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Mindfulness-Based Cognitive Therapy for Older People in a community setting: a mixed methods feasibility study

And Clinical Research Portfolio

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CHAPTER 1: SYSTEMATIC REVIEW

A systematic review and trial quality assessment of mindfulness based interventions for older people with mental health problems

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Abstract

Rationale: Mindfulness Based Interventions (MBIs) such as Mindfulness Based Cognitive Therapy (MBCT) are recommended for the treatment of recurring depression in working age adults but there is no similar recommendation for older people. There is an emerging literature base of MBIs for older people, however, there is currently no systematic review focusing on treatment outcome studies of MBIs for older people that recruit solely participants over 65 years.

Methods: A systematic search strategy included an electronic search of databases (PsychINFO (via EBSCOhost), CINAHL (via EBSCOhost), Embase (via Ovid) and Medline (via Ovid). A hand search of *Mindfulness* and *Aging and Mental Health* was also undertaken, as well as reviewing the references of included studies. Included studies were quality assessed using a critical appraisal tool. Data relevant to this review's aims was extracted and analysed for key similarities and differences.

Results: Nine quantitative articles were included in the review. The studies applied MBIs to a range of mental health problems. The majority were pilot/feasibility studies. Various outcome measures were used but most assessed symptom reduction following MBIs. Age related adaptations to treatment protocols were generally aimed at improving participant comfort and safety.

Conclusions: MBIs for older people has a small but emerging evidence base. There seems to be a need to adapt standard MBI protocols to meet the needs of older people but there is little consensus on what adaptations are required. Further research is needed to establishing meaningful outcomes and mechanisms of change that mediates treatment outcomes.

Keywords: Mindfulness, MBCT, older people, depression

Introduction

Mindfulness has been defined as “*the awareness that emerges through paying attention on purpose, in the present moment, and nonjudgmentally to the unfolding of experience moment by moment*” (Kabat-Zinn, 2003, p. 145). Research has demonstrated that mindfulness-based interventions (MBIs) are effective in various areas of health and psychological wellbeing, such as pain (Morone et al. 2008), prevention of relapse in major depression (Teasdale et al. 2000), and treatment of depression and anxiety in people with cancer (Cramer et al. 2012). Mindfulness-based Cognitive Therapy (MBCT; Segal et al. 2012) and Mindfulness-based Stress Reduction (MBSR) are two common group based MBIs applied within health care settings, which aim to develop skills to recognise mental states and use mindfulness skills to manage difficult experiences. The skills taught are derived from Buddhist practices but the groups are secular.

MBIs were initially designed and used to prevent relapse in recurrent depression. Teasdale et al. (2000) showed that MBCT significantly reduced the risk of relapse in participants who had 3 or more episodes of depression. The UK National Institute for Health and Care Excellence Guidelines (NICE 2009) recommend MBCT for treatment and management of depression in adults who are currently well but have experienced three or more episodes of depression and are at risk of relapse. The Psychological Therapies Matrix (NES 2015) also recommends MBCT for the treatment of relapsing depression in adults.

More recently, research has explored the effect of MBIs on current symptoms. Kenny and Williams (2007) reported that MBCT resulted in improved depression scores in people who were experiencing symptoms of depression at the time of the intervention. Arch et al. (2013) compared MBSR with CBT for veterans with active anxiety related diagnoses. They reported that Cognitive Behavioural Therapy (CBT) and MBSR both reduced symptom severity and whilst CBT was superior in reducing arousal levels, they concluded that MBSR might be superior at reducing associated worry.

MBIs are not currently recommended in clinical guidelines for older people with depression, including the recently published Psychological Therapies Matrix (NES 2015), despite being recommended for the adult population. It is likely that this reflects a lack of research evidence rather than a lack of efficacy. There has been an increase in publications in relation to MBIs for older people. Qualitative research of MBIs with older people suggests generally positive experiences. Smith et al. (2007) identified outcomes such as calmness, better coping and more acceptance following MBCT. Meeten et al. (2014) reported that whilst their participants gave positive feedback about MBCT, they did not feel confident in maintaining mindfulness practice post intervention. Quantitative research has also yielded positive outcomes. Splevins

et al. (2009) noted significant improvements in emotional wellbeing and mindfulness skills post-MBCT. Foulk et al. (2013) concluded that MBCT was acceptable to older people based on their recruitment and retention rate (74%) and found that participants reported less rumination, improved sleep and significantly fewer symptoms of anxiety.

Older people are susceptible to the same range of mental health problems that those under the age of 65 are. The Older People's Psychological Therapies Working Group (2011) reported that 13.5% of people over 65 years old have depression, with 40% of people living in care homes experiencing depression. In addition to this, they reported that between 10-14% of older people living in the community experience anxiety. Older people also live with long-term psychiatric symptoms that are not new to old age. Whilst they experience the same range of mental health problems as younger people, there are some issues unique to aging that impact on older people's mental health, such as increased in physical health problems (arthritis, pain, reduced mobility, respiratory problems), cognitive decline and social factors such as reduced social networks. It is well documented that the UK is facing a demographic shift with older people living longer; and therefore health services are required to be prepared to meet an increase in demand. For psychological services, this means being able to provide evidence-based interventions for a range of mental health problems experienced by older people.

Rationale for the Current Review

There is currently no systematic review and methodological quality evaluation of MBIs for older people using only participants 65 years or over. Geiger et al. (2015) published a similar review but their inclusion criteria for age was a mean age of 65 or over, which resulted in studies being included that used younger people as part of their sample. Nevertheless, Geiger et al. highlighted the need for greater understanding of the adaptations and modifications needed to effectively apply MBIs to older people. We will extend Geiger et al.'s review by conducting quality assessment with the Crowe Critical Appraisal Tool (CCAT, Crowe and Sheppard 2011) as well as describing and quantifying key implementation issues (Montgomery et al. 2013).

Aims

- 1) To describe what types of MBIs are being delivered to older people
- 2) To establish which psychological difficulties MBIs are being used to treat in older people
- 3) To identify and describe the outcome measures being used in trials

- 4) To identify and describe the types of adaptations being made to MBI protocols for older people
- 5) To assess the quality of the research papers included in the review

Method

This systematic review was conducted in accordance with the PRISMA guidelines (Liberati et al. 2009). A systematic search was conducted to identify relevant studies. Databases searched included PsychINFO (via EBSCOhost), CINAHL (via EBSCOhost), Embase (via Ovid) and Medline (via Ovid). Papers available up to the 26th of March 2016 were included. The following search terms were used: Mindfulness OR MBCT OR MBSR. Age limiters for 65 years and over were also applied to the search. Two key academic journals were identified for hand searching between the 2nd – 16th May 2016: *Mindfulness* and *Aging and Mental Health*. In *Mindfulness*, the search terms 'older people', 'older adults' and 'elderly' were used. In *Aging and Mental Health*, the term 'mindfulness'. Articles were eligible for inclusion if they detailed treatment studies (up to and including RCT) that delivered a MBI (MBSR, MBCT or another well described MBI) to older people (>65 years old), which used quantitative methods and were published in English, in a peer-reviewed journal. Articles were excluded if they used only components of mindfulness as part of a mind-body approach (yoga, tai chi), used only qualitative methods, were single case studies, or included any participants under 65 years old.

This search strategy applied to the 4 identified databases yielded 1852 papers. The hand search of academic journals yielded an additional 14 papers (4 from each journal). From the total of 1886 papers, 779 were identified as duplicates and removed. The remaining 1083 were screened against the inclusion/exclusion criteria via their title and abstract. This process excluded a further 1014 articles, leaving 69 articles for full review. Four authors were contacted to establish the age range of their sample. Following full review, 60 articles were excluded from the review. Details of reasons for exclusion are included in Figure I. The remaining 9 papers were included in this review. The references for the included studies were screened for any unidentified papers which met this reviews inclusion criteria. This search did not yield any new papers for inclusion.

Included studies were quality rated used the CCAT. The CCAT comprises of 8 sub-categories, which are scored then summed to give a total score that equates to a percentage in the CCAT user manual. The author, and an independent rater rated all papers independently before comparing scores for levels of agreement. Prior to starting the rating process, a threshold of 3 points in either direction was agreed as a

level of agreement in the overall quality rating (each paper could be awarded a maximum 40 points). The CCAT's comprehensive user guide was used by both raters to maximise inter-rater reliability.

Results

I) Overview of research design

Four of the studies were carried out in the USA (Morone et al. 2008; Morone et al. 2009; Lenze et al. 2014; Gallegos et al. 2013), 1 in Germany (Ernst et al. 2008), 1 in Denmark (O'Connor et al. 2013), 1 in China (Zhang et al. 2015), 1 in Australia (Helmes and Ward 2015) and 1 in the UK (Meeten et al. 2014).

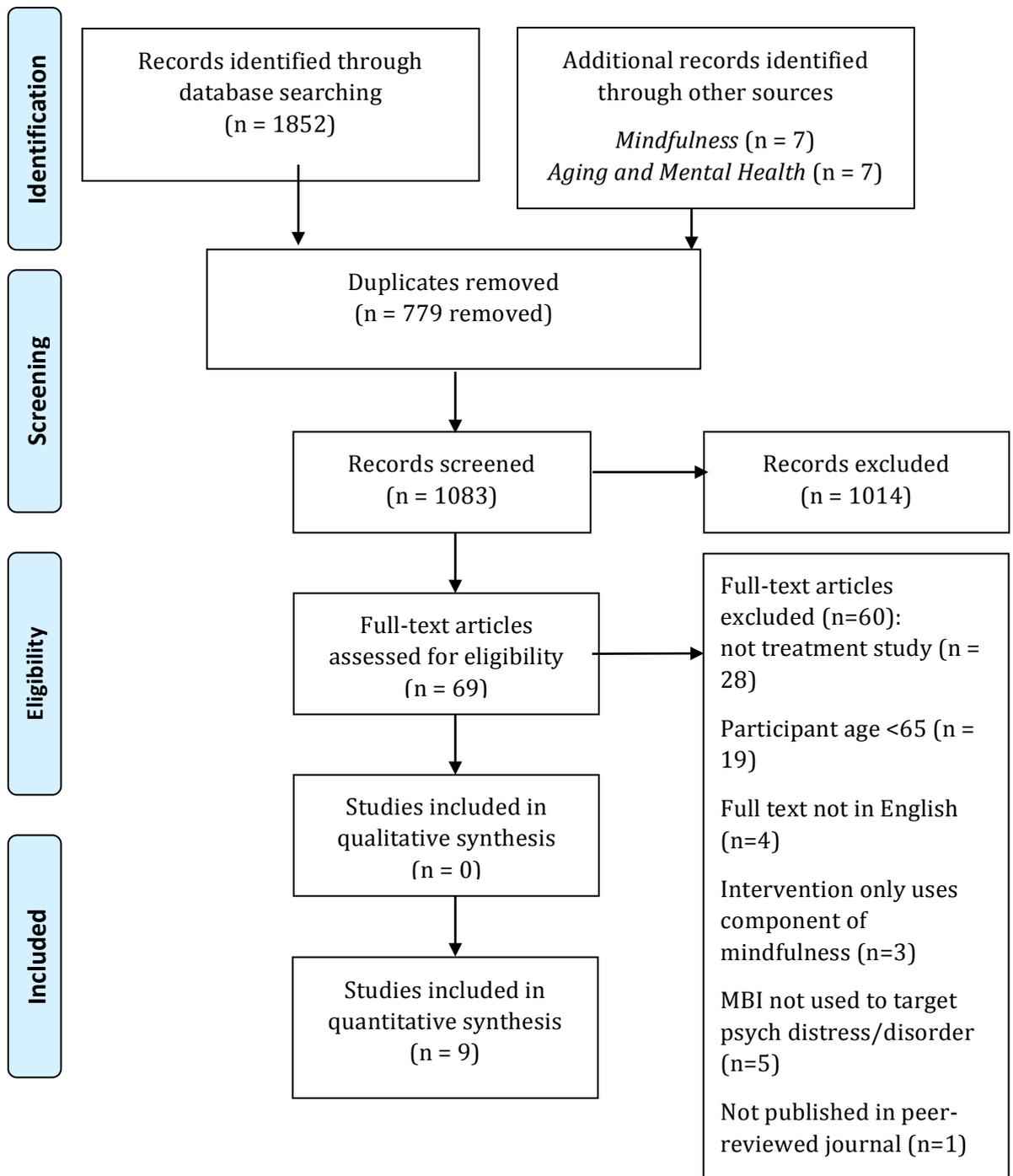
II) Sample Characteristics

The age range across age papers was 65-98 years, with sample sizes for treatment groups ranging from 12-100. Two studies combined sampling methods (Lenze et al. 2014; Zhang et al. 2015). For example, Zhang et al. (2015) recruited a community sample as well as a clinician referred sample. Four studies recruited community samples (Zhang et al. 2015; Morone et al. 2008; Morone et al. 2009; Gallegos et al. 2014), others recruited from nursing home residents (Helmes and Ward 2015; Ernst et al. 2008), outpatient psychiatric/mental health clinic (Meeten et al. 2014; Lenze et al. 2014; Zhang et al. 2015) and participants from previous studies (O'Connor et al. 2013; Lenze et al. 2014). Meeten et al. (2014) was the only study to exclusively recruit a sample from health service setting. Several studies used multiple recruitment methods, however the most common recruitment method was flyer or poster (Zhang et al. 2015; Morone et al. 2008; Morone et al. 2009; Ernst et al. 2008; Gallegos et al. 2013; Lenze et al. 2014; Helmes and Ward 2015). Other means of recruitment included information meetings (Helmes and Ward 2015; Ernst et al. 2008), clinician referral (Zhang et al. 2015, Meeten et al. 2013) and previous research samples (O'Connor et al. 2013; Lenze et al. 2014).

III) Design

Three studies were randomised controlled trials (Zhang et al. 2015; Gallegos et al. 2013; Helmes and Ward 2015). Two were randomised controlled pilot studies (Morone et al. 2009; Morone et al. 2008), two were non-randomised controlled pilot/feasibility studies (Ernst et al. 2008; O'Connor et al. 2013) and three were uncontrolled, non-randomised pilot/feasibility studies (Lenze et al. 2014; Meeten et al. 2014).

Figure I: PRISMA Flow Diagram of Study Selection



The majority of studies (n=7) included a control group (Zhang et al. 2015; Morone et al. 2008; Morone et al. 2009; Ernst et al. 2008; Gallegos et al. 2013; O'Connor et al. 2013, Helmes and Ward 2015). Four of these studies used waitlist control groups

(Morone et al. 2008; Gallegos et al. 2013; Zhang et al. 2015; O'Connor et al. 2013), one used an untreated control group (Ernst et al. 2008), one study used an education group (Morone et al. 2009) and another used a structured activity programme (Helmes and Ward 2015). Five of these studies used a process of randomization to allocate participants to either treatment or control group (Zhang et al. 2015; Morone et al. 2008, Morone et al. 2009, Gallegos et al. 2013; Helmes and Ward 2015). Five studies included a follow up post intervention (Meeten et al. 2014; Morone et al. 2008, Morone et al. 2009; Lenze et al. 2014; O'Connor et al. 2013; Helmes and Ward 2015). The follow-up periods ranged from 1 – 6 months.

IV) Type of MBIs being delivered

MBSR was used in 4 studies (Zhang et al. 2015; Ernst et al. 2008; Gallegos et al. 2013; Lenze et al. 2014). Three studies used MBCT (Helmes and Ward 2015; Meeten et al. 2014; O'Connor et al. 2013) and two studies used their own protocol based on MBSR or MBCT (Morone et al. 2008; Morone et al. 2009).

V) Treatment Targets

The inclusion criteria included treatment studies that were used to target psychological distress or wellbeing. Analysis of included studies revealed that there were a range treatment targets. All studies had more than one treatment target. The most common treatment target was depression (Gallegos et al. 2013, Zhang et al. 2015; Meeten et al. 2014; O'Connor et al. 2013). Meeten et al's treatment target was relapse prevention of depression and therefore only recruited participants who were in recovery from depression. Other treatment targets included anxiety (Zhang et al. 2015; Lenze et al. 2014; Helmes and Ward 2015), pain (Morone et al. 2008; Morone et al. 2009) and quality of life (Ernst et al. 2008; Morone et al. 2008; Helmes and Ward 2015). Two studies explored cognitive impairment co-occurring with psychological symptoms (Lenze et al. 2014; O'Connor et al. 2014). Less common treatment targets included positive affect (Gallegos et al. 2013), complicated grief (O'Connor et al. 2014), grief related post-traumatic stress (O'Connor et al. 2014), psychological wellbeing (Meeten et al. 2014), chronic insomnia (Zhang et al. 2015), physical functioning (Morone et al. 2008) and disability (Morone et al. 2009). Five studies explicitly recruited participants who were experiencing current symptoms of psychological distress (including insomnia and pain) (Morone et al. 2008; Morone et al. 2009; Zhang et al. 2015; O'Connor et al. 2013; Lenze et al. 2014).

VI) Key similarities between interventions

The majority of the studies gave at least a brief description of the key components of the intervention they delivered, with the exception of Meeten et al. (2014) and Ernst et

al. (2008) provided few details about the components of their intervention. Eight studies reported that the group facilitators were experienced mindfulness practitioners and teachers (Helmes and Ward 2015; Zhang et al 2015; Meeten et al. 2014; Morone et al. 2008; Morone et al. 2009, Ernst et al. 2008; O'Connor et al. 2013; Lenze et al. 2014). Two studies reported that the facilitators received supervision and recordings of their sessions were reviewed by their supervisor to ensure fidelity to the protocol (Helmes and Ward 2015; Lenze et al. 2014). The key similarities across interventions seemed to comprise of mindful movement (yoga or walking), sitting meditation and body scan (see Table II for full details). Fewer studies incorporated the use of informal meditation (Gallegos et al. 2013; Lenze et al. 2014). Some studies added unique components to their mindfulness protocol such as education about their treatment target (Morone et al. 2009; O'Connor et al. 2013), incorporation of attitudes of mindfulness such as acceptance, non-judging and non-striving (Morone et al. 2008) and group discussions (Helmes and Ward 2015), although the content of the discussions are unknown.

Table I: Summary of results

Author (Year)	Design	Sample	Treatment Target/ Measures*	Treatment delivered**	Adaptations	Results***
Ernst et al. (2008)	Non-randomised, controlled feasibility study, pre-post design	Nursing home residents aged 72-98 (mean 83.5)	Quality of life (SF-12), Depression (GDS), physical functioning (BI) visual analog scales for satisfaction with life, pain and major complaints	Modified 8-week MBSR vs untreated control group	Sessions shorted to 1.5hrs, reduced homework, no full-day retreat	Sig. reduction in GDS and improvement in SF-12 (physical health)
Gallegos et al. (2013)	RCT + 6 month follow up	Community sample aged >65 years (mean 72.8)	Depression (CES-D, HAM-D), positive affect (PANAS)	8-week MBSR vs waitlist control	Individual adaptations to accommodate physical, sensory and cognitive needs	Lower depression score + >70years was associated with greatest improvement in positive affect at 6 month follow up. High depression

						score + >70 years was associated with poorest outcomes
Helmes and Ward (2015)	RCT + 1 month follow up	Older adults in residential care anxiety, aged over 65 (mean 83.4)	Anxiety (GAI), Depression (MADS), Quality of life (WHOQOL-OLD), Mindfulness (MAAS)	Modified 8 week MBCT vs structured activity programme	Reduced 2 hr session to 1.5 hrs	Sig. improvement in all measures across 3 time points, except the GAI and WHOQOL-OLD at time 2:3
Lenze et al. (2014)	Non-randomised pilot study, pre-post +6month follow up	Community and clinician referred sample, aged >65 years (mean 71) with self-reported worry and subjective cognitive deficits	Anxiety (PSWQ-A), Cognitive functioning (subtests from RBANS, CVLT, D-KEFS), Mindfulness (MAAS, CAMS-R) Author devised acceptability survey	Standard 8-week MBSR vs extended 12-week MBSR	12-week MBSR included 4 extra sessions, reduced full day retreat (2.5hrs), repeated materials 3 times across course	Sig. reduced PSWQ-A for worry severity for 8 week group post treatment No advantage for 12 week MBSR for worry reduction
Meeten et al. (2014)	Uncontrolled, non-randomised Pilot/feasibility study, Pre-post + 6month follow up, mixed methods (qualitative results published elsewhere)	Clinical sample aged >65 years in recovery from recurrent depression or mild depression	Depression (DASS-21), Anxiety (DASS-21), Wellbeing (RPWI) Author devised feasibility survey	8 week MBCT	None reported	Sig. reduction in anxiety post course, sig. increase in 'purpose of life' scale (RQWI) High levels of satisfaction with course
Morone et al. (2008)	Pilot RCT + 3 month follow up,	Community sample, aged 65-84 (mean=74.9) with moderate intensity,	Pain intensity (SF-MPQ, SF-36 Pain Scale), Pain acceptance (CPAQ), quality of life	Modified 8-week MBSR vs waitlist control	Participants encouraged to change position if uncomfortable Excluded yoga	Treatment group improved CPAQ, activity engagement and physical function

		daily chronic lower back pain	(SF-36 Health Status Inventory), Physical Function (RMDQ)		(mindful movement)	when compared to control
Morone et al. (2009)	Pilot RCT + 4 month follow up	Community sample with lower back pain for > 3 months Aged >65 (Mean age 78)	Pain intensity (MPQ-SF, SF-36 Pain Scale) disability (RMDQ), self-efficacy, Quality of life (SF-36), Mindfulness (MAAS, FFMQ)	Modified 8 week MBSR vs health education control group	Participants encouraged to change position if uncomfortable	Both groups showed improvement, no sig. differences post treatment
O'Connor et al. (2013)	Non-randomised, controlled pilot study, pre-post with 5 month follow up	Older people aged 65-80 (mean 77) with bereavement and self-reported distress. Recruited from previous study	Depression (BDI), Complicated Grief (ICG-R, CES), Post-traumatic stress (related to bereavement) (HTQ), Working memory (number letter sequencing)	Modified 8-week MBCT vs waitlist control.	Reduced sessions from 2.5hrs to 2hrs, education about depression 2 booster sessions at 3 and 6 months post intervention	Sig. decrease in BDI scores across 3 time points for treatment group
Zhang et al. (2015)	RCT	Community and clinician referred sample, aged >75 years (mean 78.5)	Chronic Insomnia (PSQI), Depression (GDS), Anxiety (SAS)	8 week MBSR vs waitlist control	Excluded yoga (mindful movement)	No sig. difference found between groups

*BDI (Beck Depression Inventory), BI (Barthel Index), CAMS-R (Cognitive and Affective Mindfulness Scale – Revised), CES (Centrality of Events Scale), CES-D (Centre for Epidemiological Studies Depression Scale), CPAQ (Chronic Pain Acceptance Scale), CVLT (California Verbal Learning Test), D-KEFS (Delis-Kaplan Executive Functioning), DASS-21 (Depression, Anxiety and Stress Scale), FFMQ (Five Facet Mindfulness Questionnaire), GAI (Geriatric Anxiety Inventory), GDS (Geriatric Depression Scale), HAM-D (Hamilton Rating Scale for Depression), HTQ (Harvard Trauma Questionnaire), ICG-R (Inventory of Complicated Grief), MAAS (Mindfulness Attention and Awareness Scale), MADS (Montgomery and Asberg Depression Scale), PANAS (Positive and Negative Affect Scale), PSQI (Pittsburgh Sleep Quality Index), PSWQ (Penn State Worry Questionnaire), RBANS (Repeatable Battery for the Assessment of Neuropsychological Status), RMDQ (Roland Morris Disability Questionnaire), RPWI (Ryff Psychological Wellbeing Inventory), SAS (Self-Rating Anxiety Scale), SF-12 (General Health Survey – SF12), SF-36 (Health Status Inventory SF-36), SF-MPQ (McGill Pain Questionnaire – short form), WHOQOL-OLD (World Health Organisation Quality of Life for Older Adults) ** Key components of intervention are reported in Table II *** Only significant statistic results, and feasibility outcomes, are reported.

VII) Protocol Adaptations

Adaptations were variable between studies and there was little consensus on adaptations. Three studies reported shortening weekly sessions by 30 minutes (Ernst et al. 2008; O'Connor et al. 2013; Helmes and Ward 2015). Adaptations to the mindful movement exercises included making the movement less strenuous (Ernst et al. 2008) or excluding it completely (Zhang et al. 2015; Morone et al. 2008). Others encouraged participants to reposition themselves if they felt uncomfortable (Morone et al. 2008; Morone et al. 2009). Other adaptations included exclusion of the full day retreat (Ernst et al. 2008) or reduction of full day retreat to 2.5 hours (Lenze et al. 2014), repetition of material (Lenze et al. 2014) and reduced homework tasks (Ernst et al. 2008). The basis for these adaptations appear to be from the researchers understand of the needs of older people, such as reduced mobility, as opposed to any piloting or previous research. Not all studies provide a rationale for adapting their protocol. This would be helpful information for future studies.

Three studies reported adding in additional sessions, Lenze et al. (2014) delivered an additional 4 sessions as part of their protocol for one treatment group, O'Connor et al. (2013) included two booster sessions at three and six months' post intervention and Meeten et al. (2014) included three additional booster session at participant's request post intervention. Gallegos et al. (2013) reported that they tailored adaptations to meet individual needs of participants. Meeten et al. (2014) did not report any adaptations to their protocol out with the additional sessions.

VIII) Outcome measures

Similar to the treatment targets, the outcome measures were variable between studies and many studies used several outcome measures. This seemed mostly due to the varying treatment targets. When analysing the outcome measures used in the studies five main areas of outcome measures can be identified: mental health and wellbeing, physical functioning, mindfulness, cognitive functioning and acceptability.

i) Mental Health and Wellbeing

Mental health and wellbeing included depression (Ernst et al. 2008; Gallegos et al. 2013; Zhang et al. 2015; Meeten et al. 2014; Helmes and Ward 2015; O'Connor et al. 2013), anxiety (Zhang et al. 2015, Meeten et al. 2014; Helmes and Ward 2015; Lenze et al. 2014), wellbeing (Meeten et al. 2014; Ernst et al. 2008; Morone et al. 2008; Morone et al. 2009), grief and trauma (O'Connor et al. 2013), and chronic insomnia (Zhang et al. 2015). Within these categories, there were varying measures used to explore the same outcome. These measures were primarily used to measure symptom reduction

as an outcome measure. See Table II for a breakdown of measures used for each category.

Table II: Key Components of MBI Protocol

	Experienced facilitators	Supervision	Mindful Movement	Sitting Meditation	Body Scan	Informal meditation	Home work
Morone et al (2008)	✓		✓	✓	✓		✓
Morone et al (2009)	✓		✓	✓	✓		✓
Gallegos et al (2013)			✓	✓	✓	✓	
Zhang et al (2015)	✓		✓	✓	✓		✓
Helmes and Ward (2015)	✓	✓		✓	✓		
O'Connor et al (2013)	✓		✓	✓	✓		
Lenze et al (2014)	✓	✓	✓	✓		✓	✓
Meeten et al (2014)	✓						
Ernst et al (2008)	✓						✓

Note: An unchecked box does not represent that this component was missing from the protocol, but that it was not reported in the write up

i) Physical functioning

Three studies explored physical functioning alongside measures of psychological distress or wellbeing. The Roland and Morris Disability Questionnaire (Roland and Morris 1983) used by two studies (Morone et al. 2008; Morone et al. 2009) and one study (Ernst et al. 2008) used the Barthel Index (Mahoney and Barthel 1965).

ii) *Tests of cognitive functioning*

Two studies measured cognitive functioning co-occurring alongside a psychological symptom, one in relation to grief (O'Connor et al. 2013) and the other in relation to worry (Lenze et al. 2014). Lenze et al. included cognitive tests to examine the benefits of mindfulness on areas of cognition associated with generalised anxiety disorder in older people (memory and executive functioning). Similarly, O'Connor et al. included cognitive tests to examine the effects on working memory in their sample. Cognitive tests included subtests from the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) (Lenze et al. 2014), California Verbal Learning Test (CVLT) (Lenze et al. 2014), subtests from the Delis-Kaplan Executive Function System (DKEFS) (Lenze et al. 2014) and number letter sequencing (O'Connor et al. 2013).

Table III: Mental Health and Wellbeing measures used in included studies

Area	Measure	Studies that used measure
Depression	<i>Centre for epidemiological studies depression scale (CES-D)</i>	1; (Gallegos et al. 2013)
	<i>Beck Depression Inventory (BDI)</i>	1; (O'Connor et al. 2013)
	<i>Geriatric Depression Scale (GDS)</i>	2; (Ernst et al. 2008; Zhang et al. 2015)
	<i>Hamilton Rating Scale for depression (HAM-D)</i>	1; (Gallegos et al. 2013)
	<i>Depression, Anxiety and Stress Scale (DASS-21)</i>	1; (Meeten et al. 2014)
Well-being	<i>Ryff Psychological Wellbeing Inventory (RPWI)</i>	1; (Meeten et al. 2014)
	<i>Montgomery and Asberg Depression Scale (MADS)</i>	1; (Helmes and Ward 2015)
	<i>SF-12 General Health Survey (SF-12)</i>	1; (Ernst et al. 2008)
	<i>SF-36 Health Status Inventory (SF-36)</i>	2; (Morone et al. 2008; 2009)
	<i>Positive Affect Scale (from PANAS)</i>	1; (Gallegos et al. 2013)
Pain	<i>Chronic Pain Acceptance Scale (CPAQ)</i>	1; (Morone et al. 2009)
	<i>McGill Pain Questionnaire-Short Form (SF-MPQ)</i>	2; (Morone et al. 2008; 2009)
Grief and Trauma	<i>The Inventory of Complicated Grief (ICG-R)</i>	1; (O'Connor et al. 2013)
	<i>Centrality of events scale (CES)</i>	1; (O'Connor et al. 2013)
	<i>Harvard Trauma Questionnaire (HTQ)</i>	1; (O'Connor et al. 2013)
Anxiety and Worry	<i>Self-rating anxiety scale (SAS)</i>	1; (Zhang et al. 2015)
	<i>Depression, Anxiety and Stress Scale (DASS-21)</i>	1; (Meeten et al. 2014)
	<i>Geriatric Anxiety Inventory (GAI)</i>	1; (Helmes and Ward 2015)
	<i>Penn State Worry Questionnaire (PSWQ)</i>	1; (Lenze et al. 2014)

Sleep	<i>Pittsburgh Sleep Quality Index (PSQI)</i>	1; (Zhang et al. 2015)
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i) Mindfulness measures

Three studies incorporated a measure of mindfulness to examine mindfulness pre and post intervention (Lenze et al. 2014; Morone et al. 2009; Helmes and Ward 2015). Three measures of mindfulness were used. One study (Morone et al. 2009) used the Five Facet Mindfulness Questionnaire (FFMQ; Baer et al. 2006), one (Lenze et al. 2014) used the Cognitive and Affective Mindfulness Scale – Revised (CAMS-R; Feldman et al. 2007). All three used the Mindfulness Attention and Awareness Scale (MAAS; Brown and Ryan 2003).

ii) Acceptability questionnaire

As part of a feasibility approach, two studies included a questionnaire about the acceptability of their intervention (Meeten et al. 2014; Lenze et al. 2014). Both studies devised their own questionnaire for this purpose, which was tailored to questions they wanted to answer.

iii) Quality Ratings

Two raters reviewed each paper using the CCAT as detailed in the method section. Two papers (22.2%) had a perfect agreement score. Five papers (55.6%) reached the pre-determined level agreement. Two papers (22.2%) did not meet the level of agreement but disagreement in scores was resolved through discussion guided by the CCAT. The level of disagreement ranged from 4-8 points. The highest rated studies (Morone et al. 2008; 2009) were RCTs with robust methods (randomisation and control group), and they provided detailed description of the intervention they provided both for their experimental arm and control group. The lower scoring studies, such as Lenze et al. (2014) was scored lower due to issues around data collection and switching of measures between groups. This led to unclear and incomparable results between groups. See Table IV for rating details.

Table IV: CCAT Quality Rating Scores

	Overall Rating (max=40)	% score	Preliminaries	Intro	Design	Sample	Data Collection	Ethics	Results	Discussion
Morone et al. (2008)	35	88	5	5	4	4	4	4	4	5
Morone et al. (2009)	35	88	5	5	4	4	4	4	4	5
O'Connor et al. (2013)	32	80	4	5	3	3	4	3	5	5
Gallegos et al. (2013)	29	73	4	5	4	3	4	0	4	5
Helmes and Ward (2015)	29	73	4	4	4	4	3	2	4	4
Zhang et al. (2015)	29	73	4	4	3	3	4	4	4	3
Ernst et al. (2014)	28	70	4	4	3	3	2	3	4	5
Meeten et al. (2014)	28	70	3	4	3	3	4	3	4	4
Lenze et al. (2014)	25	63	4	4	2	4	1	4	2	4

Discussion

This systematic review aimed to address a gap in the literature by reviewing MBI treatment studies for people aged over 65. The review aimed to describe what MBIs are being delivered to older people, and for what psychological difficulties, what outcome measures are being used to evaluate these interventions and what adaptations are being made, as well as assessing the quality of the research.

Measuring Outcomes of MBIs

The results showed that primarily MBSR and MBCT were applied to a wide range of treatment targets for older people including depression, psychological wellbeing, pain, grief and trauma, anxiety and chronic insomnia. Given the wide range of treatment targets, there was also a wide range of outcome measures used as they tended to coincide with the treatment target. Pooling together the measures used highlighted that there was little consensus between studies on what outcomes should be used in mindfulness research. Interestingly only three studies included a measure of mindfulness in their outcome measures. The variability in outcome measures may serve to highlight the wider issue of knowing how to accurately capture the true outcomes of MBIs. Providing an evidence based treatment is often inferred from achieving a meaningful reduction in symptomology (Baer 2011) but more recently there has been more attention given to examine mechanisms of change in order to understand how treatments work. Kuyken et al. (2010) reported that increased mindfulness skills throughout MBCT mediated the effect on depressive symptoms. Kuyken et al. highlighted that exploring mechanisms of change will improve knowledge of how the treatment works and potentially allow clinicians to improve the efficacy of the treatment by emphasising the identified mechanisms during the intervention.

Given that the outcome measures within the included studies focus on the treatment target, it seems that research in this area is evaluating MBIs based on symptom reduction. A wider issue is to consider what meaningful outcomes would be for the patients who will receive the intervention. INVOLVE (2012) state that public and patient involvement in research can provide a better understanding of what outcome are important to public and patients. Meeten et al. (2014) was the only study to make reference to involving service users in the development of their study. Perhaps more public and patient involvement in MBI intervention is something that would enhance the current evidence base and intervention development.

Adaptations

Eight studies reported adapting their MBI protocol to meet the needs of their participants. The adaptations varied from shortened sessions to reduction or exclusion of mindful movement. Whilst there was little consensus on the adaptations for MBIs for older people, it was evident from the studies that the participants' physical safety and comfort was at the root of these adaptations. With the majority of studies making adaptations, it suggests that clinicians and researchers believe there is a need to adapt the standard MBI protocol to meet the needs of older people who may present with more physical, or cognitive difficulties than younger people. It seems more difficult to establish standard adaptations, which is fitting with the varying needs of older people. The age range of participants across studies ranged from 65-98 years which does present a challenge in making adaptations to a protocol that will suit all across this age range. Gallegos et al. (2013) reported making adaptations on an individual basis, which would be the most reasonable adjustment if the age range of the group is large.

Quality

The quality of the research included in this review was of a satisfactory standard. Each study came with its own strengths and weaknesses. Lower quality grading's were mostly due to lack of information in trial reporting (e.g. omitting information about the validity or reliability of measures, not detailing the treatment protocol). There appeared to be lack of clear reporting of the MBI protocol used which is important in being clear about the key components of an intervention. This also improves replicability of studies, which is important at this stage of intervention development of MBIs for older people.

Strengths and Limitations

This review is the first to include treatment studies of MBIs for older people that exclusively recruit people over the age of 65, whilst evaluating the quality of the research. Research using only older people is important to gain an accurate understanding of MBIs for older people, including the feasibility, acceptability and outcomes of the intervention. Results from this research may be inform service delivery such as the consideration of ageless services and whether older people respond to the same treatment protocol as younger people or adaptations are required in line with developmental needs.

A limitation of this review is that it offers no findings on the outcomes of MBIs for older people. Whilst this was never the intention of the study, the heterogeneity of most of the studies would have rendered this unachievable. This study was more interested in the similarities in differences in the research methods and interventions

associated with such studies as opposed to outcomes. This is with a view to considering a standardised approach to MBI's for older people.

Areas of future research

There is evidence to suggest that MBIs for older people are worthy of further empirical investigation. Within the context of an aging population, further research into acceptable and effective interventions seems necessary. The majority of studies included in this review are still within the pilot/feasibility stages of intervention development, however there are areas of future research that would contribute to a better understanding of MBIs when delivered to older people.

The studies in this review primarily used symptom reduction as a measure of treatment outcome. Further research is needed to better understand what meaningful outcomes would be for older people. For example, it may be more important to older people to see improvements in quality of life or perceived independence rather than a reduction in their symptoms of depression. Further information about this will allow for a clear assessment of whether MBIs can effect this change.

Furthermore, there is need to improve understanding of underlying mechanisms of change in MBIs for older people, that may mediate treatment outcomes. By incorporating a measure of mindfulness in addition to clinical measures, this may be possible. The studies in this review highlighted the wide range of treatment targets the MBIs for older people. It is reasonable to question whether MBIs can really treat all problems from pain to recurrent depression. To help make sense of this, knowing the active ingredients and mechanisms of change is important as these may map onto the underlying components of various mental health problems.

Conclusion

The nine studies included in this review highlight that research exploring MBIs for older people is emerging, feasible and worthy of further research in order to enhance the development of MBIs for older people. Analysis of the included studies demonstrated that MBIs are being used to treat a range of mental health problems. The outcomes measures used indicate that the majority of researchers are evaluating MBIs based on a reduction in symptomology as opposed to examining the mechanisms of change in mindfulness. Further research is required to understand meaningful outcomes for older people using the intervention, as well as the mechanisms of change of MBIs to better understand the active ingredients of the intervention. There is consensus that MBIs for older people require adaptation from standard protocol to

improve the comfort and safety of participants but there is little consensus on the best way to adapt the intervention.

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CHAPTER TWO: MAJOR RESEARCH PROJECT

Mindfulness-Based Cognitive Therapy for Older People in a community setting: a mixed methods feasibility study

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Plain English Summary

Title

Mindfulness-Based Cognitive Therapy for Older People living in community settings: a mixed methods feasibility study

Background

Mindfulness-Based Cognitive Therapy (MBCT) is a group-based treatment that has been developed from Buddhist practices but is non-religious. MBCT was originally developed for people who have experienced depression more than three times (Segal et al. 2002). It aims to help people become more aware their own thoughts and feelings. MBCT has been recognised as an effective treatment for depression and is recommended for recurrent depression in working age adults (NES 2015). There is limited but promising research into MBCT for older people.

Aims and Questions

This research explored whether it is possible to deliver MBCT to older people and whether older people find it an acceptable intervention. The research also looked at what changes occurred during MBCT to improve symptoms of depression.

Methods

Participants: People who are 65 years old or over living in Lanarkshire, who have a history of depression and currently have some symptoms of depression were invited to take part in the study. **Recruitment:** NHS staff working in Old Age Psychiatry teams identified potential participants. Participants were given an information pack and if they wanted to take part then the staff member let the researcher know. **Consent:** When the participant had read the information and had any questions answered, they were asked to sign a consent form. **Design of Study:** Participants attended one 2-hour session per week, for 8 weeks. They were invited to attend a semi-structured interview after the group had finished to share their experience of the group. **Data Collection:** Participants completed questionnaires at the start, middle and end of the group. The interviews were recorded and typed up word for word, with all identifiable information removed. The recordings were then destroyed. The typed information was stored in accordance with NHS Lanarkshire Data Protection Policy.

Key ethical issues – Confidentiality was discussed at the start of the groups, including limitations of confidentiality. Participants were made aware that they can leave the group at any point.

Results

Six participants completed the MBCT group. The results indicated that MBCT is feasible to deliver, and is acceptable to older people experiencing symptoms of depression. Participants reported they felt more able to cope with their symptoms of depression and also enjoyed the benefits from being part of a group and sharing the experience with others.

Conclusions: Delivering MBCT to older people is both feasible and acceptable. Further research is needed to understand what people receiving MBCT would feel would be a good outcome of the treatment e.g. improved quality of life or a reduction in their symptoms of depression.

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Abstract

Rationale: In line with complex intervention development, this research takes a systematic approach to examining the feasibility and acceptability of delivering Mindfulness-Based Cognitive Therapy (MBCT) to older people who experience symptoms of depression.

Methods: A mixed methods approach was adopted in line with recommendations made by the MRC Complex Intervention Development framework. Quantitative and qualitative methods were combined by administering questionnaires as well as conducting post intervention interviews. A number of trial feasibility factors were examined such as recruitment and attrition rates. Qualitative data was analysed using Braun and Clarke's thematic analysis framework.

Results: Nine participants started the MBCT intervention and six completed the 8-week programme. The results suggest that MBCT for older people is feasible and acceptable. Participants reported improved mindfulness skills. Participants responded positively to being asked to take part in research and appeared to particularly value the group delivery format of the intervention.

Conclusions: MBCT is both feasible and acceptable for older people experiencing symptoms of depression. Further research is needed to examine the potential barriers of referring participants to research studies in order to inform recruitment methods for future trials. Further research is required in identifying meaningful outcomes for people who receive MBCT.

Keywords: Mindfulness-Based Cognitive Therapy, MBCT, Older People, Depression

Introduction

Complex interventions are commonly used in healthcare settings to influence behaviour change (Moore et al. 2015) and are defined as interventions “...with several interacting components” (Craig et al. 2008). The Medical Research Council (MRC) Complex Intervention Framework (Craig et al. 2008) specifies four key stages to complex intervention development: Development, Feasibility/Piloting, Evaluation and Implementation and emphasises the importance of reporting findings at each stage of development. Lancaster (2015) reported that many pilot and feasibility studies have remained unpublished despite the findings of these studies being crucial to the success of a future trial. Lancaster et al. (2002) highlighted that pilot and feasibility studies can inform sample size calculations, and test integrity to study protocol, data collection methods, recruitment procedures and determine the acceptability of intervention.

Whilst Craig et al. (2008) recommended “wherever possible, evidence should be combined from a variety of sources that do not share the same weaknesses” suggesting that mixed methods would be beneficial during the pilot/feasibility stage of development; there was a lack of guidance on how to incorporate this within the research. Subsequently, Moore et al. (2015) published guidance on process evaluation. These guidelines highlighted that whilst randomised controlled trials are deemed “gold standard”, they have limited scope to provide policy makers and stakeholders vital information about how an intervention might be delivered in their service, or if the same outcomes would be achieved, suggesting that process evaluations may be valuable in answering some of these questions. Moore et al. (2015) argued that process evaluation “can help understand how interventions work in practice and are vital in building an evidence base that informs policy and practice” (p. 1). Farquhar et al. (2011) reported that at policy level, there has been an increased emphasis on understanding, and improving the patient experience of health services. Incorporating patient views into the development of complex interventions would be beneficial in order for them to help shape a service that they will use. Qualitative results often give insights in to the subjective experience of the intervention, including the impact it has had on symptoms. This data can be used to generate hypotheses of possible outcome measures, or mechanisms of change from the intervention (Farquhar et al. 2011).

Mindfulness Based Interventions (MBIs) such as Mindfulness Based Cognitive Therapy (MBCT) are complex interventions increasingly used to treat various mental health problems. MBCT is recommended for the treatment of recurrent depression in working age adults (NICE 2009; NES 2015) but the same recommendation does not exist for older people. This is likely to reflect a lack of empirical evidence for the effectiveness of MBCT in older people. The systematic literature review in the previous chapter provided an overview of 9 studies that evaluated MBIs for older people. The review concluded that MBIs, including MBCT were applied to a wide range of mental health problems in older people including depression, anxiety, worry, bereavement,

pain and insomnia. Six of the studies included in the review were feasibility/pilot studies which emphasises the early stage of development of MBIs for older people. Given that the development MBIs for older people is still in its infancy, a thorough and systematic approach is required. This study has been designed using the frameworks and literature presented above in order to test the feasibility of MBCT for older people but also understand their experience of the intervention and incorporate this into future research.

In the literature review in the previous chapter, the majority of studies used outcome measures which explored symptom reduction as a result of MBIs. There is an expanding literature base on the mechanisms of change in MBIs. One area of exploration that this research will include is distress tolerance. Lotan et al. (2013) reported that as mindfulness skills increased, their participants reported increased distress tolerance. Rumination is another area of exploration. Brennan et al. (2015) recently reported that negative rumination style plus low mindfulness ability increased the likelihood, and duration of depressive symptoms. This research will include measures which may help understand the mechanisms of change as a result of MBIs.

Rationale

This research takes a systematic, mixed methods approach to examining the feasibility and acceptability of delivering MBCT to older people in line with complex intervention development. This study will add to the current evidence base by providing information on the feasibility of delivering MBCT to older people in a community mental health setting.

Research Aims

1. To explore the feasibility and acceptability of delivering MBCT groups to older people
2. To explore the acceptability of outcome measures
3. To estimate the likely rates of recruitment and retention of participants for future trials
4. To generate data for effect size estimation for subsequent trials
5. To explore possible mechanisms of change involved in MBIs

Method

Design

A mixed methods feasibility design is utilised, drawing on the feasibility/pilot stage of the MRC Complex Intervention framework cycle (Craig et al. 2008). No control group is included in this study as the primary focus was on gathering feasibility information within a health setting as opposed to determining efficacy of the intervention.

Participants

Participants were eligible for inclusion if they were aged 65 years old or over, living in the community, had a history of depression and subjectively reported current symptoms of depression such as low mood, lack of motivation or poor concentration. Exclusion criteria included known cognitive impairment, known learning disability or current psychosis.

Sample Size

Due to the feasibility nature of this study, no formal sample size was calculated. Consideration was given to the group size, with an upper limit of 12, based on the recommendation by Segal et al. (2002). This was a clinical guideline as opposed to a research consideration.

Procedure

i. Ethical Approval

Ethical approval (REFERENCE: 15/WS/0285) was granted by West of Scotland Ethics Committee 3 in December 2015, and approved by NHS Lanarkshire Research and Development 15th January 2016. Written informed consent was given by all participants.

ii. Recruitment

Recruitment began in January 2016. Staff working within NHS Lanarkshire Old Age Psychiatry, including community psychiatric nurses, psychiatrists, psychologists, clinical associate in applied psychology (CAAP's) and nurse therapists, were advised of the study via multi-disciplinary team meetings and email reminders. Clinician information packs were disseminated to staff, as well as participant information packs to distribute to patients on their caseload that met the inclusion/exclusion criteria. Staff contacted the researchers to pass on the details of potential participants who had expressed interest in the study. The researcher made contact with all potential participant to arrange an information meeting with them, where participants could ask questions, give written informed consent and complete the pre-intervention measures if appropriate, or had the choice to consider their participation and arrange a further appointment with the researcher.

iii. MBCT Protocol

The groups followed the NHS Education for Scotland (NES) approved MBCT protocol, which is based on the work of Teasdale et al. (2014). The protocol comprised of a weekly theme, experiential mindfulness practices (body scan, mindful eating, sitting meditation, mindful movement) and homework tasks (see Appendix 2.1 for weekly session outline). Prior to commencing, the protocol was reviewed and adaptations were considered to allow all participants to take part comfortably. Minor adaptations included allowing participants to do mindful stretching seated rather than on the floor and encouraging participants to move if uncomfortable (see Appendix 2.2) Consultation on the impact of these adaptations on the integrity of the protocol was sought from an experienced mindfulness practitioner independent from this study. Two groups were run in succession. Each group ran for 8 weeks, with a 2-hour session occurring weekly. Participants were given session handouts. The same facilitators ran both groups. One facilitator is a qualified Clinical Psychologist with experience working with older people and has additional training in mindfulness, meeting the facilitator criteria set out by Segal et al. (2002). The other facilitator (the author) was a Trainee Clinical Psychologist.

iv. Data Collection

Pre-intervention measures (all measures) were completed with the researcher. At session 4, participants were given 3 mid-intervention measures (Rumination Response Scale (RRS), Acceptance and Action Questionnaire (AAQ-II) and Five Facet Mindfulness Questionnaire (FFMQ) and asked to return them completed at the next session. Time was given at the end of session 8 for participants to complete post-intervention measures (all measures), the researchers were in the room but did not offer assistance unless it was requested. Participants also completed a satisfaction questionnaire devised specifically for this research to assess acceptability of the intervention. Following the intervention, participants were asked to opt in to take part in qualitative interviews. Interviews were transcribed and anonymised, and recordings were deleted.

Measures

Geriatric Depression Scale – Short Form (Yesavage and Sheikh 1986) is a 15 item self-report measure of depression for older people. Higher scores indicate greater levels of depression. D’Ath et al. (1994) reported that GDS-sf had an internal consistency of $=.80$ within their sample.

Apathy Evaluation Scale (Marin et al. 1991) is an 18 item self-report measure of apathy. Higher scores indicate greater levels apathy. The authors reported that the internal consistency was $\alpha=.86-.94$ and test-retest reliability (over 25.4 days) of $.76-.94$.

Temporal Experience of Pleasure Scale (TEPS, Gard et al. 2006) is an 18 item self-report measure designed to capture the anticipatory and consummatory facets of pleasure. Lower scores indicate higher levels of anhedonia. The authors report good internal consistency Cronbach's α of $.79$, $.74$, and $.71$ for the total scale, anticipatory scale, and consummatory scale, respectively. Gard et al. also reported high levels of test-retest reliability for the total scale, anticipatory scale and consummatory scale at $r=.81$ ($p<.001$), $.80$ ($p<.001$), $.75$ ($p<.001$).

Five Facet Mindfulness Questionnaire (FFMQ, Baer et al. 2006) is a 39 item measure of mindfulness consisting of 5 subscales (observing, describing, acting with awareness, non-judging and non-reacting). The authors reported good internal consistency ($\alpha = .75-.91$) and test-retest reliability ($r = .65-.83$).

The Acceptance and Action questionnaire (AAQ-II, Bond et al. 2011) is a 7 item, self-rated, single factor measure of psychological inflexibility. Greater scores indicate high levels of psychological inflexibility. The authors reported good psychometric properties, $\alpha=0.84$, and a 3- and 12-month test-retest reliability of 0.81 and 0.79 respectively.

Distress Tolerance Scale (DTS, Simons and Gaher 2005) measures distress tolerance in a multidimensional framework. The authors reported that scale has good psychometric properties, including high internal consistency ($=.89$) and has demonstrated adequate 6-month test-retest reliability ($r=.61$).

Ruminative Response Scale (RRS, Traynor et al. 2003) is a 22-item, self-report measure of rumination. Higher scores indicate greater levels of rumination. Brennan et al. (2015) report that the internal consistency of the RRS in their sample was $\alpha=.86$ for depression-related rumination, $\alpha=.68$ for brooding, and $\alpha=.73$ for reflection.

Results

Feasibility

Sample Characteristics

Two groups were delivered. In total nine participants opted into the study, 4 opted into the first group and 5 opted into the second group. Four were male (44.4%) and 5 were female (55.6%). They had a mean age of 70.33 (SD 3.96). All participants reported subjective symptoms of low mood, and six describing co-morbid symptoms of anxiety. All participants were taking medication associated with their mental health, 7 (77.8%) received input from a CPN and were reviewed by a Psychiatrist, and 4 (44.4%) were receiving psychological interventions. The majority (77.8%) of participants had no previous experience of mindfulness, 1 (11.1%) had been referred to a low-intensity, mobile phone application that teaches mindfulness skills by their GP and another one (11.1%) had been previously listened to a mindfulness CD that had been provided by a clinician.

Table I: Sample Characteristics (age/gender)

	Gender		Total (n=9)
	Male (n=4)	Female (n=5)	
Mean age in years (SD)	70.55 (3.86)	70 (4.47)	70.33 (3.96)
Age Range (years)	67-76	67-77	67-77

Table II: Sample Characteristics (current treatment)

	Current treatment			
	Medication	CPN input	Psychiatry review	Psychological Intervention
N (%)	9 (100)	7 (77.8)	7 (77.8)	4 (44.4)

Recruitment period

The recruitment period was 3 weeks and 5 weeks for the first and second group respectively. Twenty clinician information packs were distributed between 3 teams and each clinician was given at least one participant information sheet and additional copies were left within their teams. A total of 20 potential participants were referred to the study, which resulted in 9 participants consenting to take part. Overall, there

was a 45% attrition rate from referral to information appointment and 18.2% attrition rate from information appointment to opt-in. See Figure I for details of participant flow, including reasons for not consenting.

Referral patterns

Referrals were received from Psychologists (n=4, 20%), and CPN's (n=16, 80%). Of those who opted in to the study, 3 (33.3%) were referred from Psychologists and 6 (66.7%) were from CPN's. No referrals were received from Psychiatrists.

Attendance rates

Of the 9 participants who started that group, 3 (33.3%) attended all 8 sessions as per protocol, 2 (22.2%) attended 7 sessions, 1 (11.1%) attended 6 sessions, 1 (11.1%) attended 5 sessions, 1 (11.1%) attended 3 sessions and 1 (11.1%) attended 1 session. When a missed session occurred, session handouts were provided at the next session and there was time to ask the facilitators about the material if required. In a planned absence, handouts were provided prior to the session and homework details were given.

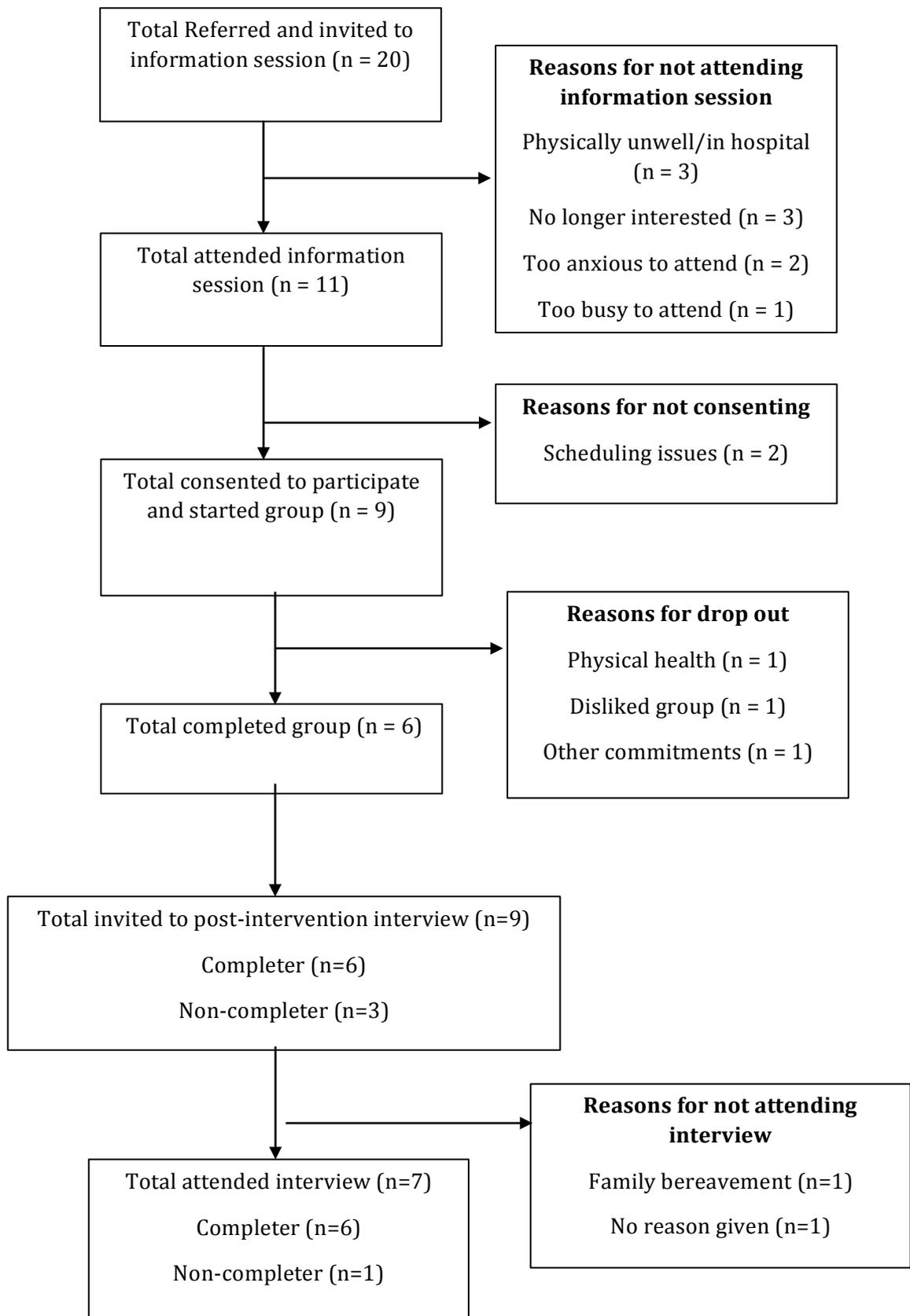
Reasons for non-attendance

Reasons given for non-attendances included hospital appointments, other family commitments or forgetting about the session. One participant was employed on a voluntary basis and therefore had 3 planned absences from the group of which the researchers were notified about at recruitment.

Completion rates

Of the 9 who opted in to the study, all started the group. One participant dropped out after session 1 due to disliking the group, another dropped out before session 4 due to poor physical health and 1 more dropped out between session 4 and 8 due to other commitments (see figure I). In the first group, there were two completers (50%), and in the second group there were 4 completers (66.7%). Combining both groups, there was a 66.7% completion rate. Completion was defined as completing at least 5 sessions including the last session where post-intervention measures were included.

Figure I: Participant Flowchart



Completion rates of questionnaires

The majority of questionnaires had an excellent completion rate at all time points (see Table III). The questionnaires with the poorest completion rates were the TEPS and the FFMQ.

TEPS - At time point 1, 4 participants (44.4%) did not respond to at least 1 item on the TEPS, three participants did not respond to 2 items (5.12%), and one did not respond to 1 item (2.5%). At time point 2, 2 participants (22.2%) did not respond to at least one question. One participant did not respond to 4 (10.25%) out of 39 items and the other did not respond to 1 item (2.5%).

Analysis of individual responses on the TEPS revealed that two questions were not completed by multiple participants:

Q5. I love it when people play with my hair

This question was not completed by 3 out of 9 participants (33.3%, 2 males, 1 female) at time point 1. At time point 3, the question was not completed by 1 participant, the other two participants who had previously missed the item at time point 1, had dropped out and did not complete outcome measures at time point 3.

Q.11 When I am on my way to an amusement park, I can hardly wait to ride the roller coasters

This question was not completed by 4 out of 9 participants (44.4%, 2 males, 2 female) at time point 1. At time point 3, one participant did not answer this question. Of the others who did not answer the question at time point 1, two participants had dropped out at time point 3 and 1 other completed the question.

As per TEPS instructions, participants were advised to think about the most similar experience they have had in order to make their response. Despite this, participants stated that they could not imagine themselves in that situation and chose not to answer it.

FFMQ - One participant (14.2%) did not complete 7 out of the 39 items (17.8%) on the FFMQ at time point 2. Since only one participant did not complete all questions on the FFMQ, no patterns were noted in non-completed items.

Methods of Data Collection

Data collection procedures differed slightly over the three time-points as detailed in the data collection section. There were unanswered questions at all time points but this was greatest at time point one, when the questionnaires were administered by the researcher particularly in relation to the TEPS (see Table III for details).

Table II: Completion rates of data collection across different time points and collection methods

Measure	Time point 1 (total n=9)	Time point 2 ¹ (Total n=7)	Time point 3 ¹ (Total n=6)
	Researcher administered	Self-completed	Self-completed with researchers in room but not offering assistance unless asked
	% of completion (n)	% of completion (n)	% of completion (n)
GDS	100 (n=9)		100 (n=6)
AES	100 (n=9)		100 (n=6)
AAQ-II	100 (n=9)	100 (n=7)	100 (n=6)
FFMQ	100 (n=9)	85.8 (n=6)	100 (n=6)
RRS	100 (n=9)	100 (n=7)	100 (n=6)
TEPS	55.6 (n=5)		83.3 (n=5)
DTS	100 (n=9)		100 (n=6)
Total Completion rate for time point	93.6	95.3	97.6

¹Values are calculated based on the participants who were remaining within the group at that time point

Quantitative Results

A Wilcoxon Signed Rank Test was used to compare scores between time 1 and time 3. This was selected due to the non-parametric nature of the data. The Wilcoxon Signed Rank Test revealed a statistically significance improvement on the GDS, AES, DTS,

TEPS (Anticipatory) and FFMQ (Non-Judging). All significant changes had a large effect size based on Cohen d's criteria. See Table III for details.

Table III: Mean scores of completers across data collection points and Wilcoxon Signed Rank Test between time 1-3

Measure	Time 1 Median (IQR)	Time 2 Median (IQR)	Time 3 Median (IQR)	Wilcoxon Signed Rank test between time 1-3	Effect size for significant results (r)
GDS	13.00 (6.5)	-	2.50 (6.5)	-2.20 (p=.03)	.63
AES	43.00 (13)	-	33.50 (15.0)	-2.03 (p=.04)	.58
RRS	55.00 (23.5)	48.00 (37.0)	42.50 (35.3)	-1.75 (p=.08)	-
DTS					
<i>Tolerance</i>	4.66 (1.55)	-	2.33 (1.8)	-2.03 (p=.04)	.58
<i>Absorption</i>	6.22 (2.16)	-	2.66 (2.8)	-1.99 (p=.05)	.57
<i>Appraisal</i>	4.74 (1.37)	-	2.66 (1.8)	-1.99 (p=.05)	.57
<i>Regulation</i>	5.23 (1.65)	-	2.66 (1.3)	-2.20 (p=.03)	.63
AAQ-II	35.00 (15.5)	24.00 (14.0)	26.50 (11.8)	-1.89 (p=.06)	-
TEPS					
<i>Anticipatory</i>	31.00 (10.5)	-	39.50 (7.8)	-2.20 (p=.03)	.63
<i>Consummatory</i>	30.00 (15.5)	-	35.00 (8.8)	-0.99 (p=.34)	-
FFMQ					
<i>Observe</i>	22.00 (13.5)	23.00 (11.0)	26.00 (8.3)	-1.57 (p=.11)	-
<i>Describe</i>	18.00 (10.5)	21.00 (5.0)	21.50 (11.3)	-1.22 (p=.22)	-
<i>Act with Awareness</i>	24.00 (12.5)	20.00 (14.0)	26.00 (10.8)	-1.78 (p=.07)	-
<i>Non-Judging</i>	16.00 (10.5)	24.00 (8.0)	26.50 (9.8)	-2.02 (p=.04)	.57
<i>Non-reactivity</i>	17.00 (7.0)	17.00 (7.0)	18.50(2.5)	-1.47 (p=.14)	-

Qualitative Results – The Participants Experience

Sample Characteristics

Seven participants opted in to attend an interview post-intervention, 4 were female, 3 were male, and had a mean age of 69.8 (SD=3.38). Six were completers with a mean

session attendance of 7.3 (range 6-8). The one non-completer had attended 5 sessions but did not complete post-intervention questionnaires.

Results

Thematic analysis was used following the six-stage process described by Braun and Clark (2006). A familiarisation process was undertaken by listening to, transcribing and reading each transcript in turn. Each transcript was then coded. Codes were then re-read and the process of deriving themes was undertaken. For data to become a theme, it had to be reported by the majority of participants. However, in some instances there was data that seemed important but it was not reported by the majority of participants. This data is still reported but it is highlighted that it was not the view of the majority of the participants. Six themes and 17 sub-themes emerged which are outlined below (see Table IV for overview).

Table IV: Themes and Subthemes

Themes	Subthemes
Pre-course apprehension	The unknown
	Curiosity
	Settling in
Striving	Getting into the frame of mind
	Making time
	Commitment
Group Delivery	Informal
	Meeting others
	Duration
Concept of Mindfulness	First Impressions
	Practice
	Shifting to independent meditation
	Ongoing journey
Perceived benefits of mindfulness	Mindfulness skills
	Psychological wellbeing
Perceptions of Research Participation	Happy to help
	Getting it right

Theme 1: Pre-course apprehension

The unknown

There was a general sense that despite being given information about the groups and the opportunity to ask questions, the participants felt unsure about what the group would be like:

'...at the start I didn't know what I was getting myself into... I just didn't know what it was going to be like, what we were going to get asked or anything' Participant 1, pg. 1 line 5-10

'At the start, there was a feeling about going into the unknown, maybe a bit worried about taking on a course, wondering if you maybe had to talk all the time or answer questions so from that point of a view I was mildly concerned...' Participant 5, pg.9, line 1-3

Curiosity

Despite this feeling of entering the unknown, the majority of participants had a sense of curiosity that helped them make the decision to take part:

'I really wanted to find out more about mindfulness so I wanted to take part' Participant 3, pg. 3, line 16-17

'I read a book before ...how to relax or something it was called...and there was a chapter on mindfulness and I hadn't a clue what it was about...so I thought I would come along here and find out more' Participant 7, pg. 7, line 5-8

Even after the first session, most participants remained unsure about the process yet their sense of curiosity served as a driver to keep coming back to the group:

'...I think I felt it must've been doing me some good and I was willing to give it a further try and keep at it and see...' Participant 5, pg. 3, line 17-18

Settling in

The majority of participants reported a period of settling in, this occurred alongside getting to know the facilitators and other group members:

'...just for the first couple, then I got to know people, I got to know you, and [the other facilitator] and the others, and I was comfortable coming then...' Participant 1, pg. 4, line 28-29

'...maybe about the second or third week or so...I settled in quite quickly' Participant 9, pg. 10, line 2-5

There was a sense that participants felt under no pressure to participate in group exercises or share their experiences during sessions, this seemed to have helped participants settle in:

'I settled in quite quickly but that is down to yourselves because you didn't say 'right now you all need to talk' because I can see, how I am, I wouldn't like that, if I was forced or expected to talk' Participant 9, pg. 10, line 5-8

'...it was quite informal and you weren't under any pressure to do or say anything...' Participant 5, p9, line 18-19

Theme 2: Striving

In contrast to the mindfulness theme of non-striving, most participants experienced some initial struggles which they strived to rectify in the early stages of the intervention. The majority of these struggles related to homework tasks. These could be separated into three subthemes:

Getting into the frame of mind

Participants found mindfulness a new way of 'being' and quite different from the usual 'automatic pilot', this created some difficulty in developing new habits:

'...I found them [homework exercises] quite difficult to start with... I think it was so different from what you normally do, it took quite a bit of practice to do things

differently, noticing, experiencing, rather than just doing [referring to automatic pilot]
Participant 3, pg. 2, line 15-21

'...just in the start trying to do...the exercises at home at the start... just getting my own mind into doing them' Participant 1, pg. 2, line 18-19

Although this was not a common theme throughout, one participant (a non-completer) found it difficult to engage in the exercises within the group session but found them more beneficial when practicing at home:

'...some of the things he [facilitator] was asking us to do...I just couldn't get into that frame of mind...although funnily enough it didn't work here but it worked in the house...[in the group] I was just feart¹ I was going to fall asleep [laughs]' Participant 2, pg. 2, line 1-4

Making time

All participants highlighted that creating time for mindfulness at home was a struggle:

'...just making time was hard, sometimes you just sit and don't do anything, where you could be doing mindfulness, but I didn't, I just sat there...in the early days' Participant 3, pg. 2, line 24-26

'...finding the time and everything...finding the time yeah...that was hard at the start...'
Participant 1, pg. 2, line 18

Despite all participants being retired, most had other commitments such as caring for partners, or grandchildren, or engaging in other leisure activities. Most participants made reference to engaging in some aspect of planning when they could fit mindfulness into their routines:

'I was pretty faithful at it [home practice]...I had to put in a bit of working out how I was going to do it, what times, certain times I could do it...' Participant 5, pg. 6, line 3-4

¹ Feart is a colloquialism meaning scared

Commitment

All participants made reference to making a commitment to practice and this appeared to assist them in persevering despite initial struggles:

'...I just said to myself in the morning, I'm just going to take this wee bit of space in the morning because I need this...and I did that.' Participant 1, pg. 3, line 5-6

'I didn't find it easy but I just made up my mind to do it...it was making your mind up to do things ...' Participant 2, pg. 3, line 15-17

Theme 3: Group Delivery

All participants made reference to the group process itself, aside from the content of mindfulness.

Informal

The majority of participants remarked that the group had an informal feel and a sense of ownership came through from the participants in that if they wanted to have a discussion about a related topic, this was allowed to happen:

'I know you had a thing...list [session plan] ...but you didn't force it, if something happened you were quite happy to let it happen and that's helpful, other groups or other people might say 'come on now we've got this to do' but that didn't happen, it was quite nice, we weren't made to do anything, we could relate or talk to each other' Participant 9, pg. 7, line 8-14

Meeting others

All participants commented on their enjoyment of meeting other participants at the group:

'I enjoyed coming to the group and I enjoyed the social aspect...' Participant 3, pg. 1, line 4-10

'I enjoyed the fact that it was a group, that there were other people there and we could all hear each other's views...' Participant 6, pg. 1, line 5-6

For some, there was a sense of learning a new skill together:

'...I enjoyed being with the group...it was a feeling that you were learning something together ...there was a sense of togetherness that I wasn't expecting... it was a shared journey' Participant 5, pg. 1, line 5-7

A shared understanding about depression and mental illness amongst group participants was noted:

'...it was nice to talk to people who understood, ordinary people...I don't mean doctors or anything, just ordinary people like [other group participants]' Participant 9, pg. 1, 4-5

Duration

Many participants remarked that 8 weeks felt short in duration:

'The only thing I would say about it if there was anything, was... that I thought could change, was to have it a bit longer than the number of weeks it was...I was just really getting into the way of things when it came to an end.' Participant 6, pg. 3, line 4-12

'No I was quite happy, I would have went on and on and on...you know on a weekly basis...I could have kept on doing it...you think '8 weeks, I'll never get to 8 weeks' and then you are there in no time' Participant 7, pg. 3, line 16-21

Theme 4: Concept of mindfulness

All participants were able to reflect on their journey of developing mindfulness skills.

First impressions

All participants reported a sense of uncertainty about mindfulness when they first started the group:

'The first couple of weeks...I thought "how is this going to help me?... I just couldn't find how this was going to help me with what was wrong with me' Participant 1, pg.1, line 13-17

'Well at the beginning you hadn't a clue what you were doing, I thought 'heck, what is this all about?' [laughs]' Participant 7, pg. 3, line 24-25

Practice

Despite these initial uncertainties about mindfulness, all participants recognised the importance of practice to improve their understanding of mindfulness:

'I found it difficult at the beginning to get the concept of mindfulness...because...it's something you didn't do before...I hadn't even heard of it...I think the longer I came, the more I heard about it, the more I practiced, it got easier...got clearer.' Participant 3, pg. 1 line 25-3

Shifting to independent meditation

Most participants reported shifting from using the guided meditations to practicing mindfulness independently within the 8-week course:

'...the CD's were very helpful in the beginning, I don't need them now but if I need a quick jolt I put the CD on again and hear another voice telling me what to do, guiding me...' Participant 7, pg. 5, line 1-3

'Well by doing the...listen to the tape...sometimes I didn't listen to the tape, I just done it myself...' Participant 3, pg. 3, line 1-3

This highlights a sense of self-efficacy in their own mindfulness practice. This is a key skill for them in being able to practice mindfulness where ever they are, whenever they need it, without requiring any equipment.

Ongoing journey

The majority of participants recognised that their mindfulness journey did not end at session 8, but rather it was just beginning:

'...what you do then [after the group has finished], that's a different matter... but I will still keep at it, no question about it.' Participant 5, pg. 3, line 27-29

For most, there was a commitment to continue their formal practice following the group:

'I know [about mindfulness] now and I can practice it and I will continue to do so ...every day, at some point in my day I take the time...just practice.' Participant 7, pg. 7, line 10-12

'I know this is a lifetime thing, there was a point in the group, learning about the acceptance of what I've got to do, there's no quick fix...that has made a big difference...there's no pill, there's nothing...I just need to work away at this [mindfulness]' Participant 9, pg. 6, line 7-10

For some participants, their ongoing journey involved engaging in literature about mindfulness, or re-reading the session materials:

'I bought that book [mindfulness book]' Participant 1, pg. 3, line 31

'...I'm going to start going through the pamphlets [session handouts] again and just read them through...there is always something new you will learn.' Participant 9, pg. 4, line 23-26

Although, not relevant for all participants, some participants remarked at the accessibility of the session handouts:

'A lot of that in there [session handouts] I've had to go over again and again...it's a lot to take in...it's a concept I hadn't thought about before...it's a bit different' Participant 5, pg. 2, line 11-1

Theme 5: Perceived benefits of mindfulness

All participants commented on the perceived benefits of mindfulness. The variance in consensus of perceived benefits highlighted the idiosyncratic nature of psychological therapies. Perceived benefits can be divided into two sub-themes:

I) *Mindfulness skills*

Some perceived benefits can be mapped onto themes of mindfulness, or skills that would be expected to improve with mindfulness training.

Present moment awareness

All participants made reference to increased present moment awareness:

'...it took quite a bit of practice to do things differently, noticing, experiencing, rather than just doing [referring to automatic pilot]' Participant 3, pg. 2, line 19-21

For some, this was about having a mindful awareness of day-to-day activities:

'...the main thing I think about is about being mindful about the things I do rather than anything else...you know?...being mindful about things I do...like when I brush my teeth...'
Participant 5, pg. 1, line 11-15

'I noticed more when I was brushing my teeth or making a meal or things like that'
Participant 6, pg. 3, line 32-33

For others it, it was about greater awareness of their surroundings:

'Just noticing things, like I said, that pond has been out the back for years and I've never noticed it but now I'm more aware' Participant 1, pg. 8, line 2-3

'Before I took the class I would have never noticed any of the things I do now, like the flowers or trees' Participant 5, pg. 6, line 29-30

'...it's amazing what you notice, the buttercups, noticing the colour and the quantity...'
Participant 9, pg. 9, line 20-21

For others, it was about using their breath to anchor them in the present moment:

'...that's the key thing for me, to go back to my breath and come to the present moment, that's the main thing at the moment...' Participant 5, pg.10, line 5-6

Non-striving/Accepting

Participants seemed more accepting of the way things were and a sub-theme of non-striving acceptance emerged from the majority of participants:

'...well there's not a right or a wrong way, it's just doing...it works both way, there's no really a wrong way to do this. It's just accepting things as they are and carry on with life as it is. I've learned to accept things as they are rather than trying to change them...'
Participant 5, pg. 4, line 5-8

Non-reacting

From many participants, there was a sense that a key new skill they had developed was the ability to step back before reacting to a situation:

'I would get it [the situation] all out of proportion and worry about it non-stop but I don't...well now I can...well I can meditate and I can put it [the thought] to the side....not away all together but I can put it aside...' Participant 6, pg. 2, line 18-21

'...mindfulness gives me something to do rather than just worry, worry, worry, going over things, getting anxious about things, I can calm down, I can breathe, then it helps me think through things slowly...' Participant 7, pg.2, line 22-24

II) Psychological Wellbeing

Most participants spoke about their own psychological well-being with reference to perceived benefits of mindfulness.

Calmness

Achieving a sense of calmness from mindfulness was commented on by all participants:

'...it made me a bit calmer...being calm was the main one, not worrying so much...about things.' Participant 3, pg. 3, line 2-5

'I sat down for 5 minutes and turned the television off, and opened up to it and breathed and it helped me calm down...' Participant 7, pg. 1, line 16-18

Coping

Many participants commented that due to the development of mindfulness skills, they felt better able to cope with their symptoms:

'I feel much better able to cope with things now because I can do that [observing] now' Participant 3, pg. 4, line 20-21

For another participant, it was about changing his perspective to a more non-striving approach. For this participant, there was a great shift in his perception of how to cope with his symptoms:

'[Before the course] I was thinking "Do I need more anti-depressants?" but I've learned it's my thoughts, it's not my...needing more medicine...yeah, I don't need tablets, I needed a different outlook, to think better...or think in a different way...' Participant 5, pg. 7, line 11-15

The quote below, highlights quite a remarkable shift in one participant's ability to cope with symptoms of health-related anxiety. It would appear that the ability to observe and not react has allowed to change their response to distress:

'...it's made me feel less anxious, calmer...whereas in the past I would have panicked at an anxious feeling and dialled 101 for an emergency doctor, I wouldn't do that now...I would stop and thinking about it, think 'calm down, just breathe'...I think now 'you're not having a stroke, or a heart attack, you are absolutely fine, you don't need to pull any

chords in the house'...I tell myself I will get through it, it will pass.' Participant 7, pg. 2, line 4-13

Theme 6: Perceptions of Research Participation

As this was a feasibility nature of this study, we felt it was important to consider the participant's views on taking part in research if further studies were undertaken to develop this intervention approach.

Happy to help

There was a consensus that participants were happy to take part in research:

'...research needs to be done for certain things and I was happy to be part of it.' Participant 6, pg. 5, line 26-27

'...it was quite a privilege really...I was very happy that you asked me...I was happy to take part.' Participant 7, pg. 5, line 30-33

Getting it right

Although this was not an issue for all participants, it is an important consideration for future research. All participants were informed that the research formed part of the author's portfolio for submission as part of a Doctorate in Clinical Psychology. Two participants expressed some worry about getting things right for the purposes of research. These issues arose during the groups and reassurance was offered.

For one participant, there was a worry that if her questionnaires were filled out to reflect how she was truly feeling at the end of the course, it would impact negatively on the outcomes:

'...mind when I told you I was worried last week [referring to completing outcome measures], I was worried I was muckin' it up for you, so when I wasn't feeling well, I worried that I was messin' up.' Participant 3, pg. 3, line 22-25

Another participant was worried about what the readers of this research would think about her responses to the questions that she was being asked:

'...am I saying things ok? If you write it up, if they read it...what are they going to think?'
Participant 1, pg. 5, line 30-31

Discussion

This mixed methods feasibility study aimed to contribute to the evidence base for MBIs for older people. At this stage in intervention development feasibility studies are important in order to systematically prepare for larger trials. Initial studies will inform researchers about decisions, directions and practical considerations for future trials. This study incorporated the experience of the participants which helped to understand their perspective of the intervention from a user perspective. Together the results indicate that MBCT is feasible and acceptable to older people, and give some insight into the mechanisms of change.

Recruitment and Attrition rates

This study had an attrition rate of 33% based on opted-in participants who dropped out before the end. This is slightly higher than Geiger et al.'s (2015) review of MBIs for older people where they reported an average attrition rate of 23%. Reasons for drop out in this study included poor physical health, disinterest in the group and other commitments such as hospital appointments, which is similar to those stated in Geiger's review. Geiger et al encouraged future researchers to ask participants about drop out when related to disinterest in the group. This study aimed to do this by inviting non-completers to the post intervention interview, however the one participant who dropped out due to disinterest declined to attend. Perhaps a postal feedback form would have been more appropriate and could be trailed in future studies.

Outcome measures

There was a high level of completion for most measures, with the exception of item 5 and 11 on the TEPS. It would appear that these items were not completed due to the participants being unable to image themselves such situations, such as riding a rollercoaster and are perhaps not appropriate for this age group. Chan et al. (2012) evaluated the TEPS in with a Chinese sample. Prior to the administration of the TEPS, the researchers deemed items 5 and 11 unsuitable for their population and therefore replaced these items with more appropriate items for their population. It may be helpful to do similar for an older adult population.

This study trialled three different data collection procedures across three time points. The completion rates of the questionnaires were similar at all time points, suggesting

that participants are as likely to complete measures independently as they are if the researcher is assisting them. Measures at time point 1 and 3 took a substantial amount of time, approximately 25 minutes to complete. No issues were raised during the qualitative interviews, or when asked specifically about the acceptability of time taken in the satisfaction questionnaire. Given high completion rates, as well as positive ratings regarding questionnaires on the satisfaction questionnaire, it can be assumed that the participants in this study found it acceptable to be asked to complete a substantial battery of questionnaires and found the measures in this study acceptable, with the exception of the two items on the TEPS.

A Wilcoxon signed rank test revealed a statistically significant change on the GDS, AES, DTS, TEPS (anticipatory) and FFMQ (non-judging), all with a large effect size. However, the lack of control group in the current study limits the extent to which the changes on the outcome measures can be attributed directly to the intervention. Future studies should aim to include a control group as well as a larger sample size in order to ascertain more robust statistical information on the efficacy of the intervention.

Understanding Mechanisms of Change

Future studies with larger sample sizes will be able to quantitatively examine the mediators of any positive outcomes following MBCT. In the meantime, the qualitative analysis completed here narrows down the range mechanisms of change. The majority of participants reported that they continued to experience symptoms of depression, or thinking styles associated with depression and anxiety but they reported that were able to alter how they responded to this experience by applying mindfulness skills, such as noticing, non-reacting. Some participants reported being able to step back and just observe that experience without further engagement. Better understanding about the functional consequences of these in everyday life, such as increased daily activity or improved quality of life is necessary. As outlined by Moore et al. (2015), this qualitative finding may help to inform the mechanisms of change in order to accurately identify a treatment outcome. This finding may indicate, for this group of participants, that change occurred in the development of mindfulness skills, such as present moment awareness, and non-reacting which allowed them to become aware of, and change their response to their inner experience. The current literature base for MBIs for older people (as outlined in the previous chapter) currently focuses on symptom reduction as an outcome of MBI, however this finding suggests that symptom reduction may be a secondary outcome measure. It is therefore important to understand the mechanisms that underlie this change, such as improvement in mindfulness skills.

Group participation and discussions

Group discussions emerged as an important component to the participants despite the group discussions not being in the protocol. The MBCT protocol calls for an *enquiry* following a mindfulness exercise which explores participant experience including both pleasant and unpleasant following mindfulness exercises. Our finding was that these enquiries often triggered other discussions about their experience of mindfulness and mental health. Participants shared tips for incorporating mindfulness into their lives, and the particular challenges of this when faced with symptoms of depression such as lack of motivation. Whilst the facilitators were able to refocus the intervention, the discussions continued to arise and appeared to be a helpful part of the process. Qualitative results suggest these discussions provided participants with a sense of support, feeling understood and learning from each other. McBee (2002) reported that qualitative accounts of mindfulness in a care home, the group experience and discussions were the most valued aspect of the experience by group members. This perhaps makes an interesting adaptation for future MBCT protocols for older people, to allow some of those wider discussions to happen.

Being part of a group appeared to meet the basic need of relatedness from an intrinsic motivation perspective. This forms part of Self Determination Theory (SDT, Ryan and Deci 1985). SDT purports that humans have inherent intrinsic motivation, but this can be disrupted by non-supportive conditions. The theory posits that three basic needs which contribute to well-being: autonomy, competence and relatedness. Relatedness refers to the feeling of being connected to others in a meaningful way (Ryan and Deci 2000). The qualitative results suggest that this need was met by being part of the group. Therefore, is it important to consider if these “non-specific’ factors are as therapeutically beneficial as learning mindfulness skills.

Strengths and Limitations

One limitation of this study, is the lack of follow-up which was not included due to time-constraints. A follow-up may have potentially added information about continued mediation post intervention. This would have been particularly interesting given that the participants voiced disappointment at the group ending and some worry about how they will manage on their own. This does not seem to a concern that is exclusive to older people. Finucane and Mercer (2006) reported in their exploratory study of MBCT with an adult population that their participants felt the 8-week protocol was too short and would have liked additional sessions. Lenze et al. (2014) compared an 8-week and 12-week MBSR group for older people and concluded that there were no superior outcomes noted for the 12-week group. As a follow up it would be of interest to determine if this concern was about self-efficacy and if it changed at follow-up.

This study was designed without the involvement of participants or patients that may receive MBCT, meaning that the design and outcomes were chosen by the researchers. INVOLVE (2012) suggests that involving participants or patients at the research planning stage is helpful in order to ensure that the outcome measures used are important to the people who will use the service, amongst other things. Whilst there was no negative feedback given regarding the outcomes used, it may be beneficial to know which outcomes would be important to the participants e.g. symptom reduction vs improved quality of life.

An important limitation of the study is the potential for bias. Due to the nature of this doctoral research, the trainee psychologist (MO) was involved in all stages of the research including initial meeting, delivering of the intervention, and the post-intervention interview. This may have led to a potential bias in data gathered at the interview, in that participants may not have wanted to give critical feedback.

A strength of this study is the systematic nature of its investigation into the acceptability and feasibility of MBCT for older people. The study benefited from drawing upon the complex intervention framework (Craig et al. 2015) and other relevant literature in order to contribute to the cycle of complex intervention development. This kind of research is important to establish what works for older people, without the assumption that what works for working aged adult will for older people. It is recognised that whilst there are people aged over 65 who are fit and healthy, as people age there is an increased likelihood of physical health conditions as well as cognitive decline, which may require adaptations to standard psychological intervention protocols in order to meet the needs of older people (Older People's Psychological Therapies Working Group 2011).

Future research

In the early stages of the recruitment phase staff initially expressed a keen interest and reported that they had potential participants in mind for the study. However, receiving referrals was a slow process. In both groups, the majority of referrals were received in the final week of the recruitment phase. Further feasibility work to gain a better understanding of barriers that may affect referral rates may better inform recruitment procedures for future research.

An aspect of further research would be to determine meaningful outcomes would be for the people who would, or have received MBCT. It would also be helpful to understand the functional effects of MBCT on older people, in order to see what

changes in mindfulness skills or symptom reduction means for them in daily life such as increased daily activity, increased motivation.

This study recruited participants who had a history of depression and at the time of recruitment reported current symptoms of depression. Whilst all participants did report symptoms of depression, many also reported symptoms of anxiety. Some participants also experienced pain as a result of a physical condition. This highlights a potential difficulty in addressing one treatment target of MBCT for older people; that they present often with complex and co-morbid conditions. It would be interesting to examine MBCT for specific transdiagnostic symptoms that are seen across disorders rather than a disorder specific treatment.

Further research is required in obtaining larger sample sizes via more robust recruitment measures. Larger sample sizes, or multi-site studies would allow statistical exploration of quantitative outcome measures, including effect size estimation.

Conclusion

MBCT is both feasible and acceptable for older people experiencing symptoms of depression. The qualitative results give some insights into the possible mechanisms of change that occur during MBCT and also emphasises the importance of group discussions as part of MBCT for older people. There were generally positive findings regarding being asked to take part in research which is promising for future trials. Further research, in keeping with a complex intervention development framework would be to perhaps do some further feasibility testing around improving referral rates during the recruitment phase, then calculating recruitment estimates in order to facilitate a larger, or multisite trial which would allow for statistical tests to be carried out. Further consideration should be given to having less restrictive recruitment criteria in order to explore MBCT for transdiagnostic symptoms.

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Appendix 1.1

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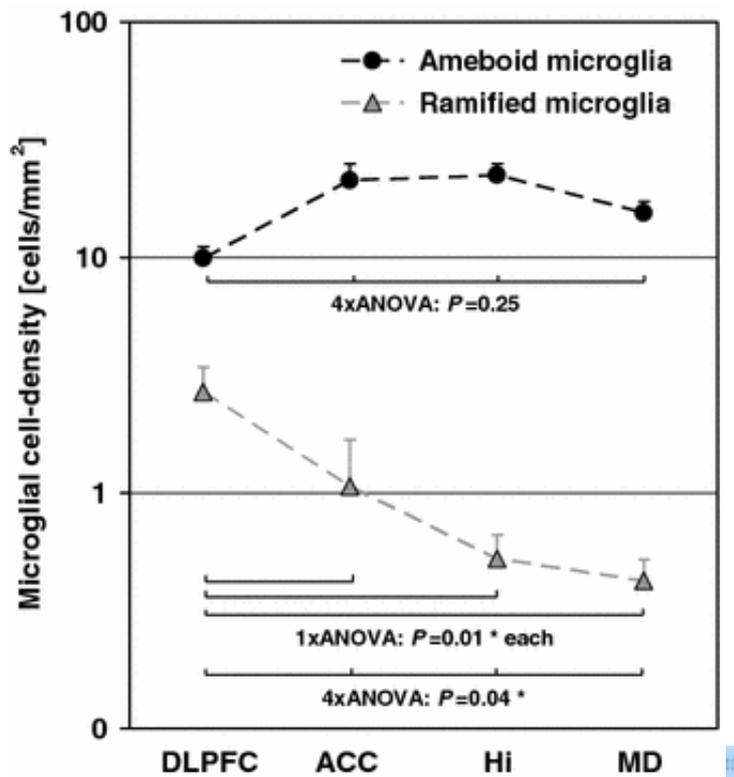
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Conflict of Interest: Author A has received research grants from Company A. Author B has received a speaker honorarium from Company X and owns stock in Company Y. Author C is a member of committee Z.

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1) Statement of human rights

When reporting studies that involve human participants, authors should include a statement that the studies have been approved by the appropriate institutional and/or national research ethics committee and have been performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

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The following statements should be included in the text before the References section:

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For retrospective studies, please add the following sentence: “For this type of study formal consent is not required.”

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The welfare of animals used for research must be respected. When reporting experiments on animals, authors should indicate whether the international, national, and/or institutional guidelines for the care and use of animals have been followed, and that the studies have been approved by a research ethics committee at the institution or practice at which the studies were conducted (where such a committee exists).

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If articles do not contain studies with human participants or animals by any of the authors,

please select one of the following statements:

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All individuals have individual rights that are not to be infringed. Individual participants in studies have, for example, the right to decide what happens to the (identifiable) personal data gathered, to what they have said during a study or an interview, as well as to any photograph that was taken. Hence it is important that all participants gave their informed consent in writing prior to inclusion in the study. Identifying details (names, dates of birth, identity numbers and other information) of the participants that were studied should not be published in written descriptions, photographs, and genetic profiles unless the information is essential for scientific purposes and the participant (or parent or guardian if the participant is incapable) gave written informed consent for publication. Complete anonymity is difficult to achieve in some cases, and informed consent should be obtained if there is any doubt. For example, masking the eye region in photographs of participants is inadequate protection of anonymity. If identifying characteristics are altered to protect anonymity, such as in genetic profiles, authors should provide assurance that alterations do not distort scientific meaning.

The following statement should be included:

Informed consent: “Informed consent was obtained from all individual participants included in the study.”

If identifying information about participants is available in the article, the following statement should be included:

“Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.”

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Appendix 2.1
MBCT weekly session outline

Session number	Theme	Exercises	Homework
1	Introduction to mindfulness	Body scan Mindful Eating	Body Scan
2	Overcoming Obstacles	Body Scan Sitting meditation (mindfulness of breath)	Body scan, daily Sitting meditation with CD Mindfulness of routine activity Log book of pleasant events
3	Staying Present	Body Scan Three Minute breathing space	Body Scan Sitting Meditation with CD 3-minute breathing space 3x daily Mindfulness of routine activity Logbook of unpleasant events
4	Staying with what is difficult/Recognising habits	Body Scan Sitting meditation (responding mindfulness when difficulties arise)	Mindful movement Sitting Meditation with CD 3-minute breathing space Mindfulness of routine activity Reflection at half way
5	Allowing things to be	Body Scan Sitting Meditation Mindful Walking	Continue with practice of your choice 3-minute breathing space Difficult communication log
6	Seeing thoughts as thoughts	Body Scan Sitting meditation (responding to unpleasant thoughts)	Continued practice without CD Introduce moments of silence
7	Theme: Lifestyle, Diet and Wellbeing	Body Scan Sitting meditation (considering own needs)	Continue with practice of your choice without CD Continue with moments of silence End of course reflection
8	Theme: Continuing your Mindful Journey	Body Scan Loving Kindness Meditation Three Minute Breathing Space	Created individual plan of how to continue mindfulness during session

Appendix 2.2

Adaptations to the standard protocol

Careful consideration has been given to the needs of older people and whether the standard protocol meets these needs. Reviewing the session-by-session plan indicate that some adaptations may be required in order to ensure safety and comfort of participants:

1. *Sitting meditation practice (30-40 minutes)* – It may be the case for some participants that sitting in a chair for lengthy periods of time is uncomfortable due to physical health difficulties such as pain. A reasonable adjustment would be to offer participants the opportunity to alter their position when they require in order to remain comfortable.
2. *Body Scan* – The protocol suggests that the body scan should be completed in a lying position. This may be difficult, or uncomfortable for some participants. The protocol states that if a lying position is too difficult the body scan can be completed in a seated position. This option will be offered to participants for health and safety purposes.
3. *Mindful Walking* – The protocol includes mindful walking. Depending on mobility of participants, this may be difficult for some. However, it may offer a comfortable alternative position for some as opposed to sitting for the full session. Smith et al. (2007) reported in their results that they had to augment the mindful walking during their sessions due to observing participants were becoming unsteady. Despite this, their qualitative findings suggest that their participants found this exercise helpful. Foulk et al. (2013) adapted the mindful walking exercise slightly and put more emphasis on the awareness of the physical sensation of walking rather than emphasizing the slow lifting and placing as they were concerned this may compromise their participants balance. Allowing participants to use the back of their chair, walking aide or a wall in order to maintain balance would be acceptable.
4. *Mindful Movement/Stretching* – This requires the participant to be in a standing position and move their arms slowly. For some participants, this may be difficult if there are difficulty with balance or being in a standing position for a short period of time. It would be a reasonable adjustment to allow participants to participant in

the mindful movement exercise from a seated position. Alternatively, inviting participants to use the back of their chair, or walking aide to support themselves during the exercise would be reasonable. Participants would be advised to do what feels comfortable and safe for them. Foulk et al. (2013) asked participants to use the back of their chair to maintain balance during the mindful movement exercise.

Appendix 2.3



Participant Information Sheet

Study Title:

Mindfulness Based Cognitive Therapy for Older People in a community setting: a mixed methods feasibility study

Who is conducting the research?

This study is being carried out by:

- Michelle O'Shea, Trainee Clinical Psychologist (NHS Lanarkshire and University of Glasgow)
- Dr Hamish McLeod (Supervisor - University of Glasgow)
- Dr David Grinter (Clinical Psychologist, NHS Lanarkshire).

Invitation

You are being invited to take part in a research study. Before you decide if you would like to take part 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. One of the research team will go through this information sheet with you and answer any questions that you have. This should take about 15 minutes. It is important that you take time to decide whether or not you wish to take part.

What is the purpose of the study?

Mindfulness Based Cognitive Therapy (MBCT) is an effective treatment for many people with depression and is recommended for recurrent depression in working age adults. However, we need to find out if these benefits reliably

occur for older people. This research will explore whether it is possible to deliver MBCT to older people and whether older people find it an acceptable intervention. It is likely that the research will be ongoing for approximately 9 months from October 2015 until July 2016, your involvement in the study will last around 3 months.

The study will be submitted as part of Michelle O'Shea's research portfolio as part of her requirements for completion of the Doctorate in Clinical Psychology at the University of Glasgow.

Why have I been Invited?

We are looking for participants who are over 65 years old, have previously experienced depression and are currently experiencing some symptoms of depression. We asked clinicians working in Old Age Psychiatry teams to identify people on their caseloads that meet these criteria and may be interested in taking part in this research.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be asked to sign a consent form. You are free to withdraw from the study at any time and without giving a reason. Regardless of whether you decided to participate or not, it will not affect any treatment you are currently receiving or any that you may need in the future.

What will happen to me if I take part?

If you decide to take part and or would like more information, please tell the person who gave you this information sheet. They will pass your name and contact details to the researcher who will contact you to make an appointment. At this meeting, you can ask any questions that you have about the research. When you are sure that you would like to take part, the researcher will ask you to sign a consent form. You will also be asked to complete some questionnaires that ask questions about mood, thoughts and behaviour. You will be asked to complete these questionnaires on two other occasions during the group, after week 4 and at the end of the last group session.

You will be invited to attend the group, which will take place weekly and run for eight weeks. Each group session will last for 2 hours with a break in the middle. The groups will take place in an NHS building. During the group, you will be invited to practice various different exercises that can help with managing the experience of depression (e.g. breathing exercises). We will give you written handouts each week that provide a summary of the information from the session.. We will also give you a CD to take home with you, so that you can practice the techniques at home. When the group has finished, we will ask you to complete a satisfaction questionnaire. A subgroup of participants will be invited to attend an interview where you can share your experience of the group. If you do not complete all 8 sessions, we would still like to hear about your experience so we will post you a letter to invite you along to an interview and you can come along if you want too.

What do I have to do?

You will be asked to attend as many group sessions as you can and practice the therapy exercises in between the groups. These will include using your CD to practice some of the exercises we have been doing during the group, or you may be asked to keep a diary to help you monitor and understand some of your thoughts and feelings.

What are the disadvantages and risk of taking part?

There is virtually no risk of harm involved in taking part in mindfulness based cognitive therapy. There is a time burden associated with taking part in this research in that we ask you to come along to the groups for 8 weeks. It is important to consider if you would be able and willing to come along for 8 weeks, this might include considering transport to the group venue.

What are the possible benefits of taking part?

By taking part in this study, you may learn some new skills that may help you manage your symptoms of depression. You will also meet others who are experiencing similar symptoms and you may find this beneficial.

Will my GP be notified?

Yes, we will ask for your consent to inform your GP that you are taking part in the study and will be attending the mindfulness group.

What happens when the research study ends?

When the research study stops, you will no longer attend the mindfulness groups but you will continue to receive any treatment or intervention that had already started, such as seeing your CPN or Psychiatrist.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. On all documents, an ID number will replace your name, and any personal information removed so that you cannot be identified from it.

What will happen to the results of the study?

The results of the study will be written into a report and submitted to the University of Glasgow as part of Michelle O'Shea's requirements for the Doctorate in Clinical Psychology. It is possible that this report will also be published in an academic journal. A summary of this report will be distributed to the Old Age Psychiatry Teams within NHS Lanarkshire. It is expected that this report will be completed by July 2016.

Who is organizing and funding this research?

The research is organised via the University of Glasgow and is supported by the NHS. There is no commercial funding associated with this research.

Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people called a Research Ethics Committee to protect your interests. This study has been reviewed by the West of Scotland Ethics Committee and favorable opinion has been given.

If you have any further questions

If you would like more information about the study and wish to speak with someone who is not closely linked to the study, please contact **Dr Sue**

Turnbull, Research Tutor, University of Glasgow, email:
s.turnbull@glasgow.ac.uk, Tel no: 0141 2113937

If you have a complaint about any aspect of the study

If you are unhappy about any aspect of the study and wish to make a complaint, please contact the researcher in the first instance. The normal NHS complaint procedure is also available for you. The contact person for making a complaint in NHS Lanarkshire is: **Laura Jack, NHS Lanarkshire Headquarters, Kirklands Hospital, Fallside Road, Bothwell, G71 8BB, Tel: 01698 858321, Email: laura.bryan@lanarkshire.scot.nhs.uk**

Contact details

If you would like further information, you can contact:

Main Researcher (Trainee Clinical Psychologist):

Michelle O'Shea

University of Glasgow

Institute of Health and Wellbeing

1055 Great Western Road

Glasgow, G12 0XH

m.o'shea.1@research.gla.ac.uk

Research Supervisors:

Dr David Grinter

Clinical Psychologist

Sir John Mann Centre

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Dr Hamish McLeod

University of Glasgow

Institute of Health and Wellbeing

1055 Great Western Road

Glasgow, G12 0XH

Hamish.McLeod@Glasgow.ac.uk

Appendix 2.4



Dear Clinician,

We are currently recruiting participants for our study entitled: **Mindfulness Based Cognitive Therapy for Older People in a community setting: a mixed methods feasibility study**. Mindfulness based cognitive therapy (MBCT) has been recognised as an effective treatment for depression and is recommended for recurrent depression in working age adults. However, there is limited but promising research into MBCT for older people. This research will explore whether it is possible to deliver MBCT to older people and whether older people find it an acceptable intervention.

We are looking for participants to take part in a Mindfulness group which will run weekly, for 8 weeks, with each session lasting 2 hours. The focus of the group was to develop Mindfulness-based skills based upon the programmes of Mindfulness Based Stress Reduction, developed by Jon Kabat Zinn, and Mindfulness Based Cognitive Therapy, developed by Williams, Teasdale and Segal.

We are looking for participants who meet the following criteria.

Inclusion:

- Have capacity to consent to take part in a research study
- 65 years old or over
- Living in the community
- History of depression
- Subjectively reporting at least one of the following symptoms:
 - Lack of motivation
 - Lack of initiative
 - Lack of goal directed behaviour
 - Difficulty maintaining roles and responsibilities
 - Poor concentration
 - Loss of interest in previously enjoyed activities
 - Low mood
 - Ruminative thinking

Exclusion:

- Known learning disability
- Known cognitive impairment
- Currently experiencing symptoms of psychosis

We would greatly appreciate your help in identifying participants for this study. If you know anyone who is currently seen within your service that meets the criteria, please provide them with an information pack about the study. If they are interested in taking part, or want to know more information, please contact me on 01698 210021 to discuss their referral.

I look forward to hearing from you.

Michelle O'Shea

Trainee Clinical Psychologist

Dr David Grinter

Clinical Psychologist

Appendix 2.5



MINDFULNESS: PRE COURSE INFORMATION

Guidelines for participation and practice

Background and aims

This eight week course is based upon the programmes of Mindfulness Based Stress Reduction, developed in the United States by Jon Kabat Zinn, and Mindfulness Based Cognitive Therapy, developed in the UK and Canada by Mark Williams, John Teasdale and Zindel Segal. It has also been shaped by our own personal experiences of mindfulness practice and we hope that it will provide rich sources of inspiration for you.

The aims of the course is to help you develop an in-depth personal experience of mindfulness and to build the foundations that will help you to applying this in a meaningful way in your life.

A growing body of evidence demonstrates that Mindfulness based approaches can be effective in the management of a range of health conditions including chronic pain, psoriasis, fibromyalgia and heart disease. There is increasing evidence to support the effectiveness of mindfulness in the treatment of depression particularly for relapsing or recurrent depression. These findings have been reflected in a number of treatment guidelines including The National Institute for Health and Clinical Excellence (2009) 'Treating Depression in Adults' and Scottish Intercollegiate Guidelines Network (2010) 'The Non-pharmacological Management of Depression in Adults'. These care standards state that Mindfulness practices appear to enable people to address current issues of low mood/depression, reduce the risk of relapse, improve sleep, and reduce anxiety.

The course mainly involves having direct experience of mindfulness training, and we would like to invite you to immerse yourself as best as you can into this process. This means adopting an attitude of curiosity to your experience in the moment and suspending judgment as to whether or not you think these approaches will work for you.

Preparation and attendance

We would very much like to encourage you to attend all of the group sessions, if at all possible. You are invited to wear loose and comfortable clothing for the course, appropriate for some gentle body movement and stretching.

If you are concerned about your health or ability to engage in some gentle stretching exercises based upon yoga, we would advise that you discuss this with your GP or the group facilitators. The stretching exercises can be done in a sitting position on a chair. It is important that you are able to work safely within your own limitations, opting out of any exercises which you do not feel confident about. The exercises have been adapted to suit the needs of people with a variety of physical conditions and we will work within the group to help participants find a suitable way to practise the exercises comfortably. The exercises in the group are relatively gentle. The primary aim is to practice movement with awareness whilst being fully sensitive to our body's needs in the moment.

Personal practice and attitudes

We would like to emphasise the important benefits gained from personal practice and we request a commitment of around 30 minutes of daily mindfulness practice for the duration of this course. The more you are able to put into the course, the more stable your practice will feel at the end and the more confident you will feel about taking these approaches forward into your life.

It can be challenging to change our habits and to practice a new skill. We may find it difficult to carve out a regular practice time, and may need to negotiate with family, friends or colleagues to ensure that we protect this dedicated space and time, free from the distractions of everyday life.

We may find that, at times, we strongly resist this change in emphasis and habit in our lives, however strong our intention may be to develop these skills. We may notice our attempts to avoid the opportunity to practice, to find countless reasons why not to, and endless lists of other more important things which demand our time. We may find that we struggle with being quietly in our own company without

distractions and without any obvious agendas. We may feel bored. We may fall asleep! We will notice how the ordinary mind is so used to distraction and dulled awareness and how much it resists change.

So, it is important to remind ourselves of why we are doing this in the first place and what our intentions are. This can provide a sense of direction and purpose which can propel us forwards, if ever we encounter difficulties or if our commitment wavers. You may find it helpful to reflect on the questions below before starting the course. You can look back to your responses as you progress as a reminder of your intention.

It is helpful to adopt an attitude of curiosity and open mindedness for the duration of the eight weeks, and to suspend judgment as to whether or not this will work for you. At the end of the course, you can reflect and make your own decision as to whether or not you will continue with the practices you have learned.

You will benefit from commencing this journey with the spirit of patience and commitment. This means not knowing what the outcome will be, or what will unfold, but trusting in the practices you are engaging in. It also means persevering, even when you feel you are making no progress or when things feel difficult.

Jon Kabat Zinn has described these practices as like "*weaving a parachute*". We don't want to start practicing when we are in difficulty and need to jump out of the plane. We want to be weaving the parachute day and night, just hoping that when we need the support of mindfulness practice, it has a better chance of supporting us.

Appendix 2.6



Centre Number:

Study Number:

Participant Identification Number for this trial:

CONSENT FORM

Title of Project: Mindfulness Based Cognitive Therapy for Older People in a community setting: a mixed methods feasibility study

Name of Researchers: Michelle O'Shea, Dr David Grinter, Dr Hamish McLeod

1. I confirm that I have read the information sheet dated 3/1/2016 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. 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.

3. I give consent to be contacted following the group to be invited to an interview, but understand that my participation in the interview is voluntary

4. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from University of Glasgow, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

5. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.

6. I agree to my General Practitioner being informed of my participation in the study.

7. I agree to take part in the above study.



Name of Participant Date Signature

Name of Person Date Signature
taking consent

Appendix 2.7

Semi-Structured Interview Schedule

Introduction

Thank you for agreeing to meet with me to share your experience of the group. As you know, this study is looking at how feasible it is deliver mindfulness based cognitive therapy to older people. As part of the study, we are keen to know what worked well during the group and what perhaps needs changed if we were to run these groups again, or do more research in this area. Your honest feedback is greatly appreciated.

The group in general

- 1) What parts of the group did you enjoy?
 - a) What was it about that/those parts that you enjoyed?
- 2) What parts of the group did you not enjoy?
 - a) What was it about that/those parts that you did not enjoy?
- 3) What parts of the group did you find most difficult?
 - a) What was it about that/those parts that you found most difficult?

Between Session Tasks

- 1) You have already completed a section in the questionnaire about the between session tasks, how did you find those tasks in general?

Follow up questions if a positive response is given –

- a) How did you fit the home practice tasks into your routine?
- b) What were the barriers to completing the home practise tasks?
- c) What were the benefits of completing the home practise tasks?
- d) What were the negative aspects of completing the home practise exercises?

Follow up questions if a negative response is given –

- a) What did you find difficult/unpleasant about the home practice?
- b) What were the barriers to completing the home practise tasks?
- c) What would make the home practise exercise easier/more acceptable?

Taking part in research

- 1) What were your initial thoughts about taking part in a research study?

If the response indicates worry/apprehension, follow up question:

- a. How did you make your decision to take part in the study?

Recommendations

I would like you to think about the whole process, from the point where you were first informed about the research, to taking part in the groups, to sitting here today...

- 1) If we were to run these groups again or do similar research, what recommendations would you give us to make them better?
- 2) What would you tell us to definitely do again?

Thank you again for taking the time to come here today and share that information with me as part of the study. It is greatly appreciated.

End of interview.

Future groups

If we were to do a similar group again, what would you change about it?

Thank you for completing this satisfaction questionnaire.

Appendix 2.9

Satisfaction questionnaire results

	Mean Score (SD)	Range
What did you think about the time of day the groups took place?	1.00 (0.00)	1-1
What did you think about the duration of the group?	1.17 (0.41)	1-2
As part of the group, we asked you to do some home practise exercises, how easy were these to fit in?	2.33 (1.03)	1-3
How did you find the types of homework tasks you were asked to do?	1.83 (0.75)	1-3
What did you think about the types of questions in the questionnaires?	1.17 (.41)	1-2
What did you think about the length of time it took you to complete the questionnaires?	1.33 (0.81)	1-3
How did it feel to be asked to take part in a research study?	1.00 (0.00)	1-1

Items were scored on a 5 point likert scale, 1 being acceptable, 5 being unacceptable

Appendix 2.10

WoSRES
West of Scotland Research Ethics Service



West of Scotland REC 3
Ground Floor – The Tennent Institute
Western Infirmary
38 Church Street
Glasgow G11 6NT
www.nhsggc.org.uk

Dr Hamish McLeod
Institute of Health and Wellbeing, University of
Glasgow
Admin Building, Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

Date 14th January 2016
Your Ref
Our Ref
Direct line 0141 211 2123
Fax 0141 211 1847
E-mail WOSREC3@ggc.scot.nhs.uk

Dear Dr McLeod

Study title:	Mindfulness Based Cognitive Therapy for Older People in a community setting: a mixed methods feasibility study
REC reference:	15/WS/0285
IRAS project ID:	180820

Thank you for the email dated 3rd January, 2016. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 23 December 2015.

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Participant information sheet (PIS)	2.0	03 January 2016

Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
GP/consultant information sheets or letters [referrer information sheet]	v1.0	23 October 2015
GP/consultant information sheets or letters [referrer initial letter]	v1.0	23 October 2015
GP/consultant information sheets or letters [referrer completion letter]	v1.0	23 October 2015
Interview schedules or topic guides for participants [interview schedule]	v1.0	23 October 2015
Letter from sponsor		23 October 2015

Letters of invitation to participant [Group invite letter]	v1.0	23 October 2015
Letters of invitation to participant [post intervention invite letter]	v1.0	23 October 2015
Non-validated questionnaire [Participant Satisfaction Questionnaire]	1	23 October 2015
Other [session 1 handout 1]	v1.0	23 October 2015
Other [session 1 handout 2]	v1.0	23 October 2015
Other [session 1 handout 3]	v1.0	23 October 2015
Other [session 1 handout 4]	v1.0	23 October 2015
Other [session 2 handout 1]	v1.0	23 October 2015
Other [session 3 handout 1]	v1.0	23 October 2015
Other [participant completion letter]	v1.0	23 October 2015
Other [session 4 handout 1]	v1.0	23 October 2015
Other [session 5 handout 1]	v1.0	23 October 2015
Other [session 6 handout 1]	v1.0	23 October 2015
Other [session 6 handout 2]	v1.0	23 October 2015
Other [session 8 handout 1]	v1.0	23 October 2015
Other [session 8 handout 2]	v1.0	23 October 2015
Participant consent form [consent form]	v1.0	14 September 2015
Participant information sheet (PIS) [Mindfulness Information Sheet]	v1.0	23 October 2015
Participant information sheet (PIS)	2.0	03 January 2016
REC Application Form [REC_Form_19112015]		19 November 2015
Referee's report or other scientific critique report		10 August 2015
Research protocol or project proposal [MRP Proposal]	v1.0	23 October 2015
Summary CV for Chief Investigator (CI)		18 September 2015
Summary CV for student [M O'Shea]		24 September 2015
Summary CV for supervisor (student research) [DJ Grinter]		21 September 2015
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Plain english summary]	v1.0	23 October 2015
Validated questionnaire [AES]		
Validated questionnaire [DTQ]		
Validated questionnaire [FFMQ]		
Validated questionnaire [GDS-short form]		
Validated questionnaire [RRS]		
Validated questionnaire [TEPS]		
Validated questionnaire [AAQ-II]		

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

15/WS/0285 **Please quote this number on all correspondence**

Yours sincerely



Liz Jamieson
REC Manager

Copy to: Mr Raymond Hamill, R&D NHS Lanarkshire

Appendix 2.11



Dr Hamish McLeod
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R&D Department
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Date 15.01.2016
Enquiries to Lorraine Quinn,
R&D Facilitator
Direct Line 01236 712445
Email lorraine.quinn@lanarkshire.scot.nhs.uk

Dear Dr McLeod

Project title: Mindfulness Based Cognitive Therapy for Older People in a community setting: a mixed methods feasibility study
R&D ID: L15061

I am writing to you as Chief Investigator of the above study to advise that R&D Management approval has been granted for the conduct of your study within NHS Lanarkshire as detailed below:

NAME	TITLE	ROLE	NHSL SITE TO WHICH APPROVAL APPLIES
Michelle O'Shea	Trainee Clinical Psychologist	Principal Investigator	Hunter Health Centre, East Kilbride Sir John Mann Centre, Bellshill

As you are aware, NHS Lanarkshire has agreed to be the Sponsor for your study. On its behalf, the R&D Department has a number of responsibilities; these include ensuring that you understand your own role as Chief Investigator of this study. To help with this we have outlined the responsibilities of the Chief Investigator in the attached document for you information.

All research projects within NHS Lanarkshire will be subject to annual audit via a questionnaire that we will ask you to complete. In addition, we are required to carry out formal monitoring of a proportion of projects, in particular those projects that are Sponsored by NHS Lanarkshire. In either case, you will find it helpful to maintain a well organised Site File. You may find it helpful to use the folder that we have included for that purpose.



For the study to be carried out you are subject to the following conditions:

Conditions

- You are required to comply with Good Clinical Practice, Ethics Guidelines, Health & Safety Act 1999 and the Data Protection Act 1998.
- The research is carried out in accordance with the Scottish Executive's Research Governance Framework for Health and Community Care (copy available via the Chief Scientist Office website: <http://www.show.scot.nhs.uk/cso/> or the Research & Development Intranet site: <http://firstport/sites/randd/default.aspx>).
- You must ensure that all confidential information is maintained in secure storage. You are further obligated under this agreement to report to the NHS Lanarkshire Data Protection Office and the Research & Development Office infringements, either by accident or otherwise, which constitutes a breach of confidentiality.
- Clinical trial agreements (if applicable), or any other agreements in relation to the study, have been signed off by all relevant signatories.
- You must contact the Lead Nation Coordinating Centre if/when the project is subject to any minor or substantial amendments so that these can be appropriately assessed, and approved, where necessary.
- You notify the R&D Department if any additional researchers become involved in the project within NHS Lanarkshire
- You notify the R&D Department when you have completed your research, or if you decide to terminate it prematurely.
- You must send brief annual reports followed by a final report and summary to the R&D office in hard copy and electronic formats as well as any publications.
- If the research involves any investigators who are not employed by NHS Lanarkshire, but who will be dealing with NHS Lanarkshire patients, there may be a requirement for an SCRO check and occupational health assessment. If this is the case then please contact the R&D Department to make arrangements for this to be undertaken and an honorary contract issued.

I trust these conditions are acceptable to you.

Yours sincerely,

Raymond Hamill – Corporate Research & Development Manager

c.c.

NAME	TITLE	CONTACT ADDRESS	ROLE
Michelle O'Shea	Trainee Clinical Psychologist	John Mann Centre	Local Collaborator
Dr David Grinter	Clinical Psychologist	Airbles Road Centre	Named Contact

Enc 1 x Site File
1 x Responsibilities as Sponsor Notes

Appendix 2.12



DOCTORATE IN CLINICAL PSYCHOLOGY

SUBMISSION COVER SHEET

Trainee Name	Michelle O'Shea
Matriculation Number	21091000
Name of Assessment	MRP proposal - Version 4
Submission Date	5.6.15
Version number	4
Proposal Title	Mindfulness Based Cognitive Therapy for Older People in a community setting: a mixed methods feasibility study
Word count	3511
Academic Supervisor (s)	Dr Hamish McLeod
Clinical Supervisor (s)	Dr David Grinter
Additional information	

Abstract

Background: Mindfulness-based interventions (MBI) are based on Buddhist practices and have been evidenced as effective treatments for depression. They are now recommended in the treatment of recurrent depression in adults. There is an expanding evidence base for MBIs for various clinical presentations. MBIs include mindfulness based cognitive therapy (MBCT), which aims to provide participants with strategies to become more aware and accepting of their thoughts and feelings; and live within the present moment. Despite a growing literature base on MBIs, there is a gap in the literature exploring MBIs with older people.

Aims: The primary aim of this study is to explore the feasibility of delivering MBCT to older people, including recruitment rates, retention rates and acceptability of protocol. An additional aim will be to begin to explore the mechanisms of change that occur through the process of MBCT.

Method: A mixed methods feasibility approach will be adopted. Participants over the age of 65, with a history of depression will take part in an 8-week MBCT programme. Participants will be asked to complete measures pre-, mid- and post-intervention. They will also be invited to a semi-structured interview following the intervention.

Application: The results will contribute to the limited, but growing evidence based for MBCT with older people and the existing literature on the mechanisms of change in MBIs.

Introduction

Background

Mindfulness has been defined as “*the awareness that emerges through paying attention on purpose, in the present moment, and nonjudgmentally to the unfolding of experience moment by moment*” (Kabat-Zinn, 2003, p. 145). Research has demonstrated that mindfulness-based interventions (MBI) are effective in various areas of health and psychological wellbeing (Cramer et al., 2012, Meeten et al., 2014). Some research has suggested that MBIs for depression is as effective as treatment usually offered (Ma and Teasdale, 2004) and comparable outcomes to antidepressant medication (Kuyken et al, 2008).

Mindfulness-Based Cognitive Therapy (MBCT) vs Mindfulness-Based Stress Reduction (MBSR)

MBCT and MBSR are two common mindfulness based interventions (MBIs). Both are group based interventions designed to explore how mental states alter in relation to life events, develop skills to recognize mental states and use mindfulness techniques to manage difficult experiences. The techniques taught are derived from Buddhist practices but the groups are secular. MBSR was designed to help manage stress, where as MBCT was developed to help prevent relapse in depression and contains elements of cognitive behavioral therapy (Segal, Williams and Teasdale, 2002).

Relapse Prevention vs Symptom reduction

Teasdale et al. (2000) provided evidence that MBCT significantly reduced the risk of relapse in participants who had 3 or more episodes of depression, indicating that MBCT is a promising intervention for preventing relapse of depression. Recently there has been a shift to focus on the reduction of clinical symptoms following MBIs. Roemer et al. (2008) reported that following MBIs, 77% of their participants no longer met criteria for generalized anxiety disorder and this was maintained at 3 and 9 month follow up. There is emerging evidence to suggest that MBIs are effective for people who are currently experiencing symptoms. This research will include participants who are currently experiencing symptoms of depression.

Mechanisms of Change

There is an expanding literature base on the mechanisms of change in MBIs. One area of exploration that this research will include is distress tolerance. Lotan et al. (2013) reported that as mindfulness skills increased, their participants reported increased distress tolerance. Rumination is another area of exploration. Brennan et al. (2015) recently reported that negative rumination style plus low mindfulness ability increased the likelihood, and duration of depressive symptoms.

Outcomes

There is a wide range of outcomes examined within MBI literature, often specific to the sample population. Within the context of older people, it would be interesting to explore the effects of mindfulness on apathy and anhedonia, which are features of depression and seen in older people who do not experience depression (Lampe et al. 2000). Most research included a measure of mood (Kuyken et al., 2008; Brennan et al., 2015).

Treatment Recommendations

National Institute for Health and Care Excellence Guidelines (NICE, 2009) recommends MBCT for treatment and management of depression in adults who are currently well but have experienced three or more episodes of depression and are at risk of relapse. The Matrix (NES, 2009) recommends MBCT for the treatment of relapsing depression in adults but not for depression in Older People. This may reflect a lack of research with this population.

MBIs for Older People

Qualitative research of MBIs with older people suggests generally positive experiences. Smith et al. (2007) identified themes such as calmness, better coping and more acceptance following MBCT. Meeten et al. (2014) reported that whilst their participants gave positive feedback about MBCT itself, they did not feel confident in maintaining mindfulness practice. This highlights the need for further feasibility research in this area.

Quantitative research has yielded positive outcomes. Splevins et al. (2009) noted significant improvements in participant's emotional wellbeing and mindfulness skills post-MBCT. Foulk et al. (2013) concluded that MBCT was acceptable to older people based on their recruitment and retention rate (74%) and found that participants reported less rumination, improved sleep and significantly fewer symptoms of anxiety.

Complex Intervention Development

This study has been designed using the frameworks outlined in the MRC Developing and Evaluating Complex interventions (Craig et al., 2008), Lancaster et al. (2004) and Thablane et al. (2010). INVOLVE briefing notes for researchers (Hayes, Buckland and Tarpey, 2012) and Yardley et al's (2015) "person based approach to intervention development", which is a mixed methods framework that attempts to "understand and accommodate the perspectives of the people who will use the interventions" has also been taken into account. The study is exploratory in nature rather than hypothesis testing, providing information for future research in the area. It will focus on the feasibility/piloting stage of the MRC Complex Intervention framework cycle (p.8) by testing procedures but also make attempts to identify measures to help understand the change process, which is included in their evaluation stage.

Current Proposed Research

This research will draw upon the frameworks noted above to examine the feasibility of MBCT groups with older people who are experiencing symptoms of depression.

Aims

6. To explore the acceptability of mindfulness groups in an older adult sample
7. To estimate the likely rates of recruitment and retention of participants for future trials
8. To generate data for effect size estimation for subsequent trials
9. To explore the acceptability of outcome measures
10. To explore possible mechanisms of change involved in MBIs

Research Questions

1. Is it feasible to deliver MBCT groups to older people in the community?
2. Is MBCT an acceptable intervention for older people?
3. Are the outcome measures used acceptable to older people?
4. What are potential mechanisms of change in MBCT?

Plan of Investigation

Participants:

Inclusion criteria

- Have capacity to consent to research
- Over 65 years old
- Living in the community
- History of depression
- Subjectively reporting at least one of the following symptoms:
 - Lack of motivation,
 - Lack of initiative,
 - Lack of goal directed behavior,
 - Difficulty maintaining roles and responsibilities,
 - Poor concentration,
 - Loss of interest in previously enjoyed activities
 - Low mood
 - Ruminative thinking

Exclusion criteria

- Known learning disability
- Known cognitive impairment
- Currently experiencing symptoms of psychosis

Recruitment Procedures

Participants will be recruited from Old Age Psychiatry Community Mental Health Teams within NHS Lanarkshire. Information packs will be distributed amongst staff to be given to potential participants. The staff will contact the researcher with names of those interested and an initial appointment will be set up. Information will be discussed and questions answered prior to participants consenting. Participants would be advised that they are free to withdraw from the study at any point.

Measures

Clinical Outcomes:

Geriatric Depression Scale – Short Form (Yesavage and Sheikh, 1986). D’Ath et al. (1994) reported that GDS-sf had an internal consistency of $\alpha = .80$ within their sample.

Apathy Evaluation Scale (Marin et al., 1991). The authors reported that the internal consistency was $\alpha = .86-.94$ and test-retest reliability (over 25.4 days) of $.76-.94$. Resnick et al. (1998) reported the internal consistency was $\alpha = .89$.

Temporal Experience of Pleasure Scale (Gard et al., 2006). Buck and Lysaker (2013) reported moderate to high test-retest reliability over 6 months and internal consistency of $\alpha = .67$ and $\alpha = .68$ for consumatory and anticipatory items respectively.

Mechanisms of Change

Five Facet Mindfulness Questionnaire (FFMQ, Baer et al., 2006). The authors report good internal consistency ($\alpha = .75-.91$) and test-retest reliability ($r = .65-.83$). Hsu et al. (2013) reported the internal consistency was $\alpha = .91$.

The Acceptance and Action questionnaire (AAQ-II, Bond et al., 2011). The authors reported good psychometric properties, with mean of $\alpha = 0.84$, and a 3- and 12-month test-retest reliability of 0.81 and 0.79 respectively.

Distress Tolerance Scale (DTS, Simons and Gaher, 2005). The authors reported that scale has good psychometric properties, including high internal consistency ($\alpha = .89$) and has demonstrated adequate 6-month test-retest reliability ($r = .61$).

Ruminative Response Scale (RRS, Traynor et al., 2003). Brennan et al. (2015) report that the internal consistency of the RRS in their sample was $\alpha = .86$ for depression-related rumination, $\alpha = .68$ for brooding, and $\alpha = .73$ for reflection.

Design

A mixed-methods feasibility design will be adopted.

Research Procedures

- *MBCT Protocol*

The programme will follow the NES approved MBCT protocol which is based on Teasdale, Williams and Segal (2014). This involves 8, weekly 2-hour sessions. The manual contains session handouts that will be given to participants on a session-by-session basis and stored in a folder supplied to each participant. The protocol includes a CD containing mindfulness exercises. This will be used within sessions and also replicated and distributed to participants to allow for home practise. Each session reviews the home practise which will explore compliance as well as address any barriers.

Consideration has been given to the needs of older people. A session-by-session review indicated that some adaptations may be required to ensure safety and comfort of participants (see Appendix 1 for details).

- *Training*

Segal et al. (2012) outline that MBCT facilitators should have:

- Accredited training in counseling, psychotherapy or another mental health profession with experience of working with mood disorders
- Training in CBT or another evidence based approach to depression
- Experience of groupwork
- Ongoing experience of mindfulness practice

One facilitator is Clinical Psychologist working with Psychological Therapies for Older People in NHS Lanarkshire and the other a trainee Clinical Psychologist.

The Clinical Psychologist has completed a Doctorate in Clinical Psychology, which includes CBT training. He has completed an 8-week NES approved MBCT course. He has several years experience of working with older people as, including groupwork.

The trainee Clinical Psychologist will be a 3rd year Older Adult aligned trainee. She has completed the 8-week Mindfulness Based Stress Reduction course in August 2013.

- *Supervision*

The clinical psychologist will provide supervision of the trainee on a weekly basis. An experienced mindfulness practitioner and trainer within NHS Lanarkshire will provide supervision to the clinical psychologist where required. To ensure adherence to the MBCT protocol, a sample of sessions will be recorded and reviewed by the experienced mindfulness practitioner.

Data collection

Pre-intervention all measures will be administered by group facilitator during an individual meeting prior to the group commencing. The RRS, AAQ-II and FFMQ will be given to participants at the end of session 4 and asked to complete for session 5. Participants will be asked to complete post- measures at the end of session 8 as well as a satisfaction questionnaire.

Following the group, participants will be invited to attend a semi-structured interview where they will be asked to discuss specific aspects of the group. The interview will be conducted by one of the group facilitators (trainee) in an NHS Lanarkshire building. It is recognised that this is a limitation of the study due to potential conflicts of the group facilitator asking for feedback on group; however within the scope of this research no alternative was possible. See Appendix 2 for further details of interview.

Interviews will be recorded, then transcribed, and the recording then destroyed. All personal identifiable information will be removed and transcriptions will be identified by number.

Data will be gathered on type of referrals are received, demographic information of the participants, attendance rate and dropout rate.

Data Analysis

The primary interest in analysis will be exploring the feasibility of the intervention by examining multiple factors including recruitment and retention rates, the completion of measures, and qualitative data gathered. Exploratory data analysis will be conducted with the quantitative data gathered to explore pre-, mid- post- changes in outcomes and mechanisms of change.

Qualitative data will be analysed using Thematic Analysis (Braun and Clark, 2006).

Sample Size, Settings & Equipment

Sample size

No formal sample size is stated due to the nature of the research design and its exploration of the feasibility of recruiting participants. When considering group numbers, Segal et al. (2002) suggest no more than 12 participants per group and it is planned to run two groups. For the qualitative component, a purposive sample will be used to explore a variety of views and explore sources of variance. This will include completers and non-completers. Qualitative sampling will be iterative until data saturation is reached. It is expected that a sample of 10-12 will be recruited from group in line with Braun and Clarke's (2013) recommendation for qualitative research.

Settings and Equipment

Groups will take place in NHS Lanarkshire buildings, in a suitable room.

Equipment

Equipment required	Source
<i>Group</i>	
MBCT handouts	Photocopying costs
Folder for each participant	To be purchased
Chocolate (mindful eating exercise)	To be purchased
MBCT CD	CD's to copy onto to be purchased
Refreshments	To be purchased
Measures (GDS, FFMQ, DTS, AAQ-II, RRS, TEPS, AES)	Available online (printing costs)
Information packs/ consent forms	Printing costs
<i>Interviews</i>	
Audio Recorder	Loan from University
Laptop and Foot pedal	Loan from University

Health & Safety and Ethical Issues

Health and Safety issues

Groups will be facilitated by two members of staff and will take place within normal working hours. Normal clinical health and safety considerations will apply.

Group facilitators will be vigilant for distress in participants. If this occurred, a group facilitator would manage it sensitively. Any adverse events as part of research procedures will be logged. See Appendix 4 for more details.

Ethical Issues

An ethics application will be submitted to the West of Scotland Research and Ethics Committee and advice will be sought from NHS Lanarkshire Research and Development team.

Confidentiality and its limits will be discussed at the start of the group. Participants will be informed that their personal identifiable information will be removed from any information used. Participants will be informed that they can leave the study at anytime and opt out of being contacted for the post-intervention interview.

Data will be handled in line with the Data Protection Act (1998), the Freedom of information Act (2000), Caldicott Guidelines and the NHS Confidentiality Code of Practise Guidelines (2003).

Financial Issues

The financial costs associated with the study will be minimal. See table 1 for items required. See Appendix 5 for costs.

Timetable and Practical Applications

April 2015: MRP Proposal submitted to university

July 2015: Complete IRAS Ethics Application

November 2015: Submit Ethics Application

December 2015: Begin recruitment

January – March 2016: Cycle 1 (delivery of 8 sessions and data collection, including post-intervention interviews)

March -May 2016: Cycle 2 (delivery of 8 sessions and data collection, including post-intervention interviews)

May-July 2016: Data analysis and write up

Practical Applications

This research will inform researchers and clinicians about the acceptability and feasibility of MBCT for older people. It is hoped that the research will be able to indicate suitable measures to be used in future research that are acceptable to older people.

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