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ORIGINAL PAPER

Feasibility and Acceptability of Mindfulness-based Cognitive Therapy Compared with Mindfulness-based Stress Reduction and Treatment as Usual in People with Depression and Cardiovascular Disorders: a Three-Arm Randomised Controlled Trial

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Abstract

Depression co-occurs in 20% of people with cardiovascular disorders, can persist for years and predicts worse physical health outcomes. While psychosocial treatments have been shown to treat acute depression effectively in those with comorbid cardiovascular disorders, to date, there has been no evaluation of approaches aiming to prevent relapse and treat residual depression symptoms in this group. Consequently, the current study aimed to examine the feasibility and acceptability of a randomised controlled trial design evaluating an adapted version of mindfulness-based cognitive therapy (MBCT) designed specifically for people with comorbid depression and cardiovascular disorders. A three-arm feasibility randomised controlled trial was conducted, comparing MBCT adapted for people with cardiovascular disorders plus treatment as usual (TAU), mindfulness-based stress reduction (MBSR) plus TAU and TAU alone. Participants completed a set of self-report measures of depression severity, anxiety, quality of life, illness perceptions, mindfulness, self-compassion and affect and had their blood pressure taken immediately before, after and 3 months following the intervention. Those in the adapted-MBCT arm additionally underwent a qualitative interview to gather their views about the adapted intervention. Three thousand four hundred potentially eligible participants were approached when attending an outpatient appointment at a cardiology clinic or via a GP letter following a case note search. Two hundred forty-two (7.1%) were interested in taking part, 59 (1.7%) were screened as being suitable and 33 (< 1%) were eventually randomised to the three groups. Of 11 participants randomised to adapted-MBCT, 7 completed the full course, levels of home mindfulness practice were high and positive qualitative feedback about the intervention was given. Twenty-nine out of 33 randomised participants completed all the assessment measures at all three time points. The means Patient Health Questionnaire (PHQ)-9 scores for the MBCT-Heart and Living Mindfully (HeLM) group were lower at post-intervention and at the 3-month follow-up compared to the MBSR and TAU groups. The sample was heterogeneous in terms of whether they reported current depression or had a history of depression and the time since the onset of cardiovascular disorders (1 to 25 years). The adapted-MBCT intervention was feasible and acceptable to participants; however, certain aspects of the trial design were not. In particular, low recruitment rates were achieved and there was a high withdrawal rate between screening and randomisation. Moreover, the heterogeneity in the sample was high, meaning the adapted intervention was unlikely to be well tailored to all the participants needs. This suggests that if the decision is made to move to a definitive trial, study recruitment procedures will need to be revised to recruit a target sample that optimally matches the adapted intervention.

Keywords MBCT · Depression · Cardiovascular disorders · Feasibility · Acceptability

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Background

Depression occurs in approximately 20% of people with cardiovascular disorders (CVDs) (Davidson 2012; Huffman et al. 2013), often running a chronic and/or recurrent course; being associated with significant functional impairment in its own right and predicting worse medical outcomes (Baumeister et al. 2015; Pelletier et al. 2015). The comorbidity between depression and CVDs is associated with poor medication adherence and reduced physical and psychological quality of life (Dickens et al. 2012; Rustad et al. 2013). Moreover, this comorbidity predicts a substantial increase in hospital admission rates and the use of health services (Baumeister et al. 2015; Guthrie et al. 2016). Notably, depression is often associated with an increase in essential CVD risk factors, including unhealthy behaviours, such as poor diet and smoking (Katon 2011; Luppino et al. 2010). This comorbidity also negatively affects people's self-care (Cameron et al. 2009; Riegel et al. 2011) and leads to a greater inability to perform routine activities (Walters et al. 2014).

There may be underlying psycho-biological mechanisms in depression that directly exacerbate cardiovascular risk (Carlson 2012; Naylor et al. 2012). In terms of biological factors, both depression and CVDs are associated with elevated platelet activation and inflammation (Dickens 2015; Guarneri et al. 2009). On the psychological level, people with these conditions experience low self-efficacy, low self-care and negative illness perceptions (Greco et al. 2014; Morgan et al. 2014; Sarkar et al. 2007; Volz et al. 2016). In addition, perseverative negative cognitive processes (worry about the future and rumination about the past) have been associated with symptoms of depression (Nolen-Hoeksema 1991). Rumination has been shown to increase the likelihood, severity and duration of depression (Watkins 2008; Watkins and Teasdale 2004). Also, these perseverative cognitive processes were found to be associated with CVDs, such as coronary heart disease and hypertension (Gerin et al. 2012; Kubzansky et al. 1997; Radstaak et al. 2011). Consequently, effective psychosocial treatments need to be developed to manage depression in this group, both to counter it and to enhance physical health outcomes.

Mindfulness-based programmes already have a proven track record in addressing both physical and mental health symptoms. Mindfulness is defined as 'paying attention in a particular way: on purpose, in the present moment, and non-judgementally' (Kabat-Zinn 1994, p. 4). Mindfulness-based programmes are based on some common, essential features, including a shared model of human experience, which addresses the causes of human distress and pathways to relieving it, and the centrality of mindfulness practice as an experiential inquiry-based learning process. However, different programmes have somewhat different emphases, depending on their specific intentions, the target contexts and populations (Crane et al. 2017). Mindfulness-based stress reduction (MBSR) and mindfulness-based cognitive therapy (MBCT) were developed as approaches to develop 'a new relationship' with experience characterised by present moment focus, decentring and an approach orientation (Crane et al. 2017). They constitute a range of formal mindfulness practices as a key method for training attentional control as well as the non-judgemental attitudinal dimensions of mindfulness (Crane et al. 2017).

MBSR was first developed to help people with chronic health problems better manage pain, health and their lives (Kabat-Zinn 1990, 2013). The intention is for participants to learn to bring non-judgmental awareness to present-moment experience and learn skilful ways of responding to physical and emotional pain. During MBSR, participants learn a set of mindfulness practices that include focus on the breath and body as well as yoga. MBSR has been found to have positive effects on anxiety, depression and worry (Hoge et al. 2013) as well as some physical symptoms, such as high blood pressure (Carlson et al. 2007; Hughes et al. 2013). However, other studies have found that it does not have effects on physical symptoms, including high blood pressure (Blom et al. 2014; Campbell et al. 2012).

MBCT combines mindfulness practices and certain cognitive therapy techniques to target negative thinking styles in individuals with a history of depression, who are at high risk of depressive relapse and recurrence (Segal et al. 2002, 2013). It is based on psychological models of mechanisms that maintain and exacerbate common psychological problems and uses behavioural, cognitive and mindfulness strategies (Michalak et al. 2011; van Aalderen et al. 2012). It helps people recognise and decentre from habitual patterns of thinking and behaving (Kuyken et al. 2010), thereby facilitating more resilient responses to challenges. MBCT addresses both universal vulnerabilities addressed by any mindfulness-based intervention and specific ones implicated in depressive relapse (Crane et al. 2017). Whilst MBCT was originally designed as an approach to preventing depressive relapse in people at risk of depression (Kearns et al. 2015; Kuyken et al. 2016), it has also been evaluated in people with sub-clinical residual symptoms (Eisendrath et al. 2016) and people suffering from physical health conditions (Schoultz et al. 2015; van Son et al. 2014). MBCT has demonstrated positive effects on worry, rumination, positive and negative affect, mindfulness and self-compassion (Geschwind et al. 2011; Kearns et al. 2015; Kuyken et al. 2008; van Aalderen et al. 2012). To the best of our knowledge, there has only been one study that has examined the effects of MBCT on depression in people with coronary heart disease (CHD) (O'Doherty et al. 2015). Whilst the outcomes of this study indicated that people in the MBCT group showed improvements regarding current depression, anxiety, quality of life and illness perceptions compared to a waiting list group, the non-randomised design used precludes strong conclusions from

being drawn. Moreover, limited information is provided about the adaptations made to the MBCT programme for CHD and hence, further research is needed.

Maximising the potential benefits of MBCT for people with comorbid depression and CVD requires careful consideration of the mechanisms that drive psychological distress in people with CVD as well as their particular intentions and functional limitations. In particular, standard MBCT focuses mainly on depression-specific mechanisms; for example, rumination about causes, meanings and the consequences of low mood. However, people with cardiovascular disorders worry about the cardiovascular event returning or the causes, meanings and consequences of a cardiac condition (Larsen and Christenfeld 2009; Rozanski et al. 1999). Moreover, given the nature of cardiovascular disorders, the body cannot be assumed to provide a safe, neutral anchor for mindfulness practice and a different focus may be required; attending to bodily sensations may increase anxiety by activating worries of a further cardiac event, which can increase pulse and/or heart rate. Furthermore, a number of studies have indicated that people with CVDs have low confidence regarding their ability to take care of their condition, also known as self-efficacy, and the associated impacts on their self-care, which can lead to worse medical outcomes (Greco et al. 2014; Riegel et al. 2011; Tovar et al. 2015; Volz et al. 2016). Hence, care is needed to consider how to enhance self-efficacy best.

MBCT adaptations are intended to target more specifically the mechanisms that drive both depression and cardiovascular disorders (e.g. rumination and worry specific to CVD, lower self-efficacy and poor self-care) as well as the general mechanisms targeted by any mindfulness-based intervention (Alsubaie et al. 2017).

Therefore, we are interested in examining whether adapted-MBCT adds value over and above MBSR, because it (a) includes a more specific hypothesised mechanism that drives the distress associated with CVDs and mood problems and (b) uses cognitive and behavioural strategies alongside those employed in MBSR. To examine this uncertainty requires a three-arm design comparing adapted-MBCT + treatment as usual (TAU) vs MBSR + TAU vs TAU alone. We hypothesised that MBCT adapted for people with depression and cardiovascular disorders would be more acceptable and effective than MBSR and TAU.

To help ensure the adaptations made to MBCT were optimally effective and likely to be implementable in practice, for our project, the Heart and Living Mindfully (HeLM), we followed the recent UK Medical Research Council guidelines (MRC) for developing complex interventions (Craig et al. 2008) and the National Institutes of Health (NIH) stage model (Onken et al. 2014). First, we established the evidence base around adapting MBCT for physical health conditions by conducting two systematic reviews (Abbott et al. 2014; Alsubaie et al. 2017). Second, an MBCT manual was adapted for people with depression and cardiovascular disorders, following a co-design process with service users and clinicians. Third, this manual was iteratively piloted with two groups of participants. The current study represents the final phase of the project, namely, a feasibility RCT to establish MBCT-HeLM's feasibility and preliminary acceptability. Feasibility studies are defined as those aimed at evaluating (a) the recruitment method and sample characteristics, (b) the optimisation of the data collection method and measures, (c) the acceptability of the intervention, (d) the availability of resources and finally, (e) the preliminary assessment of responses to the intervention (see Orsmond and Cohn 2015). Here, acceptability refers to a 'multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on the anticipated or experiential cognitive and emotional responses to the intervention' (Sekhon et al. 2017, p. 5). Thus, the current study was aimed at establishing the feasibility of conducting a large-scale randomised controlled trial of adapted-MBCT for people with depression and cardiovascular disorders. This includes (a) evaluating the recruitment methods; (b) estimating the trial recruitment, eligibility and completion rates (e.g. percentage of eligible people taking part and the percentage of participants completing the trial); (c) evaluating the three-arm design, randomisation, inclusion criteria and the data collection procedures; (d) describing the data on primary and secondary outcomes using descriptive statistics and (e) estimating the standard deviation for continuous outcome measures that will be used in the calculation of the sample size for the large-scale trial. Also, the study aimed to establish the acceptability of adapted-MBCT for people with depression and cardiovascular disorders.

Method

Participants

Eligible participants were adults aged 18 and older with a cardiovascular disorder (heart condition, stroke or hypertension). Participants also needed to have either a history of clinical depression (major depression disorder, minor depression or dysthymia) and/or current minor depression with or without anxiety symptoms. We excluded those who met the criteria for a current episode of major depression disorder. Other exclusion criteria were comorbid diagnoses of current substance dependence or abuse, organic brain damage, current or past psychosis, persistent antisocial behaviour, persistent self-injury and formal concurrent psychotherapy. Each participant received £10 as a token of appreciation for participating in the study every time (s)he completed the assessments with the researcher (£30

maximum per participant). The sample characteristics of the participants in the three groups are described in Table 1. The mean (SD) age was 64.8 (10.0), 58% were male, 61% were married and 94% were white British or Irish. Approximately two thirds were suffering from heart conditions, one third had had a stroke, four people had hypertension and five had two or more cardiovascular disorders. Seventy-six percent of the participants were not receiving any antidepressant.

We calculated the sample size based on the assumptions that about 20% of people with recent acute coronary diseases have major depression and a further 20% have raised symptoms of depression that do not meet the diagnostic threshold. There are about 1000 patients per year passing through the Exeter cardiology service following having experienced acute coronary diseases. The aim was to recruit for 7 months and based on that we expected that approximately (a) 580 patients ($7/12 \times 1000$) would pass through in that period; (b) 230 patients (40% of the 580) would have at least mild depression; (c) 92 patients (40% of the 230) would participate in the study and (d) 74 patients (80% of the 92) would be followed up at 3 months (approximately 24 per group, based on running two groups for each of adapted-MBCT and MBSR). The 580 patients with acute coronary diseases would be large enough to estimate the percentage with at least mild depression with a margin of error no greater than ± 4 percentage points, based on the width of the 95% confidence interval. The 230 patients with mild depression would be large enough to estimate the percentages that participate with a margin of error no greater than ± 7 percentage points. The 92 trial participants would be large enough to estimate the percentage followed up at 3 months with a margin of error no greater than ± 11 percentage points. The 74 participants that provide data at 3-months follow-up would be large enough to estimate the standard deviation for a continuous outcome to within 20% of the true value.

Procedures

This project is a feasibility study of a three-arm randomised controlled trial comparing adapted-MBCT (HeLM) plus treatment as usual (TAU), standard mindfulness-based stress

Table 1 Demographic characteristics

	Total ($n = 33$)	MBCT-HeLM group ($n = 11$)	MBSR group ($n = 11$)	TAU group ($n = 11$)
Age, mean (SD)	64.8 (10.0)	64.2 (11.6)	64.8 (10.6)	65.4 (8.4)
Gender, *n* (%)				
Male	19 (58%)	5	5	9
Female	14 (42%)	6	6	2
Marital status, *n* (%)				
Single	4 (12%)	1	2	1
Married	20 (61%)	6	6	8
Divorced	8 (24%)	3	3	2
Widowed	1 (3%)	1	0	0
Ethnicity, *n* (%)				
White British/Irish	31 (94%)	10	10	11
White other	1 (3%)	1	0	0
Asian British	1 (3%)	0	1	0
Employment status, *n* (%)				
Employed	10 (30%)	4	4	2
Unemployed	2 (6%)	1	0	1
Retired	21 (64%)	6	7	8
Type of CVD, *n* (%)				
Heart conditions	18 (55%)	6	5	7
Stroke	10 (30%)	4	4	2
Hypertension	4 (12%)	1	1	2
Not-specified	1 (3%)	0	1	0
Having more than one CVD, *n* (%)	5 (15%)	0	3	2
On antidepressant medication, *n* (%)				
Yes	8 (24%)	1	2	5
No	25 (76%)	10	9	6

TAU treatment as usual, *SD* standard deviation, *CVD* cardiovascular disorders

reduction (MBSR) plus TAU, and TAU alone, for the treatment of depressive symptoms in people with comorbid depression and cardiovascular disorders. For the purpose of feasibility, in this study, we intended to draw out whether conducting a three-arm design would be practicable or not. If we proceed to a main trial, we hope to compare MBCT-HeLM with MBSR to determine its relative efficacy on key primary and secondary outcomes. The study was conducted in the AccEPT Clinic/Mood Disorders Centre at the University of Exeter. Participants completed a set of self-report questionnaires and blood pressure was recorded at baseline, post-intervention and at 3-month follow-up. Those in the MBCT-HeLM group additionally took part in a short qualitative interview after completing the course to assess the acceptability of the adapted-MBCT intervention.

The recruitment process was conducted through three resources: primary care (GPs), specialised services (the cardiology department at Royal Devon and Exeter Hospital), and in the community in Exeter via distributed materials, with one objective being to assess the efficiency of these methods. Physicians and nurses in the cardiology department were invited to inform in/outpatients about the study and the outpatient's clinic nurses were asked to screen interested patients using Patient Health Questionnaire-8 (PHQ-8). This tool contains eight of the nine items of Patient Health Questionnaire-9 (PHQ-9) designed to evaluate major depressive disorder (MDD), as defined by the criteria stated in the Diagnostic Statistical Manual of Mental Disorders-Fourth Edition (DSM-IV). This brief version of the PHQ-9 has shown good validity and reliability for a general population (Kroenke et al. 2009) as well as for people with depression and heart conditions (Pressler et al. 2011). We chose to use this version excluding the suicide ideation or attempts item, as we anticipated delivering some of these questionnaires by post and we considered that this version might be more acceptable to patients completing the assessment in the absence of any researcher or clinician on hand to respond to any immediate concerns. We also added a question to assess whether the patient had a history of depression (no specific number of episodes) either after or before cardiovascular disorder onset. If a patient had a score between 5 and 15 (minimal to moderate depression) according to PHQ-8 cutoff or had a history of depression, (s)he received a copy of a poster containing a brief description of the study and a summary information sheet. GPs were also invited to refer suitable patients to the study. They were asked to identity patients registered at their surgery against the study's inclusion and exclusion criteria. Following this, patients were sent letters from the GP with a summary information sheet, which informed potentially eligible people that they could contact the researcher by post using the free envelope, telephone or e-mail. In addition, posters containing information on the study were distributed in cafés and restaurants; the posters were put on tables so potential participants could take one.

All interested people were contacted by telephone and screened after providing verbal consent. The full information sheets were sent to all eligible people by post. Subsequently, they were invited to an initial interview with the lead researcher (MA) to have the study explained further and to ensure they met the study inclusion criteria, using the structured clinical interview for DSM-IV-TR (SCID-I) (First et al. 2002). In this study, we used some parts of the mood episodes section (current major depressive episode (MDE), past MDE and current dysthymic disorders) in order to assess a potential participant's eligibility in detail. In this interview, informed written consent was obtained from all the participants and the baseline assessment was administered using questionnaires. In addition, each participant's blood pressure was measured using an automatic blood pressure monitor. The first screen was conducted during the first 4 months of the recruitment to check the inclusion/exclusion criteria of the study by MA and RV. The second was undertaken 2 weeks prior to the baseline by MA. During this phase, we checked current depression in people who were found eligible in the first screen. The reason for conducting two screens was that we thought 4-month duration of recruitment (the period between initial recruitment and randomisation) was a relatively long period of time for checking current depression and we wanted to make sure that people still wanted to take part so as to minimise drop-out post-randomisation.

Participants were randomised using sealed envelopes to conceal allocation. Blocking was used with randomly permuted block sizes in a non-systematic sequence. Randomisation of participants was stratified to ensure balance between the three trial arms based on severity of depression (based on PHQ-9 cutoff) and type of cardiovascular disorder (heart conditions, stroke and hypertension). The randomisation process was conducted by an independent researcher after the baseline assessment. It was not possible for the lead researcher (MA) to be blind at the post-intervention and follow up assessments. Participants were informed about their allocation status by post and those in the MBCT-HeLM and MBSR groups were asked to provide convenient times for meeting the mindfulness therapist (AE) for a 1-h orientation session before starting the intervention.

The MBCT-HeLM manual was developed across three stages and included two pilot MBCT groups with people with depression and CVDs. During the first stage of the manual development, seven monthly meetings were held between HeLM project's members with expertise in mindfulness interventions and people drawn from a Patient and Public Involvement (PPI) group, who had cardiovascular problems (January to July 2013). Some of the people with CVD also had comorbid mood disorders. Through these meetings, the

original MBCT manual was reviewed and the best ways to make it more appropriate for people with cardiovascular disorders were discussed in detail. For the second stage of developing the manual, a pilot group was conducted in July/August 2013 using the first draft of the manual. The group comprised four members of the HeLM project team (WK, CD, AE and RV) as well as people from the PPI group and eight further participants with depression and CVD. The aim in conducting this group was to identify any changes to the manual that were necessary through discussions among the HeLM members, PPI group and people with cardiovascular disorders on a week by week basis throughout the course. In the third stage of developing the manual, we conducted a second pilot group in October/November 2014 using the MBCT manual incorporating learning from phase 2. Weekly meetings were held after each MBCT session between the therapists (WK and AE) and the lead researcher (MA) to discuss the manual.

Participants were assessed at three time points: a baseline assessment conducted 3 weeks prior to randomisation, a post-intervention assessment taking place at the end of the MBCT-HeLM and MBSR groups and a 3-month follow-up after the interventions completion. For the TAU group, all assessments were at the same point post-randomisation. The lead researcher (MA) conducted the assessments at face-to-face meetings with the participants.

Interventions

Adapted-MBCT (HeLM) MBCT is a programme outlined by Segal et al. (2002, 2013) and developed based on MBSR. It comprises an individual orientation session and eight weekly 2.5-h group sessions. MBCT entails extensive mindfulness practices as well as cognitive-behavioural exercises. It is designed to help people become aware of problematic styles of thinking and reacting to decentre from these and respond more adaptively at times of a potential depressive relapse. The MBCT-HeLM manual maintained the essential structure and content of the original MBCT manual, but the focus and themes were reoriented to those that characterise people with low mood and CVDs. For example, in the first half of the programme, participants were oriented to turning towards bodily experiences associated with CVD, with curiosity, friendliness and care. Instead of an exclusive focus on depressive thinking, the emphasis was shifted to the ways in which physical symptoms were interpreted, for example, 'catastrophic thinking'. In session 4, the focus was on how stress/low mood/anxiety relates to bodily experience in a reciprocal relationship. We used the RAIN acronym (Recognise, Allow, Inquire and thoughts are Not facts). The first stage involves recognising when distressing bodily sensations, thoughts and images and feelings arise. Over time, the intention is to support an ability to decentre and disengage from problematic ways of reacting and learn to respond with greater understanding and compassion. In session 5, the title of the session was changed to 'Softness and Strength'. In this session, the RAIN acronym progresses to participants being invited to turn towards difficulties with a sense of allowing and inquiry. In this session, the themes around fear/hyperarousal or sadness/loss are picked up more fully with a view to beginning to decentre clearly from proliferation and over-identification. In session 6, the title of the session was changed to 'Symptoms as messages from the body; thoughts are not facts'. In this session, the RAIN acronym progresses to Inquiry and 'thoughts are not facts'. The intention is to recognise, allow and decentre from fear-based thinking/imagery, sadness/loss and proliferative thinking through disidentification with these habitual patterns of reacting. This session also includes beginning to note the possibility of responding compassionately with discernment/wisdom. Throughout the programme, there was a greater emphasis on mental and physical self-care. Participants were asked to complete a daily home practice diary 6 days per week and they were given mindfulness CDs to guide this practice. They were also invited to a long-day practice after session 6 to make sure that those in both groups were receiving the same dose of MBCT-HeLM and MBSR. The participants were asked to continue with treatment as usual (their normal clinical care). After completing the study, all the MBCT-HeLM participants were invited to regular reunion sessions in the AccEPT Clinic/Mood Disorders Centre at the University of Exeter.

Standard MBSR MBSR (Kabat-Zinn 1990, 2013) consists of eight weekly 2.5-h sessions with up to 30 participants and includes a full day of practice. MBSR comprises extensive formal and informal mindfulness-based exercises (e.g. body scan, breathing awareness, mindful yoga, mindful eating and mindful walking). The intention is to develop awareness and a new relationship with experience characterised by present moment-focus, approach orientation, compassion, understanding and equanimity. Participants were asked to complete a daily home practice diary 6 days per week, and they were given mindfulness CDs to guide this practice. They were also asked to continue with treatment as usual (their normal clinical care). After completing the study, all the MBSR participants were invited to regular reunion sessions in the AccEPT Clinic/Mood Disorders Centre at the University of Exeter.

TAU In this group, the participants were asked to continue their normal clinical care. Treatment as usual (TAU) could include psychiatric treatment, outpatient consultation, routine visits to the GP and support programmes from the mental health or cardiac nurse. These participants were offered standard MBCT service AccEPT Clinic at the Mood Disorders Centre after completing the follow up assessment.

Outcomes

The feasibility of MBCT-HeLM intervention in people with depression and cardiovascular disorders was established based on recruitment (recruitment methods, screening and baseline phases); retention rate (course completion); attrition rate (dropouts); participants' adherence (attendance, home practice and assessment completion) and other procedures, including randomisation, therapist adherence, inclusion/exclusion criteria and outcome measures. The rate of recruitment was quantified by the percentage of eligible people that were recruited and randomised. Retention and attrition were assessed by determining the percentage of completers and dropouts. The participants' adherence was measured using attendance rate and total time spent on the home mindfulness practice. In terms of assessment completion, we measured the percentage of people who fully completed each outcome assessment in each of the three groups.

We developed a short interview schedule with questions focusing on the MBCT-HeLM participants' overall satisfaction with the study, their views regarding the MBCT-HeLM techniques, home practice, the group format and the physical and psychological advantages/disadvantages from having taken part. The interviews were carried out face-to-face at the Mood Disorders Centre/University of Exeter. All the people who completed the MBCT-HeLM course were interviewed. In addition, those who dropped out were asked about their overall experience with the study and their reasons for dropping out. Each interview was audio recorded and took between 15 and 25 min, being subsequently transcribed verbatim by a transcription service. The home practice record sheet was used to assess which mindfulness practice participants were completing it and the amount of time spent on practice each week. Participants in the MBCT-HeLM and MBSR groups were asked to complete this sheet each week throughout the course and return it to the mindfulness teacher. The lead researcher photocopied the sheet and they were returned to the participants the following week.

The primary outcome was depression symptoms. Secondary outcomes were physical health-related, including blood pressure, which is considered to be an important risk factor for developing a cardiovascular disorder (Kelly and Fuster 2010) and heart-focused anxiety (HFA), which has been found to be linked to increased anxiety, depression and lower quality of life among people undergoing cardiac surgery (Hoyer et al. 2008). Further secondary outcomes are illness perceptions (participants' beliefs about their illness) which are associated with the speed and quality of recovery after myocardial infraction (Petrie et al. 1996) and general and specific quality of life in people with cardiovascular disorders, which are considered to be important indicators of the effectiveness of any treatment in people with heart disorders (Thompson and Yu 2003). Additionally, we used three process measures that we might use in a definitive trial to examine hypothesised mechanisms of action in MBCT-HeLM: mindfulness, self-compassion and positive and negative affect. These processes have been identified as mediators of outcome in previous studies of MBCT (Geschwind et al. 2011; Kuyken et al. 2010; Shahar et al. 2010). Also, mindfulness has been found to be a mediator of the effects of MBCT in people with coronary heart diseases (O'Doherty et al. 2015).

Measures

Depression Depressive symptoms were assessed using Patient Health Questionnaire-9 (PHQ-9; Spitzer et al. 1999), which contains nine items reflecting Diagnostic Statistical Manual of Mental Disorders-Fourth Edition (DSM-IV) criteria of major depression disorder (MDD). Each item is scored between 0 and 3 with a range of total scores between 0 and 27. The cutoff points of PHQ-9 are 5, 10, 15 and 20, which define the following levels of severity: none/minimal depression (0–4), mild depression (5–9), moderate depression (10–14), moderately severe depression (15–19) and severe depression (20–27). PHQ-9 has been found to have adequate psychometric properties in the UK (Cameron et al. 2008) as well as in people with coronary heart disease (Haddad et al. 2013).

Blood Pressure Levels of blood pressure in each participant were recorded using an advanced clinically validated blood pressure arm monitor, which provides readings of systolic and diastolic blood pressure.

Generalised Anxiety Severity of general anxiety symptoms was assessed using Generalised Anxiety Disorder-7 (GAD-7; Spitzer et al. 2006). This questionnaire comprises seven items reflecting the DSM-IV criteria of GAD. Each item is rated between 0 and 3 with a range of total scores between 0 and 21 with four levels of severity: none (0–4), mild anxiety (5–9), moderate anxiety (10–14), and severe (15–21). GAD-7 has been found to have good reliability and validity (Spitzer et al. 2006).

Cardiac Anxiety The Cardiac Anxiety Questionnaire (CAQ; Eifert et al. 2000) was used to assess heart-focused anxiety (HFA). The CAQ is a self-report containing 18 items reflecting three clinical aspects: cardio-protective avoidance behaviour, heart-focused attention and fears about heart sensations. Each item is scored from 0 (never) to 4 (always) with a range of total scores between 0 and 72. Higher scores indicate greater HFA. The CAQ has been found to have good internal consistency (Eifert et al. 2000). In the current study, this questionnaire was used with people with heart conditions only.

Health-Related Quality of Life The RAND 36-Item Health Survey 1.0 (Hays et al. 1993) was used to assess the participants' general quality of life. It contains 36 items, covering eight domains: physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (V), social functioning (SF), role-emotional (RE) and mental health (MH). These domains can be grouped into two main components: physical and psychological. Each item is recoded on a 0 to 100 range and then an average of the scores for the items in each domain is obtained, with higher scores being consonant with greater functioning and enhanced well-being. The RAND 36-Item has been found to have good psychometric properties (Hays et al. 1995).

Health-related Quality of Life in People with Cardiac Problems The Seattle Angina Questionnaire (SAQ; Spertus et al. 1995) is a specific measure that has been widely used to assess the health outcomes in people with angina. It contains 19 items, covering five clinical dimensions (subscales): physical limitations, angina stability, angina frequency, treatment satisfaction and disease perception. Each subscale is scored by reordering each response, summing up the scores for each subscale and then transforming the scores to a range of 0–100. No actual total for SAQ could be obtained, but those with higher scores indicate high levels of health and satisfaction. The SAQ has shown good validity and reliability in the UK (Garratt et al. 2001). In the HeLM study, we used this questionnaire with people with heart conditions only.

Illness Perception The Illness Perception Questionnaire-Revised (IPQ-R; Moss-Morris et al. 2002) was used to assess participants' beliefs about their illness. This measure is a revised version of the IPQ that was developed to assess cognitive representations. The IPQ-R measure comprises three sections; the first and third sections are called identity and causality. The second section contains 38 items covering seven dimensions: timeline acute/chronic, timeline cyclical, consequences, personal control, treatment control, illness coherence and emotional representations. In the HeLM study, we used the second section with the 38 items, each being rated between 1 and 5. The IPQ-R was scored by reversing some items and then summing up scores for each of the seven dimensions. No total for IPQ-R could be obtained. The IPQ-R measure has been used with people suffering from heart diseases and has showed good psychometric properties in the UK (Moss-Morris et al. 2002).

Mindfulness The Five-Facet Mindfulness Questionnaire (FFMQ; Baer et al. 2006) was designed to assess different aspects of mindfulness. It consists of 39 items, reflecting five facets: non-reactivity to inner experience (7 items), observing (8 items), acting with awareness (8 items) and describing (8 items) and non-judging of experience (8 items). Each item is rated on a 5-point Likert scale ranging from 1 (never or very rarely true) to 5 (very often or always true). The questionnaire is scored by reversing some items and then summing up the scores for each of the five facets. The total FFMQ score is obtained by summing up the five facet scores. The FFMQ has been found to have good psychometric properties (Baer et al. 2006, 2008).

Self-compassion The Self-Compassion Scale (SCS; Neff 2003) is a measure assessing the overall compassion according to three components: self-kindness, common humanity and mindfulness. Each component has a negative aspect: self-judgement, isolation and over-identification, respectively. It contains 26 items that are rated on a Likert scale from 1 (almost never) to 5 (almost always). The SCS subscales are scored by calculating the mean of responses on each subscale. The total SCS is scored by reversing scores of the negative subscales (self-judgement, isolation and over-identification) and then computing a mean of the subscale means. The SCS has been found to have good validity and reliability across different cultures (Neff 2003).

Positive and Negative Affect The Positive and Negative Affect Scale (PANAS; Watson et al. 1988) was used to assess participants' mood. It comprises 20 items that can be used to evaluate one's mood at various time points. The items are rated using a Likert scale from 1 (very slightly) to 5 (extremely). The positive affect subscale is scored by adding the scores of items 1, 3, 5, 9, 10, 12, 14, 16, 17 and 19. The negative affect subscale is scored by adding the scores of items 2, 4, 6, 7, 8, 11, 13, 15, 18 and 20. The PANAS has shown good validity and reliability in the UK (Crawford and Henry 2004).

Therapist Adherence and Competence

Both the MBCT-HeLM and MBSR groups were conducted by a trained and experienced mindfulness-based therapist (AE) with a considerable length of practice. The therapist received weekly supervision from an independent supervisor. The group sessions were video-recorded, and an independent mindfulness therapist evaluated two MBCT-HeLM and two MBSR sessions for competence and adherence. The Mindfulness-based Intervention: Teaching Assessment Criteria (MBI: TAC) (Crane et al. 2013), which is rated on a scale from 1 (incompetent) to 6 (advanced), was used.

Data Analyses

The data were analysed in line with the guidelines for good practice in designing, analysing and reporting pilot and feasibility studies (Lancaster et al. 2004; Lancaster 2015). The percentage of eligible people that consented to participate is reported with 95% confidence intervals. Similarly, the

percentage of the participants that provided follow-up data and the percentage of those in the MBCT-HeLM and MBSR arms that completed the interventions are reported. The characteristics of the participants in each trial arm are summarised using means and standard deviations for continuous variables and percentages for categorical ones. Given the study aims were to assess the feasibility and acceptability of MBCT-HeLM, but not testing hypotheses, we report the quantitative results in a descriptive way. We provide 95% confidence intervals, which illustrate the amount of uncertainty there is regarding the true intervention effect. For each of the primary and secondary outcomes, we used the means, standard deviations (SDs), mean differences and 95% confidence intervals between the groups. For the process measures, we used a similar method of using the means, SDs, mean differences and 95% confidence intervals between the groups. Regarding the qualitative analysis, the NVivo programme was employed to help with coding the data. We used the thematic analysis method with the six phases suggested by Braun and Clarke (2006) in order to analyse the interviews.

Results

The results of the study are reported according to guidelines for good practice in designing, analysing and reporting pilot and feasibility studies (Lancaster et al. 2004; Lancaster 2015). In addition, we used the Consolidated Standards of Reporting Trials (CONSORT) extension guidelines for reporting pilot and feasibility studies (Thabane et al. 2010). The first aim of this study was to establish the feasibility of conducting a randomised controlled trial of MBCT-HeLM in addition to TAU vs MBSR along with TAU vs TAU alone. In general, the results indicate that there are several positive indicators about the feasibility, with the main challenge being recruitment.

Recruitment Rate

Three methods of recruitment (GPs, cardiology department at Royal Devon and Exeter hospital and advertisement) were used in the HeLM feasibility study. The recruitment and screening phases were conducted over 4 months (July to October 2014). Invitations were sent to 3340 people through three GPs (two in Exeter and one in Exmouth), while a summary of the study was handed to 50–60 patients out of approximately 144 patients passing through the outpatients' clinic for about 12 weeks by the cardiac nurses in the cardiology department. This was different to our calculation of the sample size as we estimated that 82 patients would pass every month (250 for the 12 weeks). In addition, 600 copies of a study poster were distributed in nine cafés and restaurants in Exeter city centre, 3 weeks before the recruitment ended.

As shown in the CONSORT diagram (Fig. 1), of the 3340 people approached through GPs, 239 people (7.1%) were interested, 180 people (5%) showed no interest (i.e. people who sent the reply form back to the researchers stating that they were not interested in the study) and the remainder (88%) did not respond to the letters (i.e. people who did not send the reply form back to the researchers). Regarding the cardiology department, we had three interested people (5% of the 60 people who were approached through the cardiology department) and no individuals responded to the advertisements. During the first screen, 183 out of the 242 interested people (76%) were excluded for the following reasons: no low mood as people reported ($n = 99$), no cardiovascular disorder ($n = 20$), not interested anymore ($n = 15$), could not attend the group dates ($n = 20$), non-contactable ($n = 12$) and other reasons ($n = 17$). This resulted in 59 out of the 3340 approached people (1.7%) meeting the criteria of the first screen. For the second screen, two people were excluded, as they had current major depression, another one was non-contactable and 15 did not wish to continue the study. The reasons for withdrawing were health ($n = 8$), family ($n = 2$), work ($n = 3$) or holding the view that the mindfulness course did not seem right for them ($n = 2$). In the baseline phase, 41 people who met the study criteria were invited to a diagnostic interview where the SCID was applied to check for past and current major depressive disorder (MDD), minor depression as well as dysthymia. In this phase, three people were excluded, as two had current major depression and one was misusing drugs. Two people quit for health reasons (they had shortness of breath and found it hard to come to the Mood Disorders Centre/Exeter University) and three did not show up (one of them could not come as he had a cardiac problem). Finally, 33 out of the 59 eligible people (56%; 95% CI 43 to 68%) gave their consent and were randomly allocated to the three groups: MBCT-HeLM ($n = 11$), MBSR ($n = 11$) and TAU ($n = 11$). Given the total of the sent invitations comprised 3340 letters and summaries, this meant we managed to recruit only 1.0% (95% CI 0.7 to 1.4%) of these. In the orientation sessions, one participant from the MBSR group was excluded from the study, as it was agreed that her chest pain was stress-related and not a cardiovascular disorder. As this woman had recurrent major depression, she was referred to the AccEPT Clinic for standard care. No difficulties were noticed regarding running the groups or collecting data.

Retention and Attrition Rates

Seven of the 11 participants (64%; 95% CI 36 to 86%) in the MBCT-HeLM group completed the course. Of those who dropped out, three could not make the scheduled group times, two found it hard to alter their work times and one had a severe chest infection. After the third session, one woman dropped out for family reasons. Regarding the MBSR group ($n = 10$),

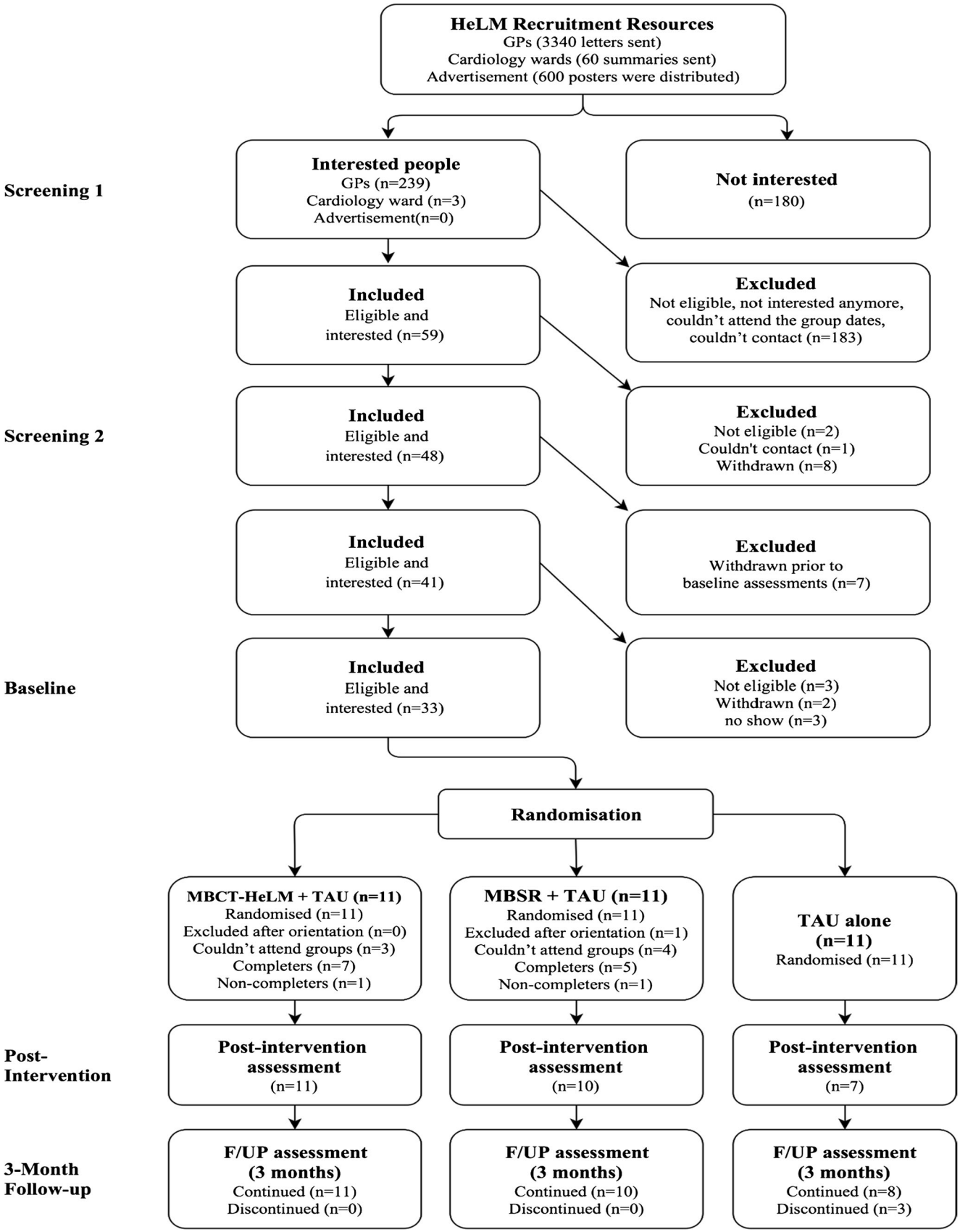

Fig. 1 CONSORT diagram of HeLM participant flow

six people (60%) started and after the second session of MBSR, a woman dropped out as she said that it was hard for her to complete the home practice and come to the Mood Disorder Centre/University due to her serious physical disability caused by a stroke. The other people ($n = 4$) could not attend the group dates; one participant got a new job, one participant had to babysit a child, one had had a surgery and one did not attend due to work-related issues.

Participants Adherence

In the MBCT-HeLM group, seven out of the eight people who took part attended between six and eight sessions while one woman only attended two. In the MBSR group, of the six who took part, four attended eight while one attended seven sessions and one woman attended two. Regarding the full-day mindfulness practice, six people from the MBCT-HeLM and five from the MBSR groups attended. We asked the MBCT-HeLM group to practise some formal and informal exercises at home for 5 days per week so as to integrate mindfulness into their daily life. Five out of the seven people who completed the course provided five out of the seven home practice sheets and two completed three. The average amount of practice was 5 days per week. Regarding assessments completion, 29 out of the 33 participants randomised into the trial (88%; 95% CI 77 to 98%) completed the assessment at post-intervention and at the 3-month follow-up phase. All participants in the MBCT-HeLM ($n = 11$) and MBSR ($n = 10$) groups completed the post-intervention and follow-up assessments, whilst three from the TAU group ($n = 11$) did not.

Therapist Adherence and Competence

For therapist adherence and competence, we used the Mindfulness-based Interventions: Teaching Assessment Criteria (MBI: TAC), which is rated on a scale from 1 (incompetent) to 6 (advanced), with the average rating being 5 (proficient) for both the MBCT-HeLM and MBSR.

Describing the Primary and Other Outcomes Data

Table 2 shows the clinical characteristics at baseline for all the study outcomes. Regarding the study primary outcome, Table 3 shows the PHQ-9 means, SDs, mean differences and 95% confidence intervals for MBCT-HeLM vs MBSR and MBCT-HeLM vs TAU at post-intervention and at 3-month follow-up. The mean PHQ-9 scores for the MBCT-HeLM group was 0.2 (CI −3.4 to 2.9) lower at post-intervention and 1.4 (CI −3.8 to 1.0) lower at 3-month follow-up, than for the MBSR group. The MBCT-HeLM mean was 2.3 (CI −7.2 to 2.5) lower at post-intervention and 5.2 (CI −8.5 to −1.8) lower at the 3-month follow-up compared to the TAU group. With regard to secondary and process outcomes, Tables 4 and 5 summarise the means, SDs, mean differences and 95% confidence intervals across the three groups at post-intervention and 3-month follow-up for the study's secondary and process outcomes. The mean GAD scores for the MBCT-HeLM and MBSR groups was lower at post-intervention and at 3-month follow-up compared to the TAU group. The mean RAND 36-Item (psychological domain) scores for the MBCT-HeLM and MBSR groups were higher at both post-intervention and at 3-month follow-up than for the TAU group, while the mean RAND 36-Item (physical domain) for the MBSR group was higher at 3-month follow-up compared to both the MBCT-HeLM and TAU groups. The means of some of the IPQ-R subscales (timeline acute, emotional representations and consequences) for the MBCT-HeLM group were lower at both post-intervention and at 3-month follow-up than for the MBSR and TAU groups, while those for the personal and treatment control subscales of IPQ-R for MBSR were lower than the means of the MBCT-HeLM and TAU groups. The mean FFMQ for MBCT-HeLM was 4.0 higher than for the MBSR and 18.0 higher than for the TAU group, at post-intervention assessment, whilst it was 6.0 lower than for the MBSR group and 10.0 higher than for TAU, at the follow-up assessment. Regarding SCS, both the MBCT-HeLM and MBSR means were higher than for the TAU group at both time-point assessments. Finally, the mean of PANAS-Positive was higher for the MBSR group compared to the other groups at both time-point assessments.

The Acceptability Interviews

The second aim of this study was to see how acceptable MBCT-HeLM was for people with depression and cardiovascular disorders. Those who completed the MBCT-HeLM course (six people with heart conditions and one participant with stroke) described it and their overall experience as enjoyable; considering it different to other psychological programmes that they had in the past; finding it flexible and helpful. They had joined the course with the expectation that it would help in controlling physical symptoms, such as high blood pressure and heart complaints as well as understanding depression and making them calmer. Participants felt that the course had met some of their expectations in terms of understanding depression and seeing things in a different way, but less in terms of managing physical symptoms. They reported that the one-to-one orientation session was helpful in terms of understanding the content of course. They generally agreed that eight sessions represented a good course length, in that they thought that they needed time to understand mindfulness and to integrate it into their daily life and two of them felt that the course needs to be more than eight sessions. All seven

Table 2 Clinical characteristics at baseline

	MBCT-HeLM group		MBSR group		TAU group	
	Mean	SD	Mean	SD	Mean	SD
Primary measure						
Patient Health Questionnaire-9 (PHQ-9)	8.4	4.8	8.5	4.6	7.0	5.0
Other measures						
Blood pressure						
Blood pressure/systolic	126.7	10.5	142.3	21.8	128.5	21.3
Blood pressure/diastolic	73.8	12.7	77.6	14.3	70.6	8.3
Generalised Anxiety Questionnaire-7 (GAD-7)	8.2	3.5	7.0	5.2	4.8	3.3
Cardiac Anxiety Questionnaire (CAQ)	17.0	9.1	22.2	8.6	34.0	13.6
RAND 36-Item Physical	53.3	18.2	43.0	24.3	59.1	31.5
RAND 36-Item Psychological	53.1	21.2	42.3	13.3	51.8	19.3
Five-Facet Mindfulness Questionnaire (FFMQ)	121.0	15.4	122.0	17.9	113.7	16.4
Self-Compassion Scale (SCS)	2.5	0.5	2.6	0.6	2.4	0.6
PANAS-positive affect	30.3	7.5	27.4	5.9	25.3	9.4
PANAS-negative affect	20.0	8.5	17.4	6.1	18.0	6.9
Illness Perception Questionnaire-Revised (IPQ-R)						
IPQ-R timeline acute/chronic	20.9	7.1	23.6	4.5	25.7	4.4
IPQ-R timeline cyclical	11.7	5.1	10.6	3.4	11.0	5.2
IPQ-R consequences	17.1	5.1	20.3	6.9	20.2	3.9
IPQ-R personal control	22.1	4.9	22.2	4.6	19.9	5.4
IPQ-R treatment control	18.9	3.5	15.9	2.8	17.3	4.4
IPQ-R illness coherence	17.5	4.7	19.2	5.8	19.6	4.7
IPQ-R emotional representations	18.3	6.2	20.7	2.6	19.7	4.3
The Seattle Angina Questionnaire (SAQ)						
SAQ-physical limitations	52.5	13.8	48.1	17.8	37.8	18.7
SAQ-angina stability	56.0	21.9	36.6	8.1	36.0	16.7
SAQ-angina frequency	70.5	11.5	70.6	14.8	58.0	27.0
SAQ-treatment satisfaction	59.8	17.0	62.3	10.1	68.0	13.8
SAQ-disease perception	52.1	20.6	47.8	19.2	43.8	28.6

TAU treatment as usual, *SD* standard deviation

participants said that the Three-Step Breathing Space exercise was the most useful and four of them found the Body Scan helpful. Participants described some challenges with the MBCT-HeLM course, in particular, being in a group and making the course a priority in their lives. Additional feedback is summarised in Table 6.

Discussion

The first aim of the HeLM study was to establish the feasibility of conducting an adequately powered randomised controlled trial of MBCT-HeLM for people with depression and cardiovascular disorders. The second aim was to assess

Table 3 Comparison of PHQ-9 at post-intervention and follow-up

Outcome	MBCT-HeLM ($n = 11$) Mean (SD)	MBSR ($n = 10$) Mean (SD)	TAU ($n = 8$) Mean (SD)	MBCT-HeLM vs MBSR		MBCT-HeLM vs TAU	
				Mean diff.	95% CI	Mean diff.	95% CI
Baseline	8.4 (4.8)	8.5 (4.6)	7.0 (5.0)				
Post-intervention	6.1 (3.1)	6.3 (3.6)	8.4 (6.3)	− 0.2	− 3.4 to 2.9	− 2.32	− 7.23 to 2.57
3-month follow-up	3.8 (2.5)	5.2 (2.4)	9.0 (4.1)	− 1.4	− 3.8 to 1.0	− 5.20	− 8.56 to − 1.83

PHQ-9 Patients Health Questionnaires-9, *TAU* treatment as usual, *SD* standard deviation, *CI* confidence interval

Table 4 Comparison of secondary outcomes at post-intervention

Outcomes	MBCT-HeLM ($n = 11$)	MBSR ($n = 10$)	TAU ($n = 7$)	MBCT-HeLM vs MBSR		MBCT-HeLM vs TAU	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean diff.	95% CI	Mean diff.	95% CI
Blood pressure							
Systolic blood pressure (mmHg)	130.4 (20.7)	143.8 (20.7)	129.8 (14.8)	− 13.4	− 42.5 to 15.7	0.6	− 20.3 to 21.4
Diastolic blood pressure (mmHg)	73.2 (16.4)	76.5 (17.8)	73.5 (9.3)	− 3.3	− 24.2 to 17.7	− 0.3	− 15.9 to 15.3
GAD-7	4.8 (4.8)	4.4 (2.8)	6.4 (3.9)	0.4	− 3.6 to 4.4	− 1.6	− 6.2 to 3.0
CAQ*	18.3 (14.3)	18.0 (1.4)	30.5 (13.6)	0.3	− 16.5 to 17.2	− 12.1	− 33.1 to 8.8
RAND 36-Item Health Survey 1.0							
RAND 36-Item Physical	49.5 (15.3)	56.4 (28.1)	59.1 (32.7)	− 6.9	− 27.6 to 13.9	− 9.6	− 40.2 to 21.2
RAND 36-Item Psychological	55 .5 (19.1)	60.8 (14.6)	48.7 (23.7)	− 5.3	− 21.6 to 11.0	6.8	− 14.7 to 28.3
FFMQ (total)	128.0 (18.0)	124.0 (18.3)	110.0 (6.7)	4.0	− 15.6 to 23.4	18.0	2.1 to 33.3
SCS (total)	2.6 (0.6)	2.8 (0.8)	2.4 (0.7)	− 0.2	− 0.9 to 0.5	0.2	− 0.5 to 0.8
PANAS-positive	25.3 (7.1)	32.7 (4.3)	28.2 (7.4)	− 7.4	− 13.6 to − 1.3	− 2.9	− 10.6 to 4.7
PANAS-negative	18.7 (9.8)	16.3 (6.6)	19.4 (9.1)	2.3	− 6.3 to 11.0	− 0.7	− 10.8 to 9.3
IPQ-R							
IPQ-R timeline acute/chronic	18.1 (3.6)	18.6 (2.8)	18.7 (6.7)	− 0.5	− 3.8 to 2.8	− 0.6	− 6.0 to 4.7
IPQ-R timeline cyclical	11.5 (4.0)	11.1 (3.2)	10.4 (4.4)	0.4	− 3.4 to 4.3	1.1	− 3.5 to 5.7
IPQ-R consequences	19.7 (6.2)	18.8 (5.3)	19.0 (6.1)	0.9	− 5.0 to 6.6	0.7	− 5.8 to 7.2
IPQ-R personal control	23.2 (3.7)	19.2 (3.9)	23.1 (4.8)	4.0	0.1 to 7.8	0.1	− 4.4 to 4.5
IPQ-R treatment control	16.8 (2.2)	13.8 (4.2)	17.7 (2.4)	3.0	− 0.4 to 6.5	− 0.9	− 3.4 to 1.7
IPQ-R illness coherence	20.3 (2.3)	16.5 (5.9)	18.8 (2.8)	3.8	− 0.7 to 8.4	1.5	− 1.3 to 4.3
IPQ-R emotional representations	17.5 (5.2)	19.3 (5.1)	18.1 (4.6)	− 1.8	− 7.2 to 3.6	− 0.6	− 6.0 to 4.8
SAQ**							
SAQ-physical limitations	43.8 (19.2)	41.8 (21.4)	41.9 (5.3)	2.0	− 25.7 to 29.7	1.9	− 25.8 to 29.5
SAQ-angina stability	52.0 (17.8)	60.0 (20.0)	50.0 (20.5)	− 8.0	− 35.7 to 19.8	2.0	− 1.3 to 65.3
SAQ-angina frequency	68.1 (13.3)	68.3 (13.6)	45.8 (17.6)	− 0.2	− 18.8 to 18.2	22.3	− 6.1 to 50.5
SAQ-treatment satisfaction	58.0 (18.5)	64.7 (11.4)	65.0 (11.9)	− 6.7	− 29.2 to 15.8	− 7.0	− 36.8 to 22.8
SAQ-disease perception	50.6 (23.4)	58.6 (12.8)	44.4 (27.7)	− 8.0	− 35.5 to 19.5	6.2	− 38.3 to 50.8

TAU treatment as usual, *SD* standard deviation, *CI* confidence intervals, *GAD-7* Generalised Anxiety Questionnaire-7, *CAQ* Cardiac Anxiety Questionnaire, *FFMQ* Five Facet Mindfulness Questionnaire, *SCS* Self-Compassion Scale, *PANAS* Positive and Negative Affect Scale, *IPQ-R* Illness Perception Questionnaire-Revised, *SAQ* Seattle Angina Questionnaire

*CAQ was completed by participants with heart conditions only (MBCT, $n = 6$; MBSR, $n = 5$; TAU, $n = 3$)

**SAQ was completed by participants with heart conditions only (MBCT, $n = 6$; MBSR, $n = 5$; TAU, $n = 3$)

how acceptable this course was to the participants. No prior statistical criteria of success have been set up for this study and instead, we have compared our results with those of other studies that used MBCT or MBSR for people with depression and/or CVDs. The results were encouraging in terms of MBCT-HeLM's acceptability and participants' engagement with the course. However, the large funnel between potentially eligible participants and those who participated in the trial suggests serious challenges with regard to recruitment to such a trial.

Recruiting through GP practices was the most useful resource of the three methods used, accounting for 239 people (99%) of all interested people. However, the percentage of those who replied to the invitation letters was only 1%, which means that the future definitive trial will need to invite 1000 people to get 10 consenting participants. This is less than reported for other MBCT trials (e.g. Kuyken et al. 2016; 2%). While recruiting to clinical trials is a challenge for many areas of research, this may be especially so for mental health ones (Barton 2000; TenHave et al. 2003), despite the high prevalence rates of mental health problems. In addition, there is limited access to evidence-based treatment. Recruitment through specialist CVD services was not successful (Fig. 1). Cardiac nurses are typically very busy and triaging to this study added to their busy schedules. Moreover, people who visit cardiac wards often attend with unstable conditions and are not in a position to consider taking part in a psychosocial intervention like MBCT or MBSR. Moreover, direct advertising did not yield any responses.

Table 5 Comparison of secondary outcomes at 3-month follow-up

Outcomes	MBCT-HeLM ($n = 11$)	MBSR ($n = 10$)	TAU ($n = 8$)	MBCT-HeLM vs MBSR		MBCT-HeLM vs TAU	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean diff.	95% CI	Mean diff.	95% CI
Blood pressure							
Systolic blood pressure (mmHg)	122.6 (16.3)	130.4 (14.1)	127.8 (14.8)	− 7.8	− 26.4 to 10.8	− 5.2	− 24.3 to 13.9
Diastolic blood pressure (mmHg)	65 (20.5)	73 (15.2)	70.7 (9.6)	− 8.0	− 29.9 to 13.9	− 5.7	− 24.8 to 13.4
GAD-7	3.2 (2.4)	3.5 (1.6)	8.0 (5.0)	−0.3	− 2.4 to 1.8	− 4.8	− 8.6 to − 0.9
CAQ*	16.6 (10)	23.0 (4.9)	30.0 (6.2)	− 6.3	− 17.5 to 4.8	− 13.3	− 26.4 to − 0.2
RAND 36-Item Health Survey 1.0							
RAND 36-Item physical	51.6 (21.4)	59.1 (24.4)	54.9 (32.4)	− 7.5	− 29.0 to 14.0	− 3.3	− 32.1 to 25.7
RAND 36-Item psychological	63.8 (18.2)	61.3 (18.3)	51.6 (20.9)	2.5	− 14.8 to 19.8	12.1	− 6.9 to 31.2
FFMQ (total)	125 (19.0)	131 (26.4)	115 (14.6)	− 6.0	− 28.0 to 14.8	10.0	− 7.3 to 26.7
SCS (total)	2.8 (.51)	2.9 (0.69)	2.7 (0.6)	− 0.1	− 0.8 to 0 .4	0.1	− 0.1 to 1.0
PANAS-positive	27.9 (6.1)	32.1 (9.8)	28.3 (9.9)	− 4.2	− 11.8 to 3.4	− 0.4	− 8.2 to 7.3
PANAS-negative	18.6 (7.4)	18.8 (7.7)	17.3 (9.6)	− 0.2	− 7.9 to 6.4	0.8	− 7.4 to 9.0
IPQ-R							
IPQ-R timeline acute/chronic	21.3 (5.5)	23.8 (4.1)	26.7 (3.5)	− 2.6	−7.5 to 2.3	− 5.5	− 10.2 to − 0.7
IPQ-R timeline cyclical	11.5 (3.7)	10.0 (3.7)	11.4 (4.7)	1.5	− 2.1 to 5.2	0.2	− 3.9 to 4.2
IPQ-R consequences	18.3 (4.9)	20.4 (5.8)	20.6 (5.6)	− 2.1	− 7.3 to 3.1	− 2.4	− 7.4 to 2.7
IPQ-R personal control	22.1 (3.5)	23.5 (3.6)	21.6 (4.4)	− 1.4	− 4.9 to 2.1	0.5	− 3.4 to 4.3
IPQ-R treatment control	17.0 (2.6)	17.3 (2.9)	19.0 (2.7)	− 0.3	− 3.0 to 2.5	− 2.0	− 4.6 to 0.6
IPQ-R illness coherence	19.3 (4.0)	18.1 (5.1)	20.0 (4.3)	1.1	− 3.2 to 5.5	− 0.7	− 4.7 to 3.2
IPQ-R emotional representations	17.9 (4.8)	18.6 (6.1)	17.8 (6.1)	− 0.7	− 6.0 to 4.6	0.1	− 5.1 to 5.4
SAQ**							
SAQ-physical limitations	46.6 (14.2)	43.5 (19.5)	48.1 (19.5)	3.1	− 18.9 to 25.1	− 1.5	− 28.1 to 25.1
SAQ-angina stability	63.3 (15.0)	50.0 (24.5)	40.0 (17.0)	13.3	− 12.8 to 39.5	23.3	− 4.1 to 50.8
SAQ-angina frequency	72.2 (10.0)	66.6 (11.7)	75.0 (11.7)	5.6	− 8.6 to 19.7	− 2.8	− 23.5 to 17.9
SAQ-treatment satisfaction	63.4 (8.8)	62.6 (11.0)	64.2 (16.8)	0.8	− 12.1 to 13.7	− 0.8	− 22.0 to 20.4
SAQ-disease perception	56.6 (13.1)	51.1 (19.6)	46.0 (28.2)	5.6	− 15.9 to 27.1	10.0	− 23.3 to 43.3

TAU treatment as usual, *SD* standard deviation, *CI* confidence intervals, *GAD-7* Generalised Anxiety Questionnaire-7, *CAQ* Cardiac Anxiety Questionnaire, *FFMQ* Five Facet Mindfulness Questionnaire, *SCS* Self-Compassion Scale, *PANAS* Positive and Negative Affect Scale, *IPQ-R* Illness Perception Questionnaire-Revised, *SAQ* Seattle Angina Questionnaire

*CAQ was completed by participants with heart conditions only (MBCT, $n = 6$; MBSR, $n = 5$ TAU, $n = 3$)

**SAQ was completed by participants with heart conditions only (MBCT, $n = 6$; MBSR, $n = 5$; TAU, $n = 4$)

The screening procedures worked well (Fig. 1). In addition, conducting a second screen enabled a further check on eligibility before moving to baseline assessment. However, in the first screen, the way to ascertain whether people were suffering from depression was mostly based on asking them a few questions about their history of depression. In future studies, it would be beneficial to use an in-depth screen in the early stage of recruitment, which could capture the history of depression in detail and might increase the eligibility rate. During the orientation sessions, one female participant was excluded due to uncertainty as to whether she was suffering cardiac problems or stress-related chest pain. In this study, the evaluative process to determine the presence of a cardiovascular disorder was based on the self-reporting of the participants. In future studies, an alternative method of determining a person's condition should be used, such as obtaining a clinical diagnosis from a potential participant's healthcare professional.

The initial drop-out rates were relatively high as 9 of the 21 (42%) randomised people in the MBCT and MBSR groups could not attend the group dates. The drop-out rate reported in this study is similar to that in the MBCT study conducted by O'Doherty et al. (2015) in people with coronary heart diseases as they had 47% drop-out rate. Specifically, only 32 out of 60 people in the MBCT group and 30 out of 57 people in the control group completed the study. In a non-controlled study (Olivo et al. 2009) using a shortened MBSR course with people with coronary heart diseases ($n = 35$) the drop-out rate reported was only 11% ($n = 4$), which is lower than ours. However, those two studies (O'Doherty et al. 2015; Olivo et al. 2009), targeting mindfulness and heart conditions used

Table 6 Themes and sample quotes from the HeLM acceptability interviews

Themes	Summary	Quotes
Diversity of expectations	Participants joined the course with different expectations of it. Two hoped to get benefit for their heart condition and high blood pressure as well as their depression. Another two wanted something to help with their depression and anxiety, so they could see things in a different and calmer way. One woman joined the course as she had a personal interest in learning cognitive therapy and meditation. One other participant joined the course without any expectations and he reported that he had not enough information about the course	'Well basically that I'd come out feeling calmer and look at things in a different perspective. Instead of being a black and white person seeing things in a calmer way perhaps' (Participant 3) 'I wanted to know about depression. Because you never know enough about it and maybe that's probably why we're depressed because we don't know enough how we need to avoid some things' (Participant 7)
Motivation	The reasons that made people to take part in the course were different, such as meeting other people and the experience its self (e.g., trying new things, coming to the university or learning meditation). One participant said that it was an opportunity and he thought he should take advantage of it. Other participants pointed out that the nature of MBCT, as a kind of psychotherapy, would not cause them any harm. Another mentioned attending so it would be possible to avoid psychiatric medications. Two participants wanted to deal with their physical conditions (heart conditions and blood pressure) and depression. Another two participants wanted to get help with their depression	'I wanted something to help me, I felt I needed some help with my condition both with the mental condition I found myself in after I got ill and the illness itself and I thought anything like this is at least worth trying' (Participant 2) 'Because at the time I was feeling rather down, and I thought it would be a way of speaking to somebody, mixing with different people and communicating to me is pretty important anyway' (Participant 3) 'I'm a supporter of anything that will take us away from chemicals. This is not a chemical or a physical intervention, it's about the mind. and therefore, you can only benefit from it' (Participant 5)
Challenges		
1. Being in group	Five of the seven participants joined the group with some worries around being in a group, mainly being worried about talking to new people, talking about personal issues with others and/or due to a language barrier. However, these people's experience was positive, with reports that the environment was encouraging and they worked well as a team. One of the things that seemed to help people to deal with their worries is that there was no pressure to talk or share feelings about depression or their physical symptoms, such as having a heart attack or stroke, if they did not wish to do so. Participant 1 did not see the course as a group therapy but more as an opportunity to share personal experiences with others, while Participant 5 said that being in a group helped in not being introspective	'Oh, my God, I was worried. First because of my language and second it was really difficult to meet new people, you know that feeling, having looked at you, you know, maybe someone start to ask you know what you've done before but yes it was a really different experience I was talking to nice people' (Participant 7). 'I haven't ever taken part in what I understand to be group therapy, but I think it is people sharing their experiences' (Participant 1) 'I think that if it were not a group it would be very easy to become extremely introspective in your perceptions of what was going on and why you were doing it. When you have a group, there is this group thing that takes over' (Participant 5)
2. Making mindfulness a priority	Four participants agreed that making the course a priority in their lives had been a challenge for them. They reported how they needed to push themselves and had to allocate time to undertaking homework every day	'If I were in your position I would be very aware that people have difficulties and you have to persuade them to priorities this project, the exercises' (Participant 5)
Effective techniques	1. Orientation session The seven participants seemed to agree that the orientation session with the therapist was very helpful in terms of providing good information about the course and what was going happen. They reported that the therapist was easy to talk to 2. Exercises The seven participants agreed that the 3-step breathing space was useful for different reasons. For example, Participant 5 thought that it is short and that it suited his lifestyle as he could use it anywhere, while Participant 2 said that he felt better regarding his breathing with this exercise. The body scan was useful for four participants. For example, participant 1 described her experience with it as it helped her to see how lucky she was comparing to other people who had physical problems. Also, talking to other people and the therapist seemed to be helpful to some participants 3. Homework and questionnaires	'The breathing space suits my life and the way I live' (Participant 5) 'When I'm faced with a stressful situation the first thing that happens is my breathing shuts down a little bit, there is already a heart condition that causes a problem with that so it's twice as bad but then I think about the responsive breathing, the breathing practice and It does seem to help there's no doubt about that' (Participant 2) 'It was quite demanding and filling in the forms but then if you didn't have the forms I think there wouldn't have been the incentive to keep going so yes it was quite demanding, but I think it probably needed to be quite demanding' (Participant 4) 'A more relaxed attitude to life. I remember we were asked that question in the group and the answer just came to me. I hadn't articulated it before. I felt that the words had been put into my mouth almost without having to think about them' (Participant 1)

Table 6 (continued)

Themes	Summary	Quotes
	Participants 1, 3, 6 and 7 described their experience with doing homework as being easy, but they had to allocate time to undertaking it. Participant 4 thought that it was demanding. Participants 2 and 5 thought that the homework was flexible, and it had helped them to do what they wanted to do. Regarding the questionnaires, participants agreed that completing them was fine. However, some said that some items did not apply to them and some were repetitive 4. The course overall It seemed that the course, overall, was acceptable to people. For example, three participants liked how flexible it was. Participant 1 described the course as delivering 'A more relaxed attitude to life'	
Ineffective techniques	1. Exercises Six out of the seven participants found that the movement exercise was not helpful. Four said that as they had other physical complaints that limited their ability to do it. Participant 3 said that it was very slow, so she did not like it. While Participant 7 thought that it did not help her to feel calm. However, Participant 5, who had hypertension, found this exercise helpful 2. Handouts Participant 2 pointed to that there was a need to emphasise more the fact that this course was for people with CVD. He also mentioned that some of terms in the handout needs to be explained further, such as automatic pilot	'Do you know I've gone to the whole 8 weeks and this business about it being special for heart conditions, hasn't really been emphasised very much. I know that's what you've got because you've got two groups, a control group and all the rest of it but there wasn't a lot of mention of that of the physical side of people's conditions in the course. It was about the mindfulness itself" (Participant 2)
Physical/psychological benefits	The benefits that participants obtained from the course were mainly around breathing, understanding depression and facing stress. For example, two participants reported that the course had helped them regarding their breathing and three said that it was helpful in terms of having another way of controlling stress as well as providing them with a different way of seeing things. One participant thought that after having the course she was able to understand depression better	'I think it's helped some of the way I think about things, not necessarily to do with my illness but maybe to do with if I feel depressed I can think "these are just thoughts" I try to if I'm thinking very negative thoughts I could sometimes look at the thoughts and think I don't need to think like this, so it had helped me' (Participant 4) 'First I feel very clear about that now, about depression and that so I can explain to someone myself what this is and how you can fight that' (Participant 7)

non-randomised or non-controlled designs. In addition, the study by (O'Doherty et al. 2015) recruited people and conducted the interventions over approximately 3 years, while that by (Olivo et al. 2009) used a short intervention (four MBSR sessions). In our study, the reasons given for withdrawing and dropping out varied, but health issues was the most common one provided. Research concerning elderly populations indicates that older people report higher chronic physical symptoms (Naylor et al. 2012) and therefore, it might be useful to consider delivering MBCT in ways and locations that are more convenient for this population. The second most common reason was work commitments, suggesting that it is important to consider the timing of MBCT sessions, which could lead to an increase in the participation rate in future studies. In sum, the need to enhance the accessibility of any psychosocial intervention for this group is evidenced.

With regard to course completion, attendance and home practice, this study attained good rates of compliance. Of those people who did engage with MBCT-HeLM, they attended most sessions and engaged with the mindfulness practice throughout the course. This suggests that of the subgroup who do attend, the course is acceptable. The Three-Step Breathing Space and Body Scan seemed to be the most important practices. Regarding assessment completion, the study had a good rate as the majority of participants completed the questionnaires at the post-intervention and follow-up phases, which indicates that the measures employed were acceptable to them. This completion rate is relatively similar to those reported in other mindfulness studies with heart conditions (O'Doherty et al. 2015; Olivo et al. 2009). The randomisation and stratification process were successful, which can be concluded because the main characteristics baselines were similar in the three groups. There was significant sample heterogeneity in terms of whether the sample was currently depressed (minor depression) or had a history of depression as well as regarding the time since the cardiac event (heart attack or stroke) and the onset of cardiovascular disorders. Importantly, there was significant heterogeneity regarding whether depression had happened before or after a CVD.

Participants who engaged with MBCT-HeLM reported a good satisfaction level with the course in terms of its content, exercises, home practice and completion of the measures. The majority of them found the 3-Step Breathing Space and Body Scan helpful. Being in a group was a challenge for some, although others said that it was helpful in terms of seeing how they were lucky compared to others. The participants' challenges in this course were mainly about how to make it a priority. Regarding the quantitative results, it is important to emphasise that we did not set out to establish effectiveness, nor was it sufficiently powered to do so. Moreover, the wide confidence intervals illustrate the imprecision with which the intervention effects are estimated.

Summary and Recommendations for the Definitive Trial

To summarise, this was a randomised controlled trial with three arms aimed at understanding the issues surrounding the feasibility and acceptability of delivering MBCT for people with depression and cardiovascular disorders. This study provides some methodological considerations for future studies, such as the use of the 3-arm design, randomisation and blindness, as well as rates of recruitment, retention, attrition and participants' adherence. We have demonstrated that an MBCT-HeLM course was feasible and acceptable to people who took part in the study. The number of people who were randomised ($n = 33$), despite the short period of recruitment (4 out of the 7 months that we planned in early stage of the study), was good. Moreover, retention and engagement rates were encouraging. However, the pool of potentially eligible participants was much larger and suggests some key barriers to the accessibility of an intervention such as MBCT, as well as to a trial such as this. Regarding the participants' feedback on the study in relation to the course content, home practice and assessments, this was broadly positive.

In any definitive trial, further effort should be given to recruiting a more representative sample in terms of targeting people with depression and cardiovascular disorders. It would also be useful to maximise the accessibility of the intervention through, for example, offering the course in appropriate places for interested people as well as offering evening classes that would suit those in full-time employment. Also, it is worth considering introducing MBCT/MBSR to participants who are inpatients on cardiology wards. In addition, using a detailed screen for depression in the early stages of the recruitment process might lead to an increased eligibility rate. When people are provided with group dates prior to randomisation to check to see whether they are available, which improves engagement and retention. With regard to the length of follow-up, in any future definitive randomised controlled trial, a longer follow-up period would be required. Finally, if the decision is made to move to a definitive trial, the study recruitment procedures will need to be revised in order to recruit a large enough sample.

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Authors' Contributions MA drafted the study protocol, prepared the study materials, applied for ethics and NHS R&D approval, conducted

the assessments and acceptability interviews, analysed the data and drafted the manuscript. WK participated in the design of the study, monitoring it and revision of the manuscript. CD contributed to the study design and commented on the manuscript. BD contributed to the study design and revised the manuscript. OU calculated the sample size, reviewed the statistical analysis and the manuscript. AE conducted the MBCT-HeLM and MBSR groups and commented on the manuscript. All authors read and approved the final manuscript.

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Compliance with Ethical Standards

The HeLM study was approved by the Cornwall and Plymouth Research Ethics Committee (REC reference: 14/SW/0048) on 17 April 2014. The NHS/HSC R&D management approval was obtained on 6 June 2014. The authors give their assurance that all procedures performed in this study were in accordance with the ethical standards of the relevant national and institutional committees on human research and with the Helsinki Declaration of 1964 and its later amendments. All the participants provided full informed consent.

Conflict of Interest WK is Director of the Oxford Mindfulness Centre and until 2015 was an unpaid Director of the Mindfulness Network Community Interest Company. He is the Principal Investigator of several externally funded projects evaluating the efficacy of MBCT. AE is co-director of the Mindfulness Network Community Interest Company and teaches nationally on MBCT. The other authors declare that they have no conflict interest.

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