehabilitation Medicine (2003), the types of ABI include traumatic brain injury (TBI), vascular accident (stroke or subarachnoid haemorrhage), cerebral anoxia, infection (e.g., meningitis, encephalitis) and toxic or metabolic insult (e.g., hypoglycaemia). In addition to cognitive impairment, people with ABI can also present with difficulties in physical (e.g., paralysis, pain, physical/cognitive fatigue), communication (e.g., dysphasia, dysarthria), behavioural and/or emotional difficulties (e.g., depression, anxiety, aggressive outbursts). Not only is the management of emotional functioning important in people with ABI to improve their quality of life, it also has wider socio-economic consequences due to the reduced social, vocational and community functioning (Gustavsson et al., 2011, National Audit Office, 2010b). Currently there is limited evidence for psychological interventions in anxiety and mood disorders

within this population due to the lack of studies and study methodology limitations for evaluating such interventions (Fann, Hart, & Schomer, 2009; Soo & Tate, 2007).

Mindfulness-based interventions

The concept of mindfulness, influenced by Buddhist philosophy, is a way of paying attention on purpose, in the present moment and in a non-judgmental manner (Kabat-Zinn, 2013). There are several differences across types of mindfulness meditation practices including length of practice, types of meditation, and specific instructions for developing and maintaining the mindful state. Lutz and colleagues (2008) proposed that mindfulness meditation is a type of open monitoring meditation, which initially uses focused attention training before transiting to open monitoring practice in the advanced stages. Focused attention training involves focusing attention on a chosen object, while constantly monitoring the quality of attention and redirecting the attention when distracted. As focused attention skills advance, open monitoring training involves only remaining in the monitoring stage, paying attention moment by moment to one's current experience without focusing on any specific object.

The most researched mindfulness-based interventions (MBIs) in clinical populations include mindfulness-based stress reduction (MBSR; Kabat-Zinn, 2013) and mindfulness-based cognitive therapy (MBCT; Segal, Williams, & Teasdale, 2002). Both types of MBIs involve both focused attention and open monitoring training (Lutz et al., 2008). There are also other interventions that appear to follow the concept of mindfulness, such as Dialectical Behaviour Therapy (Linehan, 1993) and Acceptance and Commitment Therapy (Hayes, Strosahl, & Wilson, 1999). However, formal meditation training is only a part of such interventions (Chiesa,

Calati, & Serretti, 2011). For clarity, MBIs considered in this review include only MBSR and MBCT.

MBSR is a structured programme with groups of between 10 and 30 participants. It consists of eight weekly 2.5-hour sessions with daily 45-minute home practice, and a retreat day of six hours between weeks 6 and 7. To cultivate mindfulness, both informal and formal meditation techniques are taught in sessions. The formal techniques include body scan, sitting meditation, mindful movement and walking meditation. Informal practice is encouraged through purposeful awareness during routine daily activities, such as while eating. Systematic and meta-analytic reviews suggest MBSR is effective in improving psychological functioning in physical health conditions, such as cancer, fibromyalgia, chronic pain, multiple sclerosis, psoriasis, HIV and chronic obstructive lung disease, and also in healthy participants (Chiesa & Seretti, 2010; Fjorback, Arendt, Ørnbøl, Fink, & Walach, 2011; Grossman, Niemann, Schmidt, & Walach, 2004).

MBCT consists of eight weekly 2-hour sessions which incorporates both meditation techniques from the MBSR programme and elements of cognitive behavioural therapy. MBCT develops participants' meta-cognitive awareness by focusing on greater awareness of their relationship to their thoughts and feelings, without challenging specific thoughts (Sipe, Eisendrath, & Stuart, 2012). Reviews suggest that MBCT is a useful psychological intervention in reducing major depression relapses (Chiesa & Seretti, 2011; Fjorback et al., 2011; Sipe et al., 2012), and is recommended by the NICE guidelines (2009) for relapse prevention.

Reviews found preliminary evidence that MBIs also improve cognitive functioning in healthy participants and in people with age-related cognitive decline (Chiesa & Serretti, 2010; Gard, Hözel, & Lazar, 2014). For instance, compared to

controls, participants performed better on attentional tasks after mindfulness training (e.g., Jha, Krompinger, & Baime, 2007; Valentine & Sweet, 1999). Long-term mindfulness meditators performed better on an executive attention task compared to controls (van den Hurk, Giommi, Gielen, Speckens, & Bardenregt, 2010). A study looking at brief mindfulness training found that after four 20-minute sessions, participants performed better on tasks of visuo-spatial processing, working memory and executive functioning (Zeidan, Johnson, Diamond, David, & Goolkasian, 2010).

Although in its infancy, there is emerging evidence that meditation is associated with change in brain structure in healthy participants. Hölzel et al. (2011) found increased grey matter concentration in brain regions associated with learning and memory processes, emotional regulation, self-referential processing and perspective taking, in people who participated in an MBSR programme compared to controls.

Mindfulness for people with acquired cognitive impairments

Given the evidence for the diverse benefits of MBIs in various medical and psychiatric populations, it is hypothesised that MBIs might be useful for people with acquired cognitive impairments. However, adaptations might be required because difficulties in attention and memory may impact on the ability to acquire new skills and information. A small pilot study looked at whether people with dementia could learn MBSR and the impact on their quality of life (Litherland & Robertson, 2014). Qualitative data suggested that participants, particularly those in the early stages of dementia, could learn mindfulness meditation with improvements in quality of life, such as reduced anxiety, ability to manage pain and coping with dementia. They found that participants had difficulties in understanding the ‘cognitive’ elements of

mindfulness and required support in homework practice, suggesting adaptations were required to accommodate to the abilities of this population.

In a study looking at MBSR following mild TBI (Azulay, Smart, Mott, & Cicerone, 2013), the authors found significant improvements in quality of life, perceived self-efficacy and attention. They also modified the intervention to accommodate to the cognitive impairments of the participants, such as increased in repetition of procedures and ideas with written reminders of home practice.

To date there is one systematic review of MBIs in people with ABI, more specifically in transient ischaemic attack and stroke (Lawrence, Booth, Mercer, & Crawford, 2013). The authors found four studies, only one of which was a waitlist randomised controlled trial with a small sample size. Although there were methodological limitations, there was an indication of short term psychosocial benefits of MBIs (such as depression, anxiety, mental fatigue, and quality of life), and that MBIs were unlikely to cause harm.

Current literature review

No known systematic literature review to date has been done on MBIs (i.e., MBSR and MBCT) for people with ABI. A review on MBIs for people with acquired cognitive impairments can help progress this area of research, which is still in its infancy. Acquired cognitive impairments are defined here in its broad terms so as to include cognitive impairments due to conditions such as acquired brain injuries, mild cognitive impairments and dementia.

The present review aims to address the following questions:

1. What is the available evidence for the effectiveness in mindfulness-based interventions for people with acquired cognitive impairments?
2. Were any modifications made to the intervention content and delivery?

Method

Inclusion criteria

- Studies with participants aged ≥18.
- Participants with a diagnosis of:

  (a) mild cognitive impairments, or

  (b) dementia (including all types and stages), or

  (c) acquired brain injury (including traumatic brain injury, stroke, brain tumour, meningitis, encephalitis, hydrocephalus and anoxia).
- Interventions described as Mindfulness-based Stress Reductions (MBSR), Mindfulness-based Cognitive Therapy (MBCT), or a modified version of either of the former two.
- Studies can be randomised controlled trials (RCT), pre- and post-test-only studies with or without a control group. Non-randomised studies were included as the number of RCT studies was anticipated to be limited.
- Studies with quantitative outcome measures. Psychological, cognitive and/or behavioural outcomes were included.
- Studies published in peer reviewed journal articles, in English before January 2015. Given the novelty of mindfulness interventions for people with cognitive impairments, all publication years up to January 2015 were included.

Exclusion criteria

- Interventions that only partially incorporate formal meditation training, such as Dialectical Behaviour Therapy (Linehan, 1993), and Acceptance and Commitment Therapy (Hayes et al., 1999) or other integrated rehabilitation interventions.

- Intensive meditation retreats.
- Case studies and qualitative research.
- Studies which only report biological outcome measures.

Search strategy

The PsycINFO, EMBASE, MEDLINE, Web of Science, CINAHL Plus and the Cochrane Library databases were searched in January 2015. The search was limited to peer-reviewed articles written in English. Search terms specified the populations under study (cog* impair* OR traumatic brain inj* OR dementia OR Alzheimer, brain damage OR head injur*) and the interventions being examined (mindfulness, MBCT OR MBSR OR meditation).

Titles and abstracts were reviewed and any potentially relevant papers retrieved for full review according to the inclusion and exclusion criteria. Reference sections of articles meeting the inclusion criteria were also reviewed for relevant studies.

Study quality

A modified version of the Downs and Black's (D&B; 1998) checklist was used to assess the methodological quality of both randomised and non-randomised studies of healthcare interventions (see Appendix A). The original checklist contains 27 questions across five sections: quality of the reporting of the study (10 items), external validity (three items), power of the study (one item), internal validity for bias (seven items) and confounding/selection bias (six items). For the purpose of this review, the checklist was modified by removing item 14. This item asked whether any attempt was made to blind study subjects to the intervention received, which is not applicable for most psychological intervention studies. The original scores for item 27 regarding sufficient power range from 0 to 5. Studies were regarded as better

quality i.e. additional points allocated, when the sample size was greater than an arbitrary cut-off limit (MacLehose et al., 2000). This was changed to a score of 0 to 1, representing without and with sufficient power respectively. Therefore, the total scores for the modified D&B checklist range between 0 and 27.

Quality rating scores were used for descriptive purposes only. In common with other quality assessment tools, the D&B checklist did not distinguish items relating to the quality of the study and quality of reporting of the study; it is worth noting that poor quality in reporting are not directly related to risk of bias in studies (Higgins et al., 2011). Hence, the strengths and weaknesses of the studies were qualitatively examined, with details of quality scores for each study summarised in Table 2.

Data extraction and synthesis

Consistent with the York Centre for Systematic Reviews guidelines (University of York, 2009), information extracted included the characteristics of the study, design and methods used, number and characteristics of participants, intervention details, outcomes and results. Where data were missing from the published studies, attempts were made to obtain this by correspondence with the trial authors.

Meta-analyses were not possible due to the heterogeneous nature of the papers included in the review. The review findings are presented in narrative form, according to the type of clinical presentations.

Results

Overview

A breakdown of the search process is shown in Figure 1. After de-duplication, the search resulted in 877 papers from the six databases. Three

additional papers were obtained from personal communications with researchers. Out of the total 880 papers where the titles and abstracted were screened, 22 potential articles appeared to meet the inclusion criteria. Reference lists from the potential articles were examined to see whether any additional papers were eligible. One additional paper was retrieved and excluded because the intervention for the treatment group did not include only MBSR. Full text reading resulted in 13 papers for review. Additional information was requested from some authors, and one replied with additional details regarding the intervention. Two papers did not provide sufficient information for data extraction: however, one study (Litherland & Robertson, 2014) had additional details provided in an online report (Litherland, Mason, Pilchick, Sansom, & Robertson, 2013); and the other study (Lantz, Buchalter, & McBee, 1997) had limited supplementary details in a general article (McBee, 2003). It was noted that in one included paper (Litherland & Robertson, 2014), the authors reported they were in the recruitment process for a larger trial in people with mild to moderate dementia at the time of this review.

Two papers reported results from the same study (Wells et al., 2013a, 2013b). In another instance, two papers were from the same study (Bédard et al., 2003, 2005) where the former paper reported the pretest-posttest results for both intervention and control groups, while the latter paper reported the results of a one-year follow-up of the same participants in the intervention group. Therefore, 13 papers representing 11 studies were included in this review.

Figure 1

Flowchart detailing study selection

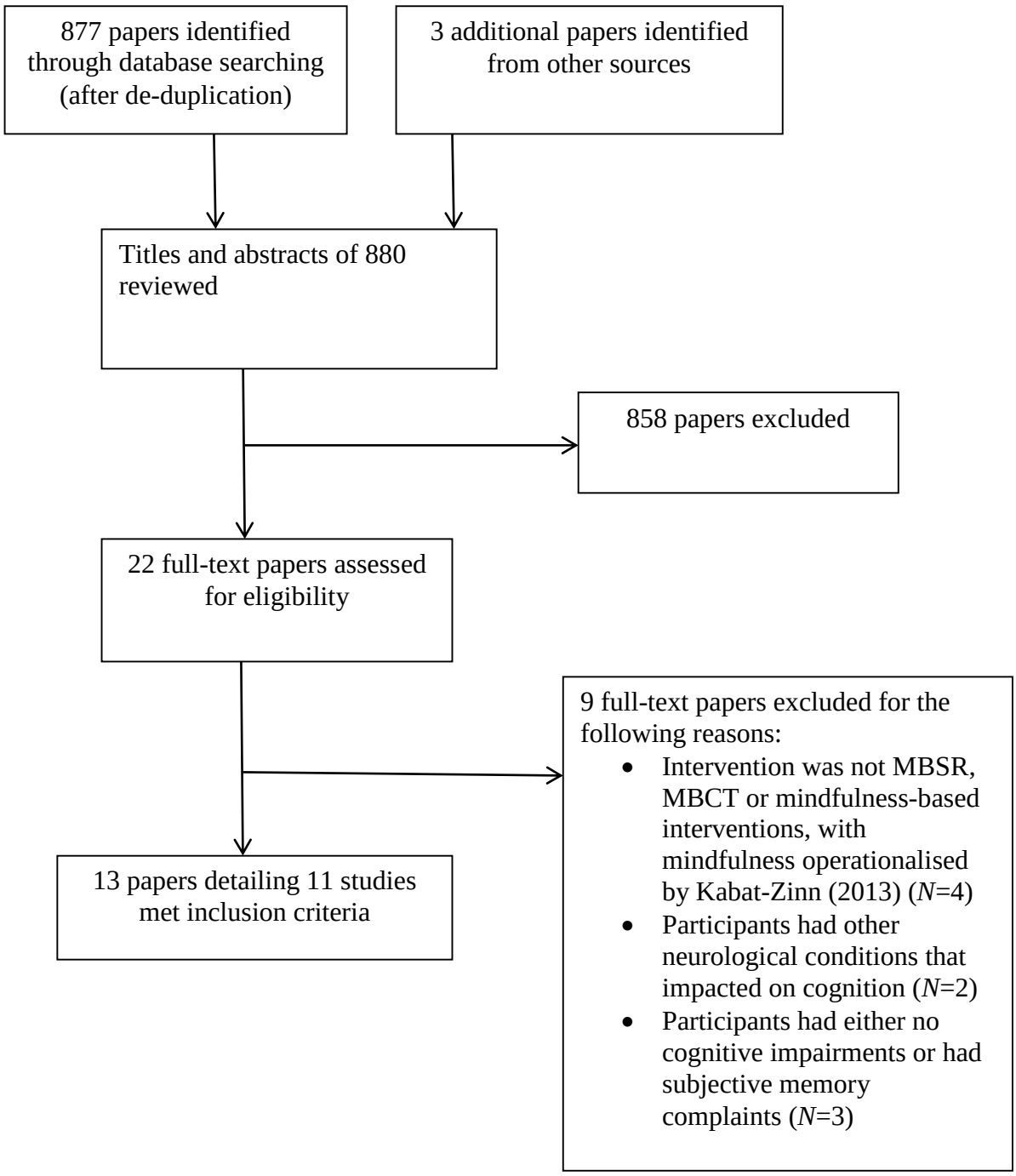

Table 1 summarises the 11 studies reviewed. Because of the limited number of studies found, they were classified into two broad categories: acquired brain injury (ABI); and mild cognitive impairment (MCI) and dementia. Several studies used mixed methods. The present review will only review the quantitative components. One study recruited both people with dementia and their carers (Litherland & Robertson, 2014). Only the data for participants with dementia will be reported.

Participants

Of the 11 studies, one investigated MBI for people with MCI (Wells et al., 2013a, 2013b) and two studied dementia. One recruited people with moderate to severe dementia in a care home (Lantz et al., 1997). The other study did not specify dementia severity or additional participant characteristics, but the participants lived in their own accommodations (Litherland & Robertson, 2014).

The remaining eight studies investigated MBI for people with ABI: five studied traumatic brain injury (TBI), two studied stroke, and one studied a mixed population of ABI, i.e. stroke and TBI. There was a varied range in severity of ABI. Five out of the eight studies either did not record or report the severity of ABI. It was not possible to classify and compare them in a meaningful manner. The majority of the studies were conducted in America or Canada, two in Europe, and one study in Korea.

Table 1

Description of studies reviewed

People with acquired brain injury (eight studies)

Authors	Participant[a]	Design, country and description of intervention	Outcome measures	Results*
Azulay et al. (2012)	Mild TBI at least more than 7 months post-injury *N* = 22 Mean age (*SD*) = 48.9 (8.3)	Design: Single group pretest-posttest design. Convenience Sampling. Country: USA Intervention details: group-based MBSR, weekly 120-min session for 10 weeks, no retreat day, daily home practice. Two facilitators in each session: Neuropsychologists with training in MBSR.	Psychological/ psychosocial measures: PQOL, PSES, NSI, MAAS. Cognitive measures: CPT-A, PASAT, CVLT-II, SPSI-R:S.	Improvements in quality of life (PQOL), perceived self efficacy (PSES), and attention (CPT-A & PASAT).

Bédard et al. (2003, 2005)	Mild to mod TBI at least 1 year post-injury *N* = 13 (EXP:10, CTL: 3) Mean age (*SD*) = 87.22 (1.5)	Design: Single group pretest-posttest design with drop-outs as controls; follow up at 12 months for the EXP group. Convenience Sampling. Country: Canada Intervention details for EXP: group-based MBSR and Kolb's (1984) experiential learning cycle, weekly session for 12 weeks (duration per session unclear), no retreat day. Facilitators: no details given.	Psychological/ psychosocial measures: SF-36, BDI-II, SCL-90-R, PSS, MHLC, CIQ.	Improvements on the 'Mental Health' domain of SF-36 (a health-related quality of life questionnaire), and reduction in depression symptoms (only in the cognitive-affective domain of BDI-II) in EXP. 1 year follow-up for EXP only: Improvements in the 'Mental Health' domain of SF-36 remained higher than the baseline level, and continued reduction in depression symptoms (in the cognitive-affective domain of BDI-II).
Bédard et al. (2012)	TBI of more than 1 year ago, with clinical depression *N* = 23 Mean age (*SD*) = 47.1 (15.7)	Design: Single group pretest-posttest design. Convenience Sampling. Country: Canada Intervention details for EXP: group-based MBCT, 1.5hrs of orientation session to introduce the intervention followed by weekly 90-min session for 8 weeks, no retreat day, daily home practice. One facilitator in each session: Trained in MBCT.	Psychological/ psychosocial outcomes: BDI-II, HADS, PHQ-9, SCL-90-R, SF-36, MPAI, self-reported pain and energy levels	Reduction in depression symptoms (BDI-II, PHQ-9, HADS depression subscale, SCL-90-R depression subscale), overall psychological symptom severity (SCL-90-R including global severity index, positive symptom distress index and subscale of obsessive-compulsive subscale), and pain intensity. Improvements in self-reported energy levels, on health-related quality of life (SF-36 subscales of general health and mental health).

Bédard et al. (2014)	TBI with clinical depression *N* = 105 (EXP 57; CTL 48) Mean age (*SD*) = EXP: 47.10 (12.03) CTL:45.81 (14.80)	Design: Pretest-posttest randomised wait-list controlled trial; follow up at 3 months. Stratified randomisation of sample to ensure balance between groups on symptoms of depression (using BDI-II score), age and sex. Country: Canada Intervention details for EXP: group-based MBCT, weekly 90-min session for 10 weeks, no retreat day, daily home practice of 20-30-min meditation. Two facilitators in each session: healthcare professionals working in rehabilitation for people with neurological conditions who were trained to deliver the modified MBCT.	Psychological outcomes: BDI-II, PHQ-9, SCL-90-R, PHLMS, TMS for only EXP.	Reduction in depression symptoms in EXP (BDI-II). 3-month follow up: Reduction in depression symptoms was maintained (BDI-II).

Johansson et al. (2012)	TBI or stroke and with pathological mental fatigue for at least 12 months *N* = 29 (Stroke: 18; TBI: 11) EXP: 15; CTL:14 Mean age (*SD*) = EXP: 53.7 (6.11) CTL: 57.1 (7.26)	Design: Pretest-posttest randomised wait-list controlled trial. Country: Sweden Intervention details for EXP: group-based MBSR, weekly 150-min session for 8 weeks, no retreat day, daily home practice of 45 min. Facilitators: no details given.	Psychological outcomes: MFS; CPRS Cognitive outcomes: Digit Symbol-Coding, Digit Span, FAS verbal fluency test, TMT Trails A & B, and authors' versions of Trails C & D.	Reduction in mental fatigue (MFS) and improvement in information processing speed (TMT Trail A) in EXP.
Joo et al. (2010)	6-months post surgery for aneurysmal subarachnoid haemorrhage *N* = 28 Mean age (range) = 52.5 (38 to 65)	Design: Single group pretest-posttest design. Country: Korea Intervention details: group-based MBSR and loving-kindness meditation, weekly 150-min session for 8 weeks, no retreat day, unclear if home practice was given. Facilitators: no details given.	Psychological outcomes: BDI-Korean version, State-Trait Anxiety Inventory	Reduction in depression symptoms (BDI-Korean version).

McMillan et al. (2002)	TBI of mixed severity between 3-12 months post-injury *N* = 145 (EXP: 50; PE:47; CTL:48) Mean age (*SD*) = EXP: 34.6(11.4) PE: 31.4(13.0) CTL:36.2 (13.4))	Design: Pretest-posttest randomised wait-list controlled trial; follow up at 6 months and 12 months 3 groups: EXP, physical exercise (PE) and CTL Country: United Kingdom Intervention details: 1:1 ACT (only mindfulness breathing technique in MBSR was taught), 45-min, 5 sessions in 4 weeks, no retreat day, home practice. Facilitator: a therapist with no mindfulness-based training (no further details given).	Psychological outcomes: HADS, GHQ, and Rivermead Post-Concussional Symptoms Questionnaire Cognitive outcomes: TEA, AMIPB, PASAT, TMT Trails A & B, EMQ and CFQ	No significant findings for all three groups post intervention, and at 6- and 12-month follow-ups.
Moustgaard et al. (2007)	History of mild to moderate stroke. *N*=30 Mean age (*SD*) = 63.3 (11.8)	Design: Single group pretest-posttest design; follow up at 3 months. Country: Canada Intervention details: group-based MBCT, weekly 105-min session for 9 weeks, no retreat day, home practice. Two facilitators in each session: One trainee clinical psychologist and one trained in mindfulness meditation and yoga instructor.	Psychological/psychosocial outcomes: BAI, BDI-II, HADS, SF-36, SS-QoL	Improvements post intervention, and maintained at 3-month follow up for anxiety (BAI, HADS), depression (BDI-II, HADS), physical & mental health status (SF-36), and overall quality of life (SS-QoL).

[a] The sample size at the start of the study, before any participants dropped out.
* All findings reported in this table were statistically significant at $p<.05$.

ACT=Attentional Control Training, AMIPB=Adult Memory and Information Processing Battery, BDI-II= Beck Depression Inventory, CFQ=Cognitive Failures Questionnaire, CIQ=Community Integration Questionnaire, CPRS= Comprehensive Psychopathological Rating Scale, CPT-A= Continuous Performance Test of Attention, CTL= Control group, CVLT-II= California Verbal Learning Test-II, EMQ=Everyday Memory Questionnaire, EXP= Experimental group, GHQ=General Health Questionnaire, HADS=Hospital Anxiety and Depression Scale, MAAS= Mindfulness Attention Awareness Scale, MFS= Mental Fatigue Scale, MHLC=Multidimensional Health Locus of Control Scale, MPAI=Mayo-Portland Adaptability Inventory, NSI= Neurobehavioral Symptom Inventory, PASAT= Paced Auditory Serial Addition Test, PHLMS=Philadelphia Mindfulness Scale, PHQ-9=Patient Health Questionnaire, PQOL = Perceived Quality of Life scale, PSES = Perceived Self-Efficacy Scale, PSS=Perceived Stress Scale, SCL-90-R=Symptom Checklist, SF-36=Short Form Health Survey, SPSI-R:S=Social Problem-Solving Inventory-Revised: Short form, SS QoL=Stroke Specific Quality of Life, TBI=Traumatic brain injury, TEA=Test of Everyday Attention, TMS=Toronto Mindfulness Scale, TMT=Trail Making Test

People with mild cognitive impairments or dementia (three studies)

Authors	Participants[a]	Design, setting and description of intervention	Outcome measures	Results*
Lantz et al. (1997)	Moderate to severe dementia *N*= 14 EXP: 8; CTL:6 Mean age (range)= EXP: 81 (70-91) CTL: 82 (70-91)	Design: Pretest-posttest non-randomised controlled trial Country: North America Intervention details: modified group- based MBSR, weekly 60-min session for 10 weeks, no retreat session. Two facilitators: 1 as key facilitator and 1 to demonstrate techniques on a 1:1 basis and physically directing residents who were agitated, restless or in need of additional assistance.	Behavioural outcome: CMAI	Reduction in agitation in EXP.
Litherland & Robertson (2014)	Dementia of mixed severity *N*=12	Design: Single group pretest-posttest design; follow up at 3 months. Country: United Kingdom Intervention details: MBSR, weekly 150-min session for 8 weeks, no retreat session, home practice. One facilitator experienced in mindfulness-based approaches.	Psychosocial outcome: WEMWBS	No significant findings.

Wells et al. (2013a, 2013b)	MCI N=14 Mean age (SD) = EXP: 73 (8) CTL: 75 (2)	Design: Randomised controlled pretest-posttest design. Block randomisation. Setting: North America. Intervention details: MBSR, weekly 120-min session for 8 weeks, one retreat day, home practice encouraged. Facilitators: no details given.	Psychological outcomes: QoL-AD, Resilience Scale, PSS, Herth Hope Index, LOT-R, CESD and MAAS Cognitive outcomes: ADAS-Cog, RAVLT, TMT Trails A & B, COWAT, Animal Naming, Boston Naming	CTL performed better on TMT Part A and Part B than at baseline.

[a] The sample size at the start of the study, before any participants dropped out.
* All findings reported in this table were statistically significant at $p<.05$.

ADAS-Cog=Alzheimer's Disease Assessment Scale cognitive subscale, CESD=Center of Epidemiologic Studies Depression Scale, CMAI=Cohen-Mansfield Agitation Inventory, COWAT= Controlled Oral Word Association Test, CTL= Control group, EXP= Experimental group, LOT-R=Life Orientation Test-Revised, MAAS=Mindfulness Attention Awareness Scale, MCI=mild cognitive impairments, PSS= Perceived Stress Scale, QoL-AD=Quality of Life-Alzheimer's Disease, RAVLT=Rey Auditory Verbal Learning Test, TMT=Trail Making Test, WEMWBS=Warwick Edinburgh Mental Well-being Scale

Study design and quality

Table 2 summarises the details of quality scores for each included study. For ABI studies, quality scores ranged from 12-19 out of a maximum 27 (M = 15). Only one study was a randomised controlled trial with three conditions, i.e. mindfulness, physical exercises and control groups (McMillan, Robertson, Brock, Chorlton, 2002). Two studies were randomised waitlist controlled trials, four used a single group pretest posttest design, and one used a single group pretest posttest design with dropouts as controls (Bédard et al., 2003, 2005). One randomised waitlist controlled trial used stratified randomisation of sample to ensure balance between groups on symptoms of depression (using Beck Depression Inventory-II scores), age and sex (Bédard et al., 2014). However, the study had 5 participants assigned to the intervention group without randomisation due to difficulties in recruitment.

Initial sample sizes ranged from 13 to 145. Reporting quality of studies was adequate with key hypotheses, outcome measures and findings described. Attrition rates ranged from 0% to 60%. Many studies did not report the reasons for dropouts.

Only some studies compared the characteristics (such as age, gender) of those who dropped out with those who did not, and no study that had high dropout rates presented an intent-to-treat analysis. Only one study provided a power calculation, but many authors acknowledged that their study was likely to be underpowered. Two studies reported blinding of outcome assessors. Four studies reported follow-up periods ranging from three to 12 months. Only one study used the Bonferroni adjustment for multiple comparisons of outcomes to reduce the risk of type one error.

Some studies had other potential biases. For instance, all the participants in the study by Azulay et al. (2012) were receiving concurrent rehabilitation with the majority having individual neuropsychological treatment. A randomised waitlist

controlled study investigating the symptoms of depression included participants who were having antidepressants in both treatment and control groups (Bédard et al., 2014).

Quality scores for studies in MCI/dementia ranged from 7-21 (mean=12). Two small studies used mixed-methods designs (Lantz et al., 1997; Litherland & Robertson, 2014). Initial sample sizes ranged from 12-14. Design of the three studies varied: single group pretest posttest design, randomised controlled trial and pretest posttest non-randomised controlled trial. The study by Wells and colleagues (2013a, 2013b) had adequate reporting quality, and the only study that had blinding of outcome assessors and recorded adverse events. One study conducted a follow-up at three months (Litherland & Robertson, 2014).

External validity for all ABI and MCI/dementia studies were poor due to recruitment difficulties, many studies using convenience sampling, and limited details regarding the source population and intervention setting.

Table 2

Quality scores for studies reviewed using the Downs & Black's (1998) checklist

People with acquired brain injuries (N = 8 studies)

	Reporting										External Validity			Internal Validity (Bias)						Internal Validity (Confounding/Selection Bias)								
	1. Hypotheses/Aims	2. Outcomes	3. Sample	4. Intervention	5. Confounders	6. Main findings	7. Variability (e.g. SD)	8. Adverse effects	9. Loss to follow-up (characteristics)	10. Exact *p* values	11. Source population representative	12. Sample representative	13. Setting representative	14. Blinding of assessors	15. Planned analyses	16. Assessment interval	17. Statistical tests	18. Intervention compliance	19. Outcome measures standardised	20. Comparable groups	21. Recruitment time	22. Randomisation	23. Blinded randomisation	24. Adjustment for main confounders	25. Loss to follow-up (numbers)	26. Power	27. Total Score (Maximum score =27)	Reviewer's comments regarding potential biases
Azulay et al. (2012)	●	●	●	●	◗	●	●	○	●	●	○	○	?	?	●	●	●	●	●	●	●	○	○	○	●	○	17	Potential bias: All the participants were in concurrent rehabilitation (with 81% receiving limited individual neuropsychology treatment) while attending the intervention.
Bédard et al. (2003, 2005)	●	●	●	◗	◗	●	●	○	○	●	○	?	?	?	●	●	●	○	●	●	●	○	○	○	○	○	13	Validity of statistical analyses: Dropouts were used as controls; in the one year follow up, only the treatment group were included. Other potential bias: 50% of the participants were taking antidepressants pre- and post-intervention; the treatment group contained only women (70% of participants).

	Reporting										External Validity			Internal Validity (Bias)						Internal Validity (Confounding/Selection Bias)								
	1. Hypotheses/Aims	2. Outcomes	3. Sample	4. Intervention	5. Confounders	6. Main findings	7. Variability (e.g. SD)	8. Adverse effects	9. Loss to follow-up (characteristics)	10. Exact *p* values	11. Source population representative	12. Sample representative	13. Setting representative	14. Blinding of assessors	15. Planned analyses	16. Assessment interval	17. Statistical tests	18. Intervention compliance	19. Outcome measures standardised	20. Comparable groups	21. Recruitment time	22. Randomisation	23. Blinded randomisation	24. Adjustment for main confounders	25. Loss to follow-up (numbers)	26. Power	27. Total Score (Maximum score =27)	Reviewer's comments regarding potential biases
Bédard et al. (2012)	●	●	●	●	◗	●	●	○	●	●	○	?	○	?	●	●	●	●	●	●	?	○	○	○	○	○	15	Potential confounder: Severity of traumatic brain injury unknown.
Bédard et al. (2014)	●	●	●	●	◗	●	●	○	○	●	○	○	?	●	●	●	●	○	●	●	●	○	○	●	●	○	17	Risk of selection bias: 5 were assigned to the intervention without randomisation. Risk of attrition bias: 29% dropouts in both treatment and control groups post intervention, with additional 16% and 27% dropouts in treatment and control groups respectively at 3-month follow-up. Other potential bias: About a third of participants in both treatment and control groups had antidepressant medications at baseline.
Johansson et al. (2012)	●	●	●	●	●	●	●	○	○	●	○	○	○	?	●	●	●	○	◗	○	?	●	?	●	●	○	15	Internal validity and reliability of measures: Researchers used their own versions of Trail Making Tests (Trails C & D).

	Reporting										External Validity			Internal Validity (Bias)						Internal Validity (Confounding/Selection Bias)								
	1. Hypotheses/Aims	2. Outcomes	3. Sample	4. Intervention	5. Confounders	6. Main findings	7. Variability (e.g. SD)	8. Adverse effects	9. Loss to follow-up (characteristics)	10. Exact *p* values	11. Source population representative	12. Sample representative	13. Setting representative	14. Blinding of assessors	15. Planned analyses	16. Assessment interval	17. Statistical tests	18. Intervention compliance	19. Outcome measures standardised	20. Comparable groups	21. Recruitment time	22. Randomisation	23. Blinded randomisation	24. Adjustment for main confounders	25. Loss to follow-up (numbers)	26. Power	27. Total Score (Maximum score =27)	Reviewer's comments regarding potential biases
Joo et al. (2010)	●	●	●	●	○	●	●	○	○	●	○	○	○	?	●	?	●	○	●	●	●	○	○	○	○	○	12	Risk of attrition bias: 60% non completers; no reasons for the dropouts were provided.
McMillan et al. (2002)	●	●	●	●	●	●	●	○	●	○	○	○	○	●	●	●	●	●	●	●	?	●	?	●	●	?	19	The intervention only included teaching one MBSR technique on an individual basis at participant's home.
Moustgaard et al. (2007)	●	●	●	●	◓	●	●	○	○	●	○	?	?	?	●	●	●	●	●	?	?	○	○	○	○	○	13	Risk of attrition bias: 23% non completers

Note: ● present (score of 1, or 2 for item 5); ◓ present, with some limitations (score of 1 for item 5 or score of 0 on other items); ○ not present (score of 0); ? unable to determine (score of 0)

People with mild cognitive impairments/dementia (N = 3 studies)

	Reporting										External Validity			Internal Validity (Bias)						Internal Validity (Confounding/Selection Bias)								
	1. Hypotheses/Aims	2. Outcomes	3. Sample	4. Intervention	5. Confounders	6. Main findings	7. Variability (e.g. SD)	8. Adverse effects	9. Loss to follow-up (characteristics)	10. Exact *p* values	11. Source population representative	12. Sample representative	13. Setting representative	14. Blinding of assessors	15. Planned analyses	16. Assessment interval	17. Statistical tests	18. Intervention compliance	19. Outcome measures standardised	20. Comparable groups	21. Recruitment time	22. Randomisation	23. Blinded randomisation	24. Adjustment for main confounders	25. Loss to follow-up (numbers)	26. Power	27. Total Score (Maximum score =27)	Reviewer's comments regarding potential biases
Lantz et al. (1997)	○	○	●	●	◗	●	●	○	○	●	○	○	○	?	?	●	?	?	●	●	?	?	○	?	?	○	9	Risk of reporting bias: Generally there were insufficient details provided regarding the study as indicated by the question marks here. E.g., it was unclear if people with dementia of mild severity participated in the study (if yes, data was not reported).
Litherland & Robertson (2014)	●	●	●	●	○	●	○	○	○	○	○	○	?	?	●	○	○	○	●	○	?	○	○	○	○	○	7	Risk of attrition bias: 33% dropped out of the intervention. Other potential bias: Intervention was delivered to both people with dementia and their carers.
Wells et al. (2013a, 2013b)	●	●	●	●	◗	●	●	●	●	●	○	○	?	●	●	●	●	●	●	●	●	●	?	●	●	○	21	

Note: ● present (score of 1, or 2 for item 5); ◗ present, with some limitations (score of 1 for item 5 or score of 0 on other items); ○ not present (score of 0); ? unable to determine (score of 0)

Intervention characteristics

All 11 studies except one (Wells et al., 2013a, 2013b) did not incorporate a retreat session. Not all studies indicated whether home practice was required. Some studies shortened the home practice duration to 20-30 minutes, and/or requested the participants to record the times they practiced.

ABI studies

Of the eight studies, five used MBSR and three used MBCT. For the three MBCT studies, the duration per session was shortened from the original 120 minutes to between 90-105 minutes. All MBCT studies addressed cognitive difficulties in the TBI/stroke populations by adapting the delivery of intervention, such as increase in repetition, use of simplified language and visual aids, shortened meditation sessions. To facilitate learning, one study also gave written handouts of each session, and participants were encouraged to record their observations and questions on "new learning" forms to make more explicit connections between learning activities (Bédard et al., 2014). They were also given a book (Williams, Teasdale, Segal, & Kabat-Zinn, 2007) to use the accompanying CD for home practice, and that they were not required to read the book. In one study of participants with stroke, other modifications included: an additional psycho-education session on stroke, simplified yoga movements to accommodate people's the physical difficulties, and facilitators meeting participants individually to review their home practice and log entries (Moustgaard, Bédard, & Felteau, 2007).

All five studies modified the MBSR intervention to some extent. The most substantial modification was in one study which introduced brief mindfulness training called "attentional control training" to participants (McMillan et al., 2002). The training incorporated only one formal meditation taught in MBSR for a total of

four sessions (i.e., a 30-minute audiotape of mindfulness of breath as obtained from Prof. Kabat-Zinn). This was also the only study that provided one-to-one sessions at the participant's home. The study with the least modification omitted the retreat session and taught an additional meditation technique called loving-kindness (Joo, Lee, Chung, & Shin, 2010). The remaining three MBSR studies modified the duration per session and/or the total number of sessions. Some studies reduced, from the original 150-min per session, to between 45 and 120 minutes, and increased the total sessions from eight to between 10-12 sessions.

Only two MBSR studies addressed the cognitive difficulties in the TBI/stroke population by modifying the delivery of the intervention. To address the difficulties in learning, memory and fatigue, Johansson and colleagues (2012) provided more time for participants to reflect in sessions. Azulay and colleagues (2012) made a number of modifications including: shortened session duration; increased number of sessions; reduced group sizes to allow time to explain and repeat concepts; provision of written information of home practice; increased modelling of abstract concepts (e.g., using mindfulness to explore emotional and physical pain); and asked participants to record the home practice frequency and observations regarding their experiences.

For all the ABI studies, several incorporated home practice between sessions: three studies shortened the home practice duration from 45 minutes to 20-30 minutes whilst some studies did not indicate the recommended duration. Only one study developed a manual to ensure consistency in intervention delivery (Bédard et al., 2003, 2005). Four studies provided the number and details of facilitators per group: three studies used two facilitators per group and one study reported using one facilitator. All four studies had at least one facilitator trained in a mindfulness-based

programme. Bédard and colleagues (2014) specifically trained the facilitators to teach MBCT to the participants with cognitive impairments (see training details of the facilitators in Gibbons et al., 2014).

MCI/dementia

All three MCI/dementia studies used MBSR. One study did not modify any elements of the MBSR programme, with the exception of a shorter duration of 120 minutes (Wells et al., 2013a, 2013b). One study modified the intervention delivery slightly, i.e., a presentation with taster session of about 60-90 minutes, reduced the length of some formal meditation practices, and shortened the duration of home practices (Litherland & Robertson, 2014).

One study modified the programme considerably to accommodate the needs of the participants with dementia at the nursing home (Lantz et al., 1997). The modifications included: grouping participants according to the severity of dementia (mild severity in one group, moderate to severe range in another group); and intervention content (modified meditation, guided imagery, and body awareness incorporating multisensory aspects, i.e., auditory, olfactory, tactile and motor awareness). Lantz and colleagues also emphasised the importance of the facilitators' flexibility in offering modifications based on participants' interests and needs as required. It was also the only study that recommended two facilitators, where one was the lead facilitator while the other to demonstrate techniques on a one-to-one basis and to physically direct participants who were agitated, restless or in need of additional assistance. The staff at the nursing home were also invited to attend the treatment group as participants.

Outcome measures

Most studies used multiple heterogeneous outcome measures. Details of the outcome measures used and the results can be found in Table 1.

Two studies used biological measures, which are not reviewed here (Joo et al., 2010; Wells et al., 2013b). Only two studies did not have any significant findings, one in the TBI population (McMillan et al., 2002) and one in the dementia population (Litherland & Robertson, 2014).

Outcomes for MCI/dementia

Outcome measures for all three studies were different. One study with only one quantitative outcome measure did not find any significant improvements in overall mental health (Litherland & Robertson, 2014). The authors suggested since the aim of mindfulness was to increase participants' awareness and understanding of their mental wellbeing, this might account for the lack of improvements in the short term.

One study in people with moderate to severe dementia in a nursing home found a significant reduction in agitation as reported by staff in the treatment group (Lantz et al., 1997). The study described grouping participants according to dementia severity. However, it was not clear from the paper whether people with dementia of mild severity participated and no such results were reported.

An RCT in people with MCI did not find any significant results in a variety of psychological/psychosocial outcomes (Wells et al., 2013a, 2013b). The only exception was that the controls performed better than the MBSR group on tests of executive functioning (i.e., Trail-Making Test Parts A and B). The authors suggested this unexpected result was due to the order of testing and fatigue.

Outcomes for people with acquired brain injury

Depression

A total of six ABI studies measured depression symptoms. Three of them used more than one mood measure. Of these, five (including three MBCT) used the Beck Depression Inventory-II (BDI-II). Four of these found a significant reduction in overall depression symptoms (Bédard et al., 2012; Bédard et al., 2014; Joo et al., 2010; Moustgaard et al., 2007), while one found significant results only on the cognitive-affective domain of BDI-II (Bédard et al., 2003, 2005). Although Bédard et al. (2014) found a significant effect on mood following the intervention on the BDI-II, there were no significant findings on two secondary scales – Patient Health Questionnaire (PHQ-9) and the depression subscale of the Symptom Checklist (SCL-90). The authors attributed the non-significant results to the lower PHQ-9 scores at baseline and that the SCL-90 was less responsive than the BDI-II. The remaining MBSR study which used the Hospital Anxiety and Depression Scale did not have any significant findings (McMillan et al., 2002).

Three studies conducted follow-ups. Reduced depression was maintained three months later in two MBCT studies (Bédard et al., 2014; Moustgaard et al., 2007). In the MBSR study by Bédard et al. (2003, 2005), they did a follow-up of only the participants in the treatment group and found a continued reduction in depressive symptoms on the cognitive-affective domain of BDI-II one year later.

Anxiety

Out of three studies (including one MBCT study) that measured anxiety symptoms, only the MBCT study found a reduction in anxiety symptoms post intervention and at 3-month follow-up (Moustgaard et al., 2007).

Overall mental health

Five studies measured overall mental health (including 2 MBCT studies) using varied outcome measures. Only one MBCT study found a significant reduction

in overall psychological distress, including positive symptom distress index and obsessive-compulsive subscale on the Symptom Checklist-90-Revised (Bédard et al., 2012).

Quality of life

Two studies (including one MBCT study) measured overall quality of life using different questionnaires. Both found significant improvements after the intervention (Azulay et al., 2012; Moustgaard et al., 2007).

All three studies (including two MBCT studies) that examined the health-related quality of life reported significant improvement in various domains on the Short Form Health Survey-36 (SF-36; Bédard et al., 2003, 2005; Bédard et al., 2012; Moustgaard et al., 2007). Two studies conducted follow-ups after the intervention. Bédard et al. (2003, 2005) followed up the treatment group only and found that the significant improvements in the 'mental health' domain of SF-36 remained higher than at baseline one year later. Moustgaard et al. (2007) found the improvements in overall health-related quality of life were maintained at the 3-month follow-up.

Other psychological outcomes

Three studies found significant results in other psychological/psychosocial domains. Johansson and colleagues (2012) measured mental fatigue and found that after controlling for age and time since brain injury/stroke, the participants reported reduced levels of mental fatigue. Azulay et al. (2012) measured self-efficacy in managing cognitive, emotional and social difficulties. Participants reported significant improvements particularly in the management of cognitive and emotional difficulties. An MBCT study found significant reductions in pain and improvements in energy levels (Bédard et al., 2012).

Other psychological/psychosocial domains evaluated in studies included: stress levels, level of functioning following a traumatic brain injury, mindfulness and symptoms of postconcussional symptoms. No significant effects were found in those domains.

Cognition

Three MBSR studies used a diverse range of cognitive tests measuring attention, learning and memory, working memory and executive functioning. One study found significant improvements on two tests of sustained attention and working memory (Azulay et al., 2012). However, another study that used the same test (Paced Auditory Serial Addition Test) did not find any significant results after a brief mindfulness training (McMillan et al., 2002). Johansson and colleagues (2012) found that the treatment group significantly improved in information processing speed on Trail Making Test, Trail A compared to the controls.

Discussion

Summary of main findings

Thirteen papers describing 11 studies met the inclusion criteria of this review. The studies used a diverse range of outcome measures, making direct comparison of studies difficult. It was not possible to evaluate the longer term effects of MBIs due to the limited number of studies doing follow-ups, where the maximum length of follow-up was 12 months. All ABI studies except one (McMillan et al., 2002) found some positive effects following the intervention. However the findings need to be interpreted with caution due to methodological limitations, such as lack of adequate statistical power and control groups.

Most of the ABI studies measured the effects of MBI in reducing depression and in improving general mental health. There is some evidence that MBIs reduce

depression symptoms in the short term as indicated in all studies except for one RCT study (McMillan et al., 2002). Although the RCT received the highest score in terms of study quality, it was difficult to directly compare its findings with the other ABI studies: this study modified the programme the most, delivering one MBSR technique over five sessions on an individual basis at the participant's home. On the other hand, this perhaps indicates other factors with potential effects, for instance, group participation and reflection, therapist contact, intervention intensity and content.

It was not possible to draw conclusions about the effectiveness of MBI for people with MCI and dementia due to the limited number of studies and the small sample sizes.

Intervention content and delivery

Many ABI studies made various modifications to address the cognitive difficulties of this population. Common themes included: shortened meditation sessions and/or shortened duration of each session, memory aids (e.g. visual cues and written handouts), increase in repetition, simplified language, and no retreat session. However, the attrition rates were high in some of those studies. Interestingly the study that made the least adaptation to the intervention had the highest number of dropouts (60%; Joo et a.l, 2010), while the study that made the most adaptations did not find any significant findings (McMillan et al., 2002).

Many ABI studies requested or recommended home practice, with some requesting participants to record the frequency of practice. However, only one study explored whether increase in home practice correlates with increase in mindfulness and/or psychological symptoms (McMillan et al., 2002). The authors found that using the amount of home practice as a covariate did not alter the results.

The extent of modification in MCI/dementia studies was too varied to identify any common themes. However, it is noteworthy that the RCT of people with MCI (Wells et al., 2013a, 2013b) did not make any amendments to the intervention. The study had a high attendance rate, no dropouts and no adverse events reported. This suggests limited evidence that MBIs are feasible for people with MCI.

Methodological issues

All the studies reviewed had a number of limitations: many did not have control groups, small sample sizes, lack of intention-to-treat analysis despite the high attrition rates in several studies, and follow-up periods were often short. Many studies used multiple measures and some studies performed multiple comparisons by analysing sub-scales of measures: this may increase the risk of type one error.

There were only two RCTs (one ABI, one MCI), and two studies with randomised waitlist controlled designs. Waitlist designs are common in psychological interventions. However, it may overestimate the intervention effects. It is possible that participants on the waiting list do not expect to have any improvements until they have had the intervention (Cunningham, Kypri, & McCambridge, 2013).

Very few included studies measured mindfulness. Measures of mindfulness should be included in order to assess whether the intervention's effectiveness was due to an increase in mindfulness skills or other nonspecific factors. In some studies, there were also confounding factors that were not considered in the statistical analysis, such as being in concurrent rehabilitation therapy, use of psychotropic medication and the inclusion of mixed severity of brain injury.

There were some studies with unclear risk of bias due to lack of adequate reporting in certain domains, such as allocation concealment, and blinding of

participants and staff to group allocation. External validity for all studies was poor due to recruitment difficulties, convenience sampling used in many studies, and limited details regarding the source population and intervention setting.

Limitations of review

The findings from this review should be interpreted with caution. First, this review included a wide range of conditions under the term acquired cognitive impairments. Although the aim of the review was to help progress this area of research, this inclusive approach presented significant challenges in assessing and assimilating the available evidence. Studies of low quality included also prohibited useful conclusions. However, this was addressed to some extent by including a checklist of study quality to facilitate the comparisons and transparently acknowledging the limited evidence from poor quality studies.

Second, the components of the MBIs such as length, duration of and modifications to the content and delivery, the settings and outcome measures used varied across studies, leading to differences in intensity and 'dosage' of the interventions. This further contributed to difficulties in interpreting the data.

Third, only a few studies conducted follow-ups, and the maximum length of follow-up in this review was 12 months. The implications of long-term benefits of MBIs for people with acquired cognitive impairments were unclear.

Fourth, the evaluation of the effectiveness of MBIs for people with MCI/dementia was limited due to the low number of studies identified, and the heterogeneity of outcome measures used.

Implications for clinical practice and future research

There is promising evidence that MBIs benefit people with ABIs in reducing symptoms of depression, although further studies are required. Future research would

benefit from high quality studies such as RCTs with adequate statistical power. There is also a need to study additional standardised and validated outcomes, particularly in mindfulness and quality of life.

It is unclear whether MBIs may benefit people with MCI/dementia due to the lack of studies. There is limited evidence that the intervention is safe, with no adverse events reported. However, future research in this population would be beneficial in terms of the feasibility and the effects of the intervention.

There are also some indications that adaptations may be required to accommodate to the cognitive impairments of these populations. Although there were modifications to the intervention reported in many of the included studies, limited details in terms of the modifications were provided with only one ABI study that developed a manual. Given the potential in MBIs for people with acquired cognitive impairments, further research may benefit from developing manuals through consultation with people with dementia and professionals, and having such manuals easily accessible for replication studies.

Future research using a mixed-methods approach may be beneficial. Although this review did not consider the qualitative components of studies, information provided from participants with acquired cognitive impairments may offer an important supplement to quantitative outcome measures.

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Part 2: Empirical Paper

A Mindfulness Programme for People with Dementia in Care Homes: A Feasibility Pilot Study

Abstract

Aims: To investigate the feasibility and the potential benefits of an adapted mindfulness programme for people with mild to moderate dementia in care homes.

Method: A single blind, randomised controlled trial design was used. Thirty-one people with mild to moderate dementia in care homes participated. Participants were randomised to either attend 10 sessions of a mindfulness programme, delivered twice weekly for an hour (n=20), or receive treatment as usual (n=11). A manual was developed through reviews of existing literature, consultation with experts and a focus group with people with dementia. Both groups were assessed using pre-post measures of quality of life, stress, cognition, mindfulness, mood and anxiety. This is a joint project with Anna Churcher Clarke. The first three measures were analysed and reported here.

Results*:* At follow-up, there was a significant improvement on the Quality of Life - Alzhiemer's Disease (QoL-AD) scale in the intervention group and a decline in the control group (p = 0.047, r = 0.38). There was no significant change in cognition or stress. No adverse events were reported.

Conclusions: The results are promising, indicating the mindfulness programme may be beneficial for quality of life in people with dementia. However this was a small sample with limited power. Further research should be conducted before firm conclusions can be reached regarding its benefits.

Introduction

There are around 36 million people with dementia worldwide. This number is expected to more than triple, to 115 million, by 2050 (Alzheimer's Disease International, 2013). In the UK, an estimated 35-50% of people with dementia live in residential care (Knapp & Prince, 2007; Macdonald & Cooper, 2007). As dementia progresses, people experience cognitive, affective, behavioural and motor difficulties (NICE, 2012). Amongst the most distressing facets of dementia are the 'behavioural and psychological symptoms in dementia' (BPSD); these include anxiety, depression, apathy, wandering and disinhibition. It is therefore not surprising that more severe BPSD are associated with reduced quality of life (Finkel, 2000).

Hall and Buckwalter (1987) proposed the progressively lowered stress threshold (PLST) model: as the condition advances, people with dementia are less able to manage daily stresses. When the stress threshold is exceeded, this may result in BPSD. Stressors can take many forms, for example changes in routine or environment, and internal or external demands that exceed the person's functional capabilities (Smith, Gerdner, Hall, & Buckwalter, 2004). Interventions based on the PLST model tend to focus on modifying activities and environmental stimuli to reduce internal and external stressors, while maintaining a reasonable level of stimulation and activity (Smith et al., 2004; Stolley, Reed, & Buckwalter, 2002).

Psychosocial interventions in dementia

Systematic reviews found some evidence that psychosocial interventions, such as behavioural management techniques, physical exercises and forms of sensory stimulation may reduce BPSD for people in long-term care, although better quality research is required (e..g, Seitz et al., 2012; Vernooij-Dassen, Vasse, Zuidema, Cohen-Mansfield, & Moyle, 2010). A recent systematic review found that cognitive

stimulation interventions consistently benefit people with dementia in both residential and community settings in terms of cognitive functioning, social interaction, communication and quality of life (Aguirre, Woods, Spector, & Orrell, 2013).

Mindfulness-based interventions

The concept of mindfulness is defined as a way of paying attention on purpose, in the present moment, and in a non-judgmental manner (Kabat-Zinn, 2013). Although there are other conceptual definitions of mindfulness, the general consensus is that mindfulness consists of two components: the self-regulation of attention maintained on the present experience, and doing so with curiosity, openness and acceptance (Bishop et al., 2004). Lutz and colleagues (2008) proposed that mindfulness meditation is a type of open monitoring meditation, which initially uses focused attention training before transiting to open monitoring practice in the advanced stages. Focused attention training involves focusing attention on a chosen object, whilst constantly monitoring the quality of attention and redirecting the attention when distracted. As focused attention skills advance, this gradually shifts to open monitoring: paying attention moment by moment to one's current experience without focusing on any explicit object.

Mindfulness-based interventions (MBIs), such as mindfulness-based stress reduction (MBSR; Kabat-Zinn, 2013) and mindfulness-based cognitive therapy (MBCT; Segal, Williams, & Teasdale, 2002) are structured group programmes that provide an experiential introduction to mindfulness skills through techniques such as breath awareness, body scan and yoga. Mindfulness meditation practices usually begin with awareness of the sensation of breathing before introducing awareness of different modalities (such as sounds, sight, taste, other body sensations, thoughts and

emotions). MBIs usually consist of eight 2-2.5-hour sessions. MBCT adopts the meditation techniques from the MBSR programme, but also incorporates elements of cognitive behavioural therapy. It aims to develop participants' meta-cognitive awareness by focusing on greater awareness of their relationship to their thoughts and feelings, without challenging specific thoughts (Sipe, Eisendrath, & Stuart, 2012).

Meta-analyses of MBIs found moderate effects in reducing stress, anxiety and depression in healthy participants, and participants with psychiatric and medical conditions (Hofmann, Sawyer, Witt, & Oh, 2010; Khoury et al., 2013). Research also suggests MBIs improve emotional wellbeing and quality of life (e.g., Carmody & Baer, 2008). A systematic review found preliminary evidence in studies consisting mainly of healthy participants that mindfulness meditation is associated with improved functioning in selective, executive and sustained attention skills (Chiesa, Calati, & Seretti, 2011).

Emerging research on the effects of MBSR for older adults suggests that lower levels of depressive symptom severity and older age are associated with greater positive affect following the intervention (Gallegos, Hoerger, Talbot, Moynihan, & Duberstein, 2013). A systematic literature review of MBIs for older adults found some evidence of reduction in depressive symptoms and anxiety symptoms (Churcher Clarke 2015b).

A systematic literature review of MBIs for people with acquired cognitive impairment by Chan (2015) reported some evidence that MBIs reduce depression symptoms in the short term following a traumatic brain injury or stroke. Evidence for the effects of MBIs for people with mild cognitive impairments and dementia was

inconclusive due to the limited available studies. However, there is limited evidence that the intervention is safe: no adverse events were reported.

The mechanisms of action underlying the benefits of MBIs remain unclear. A recent review found higher levels of self-compassion and lower experiential avoidance after attending an MBI (Chiesa, Anselmi, & Serretti, 2014). It also found lower levels of rumination in MBI groups and in active comparable conditions, such as somatic relaxation, when compared to controls. There is also preliminary evidence of a negative correlation between mindfulness and emotional deregulation. The authors suggest that such changes might mediate the benefits, such as reduced stress and depression levels, and improved psychological wellbeing. However, the findings were not conclusive due to the study quality and heterogeneous samples.

Mindfulness-based interventions for people with dementia

Mindfulness training emphasises the recognition of one's experience with curiosity, openness and acceptance (Bishop et al., 2004). Theoretically, as people with dementia improve in their awareness of their thoughts, emotions and bodily sensations, this may enhance their emotional regulation and capacity to manage stress, which in turn may improve their psychological wellbeing and quality of life.

To date, there is very limited research on MBIs for people with dementia (Chan, 2015). A pilot study of 12 people with varied severity of dementia in community settings found a slight decrease in mental health and wellbeing after attending an MBSR programme (Litherland, Mason, Pilchick, Sansom, & Robertson, 2013; Litherland & Robertson, 2014). However, on qualitative evaluation, participants reported reduction in anxiety and increased ability to cope with being diagnosed with dementia. The authors also reported that the participants could learn mindfulness, and required additional support from carers to continue practising

mindfulness meditation after the group. They concluded that the programme required adaptations to accommodate their cognitive impairments.

A randomised controlled trial published in Spanish examined the effects of a modified "mindfulness-based Alzheimer stimulation" programme in 168 people with mild to moderate probable Alzheimer's Disease in community settings (Quitana Hernández & Quitana Montescdeoca, 2014). Their programme incorporated both MBSR and Kirtan Kriya meditation. Participants attended 90-minute sessions three times weekly for almost two years. Compared to the treatment group, there was a significantly greater decline of cognitive function in the cognitive stimulation, progressive muscle relaxation and control groups.

The limited studies suggest people with dementia can learn mindfulness skills. This is likely through implicit memory. Despite widespread cognitive decline, people with dementia generally have preserved perceptual implicit memories (Harrison, Son, Kim, & Whall, 2007). Implicit memory is knowledge acquired without conscious recollection from previous experiences through priming or perceptual learning (Lezak, Howieson, Bigler, & Tranel, 2012).

There is only one known pilot study which adapted MBSR ('The Wellness Group') for people with dementia in a nursing home (Lantz, Buchalter, & McBee, 1997). It was developed based on the authors' experience in unpublished pilot studies which involved facilitating and adapting several groups in the nursing home. People with mild dementia were placed in similar groups, while those with moderate and severe dementia were grouped together in the Wellness Group. The programme consisted of weekly 1-hour sessions for 10 weeks which focused on modified meditation, relaxation, guided imagery and body awareness with multi-sensory elements incorporated. They found a reduction of agitated behaviour in participants

with moderate to severe group compared to the controls. Although there were methodological weaknesses in this study, this is a promising finding to suggest that a mindfulness-based intervention may be suitable for people with dementia in care homes.

Current study

Aims

The aims of the pilot study were to:

- develop a mindfulness programme for dementia (using existing literature and guidelines) and refine this in response to consultation with people with dementia and experts.
- assess the feasibility of this mindfulness programme for people with mild to moderate dementia in care homes; and
- investigate whether attending the mindfulness programme has any effects on: cognition, quality of life, stress, mindfulness, mood and anxiety.

Hypotheses

- Delivery of a mindfulness programme within care homes will be feasible and acceptable; and
- When compared to the control group, the mindfulness programme will lead to reductions in stress, depression and anxiety, and improvements in quality of life, cognition and mindfulness for people with mild to moderate dementia.

Joint project

This study was conducted jointly with Anna Churcher Clarke. Both contributed to the programme design and facilitated the mindfulness groups at the care homes. The current study describes the details of the adapted mindfulness programme, and examines the impact of attending the mindfulness programme on

cognition, quality of life, and perceived level of stress for people with dementia. Churcher Clarke (2015a) reports the feasibility of the programme, and the impact of the programme on anxiety, depression and mindfulness. Appendix B outlines the contribution of each trainee to the research process.

Method

This study had two phases based on the Medical Research Council's guidelines for developing, piloting and assessing the feasibility of the mindfulness programme (Moore et al., 2014).

Phase I: Development phase

The mindfulness techniques incorporated in Version 1 of the manual were guided by: (1) MBSR (Kabat-Zinn, 2013) and MBCT (Segal, Williams & Teasdale, 2002; Williams & Penman, 2011); (2) the techniques outlined in the Wellness Group (Lantz et al., 1997); (3) recommended mindfulness techniques for older adults (McBee, 2008) and (4) consultations with our supervisors. The opening and closing of each session adopted the structure of cognitive stimulation therapy (Spector et al., 2001). The modification of scripts for the techniques, and the intervention structure and delivery were guided by systematic literature review on mindfulness-based interventions for people with acquired cognitive impairments (Chan, 2015) and for older adults (Churcher Clarke, 2015b).

Expert consultation

Version 1 of the manual was then sent to 13 professionals for their feedback regarding the programme structure and manual scripts. The professionals included the co-founder of the Wellness Group (Lucia McBee), ten clinical or counselling psychologists working in dementia care/older adults and/or delivering mindfulness-based interventions, one occupational therapist and one physiotherapist working in dementia care.

The key issue arising from the majority of the experts and literature reviews was the need to address the physical and cognitive difficulties that people with dementia experience (e.g., attention, memory, abstract reasoning, and language). This resulted in Version 2 of the manual with modifications to the mindfulness techniques, intervention structure and delivery.

Focus group

A 180-minute focus group was then conducted with four people with dementia living in their own homes. They were peer support workers recruited from a memory clinic. The aims for the group were to seek their opinions regarding the programme structure of Version 2 and their experiences of doing the shortened mindful breathing and body scan.

Focus group members were also asked to complete measures of mindfulness and stress that were not validated in people with dementia and rate the ease of completion. This was to facilitate the final choice of measures used. The mindfulness measures were Five Facet Mindfulness Questionnaire – Short Form (Bohlmeijer, ten Klooster, Fledderus, Veehof, & Baer, 2011) and the Cognitive and Affective Mindfulness Scale-Revised (Feldman, Hayes, Kumar, Greeson, & Laurenceau, 2007). They did not complete the Perceived Stress Scale due to time constraints (Cohen, Kamarck, & Mermelstein, 1983).

Questions asked included their general opinions of the project, the programme structure, the language used for the exercises, and any other practical issues to be considered. Overall, the focus group members thought: the intervention structure was good; the exercises were “relaxing” and “enjoyable”; and they thought the guided instructions were mostly clear. They recommended slight changes to the instructions: more reminders about bringing participants’ attention back to their

breath particularly when there were sudden sounds in the environment, and to adjust their sitting position if in pain. This resulted in Version 3 of the manual created.

Below are the details of adaptation from conventional mindfulness used in the care homes:

Mindfulness techniques

First, this programme concentrated on focused attention training, the initial stages of mindfulness meditation. However, participants were invited to practise aspects of open monitoring skills at opportunities that arose. Second, the mindful movement practice was simplified to address participants' physical limitations. Third, the body scan was shortened to focus on only the top half of the body. This was to address difficulties in switching attention to various parts of the body. Fourth, all meditation practices were shortened to 10-15 minutes with a 5 minute break between the two mindfulness practices. The 3-minute breathing practice was simplified to focus on the first two steps i.e., becoming aware of present moment and gathering and focusing attention on the breath. Fifth, although other core mindfulness practices like mindful movement and body scan were taught, the mindful breathing technique was practiced in every session. Both mindful breathing and the 3-minute breathing practices were the only techniques encouraged to be practised between sessions. The rationale was to facilitate development of focused attention training through repetitions of mindful breathing. At the same time, the researchers acknowledged that care home staff might not always have time to practice the 10-minute mindful breathing with participants. Therefore, the 3-minute breathing practice was also incorporated as another recommended home practice.

Sixth, mindfulness techniques incorporated sensory elements, teaching focussing attention on one sense at a time. The ability to constantly monitor attention

on one object making use of multiple senses simultaneously is potentially a challenge for people with dementia. This is due to their difficulties in sustained and divided attention which increase with task complexity (Lezak et al., 2012). The practices included mindful listening, seeing, smelling and touching. Seventh, in line with encouraging personhood and engagement, not all the sensory elements may necessarily be included in order to meet the capabilities and preferences of the group. Lastly, to increase engagement and orient participants to the mindfulness programme, a mindful warm-up activity was introduced to encourage participants to share how they were feeling at that present moment.

Intervention structure

The number of sessions was increased from eight to 10 sessions, following the 10-week structure of the "Wellness Group" (Lantz et al., 1997). The frequency of sessions was also increased to twice a week to enhance learning through less time between sessions. This number was also based on evidence from research in cognitive stimulation therapy that there was no benefit from weekly sessions, indicating twice weekly sessions were more beneficial (Cove et al., 2014). Group size was reduced from the usual average of between 10 and 30 to an average of five per group to allow more time for participants to process their experiences. The duration per session was reduced from 2.5 hours to 1 hour, with a tea break between mindfulness practices. This was to address attention difficulties, and to avoid pain and/or discomfort from sitting for too long.

To remind staff to practise the techniques with the participants, laminated visual cues with the phrase "take a breath" (see Appendix D) were given to staff to place at strategic locations in the care home (e.g., in common areas where staff tended to be, and at eye level).

Intervention delivery

There was an increased amount of modelling from facilitators with use of simplified concrete language. There were also more repetitions and time allocated to explain concepts. Guidance and reminders during meditation was frequent to address confusion (e.g. forgetting what they were doing or where they were) and to check in with participants in terms of any physical discomfort and/or distress.

Additional modifications after first care home

Version 3 was then modified slightly after running it in the first care home: psychoeducation about stress in the first session was removed due to the lack of engagement; instead of having mindful breathing in the first six sessions and body scan in the remaining four sessions, it was changed to mindful breathing practice in every session. This was partly due to some participants experiencing difficulties in maintaining their attention during body scan while the majority could do mindful breathing, and partly to increased repetitions in at least one core practice to facilitate learning. The initial plan of incorporating 3-minute breathing as part of closing activity was not always possible within the 1-hour session, and hence was changed to an optional activity if time permitted from the second session onwards. The researchers felt it was important to still teach the 3-minute breathing practice in the first session, as this was part of the recommended home practice. This resulted in Version 4 of the manual which included the principles of the programme, guidelines for facilitators and scripts (Appendix C).

Phase II: Pilot study

Design

This study used a single blind, pretest posttest randomised controlled design. Participants were randomised to either attend a 10-week mindfulness programme or receive treatment as usual, i.e., continue with their usual activities.

Recruitment of care homes

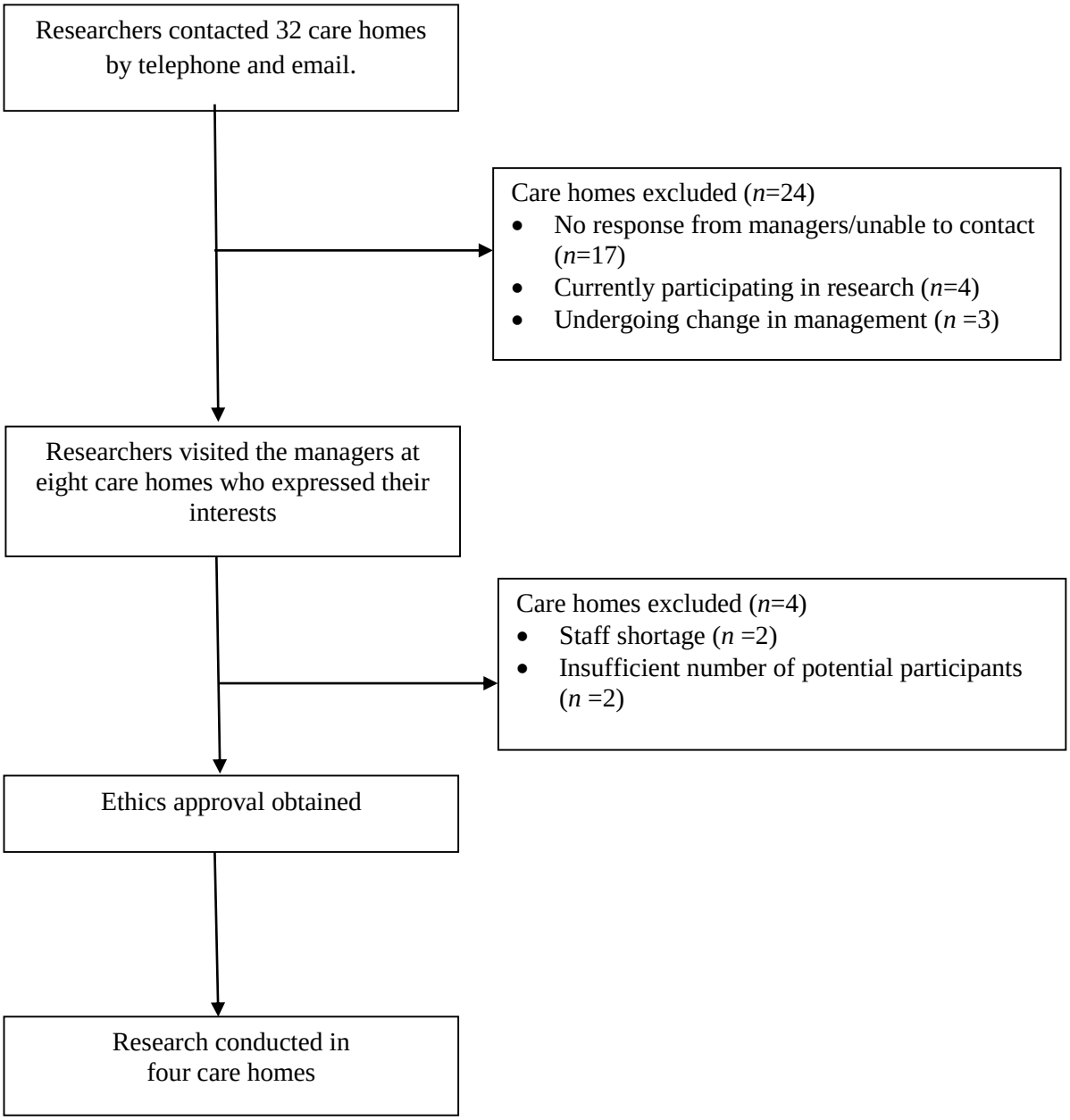
Recruitment of care homes was conducted by the two researchers. For clarity, the researchers described in this article refer to the author (JC) and co-researcher, Anna Churcher Clarke (ACC). All care homes contacted were privately owned.

Recruitment of care homes was facilitated through: the ENRICH (Enabling Research in Care Homes) database; care home contacts of previous research from the researchers' supervisor; researchers' networking at the UK Care Network Conference; and care home managers.

The researchers contacted the managers of 32 care homes in Greater London via telephone and emailed them the information sheet of the study (see Appendix F). Care homes that expressed interest in participating were then asked to identify residents with dementia who were likely to meet the inclusion criteria after the ethics approval was obtained. Previous research on cognitive stimulation therapy (Spector et al., 2003) found that often care homes had only eight or nine suitable participants for group activities. Therefore, at least eight eligible residents were required in each care home. Of the 32 care homes, four were recruited. Details of the care home recruitment process are shown in Figure 1.

Figure 1

Flowchart detailing the care home recruitment process



Participants

Inclusion criteria

Inclusion criteria for full assessment and participation were:

- Diagnosis of dementia according to the DSM-IV criteria (American Psychiatric Association, 1994);
- Mild to moderate cognitive impairment, defined as scores between 10 and 26 on the Mini Mental State Examination (Folstein, Folstein, & McHugh, 1975);
- Capacity to consent for themselves;
- Some ability to communicate and understand communication, based on judgement of care home staff and assessor;
- Ability to see and hear well enough to participate in the group and make use of most of the material in the programme, as determined by the care home staff and assessor;
- Functionally able to attend a group (i.e. able to maintain some concentration and remain in a 45-60 minute session, minimal challenging behaviour that would be unlikely to cause disruption) based on judgement of care home staff and assessor;
- Ability to understand and communicate in English.

Exclusion criteria

- Major physical illness or disability which could impact participation;
- Diagnosis of a learning disability;
- Actively practicing meditation or yoga;
- History of brain lesion or major head trauma.

Ethics

Ethical approval was obtained from the Camberwell and St Giles NHS Research Ethics Committee (Appendix E). Care home staff gave all identified potential participants an information sheet regarding the study 24 hours before the researchers visited. The researchers then met with the potential participants to explain the purpose of the study and obtain consent using the guidance from the Mental Capacity Act Code of Practice (2007) and the British Psychological Society guidelines (Dobson, 2008) regarding consent from people with cognitive impairment. A caregiver (either a member of staff or a family member) witnessed the informed consent process whenever possible. Consent was also sought from care home staff who provided information about the participants. All included participants' General Practitioners were informed of their participation. Information sheets and consent forms used can be found in Appendix F.

Procedure

Once informed consent was obtained, potential participants were screened by research assistants using the MMSE. Full assessments were then conducted 1 week before the intervention period mainly by a research assistant, with some assistance from JC and ACC. All were blind to potential group allocation at that time. Follow-up assessments were conducted 1 week after the end of the 5-week intervention by research assistants blinded to group allocation. Assessments involved interviewing participants and care home staff who knew the participant well. When possible, the same caregiver was interviewed at both time points.

After all baseline assessments were conducted, participants were then allocated to either the treatment or control group using the Random Allocation Software (Saghaei, 2004). Randomisation was conducted separately at each care

home. Given the difficulties in recruitment and/or possibility of attrition, a block randomisation method was used where more participants were randomised to the treatment group, i.e., five to treatment group and remainder to the control group.

Prior to commencement of the mindfulness programme at each care home, staff were invited to attend a 1-hour taster session to introduce the research project and to participate in a 15-minute mindful breathing practice. The aims were to orientate staff to the research project including the recommended home practice with the participants in the treatment group, and to encourage them to attend the sessions whenever they could.

Intervention Procedure

Participants in the treatment group attended the group-based mindfulness programme. The programme ran for ten sessions, twice a week for an hour per session over 5 weeks in a quiet room at the care home. Intervention sessions were recorded whenever practical and where permission was obtained from participants. The recordings were used for peer supervision and with the external supervisor. The intervention was intended to be facilitated by both researchers.

At least one staff member was invited to attend the group as a participant with the aims of supporting the participants in practising the skills between-sessions and to promote personhood. As staff worked in shifts, it was emphasised that any staff were welcome to attend the sessions whenever they were available. The researchers recorded the attendance and staff were asked the rationale for those who did not attend. At the end of each session, participants completed the 'Participant Rating Form' (Appendix D) as part of feasibility assessment. Staff and researchers assisted in completing the rating form if participants had difficulties in completing them.

One facilitator took the role of engaging the group in the goal for the session, while the other actively demonstrated techniques on an individual basis and physically directed those who required additional assistance. An overview of the mindfulness programme is shown in Table 1. Some flexibility was required in terms of the type of sensory element incorporated in the mindfulness practices in order to meet the capabilities and preferences of the group.

Between sessions, participants were encouraged to practice a 10-minute mindful breathing and/or 3-minute breathing space meditation with staff support daily using supplied CDs. A summary of each session was given to staff each week along with a home practice log sheet to record the number of times and the technique(s) practiced every week (Appendix D).

Facilitator experience

Both facilitators have completed the mindfulness-based stress reduction course as participants and had some experience working with people with dementia, and teaching mindfulness meditation techniques to older adults in individual settings. In addition, the author has been actively practicing meditation as a Buddhist for over a decade while the co-researcher has been practising yoga for over a decade. To monitor the quality of the intervention, regular supervision was provided by the external supervisor who had experience delivering mindfulness-based interventions to older adults, and is currently undergoing teaching training in mindfulness-based cognitive therapy. There was also peer supervision between the researchers.

Format of sessions

To facilitate learning and familiarity, the format for all sessions was standardised:

1) The opening of each session included introductions of facilitators, reminder of the purpose and aim of the group, emphasis that participation was

voluntary, the aim of the session and a brief recap of the previous session's activity. This was followed by a mindful warm up activity and a song that was chosen collectively in the first session. The mindful warm up activity involved every participant taking turns to hold a soft ball and spend a brief moment to pause, think and share with the group how they felt at that present moment. The rationale for the activity was to start introducing elements of mindfulness by providing participants opportunities to be in tune with and express their emotions (however much they would like to share in the group). The song was sung just before and after the main mindfulness activities. As well as facilitating engagement, it also served as a reminder that the mindfulness activity has started/ended.

2) In each session (except the first session), there were two guided mindfulness meditations each lasting 10-15 minutes, and each followed by 5-10 minutes of group discussion. The group discussions included modelling by facilitators and the use of participants' language and experiences. The aim of the group discussions was to facilitate understanding of using mindfulness to explore thoughts, feelings and sensations, including pain.

   The first practice was always mindful breathing. The second practice was another core mindfulness practice (either mindful movement or body scan depending on the capabilities and preferences of the group) alternating with an informal mindfulness technique incorporating a sensory element (mindful listening, seeing, smelling or touch). The choice of sensory element depended on the capabilities and preferences of the group.

   There was a 5-10 minute break between the two practices where tea and biscuits were provided by the care home.

3) Closing of the session included an optional 3-minute breathing space practice, a brief summary of the session activity, and the group song.

Table 1

Overview of the modified mindfulness programme

Session 1
Introduction to the Mindfulness Programme Mindful warm-up activity with soft ball Choice of group name and song **Mindfulness meditation 1: Mindful Breathing (with MBAS* measure)** Group discussion 3-minute breathing space Song Participant rating form
Session 2
Introductions Orientation to the programme and recap of previous session Mindful warm-up activity with soft ball Song **Mindfulness meditation 1: Mindful Breathing** Group discussion **Mindfulness meditation 2: Mindfulness Listening** Group discussion 3-minute breathing space (optional) Song Participant rating form
Session 3**
Mindfulness meditation 1: Mindful Breathing **Mindfulness meditation 2: Body Scan**
Session 4**
Mindfulness meditation 1: Mindful Breathing **Mindfulness meditation 2: Mindful Movement**
Session 5**
Mindfulness meditation 1: Mindful Breathing **Mindfulness meditation 2: Mindful Listening, Seeing, Smelling, Touch*****
Session 6**
Mindfulness meditation 1: Mindful Breathing (with MBAS* measure) **Mindfulness meditation 2: Body Scan or Mindful Movement*****

Session 7**
Mindfulness meditation 1: Mindful Breathing **Mindfulness meditation 2: Mindful Listening, Seeing, Smelling, Touch*****
Session 8**
Mindfulness meditation 1: Mindful Breathing **Mindfulness meditation 2: Body Scan or Mindful Movement*****
Session 9**
Mindfulness meditation 1: Mindful Breathing **Mindfulness meditation 2: Mindful Listening, Seeing, Smelling, Touch*****
Session 10**
Mindfulness meditation 1: Mindful Breathing (with MBAS* measure) **Mindfulness meditation 2: Body Scan or Mindful Movement*****

* Modified version of MBAS measure (Meditation Breath Attention Score; Frewen, Evans, Maraj, Dozois, & Patridge, 2008).
** The session structure as shown in session 2 was repeated for the remainder of the programme. The two mindfulness meditations in each session are in bold type.
*** Depending on capabilities and preferences of the group.

Measures

Demographic information collected included: age, gender, ethnicity, marital status, education, dementia sub-type and diagnosis of mental health problems.

ACC analysed depression using the Cornell Scale for Depression in Dementia (Alexopoulos, Abrams, Young, & Shamoian, 1988), anxiety using the Rating Anxiety in Dementia scale (Shankar, Walker, Frost, & Orrell, 1999), and mindfulness using both Cognitive and Affective Mindfulness Scale-Revised (Feldman et al., 2007), and the Meditation Breath Attention Score (MBAS; Frewen et al., 2008). Participants completed the MBAS in the first, sixth and the last sessions of the programme.

JC analysed the data for the following three measures:

Cognition

Cognitive function was measured using the Mini Mental State Examination (MMSE; Folstein et al., 1975). The measure covers domains including orientation, attention, short-term memory, language and visual construction. The maximum score is 30, with 21–26 indicating mild cognitive impairment, 10–20 as moderate cognitive impairment, and less than 10 representing severe cognitive impairment (NICE, 2011). It is a brief measure widely used in clinical practice and research, with good reliability and validity.

Quality of life

The Quality of Life – Alzheimer's Disease scale (QoL-AD; Logsdon, Gibbons, McCurry, & Teri, 1999) was used to evaluate the quality of life. It is a 13-item self-report questionnaire which can be completed separately by the person with dementia and their carer. It covers the domains of physical health, energy, mood, friends, fun, self and life as a whole. Each item is rated on a four point scale from poor (1) to excellent (4). An overall composite score can be derived by combining self-report and carer's report scores: the self-report score is multiplied by two, added to the carer's score, and the sum is then divided by three. Scores range from 13 and 52, with higher scores indicating better quality of life. It has good inter-rater reliability and internal consistency, and content, criterion and construct validity (Thorgrimsen et al., 2003).

Although the self-report and carer-report scores can be analysed separately, the composite score in this study was analysed. This is an accepted approach to adjust for discrepancies in reports of QoL between people with dementia and their carers. Twice as much weight is given to self-report due to the subjective nature of QoL (Logsdon et al., 1999; Zhao et., 2012). Several studies suggest carers tend to

underestimate the quality of life in people with dementia due to factors such as carers' mood and burden (Ready & Ott, 2003; Thorgrimsen et al., 2003; Zhao et al., 2012). On the other hand it is possible that some people with dementia may overestimate their QoL when they feel well (e.g., no pain or physical and/or mental illnesses), show indications of anosognosia or have a tendency to minimise the difficulties experienced (Zhao et al., 2012).

Perceived level of stress

Psychological stress was assessed using the 13-item version of a self-report measure - Perceived Stress Scale (PSS-13; Cohen et al., 1983). It is designed to tap on how unpredictable, uncontrollable, and overloaded respondents find their lives. Items are rated on a 5-point scale ranging from never (0) to very frequent (4). Total scores range from 0 and 52, with higher scores indicating higher levels of stress.

There are several versions of the PSS including the original 14-item scale, 13-item, 10-item and 4-item scales. The 13-item version was chosen as, compared to the other versions, PSS-13 showed better reliability and validity in older adult populations with mild cognitive impairment (Ezzati et al., 2014). As PSS-13 is not validated in people with dementia, three experts in dementia care were consulted for face validity. The scale was also intended to be administered with the focus group of people with dementia. It did not happen due to lack of time. A copy of the PSS-13 can be found in Appendix G.

Assessment of feasibility

Feasibility of the study was evaluated by ACC using: records of attendance and drop outs, reasons for dropouts, records of any adverse events during the intervention, home practice log sheet, sessional participant rating forms, and the mindfulness staff taster.

Power analysis

Given the lack of previous research on the effects of mindfulness programmes in people with dementia in care homes, the likely effect size of the intervention could not be accurately estimated. The researchers then considered the findings in higher quality studies of mindfulness-based interventions in older adults and in people with traumatic brain injury which found moderate to large effect sizes in reducing symptoms of depression, anxiety, and/or quality of life. Assuming that there is a correlation among repeated measures and sphericity is not violated, sample size for a mixed between-within subjects Analysis of Variance (ANOVA) was calculated using the G*Power 3 computer software (Faul, Erdfelder, Lang & Buchner, 2007) based on medium effect size with alpha setting at 0.05 and desired power at 0.80. A sample size of 34 was estimated to be sufficient to detect significant group differences.

Data analysis

Data analysis was conducted using Statistical Package for the Social Sciences version 20.0. An independent t-test was conducted to check for any differences in the severity of dementia, as measured by scores on the MMSE, between participants in the treatment and control groups at baseline. Data for all outcome measures were tested for assumptions of normality for each group at each time point. A 2 x 2 mixed ANOVA was used to analyse the outcome measures with group (control and treatment groups) as between subject factor and the conditions (baseline and post-intervention measures) as within subject factor. A Bonferroni adjustment for multiple comparisons was not made due to the small sample size and the exploratory nature of the study. Effect sizes were calculated using Pearson's *r*.

Data were analysed as allocated. This meant that all available data including

for those who did not complete the intervention were analysed.

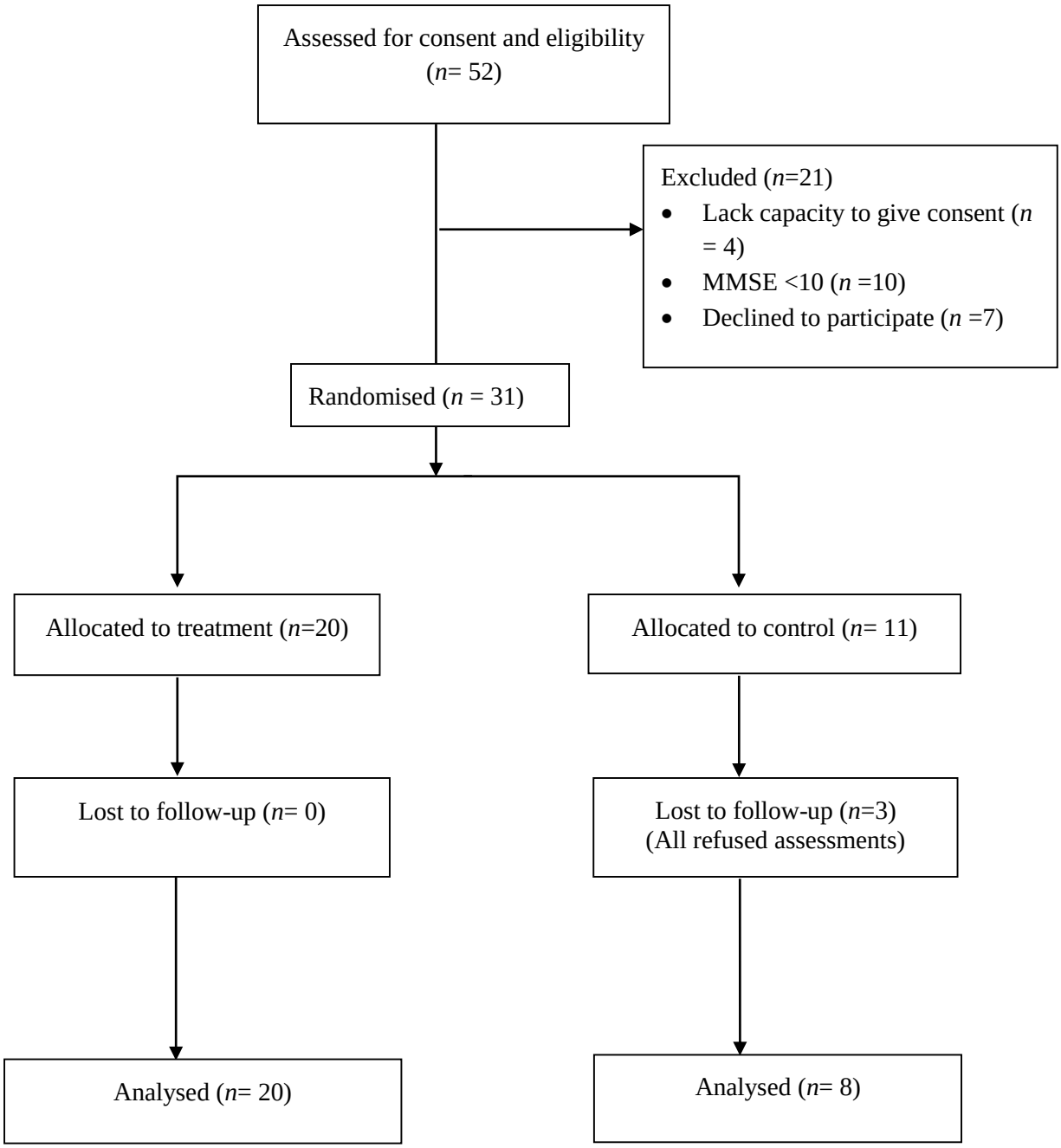
Results

Participants

The flowchart for participant recruitment is shown in Figure 2. 28 participants were assessed at follow-up (20 treatment, 8 controls). Three controls declined follow-up assessments. The mean attendance was 8.15 sessions (*SD*=2.46, range 1–10). One participant attended only one session due to ill health. 80% of people attended seven or more sessions. The main reasons for missing a session included: being unwell, medical appointments or were asleep. One to two care home staff attended most sessions.

Figure 2

CONSORT participant flow diagram



Missing data analysis

About 54% (*n*=15) of participants were missing data on one or more items on the PSS-13. Item nonresponse ranged from a minimum of one item (*n*=6; about 21%) to a maximum of eight items (*n*=1). The data for PSS-13 were missing completely at random as indicated by a non-significant Little's (1988) MCAR test, $\chi 2 = 36.44$, df = 35, $p = .402$. This indicates there is no relationship between the pattern of missing data and any values of variables in the data set, missing or observed.

In order to reduce bias in data analysis where missing data were greater than 10% (Bennett, 2001), the Expectation Maximization (EM) algorithm was used to impute the missing values of those data where there was only one nonresponse item on PSS-13 at both pre- and post-intervention time points. This resulted in data from an additional six participants being included in the analysis for PSS-13.

The EM method derives likelihood-based inferences from incomplete data, using an iterative procedure with two steps in each iteration (Bethlehem, Cobben, & Schouten, 2011): The expectation step (E-step) computes expected values for the missing data based on all available data (i.e., age, mean scores on MMSE, QoL-AD, RAID and Cornell Scale for Depression). This is followed by the maximization step where missing values are replaced by synthetic values computed in the E-step. The two steps continue until the estimates change very little from one iteration to the next. This imputation method was chosen because it met the assumption that the missing data was missing completely at random and it produces good estimates of the variability in the dataset (Bennett, 2001). However, as this measure is not validated in people with dementia, the results for PSS-13 need to be interpreted with caution. Analysis of both with (*n*=19) and without (*n*=13) data imputations on the PSS-13 scores are presented in Table 3.

Table 2 outlines the treatment and control participants' characteristics. Data on years of education was unavailable for the vast majority. 55% of participants in both treatment and control groups were diagnosed with dementia, subtype unspecified. The majority had dementia of moderate severity: 95% and 81.8% in the treatment and control groups respectively. The severity of dementia did not differ significantly between groups, $t(29)=0.96$, $p= .347$.

Table 2

Demographics and clinical characteristics of participants

Characteristics	**Treatment group (*n*=20)**	**Control group (*n*=11)**
Gender		
Female (%)	12 (60.0)	3 (27.3)
Male (%)	8 (40.0)	8 (72.7)
Age, mean (SD)	81.30 (9.29)	79.36 (9.91)
MMSE score (SD)	15.85 (3.68)	14.45 (4.28)
Severity of dementia		
Mild (%)	1 (5.0)	2 (18.2)
Moderate (%)	19 (95.0)	9 (81.8)
Dementia diagnosis		
Alzheimer's Disease	4	2
Vascular Dementia	3	3
Alcohol-Related Dementia	2	0
Dementia unspecified type (%)	11 (55.0)	6 (54.5)
Ethnicity		
White British (%)	15 (75.0%)	9 (81.8)
Black Caribbean	4	1
White European	1	0
Black African	0	1
Marital status		
Widowed	10	4
Married	6	2
Single	2	4
Divorced	1	0
Unknown	1	1

History of mental health problems		
History of schizophrenia	1	1
History of depression	1	1

Analysis of outcomes

Data from the MMSE, PSS-13 and QoL-AD did not violate the assumptions of normality. Table 3 show the results for the ANOVA analysis and effect sizes.

Cognitive functioning

The main effect of time (baseline – follow-up) was approaching significance, $F(1, 26) = 4.02$, $p = .056$, $r = .37$. Both treatment and control groups had a reduction in MMSE scores at follow-up, with a steeper decline in the control group (mean decrease = 2.25) compared to the treatment group (mean decrease = 0.60). The main effect of group was not significant, $F(1, 26) = 0.30$, $p = .59$, $r = .11$. There was no significant interaction between time and group, $F(1, 26) = 1.35$, $p = .26$, $r = .22$.

Quality of life

The main effect of time was not significant, $F(1, 26) = 2.30$, $p = .14$, $r = .28$. The main effect of group was not significant, $F(1, 26) = 0.03$, $p = .86$, $r = .04$. There was a significant interaction between group and time, $F(1, 26) = 4.36$, $p = .047$, with a medium effect size ($r = 0.38$). The treatment group rated an increase in their quality of life post-intervention (mean increase = 2.35), while the control group reported a reduction in their quality of life (mean decrease = 1.79).

Perceived level of stress

Analysis of PSS-13 scores without data imputations (n=13) revealed no significant findings. The main effect of time was not significant, $F(1, 11) = 0.73$, $p = .41$, $r = .25$. The main effect of group was not significant, $F(1, 11) = 0.09$, $p = .77$, $r = .03$. There was no significant interaction between time and group, $F(1, 11) = 0.23$, $p = .64$, $r = .14$.

When analysis of PSS-13 scores included participants with data imputations (n=19), there was a significant main effect of time, indicating that for the two groups combined, stress levels increased from (M = 19.77) at baseline to (M = 24.51) at follow-up: $F(1, 17) = 4.46$, $p = .05$, $r = .46$. The main effect of group was not significant, $F(1, 17) = 0.88$, $p = .36$, $r = .22$. There was no significant interaction between time and group, $F(1, 17) = 0.26$, $p = .62$, $r = .12$.

Table 3

Pre/post-intervention changes in outcome measures of cognitive functioning, quality of life and stress

Variable assessed	Baseline scores Mean (SD)	Follow-up scores Mean (SD)	Change from baseline	ANOVA	F	P	Effect Size r*
MMSE (+)							
Treatment group	15.85 (3.68)	15.25 (4.35)	-0.60	Time	4.02	0.056	0.37
Control group	15.75 (4.27)	13.50 (6.14)	-2.25	Group	0.30	0.59	0.11
				T x G	1.35	0.26	0.22
QoL-AD (+)							
Treatment group	34.02 (4.24)	36.37 (4.27)	+2.35	Time	2.30	0.14	0.28
Control group	34.58 (4.69)	32.79 (4.44)	-1.79	Group	0.03	0.86	0.04
				T x G	4.36	0.047	0.38
PSS-13 (-)							
Without imputations							
Treatment group (*n*=9)	20.33 (7.12)	23.89 (7.59)	+3.56	Time	0.73	0.41	0.25
Control group (*n*=4)	22.50 (4.66)	23.50 (4.04)	+1.00	Group	0.09	0.77	0.03
				T x G	0.23	0.64	0.14
With imputations							
Treatment group (*n*=13)	18.07 (8.45)	23.96 (6.20)	+5.89	Time	4.46	0.05	0.46
Control group (*n*=6)	21.47 (3.95)	25.06 (4.63)	+3.59	Group	0.88	0.36	0.22
				T x G	0.26	0.62	0.12

(+) = improvement is based on higher test scores
(-) = improvement is based on lower test scores

MMSE=Mini Mental State Examination, QoL-AD=Quality of Life- Alzheimer's Disease, PSS-13=Perceived Stress Scale-13 item version
**R* effects: small ≥ .10, medium ≥ .30, large ≥ .50 (Field, 2013)

Discussion

Summary of findings

The treatment group reported an increase in quality of life after attending the mindfulness programme, while the control group showed a decline, with a medium effect size observed. There were no significant improvements in cognitive functioning and stress levels at follow-up. Neither were there any improvements in mindfulness, mood and anxiety (Churcher Clarke, 2015a).

Interpretation of findings

The observed moderate effect size in quality of life is consistent with findings in a modified MBSR study of people with traumatic brain injuries (Azulay, Smart, Mott, & Cicerone, 2013), and in a meta-analysis in adults without cognitive impairments (de Vibe, Bjørndal, Tipton, Hammerstrøm, & Kowalski, 2012). Although improvements in quality of life were sufficiently robust in our small, heterogeneous sample, non-specific factors, rather than the mindfulness training per se, cannot be discounted e.g., increased social interactions, and the opportunities to be able to express their opinions and being listened to. Indeed, a meta-synthesis of qualitative studies identified factors such as social interactions characterized by respect and kindness, the ability to express themselves and autonomy, and happiness characterized by contentment, and pleasure, improve quality of life of people with dementia in both community and long term care settings (O'Rourke, Duggleby, Fraser, & Jerke, 2015). Another possible non-specific factor is the impact of interactions with facilitators who are outside the care home on their quality of life. In another qualitative meta-synthesis, Lawrence and colleagues (2012) identified psychosocial interventions involving connections with people outside the institutionalised settings as particularly valuable in improving quality of life.

Examination of the mean baseline and follow-up MMSE scores for both groups found a slight decrease in cognitive functioning (an average of less than one point) in the treatment group, whilst the control group showed a higher decrease. This trend was also found in an MBSR study of older adults without cognitive impairments living in a care home (Ernst et al., 2008). Although the cognitive function did not improve after attending the mindfulness programme, the findings indicate mindfulness training may slow down cognitive decline. This hypothesis is consistent with the significant findings in the randomised controlled trial of mild to moderate probable Alzheimer's Disease (Quitana Hernández & Quitana Montescdeoca, 2014). It is noteworthy that that study delivered the modified MBI for almost two years. This suggests a longer term intervention slows down cognitive decline.

There was no significant reduction in stress levels at follow-up. The mean baseline and follow-up PSS-13 scores indicate that the treatment group was more stressed than the control group at follow-up. A possibility is that the treatment group became more aware of their stress levels following mindfulness training. However, only about half of the participants were able to fully complete the PSS-13, which is not validated in people with dementia. Qualitatively, the assessors observed that participants had difficulties understanding questions such as "In the last month, how often have you felt that you were on top of things?", interpreting the phrase "on top of things" literally. Some participants also found questions that were not applicable to them, such as, "In the last month, how often have you felt that you were effectively coping with important changes that were occurring in your life?" Therefore, the findings need to be interpreted cautiously due to the lack of validity in PSS-13.

Limitations

This study had several limitations. The study was slightly under-powered, which meant that the probability of making Type II error was increased. Further, this was a small heterogeneous sample with fewer participants in the control group. It is difficult to be confident that the effects are attributable to the specific therapeutic impact of the mindfulness programme rather than non-specific factors because the control group were not exposed to a comparable treatment or intervention (e.g., relaxation or a recreational activity). Adherence to the mindfulness programme was monitored by peer supervision and sessions with an external supervisor. Using a standardised adherence checklist such as the Mindfulness-Based Interventions-Teaching Assessment Criteria (Crane et al., 2013) would enable a more valid and reliable estimation of treatment fidelity to be made. Pharmacological treatments were not recorded and monitored during the research phase and so other confounding factors could not be discounted.

Another limitation is related to outcome measures. First, baseline and follow-up of QoL-AD were not all completed by the same staff or research assistants due to availability. A few staff who completed the questionnaires also attended some of the mindfulness programme, which might have resulted in response bias. However, the consistency was somewhat maintained as the measure was also rated by the participants. There are different approaches to analysing the QoL-AD. An alternative would be to analyse the QoL scores separately for self-report, carer-report and the composite scores. This would require adjustments for the multiple comparisons to reduce Type I error. However, this would not be recommended in such a small sample as it would further reduce the power of the study. Second, there is no perceived stress scale that has been validated in people with dementia. The PSS-13

was chosen for its face validity, however it was observed that some participants had difficulty completing it.

The home practice between sessions was dependent on care home staff for support. Not all care homes had sufficient resources to do this consistently. It remains unclear whether home practice is associated with positive outcomes. A review found only a quarter of the studies investigated the relationship between home practice and outcomes, with just over half of the included studies reporting a positive association between home practice and outcomes including mindfulness, mood and anxiety (Vettese, Toneatto, Stea, Nguyen, & Wang, 2009).

Implications for care practice and future research

The mindfulness programme was well received with no adverse events reported in people with mild to moderate dementia in care homes. However, there is insufficient evidence at this stage to recommend this intervention to care homes.

Further research is required to explore the potential value of this mindfulness programme. Future studies should also address the current limitations by: recruiting a bigger sample size with an active comparable treatment or intervention; incorporating an adherence to mindfulness checklist; consider alternative measure of stress and/or a mixed-method approach, for instance, interviewing participants and/or carers to explore additional perceived benefits of the mindfulness programme that might not be captured in a quantitative study; and to identify potential confounders such as pharmacological interventions. Further modification of the programme might be required e.g., increase in number of sessions, to maximise the desired effects.

Research in delivering the modified mindfulness programme to people with mild to moderate dementia in non-institutional settings could also be conducted to assess the effects on their cognition, emotional wellbeing and quality of life.

Conclusion

This pilot study found promising results that the modified mindfulness programme may be beneficial for quality of life in people with dementia. The mindfulness programme was well received with no adverse events reported. However, there is insufficient evidence at this stage to recommend this intervention to care homes. Further research should be conducted before firm conclusions can be reached regarding its benefits.

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Part 3: Critical appraisal

Introduction

This paper will reflect on the process of conducting the research, including: strengths of the study, my qualitative observations of participants and the care home staff, the main challenges encountered during study design, recruitment and intervention delivery and implementation, and the implications for future research.

Strengths of the study

To enhance the quality of the study, we used the Medical Research Council's guidelines (MRC; Moore et al., 2014) to develop, pilot and assess the feasibility of the mindfulness programme. To reduce the chance of selection bias, participants were randomly allocated to either the treatment or control group. There was also allocation concealment from participants, care home staff and researchers until recruitment was complete. The chance of measurement bias was also reduced as assessors were blinded to group allocation.

Although the mindfulness programme required some flexibility in the choice of mindfulness practices in order to meet the capabilities and preferences of the group, the format of each session and the duration of the programme were standardized for each care home. There was also a manual developed which included scripts and key principles of the programme to provide further consistency in intervention implementation.

Qualitative observations

Although this study did not set out to incorporate qualitative methods, we recorded participants' experiences of the sessions to facilitate supervision. There were qualitative elements which were not captured in the results of the empirical paper. Such elements provide additional information regarding the participants' experiences and their perceived benefits of attending the programme. The following were quotes from some participants after mindfulness practices: "I was relaxed…not

thinking at all about anything…just doing it for myself", "I know I'm alive because I'm breathing", and "It's good…my mind needs the exercise too – it's mental exercise." On the other hand, some minorities described some practices, such as body scan and mindful seeing, as "boring".

The quantitative results also did not capture the observations from staff and from us as facilitators. These observations were recorded in my research journal. Staff told us they observed new behaviours in some participants e.g., participating in singing or having a discussion in a group. Staff reports of new behaviours in residents were also observed in the study by Lantz and colleagues (1997) and may indicate a change in behaviour or a change in staff perception of the participants as individuals with abilities. A qualitative meta-synthesis of psychosocial interventions in care homes reported that simply participating in the interventions with the residents helped the staff to see beyond the symptoms of dementia and to extend their views of caregiving role beyond physical care and safety (Lawrence, Fossey, Ballard, Moniz-Cook, & Murray, 2012). One staff member told me how a participant found practising the mindful breathing using our supplied CD prior to her bedtime was helpful in improving her sleep. We as facilitators also observed indications of implicit learning. After several sessions, some participants automatically adjusted their sitting positions and placed their hands on their lap when we said we were going to start the mindfulness practice.

I observed some instances of benefits in delivering the intervention in a group setting. This included: support from peers, learning from one another's experiences, and increased motivation to practise the techniques in a group setting, particularly as the sessions progressed. For instance, when one participant was having difficulties in trying to describe her experience of a mindfulness practice, other participants started

to help her. In another instance, a participant was highly self-critical when she could not always maintain her attention during a mindfulness exercise, commenting that she "should" be able to do it. Another group participant then reassured her, saying that she was not the only person who could not constantly maintain her attention. This prompted several other participants to nod in agreement. There was indication that home practice conducted in groups worked better, possibly due to increased motivation. Several staff in two care homes observed that when the participants did the home practice alone in their rooms, some participants were unable to follow the instructions on the CD and were looking around the room instead. However, they observed increased participation when several members of the treatment group gathered together for the home practice. An activity coordinator found the home practice worked better when she incorporated it as a group activity whenever she could.

Study design

Research methodology

The MRC guidelines for designing and testing complex interventions (Moore et al., 2014) recommend a mixed-method approach at the feasibility and piloting stage where qualitative data may facilitate understanding of intervention functioning. During the initial planning stages, we considered a mixed-method approach where one trainee would undertake the quantitative aspects of the study, while the other trainee would interview the care home staff regarding their perception of the intervention and their observations of the participants between-sessions. However, we decided that this would be unrealistic given the short time frame we had to develop and deliver a modified mindfulness programme. An additional trainee would be required to conduct and analyse qualitative interviews.

Modifications to the intervention

One key challenge in assessing the feasibility of the programme is the treatment fidelity and the extent of adaptations. Following the MRC framework (Moore et al., 2014), we modified the programme following review of existing literature and consultation with clinicians experienced in dementia care and/or working with older adults and/or in delivering mindfulness-based interventions. We then consulted a focus group before making additional modifications after delivering it to the first care home. The rationale and details of the modifications were detailed in my empirical paper to allow readers to make an informed judgement regarding the treatment fidelity. As acknowledged in my empirical paper, on hindsight, using a standardised adherence checklist such as the Mindfulness-Based Interventions-Teaching Assessment Criteria (Crane et al., 2013) might have increased the validity and reliability of treatment fidelity.

In addition to teaching formal practices such as mindful breathing, body scan and mindful movement, we also incorporated techniques using sensory elements. It was challenging to select the materials for the sensory elements. Not only did we have to consider the age-related decline in senses, we also needed to strike a balance between increasing participant engagement and turning the session into a recreational activity. Through expert consultations, it was decided that the materials used needed to be ambiguous. For instance, in the session of mindful listening we avoided mainstream music and used music which was more instrumental-based. For the mindful seeing practice, we used abstract images, such as the space projector which projected circles of different colours.

Outcome measures

Selecting outcome measures was challenging, as we needed to ensure a balance between capturing the potential benefits of attending the mindfulness programme and minimising participant response burden. It was particularly challenging to find measures of stress and mindfulness which were validated in people with dementia. The initial plan was to ask the focus group to complete the questionnaires and rate the ease of completion. Due to time constraints, we had to make the difficult decision of which ones to prioritise. We decided to leave out the Perceived Stress Scale, 13-item (PSS-13; Cohen, Kamarck, & Mermelstein, 1983) and ask the focus group participants about the measures of mindfulness instead. This was because although PSS-13 is not validated in people with dementia, it has good reliability and validity in older adult populations with mild cognitive impairment (Ezzati et al., 2014). On the other hand, neither mindfulness measure, i.e., Five Facet Mindfulness Questionnaire – Short Form (Bohlmeijer, ten Klooster, Fledderus, Veehof, & Baer, 2011) nor the Cognitive and Affective Mindfulness Scale-Revised (Feldman, Hayes, Kumar, Greeson, & Laurenceau, 2007) has been validated in older adults and/or people with cognitive impairments. In hindsight, we could have presented a few questions from the PSS-13 questionnaire for them to rate the ease of understanding each question.

Recruitment

To maximise the numbers of suitable participants, the initial plan was to approach only care homes with a minimum of 60 residents. However, due to recruitment difficulties we lowered the threshold to care homes with a minimum of 10 potential participants with mild to moderate dementia. Care homes were contacted in April 2014 to introduce the study and to screen for suitability. Care homes were mainly identified through the ENRICH (Enabling Research in Care Homes) database

and our networking at the UK Care Network Conference. Care homes from such sources tend to be already participating in some form of research. However, the managers were also able to identify additional care homes within the same care home group. When we approached these additional care homes, several were keen to participate. They were not aware that they could register with the ENRICH database if they would like to participate in research. Future research in care homes could consider recruitment within established care home groups.

Although we had interest from several care homes, the actual recruitment of participants was only able to commence in July 2014 after ethics approval was obtained. This resulted in a delay in screening potential participants for eligibility. Consistent with Spector and colleagues' (2003) research in cognitive stimulation therapy, care homes had only eight or nine suitable participants for group activities. This resulted in only 32 participants being recruited for the study. On the other hand, despite the recruitment difficulties, we were able to recruit this number of participants within three months. It is possible that the recruitment was facilitated by the idea that people external to their care home would be the group facilitators without any additional materials required.

Intervention delivery and implementation

Number of facilitators

Although my co-researcher and I aimed to deliver the intervention together in all four care homes, it was not always possible. Due to practicalities, two out of the four care homes had two facilitators on alternate sessions. However to maintain some consistency and familiarity with staff and participants, the same researcher was always the lead facilitator in every session at these care homes. McBee (2008), one of the researchers who delivered an adapted mindfulness-based intervention to

people with dementia in a nursing home, suggested that it was possible to run such groups by one facilitator.

However, from our experience, it was better to have two facilitators: one lead facilitator doing the mindfulness practice with the participants, and the co-facilitator actively demonstrating techniques on an individual basis and physically directing those who required additional assistance. For instance, during an exercise where participants were asked to touch a seashell of their choice in a mindful manner, a participant tried to bite the seashell. The co-facilitator then sat beside that participant to assist by guiding her hand to touch the object, while the lead facilitator continued with the exercise.

Facilitator's experience in mindfulness practice

In mindfulness-based interventions, such as mindfulness-based stress reduction (Kabat-Zinn, 2013) and mindfulness-based cognitive therapy (Segal, Williams, & Teasdale, 2002), it is recommended that the facilitators are practising mindfulness themselves. Kabat-Zinn (2003) suggested that the mindfulness practice allows the facilitator to know how to respond appropriately in group discussions by using their own experience, rather than relying solely on theoretical concepts. I personally found it helpful that I actively practice mindfulness. This enabled me to share my own experiences with the participants and also to help me aim for a non-striving stance throughout the sessions. Non-striving stance refers to in the present moment without trying to get anywhere or expect any particular results (Kabat-Zinn, 2013). Maintaining this stance had been challenging at times. This was particularly noticeable at the first care home. For instance, a participant said her "mind went for a walk and came back". We attempted on numerous occasions to enquire how her attention returned. She was unable to say more than "it just came back" which

resulted in us feeling stuck with the enquiry. Through supervision, we reflected that this tendency to strive for certain responses was very likely influenced by our additional roles as researchers wondering about the outcomes of the project.

To ensure we maintained a non-striving stance during sessions, we subsequently made several modifications to our approach. We monitored this through regular supervision. The co-facilitator helped to guide the group discussion accordingly when one of us steered away from being mindful. We practiced the 10-minute mindful breathing together prior to the commencement of the sessions whenever practical. I also did informal mindful practices e.g., mindful walking or a brief mindful breathing exercise while travelling to the care home.

Culture of care homes: management and staff

Common themes identified in a qualitative meta-synthesis of barriers to successful implementations of psychosocial interventions in care homes included institutional philosophy (e.g., focussing on physical care and safety, person-centred care), attitudes of staff and care home resources (Lawrence et al., 2012). Indeed, these were some factors I observed which impacted on our intervention implementation.

Support from management in the project varied across the care homes. Two care home managers modified staff's work schedules to allow staff to attend the taster session, and ensured that at least one staff member attended the sessions regularly. They were also interested in the progress of the sessions, making time to chat with us after our sessions whenever they could. The majority of the staff in those two care homes were aware of our project, and participants tended to arrive on time at the designated room. They were also the care homes with the higher rates of attendance and home practice. There were also some insights to staff attitudes to

dementia care. I noticed instances out of the sessions when staff were chatting, singing or dancing with the residents out of regular group activities. In another instance, a team leader who regularly attended the sessions also came once during her off day.

On the other hand, managers from the other two care homes had minimal involvement, handing over the support to the activity coordinators. Arrangement of taster sessions was difficult in those homes, with many staff unaware what we were doing. In one care home, the staff asked if other residents could also attend the sessions. They were also the homes where there were sometimes no staff attending sessions, due to lack of staff. To help those two care homes understand what we were doing, we regularly spoke to the staff whenever possible.

It is possible that the lower levels of engagement from the other two managers and staff could be due to the lack of resources, scepticism of the benefits of the intervention particularly after we completed the intervention, and/or that they perceived the benefits were higher than the cost of the extra workload of e.g., attending the sessions and support the residents with the home practice. This also reflects the importance of allowing sufficient time to build rapport with staff. This could be facilitated through staff taster sessions prior to commencing the intervention and to ensure regular interactions with staff whenever possible. In terms of home practice, one way could be to embed the activity into daily care. For instance, as mentioned earlier, an activity coordinator incorporated the home practice as a regular group activity. As culture in care homes differ, collaborative approaches should be adopted. For instance, checking with staff during the staff taster to get their perspectives on the intervention, home practice and any concerns they might have. This also reflects the importance of having managerial support in facilitating

interventions and influencing cultural change within the home (Lawrence et al., 2012).

Directions for future research

As mentioned in my empirical paper, future research could consider a mixed method study. To investigate participants' perceived benefits of attending the programme, future studies could conduct structured observations of audio recorded intervention sessions to supplement quantitative methods. Studies could also include qualitative interviews of staff's perceptions of the mindfulness programme, including their observations of participants during and between-sessions. Drawing on the MRC framework (2014), future research should consider the next phase in evaluating complex interventions, i.e., to evaluate the effectiveness of the programme in a larger scale randomised controlled trial.

It might also be beneficial to consider whether delivering a mindfulness-based intervention to care home staff might impact on their perceptions and provision of dementia care. Kitwood (1997) suggested a list of requirements of a caregiver which may enhance person-centred interactions with people with dementia. For instance, when the caregiver needs to be non-judgemental and be able to be 'present' without being caught up with their personal worries about the past or the future reactions and feelings. Theoretically, mindfulness meditation may facilitate development of such skills.

Conclusions

Overall, this study aimed for the highest possible quality in terms of designing and piloting the mindfulness programme. There were several challenges through the whole process, summarised in this chapter. There needs to be careful

consideration into how to work with people with dementia, the professional carers and managers.

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Appendices

Appendix A

Modified Downs & Black's (1998) checklist*

No.	Question	Score
	Reporting	
1.	*Is the hypothesis/aim/objective of the study clearly described?*	Yes (1) No (0)
2.	*Are the main outcomes to be measured clearly described in the Introduction or Methods section?*	Yes (1) No (0)
3.	*Are the characteristics of the patients included in the study clearly described?* In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given.	Yes (1) No (0)
4.	*Are the interventions of interest clearly described?* Treatments and placebo (where relevant) that are to be compared should be clearly described.	Yes (1) No (0)
5.	*Are the distributions of principal confounders in each group of subjects to be compared clearly described?* Measures of central tendency (mean or median) and dispersion (standard deviations or interquartile range) should be reported in both control and intervention groups.	Yes (2) Partially (1) No (0)
6.	*Are the main findings of the study clearly described?* Simple outcome data should be reported for all major findings so that the reader can check the major analyses and conclusions. This question does not cover statistical tests which are considered below.	Yes (1) No (0)
7.	*Does the study provide estimates of the random variability in the data for the outcomes?* In non normally distributed data, the interquartile range of results should be reported. In normally distributed data, the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.	Yes (1) No (0)
8.	*Have all important adverse events that may be a consequence of the intervention been reported?* This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events.	Yes (1) No (0)
9.	*Have the characteristics of patients lost to follow-up been described?*	Yes (1)

	This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no where a study does not report the number of patients lost to follow-up.	No (0)
10.	*Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the outcomes except where the probability value is less than 0.001?*	Yes (1) No (0)
	External Validity	
11.	*Were the subjects asked to participate in the study representative of the entire population from which they were recruited?* The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised of the entire population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant population exists Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine.	Yes (1) No (0) Unable to determine (0)
12.	*Were those subjects who were prepared to participate representative of the entire population from which they were recruited?* The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.	Yes (1) No (0) Unable to determine (0)
13.	*Were the staff, places, and facilities where the patients were treated representative of the treatment of the majority of patients receive?* For the question to be answered yes, the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no, if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.	Yes (1) No (0) Unable to determine (0)
	Internal Validity (Bias)	
14.	*Was an attempt made to blind those measuring the main outcomes of the intervention?*	Yes (1) No (0) Unable to determine (0)
15.	*If any of the results of the study were based on "data dredging", was this made clear?* Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer yes.	Yes (1) No (0) Unable to determine (0)
16.	*In trials and cohort studies, do the analyses adjust for different*	

	lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls? Where follow-up was the same for all study patients the answer should yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.	Yes (1) No (0) Unable to determine (0)
17.	*Were the statistical tests used to assess the main outcomes appropriate?* The statistical techniques used must be appropriate to the data. For example nonparametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.	Yes (1) No (0) Unable to determine (0)
18.	Was compliance with the intervention/s reliable? Where there was non compliance with the allocated treatment or where there was contamination of one group, the question should be answered no. For studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered yes.	Yes (1) No (0) Unable to determine (0)
19.	Were the main outcome measures used accurate (valid and reliable)? For studies where the outcome measures are clearly described, the question should be answered yes. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered as yes.	Yes (1) No (0) Unable to determine (0)
	Internal Validity (Confounding/Selection Bias)	
20.	Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population? For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case-control studies where there is no information concerning the source of patients included in the study.	Yes (1) No (0) Unable to determine (0)
21.	Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time? For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.	Yes (1) No (0) Unable to determine (0)
22.	Were study subjects randomised to intervention groups? Studies which state that subjects were randomised should be answered yes except where method of randomisation would not	Yes (1) No (0) Unable to

	ensure random allocation. For example alternate allocation would score no because it is predictable.	determine (0)
23.	Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable? All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.	Yes (1) No (0) Unable to determine (0)
24.	Was there adequate adjustment for confounding in the analyses from which the main findings were drawn? This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In non-randomised studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.	Yes (1) No (0) Unable to determine (0)
25.	Were losses of patients to follow-up taken into account? If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine. If the proportion lost to follow-up was too small to affect the main findings, the question should be answered yes.	Yes (1) No (0) Unable to determine (0)
	Power	
26.**	Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%? Sample sizes have been calculated to detect a difference of x% and y%.	Yes (1) No (0)

* The original Item 14 was removed in the modified checklist. The item asked whether there was any attempt made to blind study subject to the intervention they received, which is not applicable for most psychological intervention studies.

** The original scores for Question 26 regarding sufficient power range from 0 to 5. Studies were regarded as better quality i.e. additional points allocated, when the sample size was greater than an arbitrary cut-off limit (MacLehose et al, 2000). This was changed to a score of 0 to 1, representing without and with sufficient power respectively.

Appendix B

Trainees' contribution to the joint research project

The design of the research study, ethics application, development of the manual and focus group were conducted jointly by both trainees – Joanne Chan and Anna Churcher Clarke. The task of expert consultations were identified and divided evenly. The outcome measures for stress and mindfulness were researched by Joanne and Anna respectively; the other outcome measures and feasibility indicators were jointly researched. The list of identified measures was then discussed together with supervisors and in consultation with the focus group. Both trainees identified a list of care homes and divided the list equally to contact and introduce the project. The list of potential participants identified in care homes was divided equally to introduce the project and to seek consent. Baseline assessments were mainly carried out by a research assistant working in the North East London Foundation Trust with assistance from both trainees follow-up assessments were carried out by two research assistants from that same trust. Scoring of assessments was evenly divided. Each trainee analysed the data related to their own thesis separately and independently wrote up their own thesis.

Appendix C

Manual for the Mindfulness Programme

Principles of the Mindfulness Programme

Facilitate learning in ways which promote personhood

- Acknowledge and validate participants' diverse experiences during sessions, e.g. reminding participants *'these are your own, unique experiences'*.

- Participants of this cohort may be self-critical and may be concerned about 'getting it right' in the context of learning the mindfulness practices. Therefore, facilitators will reinforce the idea that *'there is no right or wrong way to do it'*.

- Use participants' own language and experiences at all times (i.e. during meditation guidance, group discussion and summarising), e.g. participants may be more engaged with the phrase *'our minds go for a walk'* instead of '*our minds tend to wander'* so, be flexible in the way instructions are provided.

Maintain a mindful stance at all times

- It is important for the facilitators to maintain their own mindfulness practice in order to maintain a mindful stance. Maintaining a mindful stance means embodying the following seven attitudes of mindfulness practice: non-judging, patience, beginner's mind, trust, non-striving, acceptance, and letting-go (Kabat-Zinn, 2013).

- The session needs to be appropriately paced according to the needs and capabilities of the participants, i.e. do not strive to work through all the session content at the cost of minimising learning opportunities.

- A mindful stance means not striving for a particular result from participants. For example, in group discussion, participants may have difficulties in describing how they brought back their attention to their breath. The lead facilitator can model curiosity by wondering out loud *'isn't that interesting how your attention just came back, I wonder how that happens'*.

- Be flexible and remain open to whatever arises in order to maximise opportunities for experiential learning, e.g. in the group discussion, a participant may express boredom about the preceding exercise and say that they felt like leaving the room; acknowledge the boredom and remain curious by enquiring what made them engage in the exercise, despite being bored.

Guidelines for facilitating the group

Mindful warm-up activity

- Sometimes participants might become distracted from the task, e.g. showing interest in the features of the ball (e.g. '*I like yellow*'). The lead facilitator can acknowledge and validate participant's experience, whilst reframing this to facilitate awareness of the here-and-now (e.g. *'You are noticing the ball is yellow, and you like that colour'.)*

During mindfulness practices

- The scripts provided are only guides. Stick to simple, concrete language with repetition to accommodate cognitive impairments.

- If a participant falls asleep during a mindfulness practice, it may be helpful to do one or more of the following: Remind participants to open their eyes or adjust their sitting position (see scripts); check in with everyone in the group individually by name, e.g. *'I'd just like to check how everyone is doing..'*; allow the participant to sleep and check in again during group discussion.

Group discussion

- Group discussion aims to facilitate participants' learning by: (1) Noticing sensations (including pain), thoughts and feelings (i.e. connecting with their direct experience of the practice); (2) Discussing how they related to these experiences and made sense of them (i.e. the effects of bringing awareness); (3) Linking to mindfulness principles.

- The lead facilitator uses funnelling questions, i.e. start with an open question, *'How was that for you?'* Use initial responses from participants to encourage further discussion. Where people are struggling with an open question, it may be useful to provide options in a closed question format, whilst always allowing for the possibility of alternative experiences, e.g., '*Some people found the breathing relaxing, some people found it boring. What about other people? Did others find it relaxing, boring, or something else?'*

- Facilitators may use their own experiences of the practice as a form of modelling, e.g. *'I noticed my breath becoming slower.'*

Session	Session Content
1	• Introduction to the Mindfulness Programme (written and verbal information) • Mindful warm-up activity with soft ball • Choice of group name and song • Mindfulness meditation 1: Mindful Breathing (with MBAS* measure) • Group discussion • 3-minute breathing space • Song • Feedback (participant rating form)
2**	• Introductions • Orientation to the programme and recap of previous session (written and verbal information) • Mindful warm-up activity with soft ball • Song • **Mindfulness meditation 1: Mindful Breathing** • Group discussion • **Mindfulness meditation 2: Mindful Listening** • Group discussion • 3-minute breathing space (optional) • Song • Feedback (participant rating form)
3	• **Mindful Breathing** • **Body Scan**
4	• **Mindful Breathing** • **Mindful Movement**
5	• **Mindful Breathing** • **Mindful Listening, Seeing, Smelling, Touch*****
6	• **Mindful Breathing (with MBAS measure)** • **Body Scan or Mindful Movement*****
7	• **Mindful Breathing** • **Mindful Listening, Seeing, Smelling, Touch*****
8	• **Mindful Breathing** • **Body Scan or Mindful Movement*****
9	• **Mindful Breathing** • **Listening, Seeing, Smelling, Touch*****
10	• **Mindful Breathing (with MBAS measure)** • **Body Scan or Mindful Movement*****

* Mindful Breath Attention Scores (Frewen, Evans, Maraj, Dozois & Patridge, 2008); ** The session structure as shown in session 2 is to be repeated for the remainder of the programme. The mindfulness practices are indicated in bold with scripts attached in the following pages. ***Depending on the capabilities and preferences of the group.

Session number: 1
Session goal: Introduction to mindfulness, mindful breathing exercise

Materials:

Labels for name badges, flipchart and markers, meditation bell, attendance list, participant rating forms and pens, baseline MBAS

Introduction [10-15 minutes]:

- Introductions; name labels; welcome everyone; statement of session goals
- Mindful warm-up activity: using soft ball to introduce name and feelings at the present moment (emphasis right here right now e.g. not "two minutes ago or yesterday")
- Choosing of song to open session; see the following page for possible options if participants do not identify a song
- Song

Main activity [30 minutes]:

- Introduction of mindfulness concept [5 minutes]
- Introduction and practice ***of mindful breathing with Mindful Breath Attention Scores (MBAS)*** measure [10-15 minutes]
- Group discussion [5 minutes]

Closing [10-15 minutes]:

- Introduction and practice of ***3-minute breathing space***
- Song
- Reminder re next session; thank everyone for attending
- Participant rating form

Session 1

Example songs
You Are My Sunshine You are my sunshine, my only sunshine You make me happy when skies are grey You never know, dear, how much I love you Please don't take my sunshine away
What A Wonderful World I see trees of green, red roses too. I see them bloom, for me and you. And I think to myself, what a wonderful world.
Somewhere over the rainbow Somewhere over the rainbow Way up high And the dreams that you dreamed of Once in a lullaby Somewhere over the rainbow Blue birds fly And the dreams that you dreamed of Dreams really do come true ooh oh

Scripts for Session 1, 6 and 10

MINDFUL BREATHING (adapted from McBee, 2008: 181)

(incorporating Mindfulness Breath Attention Scores measure)

Introduction:

In this exercise we are going to learn to pay attention to our breath.

At several points throughout this exercise we will ring this bell [DEMO]. At that point we want to find out if you have been paying attention to your breath. If your attention was still on your breath, we will ask you to raise your hand. Don't worry, we will remind you of these instructions each time we ring the bell.

Preparing for the exercise:

First, let's prepare for the exercise.

Place your feet flat on the floor, with your legs uncrossed.

Settle into a comfortable sitting position on your chair. Sit up as straight as you can, without hurting yourself. Place your hands gently on your lap [DEMO].

For this exercise, try to close your eyes [DEMO].

Bring your attention to the sensations of your body in the chair. Ask yourself can you feel your feet on the floor, or can you feel your hips in the chair?

Sometimes you may notice that you lose concentration while doing the exercise. This is perfectly OK. Getting distracted happens to everyone. Our minds like to go for a walk. [REPEAT DURING EXERCISE FREQUENTLY]

Throughout the exercise the facilitator should also remind participants (as and when appropriate):

- If you notice any tension or pain, ask yourself what does it feel like? Ask yourself can you observe these sensations as they rise and fall? Come and go?
- Instead of pushing pain away, approach these sensations with curiosity and kindness as best as you can.
- The idea here is not to stay in the same sitting position until it is too painful. Please change your sitting position if you need to. Do what works for you.
- If you are starting to feel sleepy, it can help to open your eyes for a moment or change your sitting position, and gently bring your attention back to wherever we are in the exercise at that moment.

Exercise:

Focus your attention on your breath, let the breath be, without changing it in any way. Notice how it feels in your body to sit here and breathe.

- Now focus your attention on your stomach. Notice the gentle rise of your stomach as you breathe in, and the gentle fall of your stomach as you breathe out.
- Imagine your stomach is like a balloon, as you breathe in the stomach stretches, and as you breathe out it becomes flatter.
- Notice how it feels in your body to sit here and breathe.
- PAUSE TO 1 MIN

[BELL] Just before you heard the bell, were you paying attention to your breath? If your attention was still on your breath, please raise your hand. [CHECK RESPONSES]. If you have your hand raised please lower it now. Notice how it feels in your body to sit here and breathe.

- Now focus your attention on another part of your body where you can feel the breath – your chest, noticing the gentle rise of the chest as you breathe in and the gentle fall of the chest as you breathe out.
- Imagine your chest is like a balloon, as you breathe in the chest stretches, and as you breathe out it becomes flatter.
- Notice how it feels in your body to sit here and breathe.
- PAUSE TO 1 MIN

[BELL] Just before you heard the bell, were you paying attention to your breath? If your attention was still on your breath, please raise your hand. [CHECK RESPONSES]. If you have your hand raised please lower it now. Notice how it feels in your body to sit here and breathe.

- As best as you can, try not to change or control your breath, simply let it be. Just notice and observe. Just answer in your mind what is your breath like right now? Notice if your breath is short or long. Notice if your breath is deep or shallow. Notice if your breath is fast or slow. Notice in your mind if your breath is even or uneven? Just be with your breath.
- Notice how it feels in your body to sit here and breathe.
- PAUSE TO 1 MIN

[BELL] Just before you heard the bell, were you paying attention to your breath? If your attention was still on your breath, please raise your hand. [CHECK RESPONSES]. If you have your hand raised please lower it now. Notice how it feels in your body to sit here and breathe.

- Let's sit quietly for a while, and just simply observe your breath. If you need to move or change your posture, bring your full attention to this experience. Notice all the sensations connected with moving your body.
- Keeping your attention focused on the breath - maybe on your stomach, or your chest, noticing the gentle rise as you breathe in, and the gentle fall as you breathe out.
- Notice how it feels in your body to sit here and breathe.
- PAUSE TO 1 MIN

[BELL] Just before you heard the bell, were you paying attention to your breath? If your attention was still on your breath, please raise your hand. [CHECK RESPONSES]. If you have your hand raised please lower it now. Notice how it feels in your body to sit here and breathe.

- As best as you can, try not to change or control your breath, simply let it be. Just notice and observe. Just answer in your mind what is your breath like right now? Notice if your breath is short or long. Notice if your breath is deep or shallow. Notice if your breath is fast or slow. Notice in your mind if your breath is even or uneven? Just be with your breath.
- Notice how it feels in your body to sit here and breathe.
- PAUSE TO 1 MIN

[BELL] Just before you heard the bell, were you paying attention to your breath? If your attention was still on your breath, please raise your hand. [CHECK RESPONSES]. If you have your hand raised please lower it now. Notice how it feels in your body to sit here and breathe.

Script for Session 1

(For remaining sessions, it is an optional practice as part of closing activity)

3-MINUTE BREATHING SPACE (adapted from Kabatt-Zinn, 2013:25)

Introduction:

In this exercise we are going to learn a short breathing practice.

The 3-minute breathing space is a short practice which aims to bring your attention to the present moment. The 3-minute breathing space may also help you when you experience difficult feelings, like stress or frustration.

Try practising the 3-minute breathing space every day.

Preparing for the exercise:

First, let's prepare for the exercise.

Place your feet flat on the floor, with your legs uncrossed.

Settle into a comfortable sitting position on your chair. Sit up as straight as you can, without hurting yourself. Place your hands gently on your lap [DEMO].

For this exercise, try to close your eyes [DEMO].

Bring your attention to the sensations of your body in the chair. Ask yourself can you feel your feet on the floor, or can you feel your hips in the chair?

Sometimes you may notice that you lose concentration while doing the exercise. This is perfectly OK. Getting distracted happens to everyone. Our minds like to go for a walk. [REPEAT DURING EXERCISE FREQUENTLY]

Exercise:

First Minute – Awareness:

- Bring yourself into the present moment. Ask yourself: "What is going on in me right now… What am I thinking? What are my feelings? Can I feel any sensations in my body?"

- Whatever you are experiencing, just notice it as it is – not judging it. Simply be aware of what is going on in you at this present moment.

Second and Third Minute – Gathering:

- Now direct your full attention to your breathing. Be aware of how it feels in your body each time you breathe in, and each time you breathe out.

- Notice the gentle rise of your stomach as you breathe in, and the gentle fall of your stomach as you breathe out.

- Bring your full attention to each breath, as one breath follows the other.

- Your breath can help bring your attention into the present moment.

When you hear the sound of a bell, you may open your eyes and bring your attention to the room whenever you are ready. As you start activity again, pay attention to the breath. The breath is always there for you. The breath can help bring you back to the present. It is like a good friend. It reminds you that you are OK just as you are. [BELL]

Session number: 2
Session goal: Introduction to mindful listening

Materials:

Labels for name badges, flipchart and markers, meditation bell, attendance list, participant rating forms, pens, CD, CD player

Introduction [10 minutes]:

- Introductions; name labels; welcome everyone; orientation to the programme, brief recap of previous session, statement of session goals

- Mindful warm-up activity: using soft ball to introduce name and feelings at the present moment (emphasis right here right now e.g. not "two minutes ago or yesterday")

- Song

Main activity [30-35 minutes]:

- Practice of ***mindful breathing without MBAS measure*** [10 minutes]

- Group discussion [5 minutes]

- Introduction and practice of ***mindful listening*** [10 minutes]

- Group discussion [5 minutes]

Closing [10-15 minutes]:

- Practice of 3-minute breathing space (optional if time permits)

- Song

- Reminder re next session; thank everyone for attending

- Participant rating form

Script for sessions 2, 3, 4, 5, 7, 8, and 9

MINDFUL BREATHING (adapted from McBee, 2008: 181)
(without Mindfulness Breath Attention Scores measure)

Introduction:
In this exercise we are going to learn to pay attention to our breath.

Preparing for the exercise:

First, let's prepare for the exercise. Place your feet flat on the floor, with your legs uncrossed [DEMO].

Settle into a comfortable sitting position on your chair. Sit up as straight as you can, without hurting yourself. Place your hands gently on your lap [DEMO]. For this exercise, try to close your eyes [DEMO].

Bring your attention to the sensations of your body in the chair. Ask yourself can you feel your feet on the floor, or can you feel your hips in the chair?

Sometimes you may notice that you lose concentration while doing the exercise. This is perfectly OK. Getting distracted happens to everyone. Our minds like to go for a walk. [REPEAT DURING EXERCISE FREQUENTLY]

Throughout the exercise the facilitator should also remind participants (as and when appropriate):

- If you notice any tension or pain, ask yourself what does it feel like? Ask yourself can you observe these sensations as they rise and fall? Come and go?
- Instead of pushing pain away, approach these sensations with curiosity and kindness as best as you can.
- The idea here is not to stay in the same sitting position until it is too painful. Please change your sitting position if you need to. Do what works for you.
- If you are starting to feel sleepy, it can help to open your eyes for a moment or change your sitting position, and gently bring your attention back to wherever we are in the exercise at that moment.

Exercise:

Focus your attention on your breath, let the breath be, without changing it in any way. Notice how it feels in your body to sit here and breathe.

- Now focus your attention on your stomach. Notice the gentle rise of your stomach as you breathe in, and the gentle fall of your stomach as you breathe out.
- Imagine your stomach is like a balloon, as you breathe in the stomach stretches, and as you breathe out it becomes flatter.
- Notice how it feels in your body to sit here and breathe.
- PAUSE TO 1 MIN

- Now focus your attention on another part of your body where you can feel the breath – your chest, noticing the gentle rise of the chest as you breathe in and the gentle fall of the chest as you breathe out.
- Imagine your chest is like a balloon, as you breathe in the chest stretches, and as you breathe out it becomes flatter.
- Notice how it feels in your body to sit here and breathe.
- PAUSE TO 1 MIN

- As best as you can, try not to change or control your breath, simply let it be. Just notice and observe. Just answer in your mind what is your breath like right now? Notice if your breath is short or long. Notice if your breath is deep or shallow. Notice if your breath is fast or slow.

Notice in your mind if your breath is even or uneven? Just be with your breath.

- Notice how it feels in your body to sit here and breathe.
- PAUSE TO 1 MIN

- Let's sit quietly for a while, and just simply observe your breath. If you need to move or change your posture, bring your full attention to this experience. Notice all the sensations connected with moving your body.
- Keeping your attention focused on the breath - maybe on your stomach, or your chest, noticing the gentle rise as you breathe in, and the gentle fall as you breathe out.
- Notice how it feels in your body to sit here and breathe.
- PAUSE TO 1 MIN

- As best as you can, try not to change or control your breath, simply let it be. Just notice and observe. Just answer in your mind what is your breath like right now? Notice if your breath is short or long. Notice if your breath is deep or shallow. Notice if your breath is fast or slow. Notice in your mind if your breath is even or uneven? Just be with your breath.
- Notice how it feels in your body to sit here and breathe.
- PAUSE TO 1 MIN

When you hear the sound of a bell, you may slowly awaken the body to movement, moving your fingers or toes in any way you like. As you start activity again, pay attention to the breath. The breath is always there for you. The breath can help bring you back to the present. It is like a good friend. It reminds you that you are OK just as you are. [BELL]

Script for session 2

(Depending on the capabilities and preferences of the group, mindful listening may be repeated at **Session 5, 7 and/or 9)**

MINDFUL LISTENING

(adapted from Kabatt-Zinn, 2013: 72; Williams & Penman, 2011: 143-145)

Introduction:

Discussion of types of music liked/disliked by participants, link to thoughts, feelings, bodily sensations and behaviour. The sitting with music exercise will be using hearing as the main way of focusing your attention on the present moment (prompts: hear the music as it is, not listening out for certain sounds or instruments).

Preparing for the exercise:

First, let's prepare for the exercise. Place your feet flat on the floor, with your legs uncrossed [DEMO].

Settle into a comfortable sitting position on your chair. Sit up as straight as you can, without hurting yourself. Place your hands gently on your lap [DEMO]. For this exercise, try to close your eyes [DEMO].

Bring your attention to the sensations of your body in the chair. Ask yourself can you feel your feet on the floor, or can you feel your hips in the chair?

Sometimes you may notice that you lose concentration while doing the exercise. This is perfectly OK. Getting distracted happens to everyone. Our minds like to go for a walk. [REPEAT DURING EXERCISE FREQUENTLY]

Throughout the exercise the facilitator should also remind participants (as and when appropriate):

- If you notice any tension or pain, ask yourself what does it feel like? Ask yourself to observe these sensations as they rise and fall? Come and go?
- Instead of pushing pain away, approach these sensations with curiosity and kindness as best as you can.
- The idea here is not to stay in the same sitting position until it is too painful. Please change your sitting position if you need to. Do what works for you.
- If you are starting to feel sleepy, it can help to open your eyes for a moment or change your sitting position, and gently bring your attention back to wherever we are in the exercise at that moment.

Exercise:

- Focus your attention on your breath. Let the breath be, without changing it in any way. Notice how it feels in your body to sit here and breathe. [PAUSE TO 1 MIN]

- Now when you are ready, allow the focus of your attention to shift from sensations in the body to hearing.

[PLAY MUSIC]. NB: Improvise script according to the choice of music. Prompt with the following lines as and when appropriate.

- When you hear the music, hear each note as it comes and goes.

- When you hear the music, hear as best you can the rise and fall of the sounds.

- There is no need to listen out for particular sounds. As best you can, pay attention to sounds from all directions as they arise.

- As best as you can, try breathing the sounds into your body as you breathe in and letting the sounds flow out again as you breathe out.

- Imagine that sounds can move in and out of your body as you breathe. Notice how that feels like in your body.

- Imagine that sounds can be felt by your very bones. Notice how this feels.

When you hear the sound of a bell, you may open your eyes and bring your attention to the room whenever you are ready. As you start activity again, pay attention to the sounds around you. Sounds may help bring you back to the present. [BELL]

Session number: 3
Session goal: Body scan

Materials:

Labels for name badges, flipchart and markers, meditation bell, attendance list, participant rating forms and pens

Introduction [10 minutes]:

- Introductions; name labels; welcome everyone; orientation to the programme, brief recap of previous session, statement of session goals

- Mindful warm-up activity: using soft ball to introduce name and feelings at the present moment (emphasis right here right now e.g. not "two minutes ago or yesterday")

- Song

Main activity [30-35 minutes]:

- Practice of ***mindful breathing without MBAS measure*** [10 minutes]

- Group discussion [5 minutes]

- Introduction and practice of ***body scan*** [10-15 minutes]

- Group discussion [5 minutes]

Closing [10-15 minutes]:

- Practice of 3-minute breathing space (optional if time permits)

- Song

- Reminder re next session; thank everyone for attending

- Participant rating form

Script for session 3

(Depending on the capabilities and preferences of the group, body scan may be repeated at **Session 6, 8 and/or 10**)

BODY SCAN WHILE SITTING (adapted from McBee, 2008: 182)

Introduction:
The body scan is a slow, detailed awareness of body sensations. We will start from the toes and slowly work our way up to the top of the head.

Preparing for the exercise:

First, let's prepare for the exercise. Place your feet flat on the floor, with your legs uncrossed [DEMO].

Settle into a comfortable sitting position on your chair. Sit up as straight as you can, without hurting yourself. Place your hands gently on your lap [DEMO]. For this exercise, try to close your eyes [DEMO].

Bring your attention to the sensations of your body in the chair. Ask yourself can you feel your feet on the floor, or can you feel your hips in the chair?

Sometimes you may notice that you lose concentration while doing the exercise. This is perfectly OK. Getting distracted happens to everyone. Our minds like to go for a walk. [REPEAT DURING EXERCISE FREQUENTLY]

Throughout the exercise the facilitator should also remind participants (as and when appropriate):

- If you notice any tension or pain, ask yourself what does it feel like? Ask yourself to observe these sensations as they rise and fall? Come and go?
- Instead of pushing pain away, approach these sensations with curiosity and kindness as best as you can.
- The idea here is not to stay in the same sitting position until it is too painful. Please change your sitting position if you need to. Do what works for you.
- If you are starting to feel sleepy, it can help to open your eyes for a moment or change your sitting position, and gently bring your attention back to wherever we are in the exercise at that moment.

Exercise:

- Focus your attention on your breath, let the breath be, without changing it in any way. Pay attention to how it feels in your body to sit here and breathe. [PAUSE TO 1 MIN].

- Let's start by bringing your attention to include your back, the lower back, middle and upper parts. You may notice areas of tension, pain, or stress in your back. Notice the sensations as you breathe in and out. If there is tension or pain, notice what it feels like. Ask yourself if you can observe the sensations as they rise and fall? Come and go? See if you can you feel the expansion and contraction of the back ribs as you breathe in and breathe out.

- Turn your attention to your stomach, your front ribs, and your chest. As best as you can, notice where you feel your breath. See if you can become aware of your internal organs, your lungs, heart, all the organs that support us every day. Simply observe your body as you sit here, breathing.

- Now, focus your attention on your arms. Bring your attention all the way down to the fingers as you breathe in and breathe out. See if you can notice any sensations: any tingling, throbbing, itching, moisture? Notice your palms, the top of your hands, and your wrists. Notice your hands at rest.

- Move your attention to your shoulders and neck, areas where you may experience tension and tightness. As best as you can, let your neck and shoulders be as they are for now as you breathe in and breathe out.

- From your neck, bring your attention to your throat, as best as you can feel your breath as it travels from your mouth or nose to your lungs.

- Bring your attention up to your head, the back of your head and the scalp area. See if you can notice any sensations, perhaps tingling, itching, warmth or coolness. Or maybe there are no sensations?

- Move your attention to your face. Start with your jaw, Notice if your teeth are clenched. Notice your teeth, your tongue, and your lips. Now focus on your cheeks, your nose, your nostrils, and the area below your nostrils. You may notice your breath, entering cool, coming out warm. Bring your attention to your eyes, the area around your eyes, your eyeballs and your eyebrows. Now move your attention to your forehead. As best as you can, simply see if you can notice any sensations on your forehead as you sit here, breathing.

- Now simply let your breath to return to normal, without controlling it in any way. Take a few more moments to notice the physical sensations you are feeling right here and now, and where you are feeling them. You may also want to observe feelings and thoughts that arise. Take a few moments to observe your body as a whole.

When you hear the sound of a bell, you may slowly awaken the body to movement, moving your fingers or toes in any way you like. As you start activity again, pay attention to your body. Your body may help bring you back to the present. [BELL].

Session number: 4
Session goal: Body awareness with mindful movement

Materials:

Labels for name badges, flipchart and markers, meditation bell, attendance list, participant rating forms and pens

Introduction [10 minutes]:

- Introductions; name labels; welcome everyone; orientation to the programme, brief recap of previous session, statement of session goals

- Mindful warm-up activity: using soft ball to introduce name and feelings at the present moment (emphasis right here right now e.g. not "two minutes ago or yesterday")

- Song

Main activity [30-35 minutes]:

- Practice of ***mindful breathing without MBAS measure*** [10 minutes]

- Group discussion [5 minutes]

- Introduction and practice of ***mindful movement*** [10 minutes]

- Group discussion [5 minutes]

Closing [10-15 minutes]:

- 3-minute breathing space (optional if time permits)

- Song

- Reminder re next session; thank everyone for attending

- Participant rating form

Script for session 4

(Depending on the capabilities and preferences of the group, mindful movement may be repeated at **Session 6, 8 and/or 10**)

MINDFUL MOVEMENT WHILE SITTING

(adapted from Williams & Penman, p.119-122; McBee, p.102)

Introduction:

The mindful movement while sitting exercise will be practising paying attention to our body while we do some gentle stretching.

Highlight that the movements should be done slowly and mindfully by paying attention to the parts of the body and the sensations, and do what feels right.

Preparing for the exercise:

First, let's prepare for the exercise. Place your feet flat on the floor, with your legs uncrossed [DEMO].

Settle into a comfortable sitting position on your chair. Sit up as straight as you can, without hurting yourself. Place your hands gently on your lap [DEMO].

Bring your attention to the sensations of your body in the chair. Ask yourself can you feel your feet on the floor, or can you feel your hips in the chair?

Sometimes you may notice that you lose concentration while doing the exercise. This is perfectly OK. Getting distracted happens to everyone. Our minds like to go for a walk. [REPEAT DURING EXERCISE FREQUENTLY]

Throughout the exercise the facilitator should also remind participants (as and when appropriate):

- Do not forget to breathe. Just breathe in and breathe out freely at your own pace.
- Only what feels right to you.
- If you find that you cannot do the movement. That's okay. Simply pay attention to your breathing and imagine that you are doing [name the pose] with us.
- Do it very slowly, paying attention to your [name part of body].

Facilitator should explain each pose, demonstrate, and then ask the participants to do it. Offer hands-on assistance as necessary. Remember to offer lots of encouragement and praise.

Exercise:

- Focus your attention on your breath, let the breath be, without changing it in any way. Notice how it feels in your body to sit here and breathe [PAUSE TO 1 MIN].

- Now when you are ready, take a breath and very slowly raise your hands in front of you and very slowly wriggle your fingers. If you cannot use one hand, simply stretch the other hand. If you cannot move both hands at all, simply pay attention to your breathing and imagine that you are wriggling your fingers with us.

- Take some time to feel the sensations of the muscles and joints in your fingers as you wriggle your fingers very slowly.

- When you are ready, slowly - very slowly- as you breathe out, allow your hands to come to rest. Lower them slowly, feeling the changing sensations as your hands slowly come to rest.

- Now gently close your eyes for a moment, and pay attention to your breath and the sensations throughout your body. Perhaps notice the after-effects of doing the stretch [PAUSE TO 1 MIN].

- Now very slowly raise your arms out in front of you and stretch. If you cannot use one arm, simply stretch the other arm. If you cannot move both arms at all, simply pay attention to your breathing and imagine that you are stretching with us.

- As you are stretching your arms, take some time to feel the sensations of stretch in the muscles and joints in your body. As you slowly raise your arms, pay attention to your arms. If you notice any tension or pain, ask yourself what does it feel like? Ask yourself can you observe these sensations as they rise and fall? Come and go?

- When you are ready, slowly - very slowly- as you breathe out, allow your arms to come back down. Lower them slowly, feeling the changing sensations as they come down. Perhaps you might also feel the clothes moving on the surface of your skin. Pay attention to the sensations as your arms slowly come back to rest.

- Now gently close your eyes for a moment, and pay attention to your breath and the sensations and feelings throughout your body. Perhaps notice the after-effects of doing the stretch [PAUSE TO 1 MIN].

- Slowly open your eyes. Take a breath and very slowly open your arms wide and stretch. As you stretch very slowly, see if you can pay attention to the sensations in the muscles as the muscles work to lift the arms. Pay attention to the muscles as they help the arms to stretch.

- Now we are going to fold our bodies, just like flowers closing. As you breathe out, allow your arms very slowly to hug yourself. As your arms, very slowly, start to hug yourself, see if you can notice any changing sensations in your body.

- Now gently close your eyes for a moment, and pay attention to your breath and the sensations and feelings throughout your body. Perhaps noticing the after-effects of doing the stretch.

When you hear the sound of a bell, you may open your eyes and bring your attention to the room whenever you are ready. As you start activity again, pay attention to the movements of your body. Noticing the sensations of movement in your body may help bring you back to the present moment. [BELL]

For **sessions 5, 7 and 9**, the first mindfulness practice will be **Mindful Breathing without MBAS measure** (see session 2 for the script). Facilitators can choose any of the following as the second mindfulness practice. The choice should be dependent on the capabilities and preferences of the group members:

(1) **Mindful Listening** – see session 2 for the script
(2) **Mindful Seeing**
(3) **Mindful Smelling**
(4) **Mindful Touch**

Scripts for the latter three are available in the following pages.

For **sessions 6 and 10**, the first mindfulness practice will be **Mindful Breathing with MBAS measure** (see session 1 for the script). The second mindfulness practice can be **either Body Scan** (see session 3 for the script) **or Mindful Movement** (see session 4 for the script). The choice of the second practice should be dependent on the capabilities and preferences of the group members.

For **session 8**, the first mindfulness practice will be **Mindful Breathing without MBAS measure** (see session 2 for the script). The second mindfulness practice can be **either Body Scan** (see session 3 for the script) **or Mindful Movement** (see session 4 for the script), depending on the capabilities and preferences of the group members.

Session number: 5, 7 and/or 9
Session goal: Connection between mind and body with focused visual component

Materials:

Labels for name badges, flipchart and markers, meditation bell, attendance list, participant rating forms and pens, laminated abstract art images as focus for attention (e.g. Rothko multiform painting) or space projector (e.g. Snoezelen)

Introduction [10 minutes]:

- Introductions; name labels; welcome everyone; orientation to the programme, brief recap of previous session, statement of session goals

- Mindful warm-up activity: using soft ball to introduce name and feelings at the present moment (emphasis right here right now e.g. not "two minutes ago or yesterday")

- Song

Main activity [30-35 minutes]:

- Practice of ***mindful breathing without MBAS measure*** [10 minutes]

- Group discussion [5 minutes]

- Introduction and practice of ***mindful seeing*** [15 minutes]

- Group discussion [5 minutes]

Closing [10-15 minutes]:

- Practice of 3-minute breathing space (optional if time permits)

- Song

- Reminder re next session; thank everyone for attending

- Participant rating form

Script for session 5, 7 and/or 9
MINDFUL SEEING

Introduction:
Discussion of what participants like to look at in their environment, e.g. what they find pleasant/unpleasant.

Pass around laminated images as focus for attention [abstract art] OR explain that there will be some images that will be projected on the wall [space projector]. Emphasise that the images are abstract, and the idea is not trying to guess what the images are. Simply be curious when looking at the images.

The sitting with what we can see exercise will be using sight as the main way of focusing your attention on the present moment.

Preparing for the exercise:

First, let's prepare for the exercise. Place your feet flat on the floor, with your legs uncrossed [DEMO].

Settle into a comfortable sitting position on your chair. Sit up as straight as you can, without hurting yourself. Place your hands gently on your lap [DEMO]. Do this exercise with your eyes open.

Bring your attention to the sensations of your body in the chair. Ask yourself can you feel your feet on the floor, or can you feel your hips in the chair?

Sometimes you may notice that you lose concentration while doing the exercise. This is perfectly OK. Getting distracted happens to everyone. Our minds like to go for a walk. [REPEAT DURING EXERCISE FREQUENTLY]

Exercise:

- Focus your attention on your breath, let the breath be, without changing it in any way. Notice how it feels in your body to sit here and breathe. [PAUSE TO 1 MIN].

- Now when you are ready, allow the focus of your attention to shift from sensations in the body to what you can see in the image you are holding.

- Really pay attention to the lines, colours and shapes.

- Allow your attention to settle on one part of the image. Ask yourself what happens to the quality of the colour, shape and texture as you move your eyes across this part. Just answer in your mind what is the colour like? Notice if its tone becomes duller or brighter? Notice what happens at the point where shape becomes another. Notice the surface of the colour, the areas where it seems to become thicker and thinner? Notice if there is any variation in the roughness or smoothness of the surface.

- As best as you can, simply see what is here to be seen, without judging it.

- You may find that you are thinking about the image looks like. As best you can, see if you can let go of those ideas and bring your attention to the qualities of colour, shape and texture as you focus your attention on the image.

- Notice what it feels like in your body, right here and now, while you are looking at the image. And if there is a lack of any sensations, simply notice how that feels as best as you can. [PAUSE TO 1 MIN].

When you hear the sound of a bell, you may bring your attention to the room whenever you are ready. As you start activity again, pay attention to what you can see around you. Noticing what you can see may help bring you back to the present moment. [BELL]

Session number: 5, 7 and/or 9
Session goal: Body awareness with focused olfactory component

Materials:

Labels for name badges, flipchart and markers, meditation bell, attendance list, participant rating forms and pens, handkerchiefs and essential oils for smelling

Introduction [10 minutes]:

- Introductions; name labels; welcome everyone; orientation to the programme, brief recap of previous session, statement of session goals

- Mindful warm-up activity: using soft ball to introduce name and feelings at the present moment (emphasis right here right now e.g. not "two minutes ago or yesterday")

- Song

Main activity [30-35 minutes]:

- Practice of ***mindful breathing without MBAS measure*** [10 minutes]

- Group discussion [5 minutes]

- Introduction and practice of ***mindful smelling*** [15 minutes]

- Group discussion [5 minutes]

Closing [10-15 minutes]:

- Practice of 3-minute breathing space (optional if time permits)

- Song

- Reminder re next session; thank everyone for attending

- Participant rating form

Script for session 5, 7 or 9
MINDFUL SMELLING

Introduction:
Discussion of types of smell liked/disliked by participants. Let participants choose a scent for this exercise. The sitting with smell exercise will be using smelling as the main way of focusing your attention on the present moment.

Preparing for the exercise:

First, let's prepare for the exercise.

Place your feet flat on the floor, with your legs uncrossed.

Settle into a comfortable sitting position on your chair. Sit up as straight as you can, without hurting yourself. Place your hands gently on your lap [DEMO].

Do this exercise with your eyes open.

Bring your attention to the sensations of your body in the chair. Ask yourself can you feel your feet on the floor, or can you feel your hips in the chair?

Sometimes you may notice that you lose concentration while doing the exercise. This is perfectly OK. Getting distracted happens to everyone. [REPEAT DURING EXERCISE IF NECESSARY]

Exercise:

- Focus your attention on your breath, let the breath be, without changing it in any way. Notice how it feels in your body to sit here and breathe. [PAUSE TO 1 MIN].

- Now when you are ready, allow the focus of your attention to shift from sensations in the body to smelling.

- Bring the handkerchief up towards your face and see if you can smell it. Be open to the smells as they arise.

- As best as you can, simply smell what is here to be smelt, without judging or thinking about what you are smelling. Perhaps there is a lack of smell.

- You may find that you are thinking about the smells. You might wonder what the smells are. You might be thinking of a time in the past when you have smelt the smell before.

- Bring your attention to the smell of the object, as if you are smelling this smell for the very first time.

- Notice what it feels like in your body, right here and now, while you are smelling the handkerchief. And if there is a lack of smell, simply notice how that feels in your body as best as you can. [PAUSE TO 1 MIN].

When you hear the sound of a bell, you may bring your attention to the room whenever you are ready. As you start activity again, pay attention to what you can smell around you. Noticing what you can smell can help bring you back to the present. [BELL]

Session number: 5, 7 or 9
Session goal: Body awareness with focused tactile component

Materials:

Labels for name badges, flipchart and markers, meditation bell, attendance list, participant rating forms and pens, objects for touching (e.g. shells)

Introduction [10 minutes]:

- Introductions; name labels; welcome everyone; orientation to the programme, brief recap of previous session, statement of session goals

- Mindful warm-up activity: using soft ball to introduce name and feelings at the present moment (emphasis right here right now e.g. not "two minutes ago or yesterday")

- Song

Main activity [30-35 minutes]:

- Practice of ***mindful breathing without MBAS measure*** [10 minutes]

- Group discussion [5 minutes]

- Introduction and practice of ***mindful touch*** [15 minutes]

- Group discussion [5 minutes]

Closing [10-15 minutes]:

- Practice of 3-minute breathing space (optional if time permits)

- Song

- Reminder re next session; thank everyone for attending

- Participant rating form

Script for session 5, 7 or 9
MINDFUL TOUCH

Introduction:
Discussion of types of textures liked/disliked by participants (example prompts: animals – cats, snakes; places – sand, pebbles). Let participants choose a material for this exercise. The sitting with touch exercise will be using touch as the main way of focusing your attention on the present moment.

Preparing for the exercise:

First, let's prepare for the exercise.

Place your feet flat on the floor, with your legs uncrossed.

Settle into a comfortable sitting position on your chair. Sit up as straight as you can, without hurting yourself. Place your hands gently on your lap [DEMO].

Do this exercise with your eyes open and looking at the material [DEMO].

Bring your attention to the sensations of your body in the chair. Ask yourself can you feel your feet on the floor, or can you feel your hips in the chair?

Sometimes you may notice that you lose concentration while doing the exercise. This is perfectly OK. Getting distracted happens to everyone. [REPEAT DURING EXERCISE IF NECESSARY]

Exercise:

NB: participants may swap objects for this exercise if time permits.

- Focus your attention on your breath, let the breath be, without changing it in any way. Notice how it feels in your body to sit here and breathe. [PAUSE TO 1 MIN].

- Now when you are ready, allow the focus of your attention to shift from sensations in the body to touching the object.

- Hold the object in your hand and run your fingers over its surface. Really pay attention to where your fingers make contact with the surface.

- As you move your fingers across the object, simply notice if there are any changes in its texture. However, small these may be. Perhaps the object feels the same all over. Ask yourself if the sensations in your fingers change as you move from the object's centre to its edges.

- As best as you can, simply touch what is here to be touched, without judging or thinking about what you are touching.

- You may find that you are thinking about the textures you can feel. You might wonder what the object is or where it has come from. You might be thinking of a time in the past when you have come into contact with this texture before.

- Bring your attention to the feel of the object, as if you are touching the object for the very first time.

- Notice what it feels like in your body, right here and now, while you are touching the object. [PAUSE TO 1 MIN].

When you hear the sound of a bell, you may open your eyes and bring your attention to the room whenever you are ready. As you start activity again, pay attention to touch and texture. Noticing what textures you can feel can help bring you back to the present. [BELL]

Appendix D

Intervention-related documents

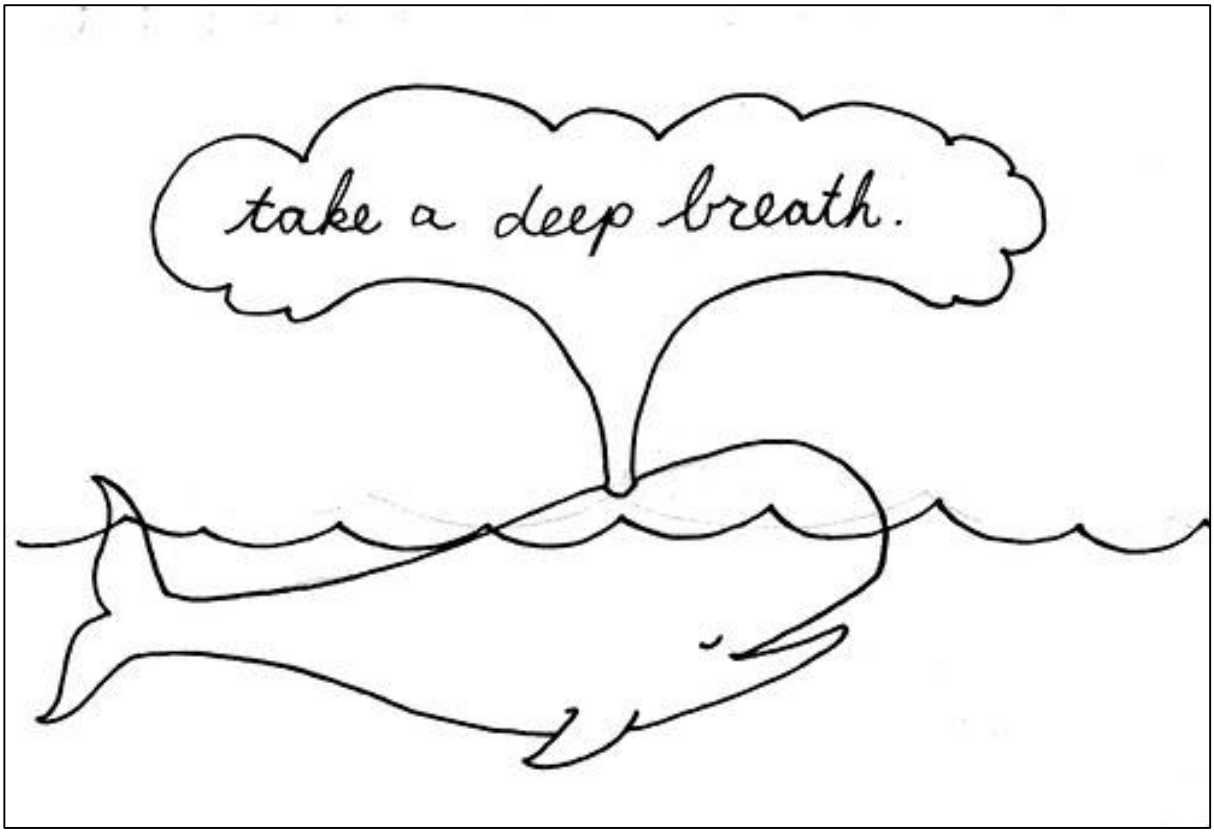
Visual cue for care homes

Session summary sheet

Participant rating form

Home practice log sheet

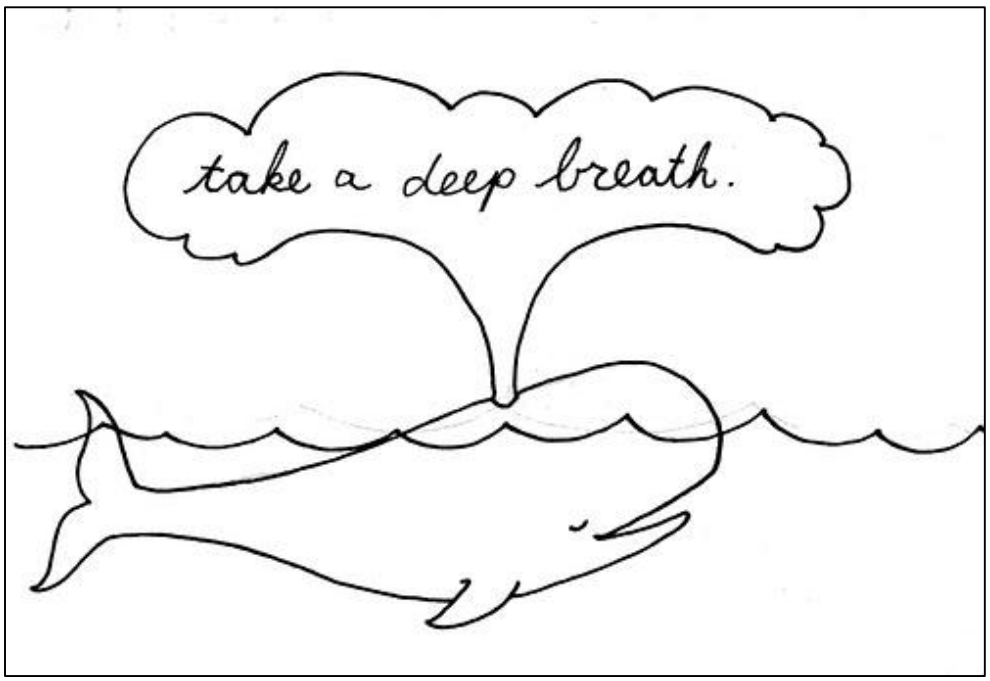
Visual cue for care homes



Example of a session summary sheet

Mindfulness programme
Session 1 summary sheet

- The breath is always there for you.
- The breath is like a good friend. It reminds you that you are OK just as you are.
- The breath can help bring you back to the present moment.
- When you notice that your attention has wandered, gently bring it back, without criticising yourself.



Participant Rating Form

Date completed:

We want to develop these sessions so that they are as helpful as possible. Please help us to improve these by answering the questions below:

1. How satisfied were you with your experience of coming to the session today?

   0 – not at all 1 – somewhat satisfied 2 – very satisfied

2. What was good about the session (if anything)? For example, was there anything you found helpful or enjoyable?

3. What was bad about the session (if anything)? For example, was there anything you found unhelpful or not enjoyable?

Thank you for taking the time to complete the participant rating form!

Home practice log sheet

Mindfulness and dementia study – home practice log sheet

NAME OF PARTICIPANT:_____ **WEEK COMMENCING:** _____

Research shows that mindfulness works much better when people practice the techniques outside of sessions.

The main technique we would like people to practice every day is the 3-minute breathing space. **PLEASE CIRCLE YES OR NO.** People may also want to practice the breath awareness exercise (10 minutes).

However, if you practice any of the other techniques learnt during the sessions, please describe.
It is also okay if the participant has not practiced any techniques – we would really appreciate your honesty ☺

Thursday	Friday	Saturday	Sunday	Monday	Tuesday	Wednesday
3-min breathing YES/NO Breath awareness YES/NO	3-min breathing YES/NO Breath awareness YES/NO	3-min breathing YES/NO Breath awareness YES/NO	3-min breathing YES/NO Breath awareness YES/NO	3-min breathing YES/NO Breath awareness YES/NO	3-min breathing YES/NO Breath awareness YES/NO	3-min breathing YES/NO Breath awareness YES/NO

Thank you for taking the time to complete this sheet. Do come and talk to us if you want to discuss the techniques,
Anna and Joanne (researchers)

Appendix E

Approval letter from the Research Ethics Committee

NHS
Health Research Authority

NRES Committee London - Camberwell St Giles
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 0117 3421391

03 July 2014
Amended and Reissued 04.07.14

Dr Aimee Spector
Clinical Psychologist/Lecturer
University College London
Department of Clinical, Educational and Health Psychology, UCL
Gower Street
London
WC1E 6BT

Dear Dr Spector

Study title:	**A Mindfulness-Based Group for People with Dementia in Care Homes: A Feasibility Pilot Study**
REC reference:	**14/LO/0581**
Protocol number:	**N/A**
IRAS project ID:	**144773**

Thank you for your letter of 19 May 2014, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

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 Assistant, Miss Elizabeth Hearn, nrescommittee.london-camberwellstgiles@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.

Mental Capacity Act 2005

The committee did not approve this research project for the purposes of the Mental Capacity Act

2005. The research may not be carried out on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

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

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System 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 approvals 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).

NHS
Health Research Authority

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

I can confirm that the committee has considered your application for SSI exemption for the proposed study. However the REC concluded that as you have stated in your response to their provisional opinion that you will not be including Adults lacking capacity in the proposed research Site Specific Assessment was not necessary.

Approved documents

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

Document	*Version*	*Date*
Covering letter on headed paper		19 May 2014
Covering letter on headed paper		21 March 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		26 July 2013
GP/consultant information sheets or letters	2	10 March 2014
Other [CV - Ms A Clarke]		
Other [Peer Review, Student 1]		23 October 2013
Other [CV - Dr L Royan]		
Other [Letter of Invitation, Letter to Care Homes]	1	09 February 2014
Other [Letter from Funder, A4C Student 1]		26 September 2012
Other [Peer Review, Student 2]		17 October 2013
Other [CV - Ms J Chan Mun Yean]		
Other [Letter from Funder, A4C Student 2]		26 September 2012
Other [CV - Dr A Spector]		
Participant consent form [Participant Consent]	1	09 February 2014
Participant consent form [Staff Consent Form]	1	09 February 2014
Participant information sheet (PIS) [Staff]	2	10 March 2014
Participant information sheet (PIS) [Participants]	2	10 March 2014
REC Application Form		24 March 2014
Research protocol or project proposal	3	06 June 2014
Response to Request for Further Information		19 May 2014
Response to Request for Further Information		11 June 2014
Summary CV for Chief Investigator (CI) [Anna Churcher Clarike]		01 April 2014
Summary, synopsis or diagram (flowchart) of protocol in non technical language	2	06 June 2014

Validated questionnaire [Perceived Stress Scale]		
Validated questionnaire [Mini Mental State Examination]		
Validated questionnaire [CAMS R]		
Validated questionnaire [Cornell Scale for Depression in Dementia]		
Validated questionnaire [RAID]		
Validated questionnaire [Quality of Life - AD]		
Validated questionnaire [Participant Rating Form]	1	10 March 2014
Validated questionnaire [Perceived Stress Scale 13 item b]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

14/LO/0581	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

NHS
Health Research Authority

[redacted]

Mr John Richardson
Chair

Email: nrescommittee.london-camberwellstgiles@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Ms Suzanne Emerton*

Appendix F

Information sheets and consents forms

Information sheet for care homes

Information sheet and consent form for residents

Information sheet and consent form for staff

Information sheet for General Practitioner

Information sheet for care homes

Research Department of Clinical,
Educational and Health Psychology

Department of Clinical, Educational and Health Psychology
University College London
Gower Street
London
WC1E 6BT
Phone: 020 7679 1897
Fax: 020 79161989

[Enter Name and Address of Recipient]

Research study: A Mindfulness-Based Group for People with Dementia in Care Homes

Dear [Enter Recipient's name],

We are writing to enquire whether your care home would be interested in taking part in a research project, which will go ahead subject to approval from a local NHS ethics committee, who are currently reviewing the proposed study. We are conducting this research as part of our clinical psychology training (doctoral level) at University College London (UCL).

There are a limited number of psychosocial interventions to support people with dementia. 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' can 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 which suggests mindfulness may be beneficial for older people with dementia. **This study aims to find out whether mindfulness training could help people with mild to moderate dementia in care homes to deal with the stresses and strains of everyday life.**

What would taking part in the research involve?

- We would be in touch or visit the care home to find out which residents would be suitable to participate in the study.
- We want to see if mindfulness training is better than usual care that people receive in care homes. Therefore, of the participants we recruit for the study, around half will be randomly allocated to a mindfulness-based group, and around half would receive their usual care.

- We would come to the care home to facilitate a mindfulness-based group there, twice a week over five weeks.
- Participants will be helped to fill out some questionnaires by an Assistant Psychologist prior to the first group session and after the final group session.
- We would like to invite a member of your staff team to attend the group themselves.
- In order to facilitate the group, we would need a quiet room with some chairs.

What are the benefits of taking part?

- A psychosocial group facilitated for FREE by trainee clinical psychologists may help care home residents develop new skills to deal with the stresses and strains of everyday life.
- A link to current research taking place at UCL, which may be positive for the development and profile of the care home.
- Provide an opportunity for staff themselves to be introduced to mindfulness techniques, which may be of direct benefit to them working in a busy and, at times, stressful environment. Previous research has shown this to have a positive impact on residents, and on staff's coping skills.

Thank you for taking the time to read the information set out here. Please contact us at the above address or via email: joanne.chan.12@ucl.ac.uk; anna.clarke.11@ucl.ac.uk to express your interest, or if you would like to discuss this further.

Yours sincerely,

Joanne Chan Mun Yean
Trainee Clinical Psychologist

Anna Churcher Clarke
Trainee Clinical Psychologist

Information sheet and consent form for residents

RESEARCH DEPARTMENT OF CLINICAL, EDUCATIONAL
AND HEALTH PSYCHOLOGY

PARTICIPANT INFORMATION SHEET

Study Title: A Mindfulness-Based Group for People with Memory Problems in Care Homes: 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 could help people with memory problems to deal with the stresses and strains of everyday life.

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 which 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: attention, mood, anxiety and stress levels, quality of life and thinking.

We want to see if mindfulness training is better than usual care that people receive in care homes. 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 which will not contain any personal information about you.

This study is a 'pilot'. This means it is a small scale study which 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 five-week course, and sessions take place twice a week, lasting for about 45 minutes each time. They will be run by Joanne Chan and Anna Churcher Clarke, who work as Trainee Clinical Psychologists. The sessions will involve a group of about 5-10 people with memory problems. During the sessions you will do activities like: gentle breathing, learning to focus on your body and touching textured materials, such as clay.

Why have I been invited to take part?

You have been invited to take part because you are considered to be experiencing memory problems.

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, stress levels, 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 twice-weekly mindfulness training sessions OR receive your usual care for five weeks.

- Meet with a researcher again to answer the same questions as before.

The researcher will also meet with a member of staff working at your care home who knows you well, and look through your personal file to help them complete some assessments about you. The mindfulness training sessions will be audio recorded and will be kept password protected.

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 10 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 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?

If you do decide to take part in the study, we hope that attending the sessions is a helpful and enjoyable experience, although we cannot promise this. Previous research into mindfulness suggests that people can experience greater awareness, acceptance, control, improved coping and enjoyment. 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 through 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 and your carers.** All documents that leave the care home will have your name removed with the exception of a consent form. Once the study has finished, University College London will keep the study data in a secure location.

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 care home'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.

Who is organising and funding the research?

The research is being organised and funded by University College London. The study will be conducted by Joanne Chan Mun Yean and Anna Churcher Clarke. **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, who is a Clinical Psychologist at UCL.

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 cleared by the Camberwell and St Giles NHS Research Ethics Committee.

Who can I contact for further information?

For more information about this research, please contact:

Joanne Chan and Anna Churcher Clarke

Department of Clinical, Educational and Health Psychology
UCL
Gower Street
WC1E 6BT
Email: joanne.chan.12@ucl.ac.uk; anna.clarke.11@ucl.ac.uk

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

Dr Will Mandy
Department of Clinical, Educational and Health Psychology
UCL
Gower Street
WC1E 6BT
Email: w.mandy@ucl.ac.uk

Or if you have any complaints about this study please contact:

Dr Aimee Spector
Department of Clinical, Educational and Health Psychology
UCL
Gower Street
WC1E 6BT
Email: a.spector@ucl.ac.uk
Tel: 0207 679 1844

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

RESEARCH DEPARTMENT OF CLINICAL, EDUCATIONAL
AND HEALTH PSYCHOLOGY

PARTICIPANT CONSENT FORM

Study Title: A Mindfulness-Based Group for People with Memory Problems in Care Homes: A Feasibility Pilot Study (Student Research Project)

Participant Number:
Name of Researchers:
Joanne Chan Mun Yean and Anna Churcher Clarke

	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 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

Information sheet and consent form for staff

RESEARCH DEPARTMENT OF CLINICAL, EDUCATIONAL AND HEALTH PSYCHOLOGY

STAFF INFORMATION SHEET

Study Title: A Mindfulness-Based Group for People with Dementia in Care Homes: 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 could help people with memory problems to deal with the stresses and strains of everyday life.

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' can 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 which 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: attention, mood, anxiety, stress levels, quality of life and thinking.

We want to see if mindfulness training is better than usual care that people receive in care homes. To do this half of the people that take part in the study will attend mindfulness sessions and half will receive usual care.

This study is a 'pilot'. This means it is a small scale study which 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 for people with memory problems?

Mindfulness training is a FREE five week course, and sessions take place twice a week, lasting for about 45 minutes each time. They will be run by Joanne Chan and Anna Churcher Clarke, who are Trainee Clinical Psychologists. The sessions will

involve a group of usually 5-10 people with memory problems. During the sessions, participants will do things like: gentle breathing, learning to focus on your body and touching textured materials, such as clay.

Why have I, as a staff member, been invited to take part?
You have been invited to take part because you know the residents in the care home, and therefore could assist the researchers in completing some assessments about the participants.

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.

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, you will be asked to meet with a researcher for around half an hour to answer questions about residents' mood, anxiety levels and quality of life. After the five-week course, you will be asked to meet with a researcher to answer the same questions as before.

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. 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 care home'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.

Who is organising and funding the research?
The research is being organised and funded by University College London. The study will be conducted by Joanne Chan Mun Yean and Anna Churcher Clarke. 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, who is a Clinical Psychologist at UCL.

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 cleared by the Camberwell and St Giles NHS Research Ethics Committee.

Who can I contact for further information?

For more information about this research, please contact:

Joanne Chan and Anna Churcher Clarke
Department of Clinical, Educational and Health Psychology
UCL
Gower Street
WC1E 6BT
Email: joanne.chan.12@ucl.ac.uk; anna.clarke.11@ucl.ac.uk

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

Dr Will Mandy
Department of Clinical, Educational and Health Psychology
UCL
Gower Street
WC1E 6BT
Email: w.mandy@ucl.ac.uk

Or if you have any complaints about this study please contact:

Dr Aimee Spector
Department of Clinical, Educational and Health Psychology
UCL
Gower Street
WC1E 6BT
Email: a.spector@ucl.ac.uk
Tel: 0207 679 1844

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

RESEARCH DEPARTMENT OF CLINICAL, EDUCATIONAL
AND HEALTH PSYCHOLOGY

CONSENT FORM FOR STAFF

Study Title: A Mindfulness-Based Group for People with Dementia in Care Homes: A Feasibility Pilot Study (Student Research Project)

Patient Number:
Name of Researchers: Joanne Chan Mun Yean and Anna Churcher Clarke

	Please initial boxes
➢ I confirm that I have read and understand the information sheet [insert version, insert date] 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 and there will be no detrimental effect on my employment.	
➢ I understand that all information given by me or about me will be treated as confidential by the research team (unless poor practice is discovered).	
➢ 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

Information sheet for General Practitioner

RESEARCH DEPARTMENT OF CLINICAL, EDUCATIONAL AND HEALTH PSYCHOLOGY

Department of Clinical, Educational and Health Psychology
University College London
Gower Street
London
WC1E 6BT
Phone: 020 7679 1897
Fax: 020 7916 1989

[Enter Name and Address of Recipient]

Dear [Enter Recipient's name]

GENERAL PRACTITIONER INFORMATION SHEET

Study Title: A Mindfulness-Based Group for People with Dementia in Care Homes: A Feasibility Pilot Study (Student Research Project)

……..(DOB) has been invited and consented to take part in a research study. Please let us know if there is anything that is not clear, or if you would like more information.

The study will be conducted by Joanne Chan Mun Yean and Anna Churcher Clarke. **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, who is a Clinical Psychologist at UCL.

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.

There is good evidence that such interventions improve emotional wellbeing and quality of life, and reduce stress, anxiety and depression in both clinical and non-clinical populations. However, the research on mindfulness for older people with varying levels of cognitive impairment is limited. This study is therefore designed to find out if people with mild to moderate dementia in care homes attending a

mindfulness-based group will experience improvements in their: levels of mindfulness, mood, anxiety, quality of life, stress and cognition.

This study is a randomised controlled trial. We want to see if our intervention is better than usual care that people receive in care homes. To do this, participants will be randomly allocated to an intervention group or a treatment as usual group.

The group sessions will last approximately one hour, and will occur twice-weekly over five weeks. Each group will consist of 5-10 participants with mild to moderate dementia. Sessions will be facilitated by Joanne and Anna in the participant's care home. Techniques will include modified meditation, relaxation, guided imagery and body awareness, with a multi-sensory element incorporated.

Participants will be assessed by an assistant psychologist prior to and immediately following the five-week intervention period. The assessment will take approximately an hour to complete and will use outcome measures looking at: levels of mindfulness, mood, anxiety, quality of life, stress and cognition.

The study will **not** affect your patient's current or future treatment.

The results of this study are expected to be published in relevant journals and at conferences. All interviews are confidential and will not be disclosed to anyone else unless there is a concern about risk to the participant or someone around them. **If this is the case, the researchers will discuss their concerns with the participant's care team.** The information collected in the study will be anonymous and patients will not be identified in any report/publication.

All proposals for research using human subjects are reviewed by the local Ethics Committee before they can proceed. The appropriate permission has been granted by the Camberwell and St Giles NHS Research Ethics Committee.

Thank you for reading this information sheet. Please do not hesitate to contact us at the above address or via email: joanne.chan.12@ucl.ac.uk; anna.clarke.11@ucl.ac.uk if you need any further information.

Yours sincerely,

Joanne Chan Mun Yean
Trainee Clinical Psychologist

Anna Churcher Clarke
Trainee Clinical Psychologist

Appendix G

Perceived Stress Scale (with participant)

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, you will be asked to indicate how often you felt or thought a certain way.

Although some of the questions are similar, there are differences between them and you should treat each one as a separate question.

The best approach is to answer each question fairly quickly. That is, don't try to count up the number of times you felt a particular way, but rather indicate the alternative that seems like a reasonable estimate.

0 = Never 1 = Almost Never 2 = Sometimes 3 = Fairly Often 4 = Very Often

		Rating
1.	In the last month, how often have you been upset because of something that happened unexpectedly?	
2.	In the last month, how often have you felt that you were unable to control the important things in your life?	
3.	In the last month, how often have you felt nervous and “stressed”?	
4.	In the last month, how often have you dealt successfully with irritating life hassles?	
5.	In the last month, how often have you felt that you were effectively coping with important changes that were occurring in your life?	
6.	In the last month, how often have you felt confident about your ability to handle your personal problems?	
7.	In the last month, how often have you felt that things were going your way?	
8.	In the last month, how often have you found that you could not cope with all the things that you had to do?	
9.	In the last month, how often have you been able to control irritations in your life?	
10.	In the last month, how often have you felt that you were on top of things?	
11.	In the last month, how often have you been angered because of things that happened that were outside of your control?	
12.	In the last month, how often have you been able to control the way you spend your time?	
13.	In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	

Total score: _____