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A Controlled Evaluation of Mindfulness Based Cognitive Therapy for Patients with Coronary Heart Disease and Depression

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ORIGINAL PAPER

A Controlled Evaluation of Mindfulness Based Cognitive Therapy for Patients with Coronary Heart Disease and Depression

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ABSTRACT

This study evaluated the effectiveness of an eight-session mindfulness-based cognitive therapy (MBCT) group intervention programme for treating depression in coronary heart disease (CHD) patients. Thirty-two depressed CHD patients were assigned to an MBCT treatment group and a demographically and clinically similar group of 30 cases were assigned to a waiting-list control group. Participants were evaluated at baseline, 8 weeks, and 6 months follow-up with the Hospital Anxiety and Depression Scale (HADS), Brief Symptom Inventory (BSI), Profile of Mood States (POMS), Psychosocial Adjustment to Illness Scale (PAIS) and the Mindful Attention Awareness Scale (MAAS). After each session MBCT participants completed the post-session Questionnaire (PQ) on helpful aspects of therapy, and after the programme completed the Client Satisfaction Questionnaire (CSQ). At follow-up 71% of the MBCT group were clinically recovered from depression compared with 50% of the control group. The MBCT group showed significantly greater improvement than the control group on all measures with effect sizes at follow-up of $d = 0.43 - 1.0$. Increases in mindfulness on the MAAS correlated significantly with improvements on the HADS, BSI, POMS and PAIS. Key helpful aspects of therapy identified by MBCT participants included learning meditation, obtaining group support, and developing optimism. There was a high level of satisfaction with the MBCT programme. These results indicate that a randomized controlled trial of MBCT for depressed CHD patients is now warranted.

INTRODUCTION

About 20% of people with coronary heart disease (CHD) have co-morbid major depressive disorder, and rates of depression and depressive symptoms are higher among people with CHD compared with individuals without CHD (Carney & Freedland, 2008; Rutledge et al., 2006). Both premorbid and post-morbid major depression, and elevated depressive symptoms are associated with worse prognosis in patients with CHD (Leung et al., 2012; Rugulies, 2002; VanMelle, 2004). Depression doubles the risk of cardiac events in the 2-year period after myocardial infarction, and also doubles the mortality risk (Barth et al., 2004; Goldston & Baillie, 2008). The effective treatment of depression in CHD patients is therefore a priority.

The psychological mechanisms by which CHD contributes to the development of depression, and by which depression places people at risk for further cardiac events are poorly understood. With regard to CHD as a risk factor for depression, one hypothesis derived from cognitive behaviour therapy is that stressful demands and losses associated with CHD, the catastrophic way in which CHD and its symptoms are appraised, and the extent to which patients ruminate about their CHD symptoms play a central role in the development of depression in cardiac patients (Goldston & Baillie, 2008). A number of social characteristics and lifestyle behaviours which have been found to typify depressed CHD patients may contribute to increased risk of further cardiac events. These include failure to develop an adequate social support network, and problematic stress management behaviours such as smoking, comfort eating/poor diet, infrequent exercise, and non-compliance with medical treatment/rehabilitation regimes (Everson-Rose & Lewis, 2005; Goldston & Baillie, 2008; Lichtman et al., 2008; Lett et al., 2004). These considerations have informed the development of cognitive behavioural intervention programmes for depressed CHD patients, which aim to enhance their capacity to cope in healthier ways with CHD-

related stresses.

There is growing evidence for the effectiveness of psychological interventions for depression associated with CHD. Dickens et al. (2013) conducted a meta-analysis of 64 trials which evaluated the effects of a range of therapeutic interventions on depressive symptoms in CHD patients. Most interventions were based on a cognitive behaviour therapy framework and included psychoeducation, relaxation training, problem-solving, skills training and comprehensive cognitive-behaviour therapy. Using Cohen's (1988) criteria, a small effect size ($d = 0.18$) for post-treatment depressive symptoms was found in a combined analysis of results from trials of all types of interventions involving CHD patients recruited irrespective of their status on diagnostic criteria for major depression. For trials involving CHD patients with major depression, only comprehensive cognitive behaviour therapy programmes showed significant but small effects on depressive symptoms ($d = 0.31$). It is noteworthy that these results are comparable to those from trials of the selective serotonin reuptake inhibitor (SSRI) antidepressants, sertraline and citalopram (Lesperance et al., 2007; Glassman et al., 2002).

The results of the meta-analysis by Dickens et al. (2013) indicate that more effective psychological interventions for depression in CHD patients need to be developed. That is, there is a need to identify psychological interventions that yield large effect sizes and which lead to clinically significant improvements in depression for most CHD patients.

Mindfulness-Based Cognitive Therapy (MBCT, Segal et al., 2002) is an 8-session group-based programme which integrates meditation practices from Kabat Zinn's (1990) Mindfulness-Based Stress Reduction (MBSR) programme for chronic pain and aspects of cognitive behaviour therapy for depression (Beck et al., 1979). Within MBCT patients develop a conceptual understanding of mindfulness meditation and depression within the context of a cognitive behaviour therapy framework, practice meditation exercises, and use

these to cope with negative mood states. In a meta-analysis of 6 randomized controlled trials, Piet and Hougaard (2011) found that MBCT significantly reduced the risk of relapse among people with recurring major depression. Results of meta-analyses of MBCT and other mindfulness-based therapies show that these interventions lead to significant improvements in depression, anxiety and other indices of psychosocial adjustment for people with a wide range of physical (Bohlmeijer et al., 2010; Grossman et al., 2004) and mental health (Chiesa & Serretti, 2011; Klainin-Yobas et al., 2012) difficulties, including cancer (Ledesma et al., 2010; Piet et al., 2012), chronic pain (Inga, 2011), anxiety and depressive symptoms (McCarney et al., 2012; Piet et al., 2012), recurrent depression (Piet et al., 2011), anxiety disorders (Vøllestad et al., 2012), and life stress (Chiesa & Serretti, 2009).

To date three studies of mindfulness-based interventions have been conducted with CHD patients. Sullivan et al. (2009) evaluated the effectiveness of MBSR in a trial involving 208 cardiac patients, who had elevated depressive symptoms but who were not diagnosed with major depression. Compared with a control group, cases who completed MBSR showed significant improvements in depression, anxiety, and cardiac symptoms at 3, 6, and 12 months follow-up. In a pilot study involving 20 female cardiac patients, Tacon et al., (2003) found that compared with a control group, patients who completed MBSR showed greater reductions in anxiety, suppression of negative emotion, and the use of reactive or impulsive strategies for coping with stress. In a small qualitative study of depressed cardiac patients' experiences of MBCT, Griffiths et al., (2009) found that the development of awareness, commitment, within-group experiences, relating to MBCT training material and acceptance as central experiential themes. These three studies have significant methodological limitations. The first two provided no information on the status of patients with respect to diagnosis of major depression, and the second and third studies contained few participants. However, taken together, the results of these three studies suggest that mindfulness-based interventions may be useful for depressed cardiac patients and deserve further investigation.

The present study aimed to evaluate the effectiveness of an MBCT group programme for depressed CHD patients. The main hypothesis was that depressed CHD patients who participated in an MBCT programme would show greater recovery from depression than untreated controls. A subsidiary hypothesis was that increases in mindfulness would be correlated with clinical improvements in depression and psychological adjustment.

METHOD

Participants

Participants were recruited from cardiology departments of two large Dublin teaching hospitals in Ireland. Cases were eligible for inclusion if they were over 18 years, had a hospital diagnosis of CHD, met the criteria for a current DSM IV major depressive episode assessed with the mood disorder module of the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID, First et al., 2002) and scored above the clinical cut-off of 8 on the depression scale of the Hospital Anxiety and Depression Scale (HADS, Zigmond & Snaith, 1983). A HADS cut-off score of 8 was chosen because Bjelland et al. (2002), in a review of 24 papers, found that optimal balance between sensitivity and specificity for the HADS depression subscale as a screening instrument was achieved most frequently at a cutoff score of 8+ giving sensitivities and specificities of approximately 0.80. Cases with other major medical or psychiatric diagnoses, or involved in other psychosocial interventions were excluded. A power analysis showed that a trial-completer sample size of 60 (i.e., 30 cases in each of two trial arms) was required in order for statistical tests with a *p* value of .05 and a power value of 80% to be able to detect moderate intergroup differences ($d = 0.75$) (Chan, 2003).

Data were collected between June 2008 and May 2012. MBCT group data collection occurred between June 2008 and December 2011. Control group data were collected

between August 2008 and May 2012. Cases were referred to the trial by cardiologists at participating hospitals who judged them to require psychological intervention for low mood. A total of 158 referred patients were assessed for eligibility in face-to-face screening interviews with the first author. These interviews included the depression module of the SCID and the HADS. Patients who met the DSM IV criteria for major depressive disorder and scored above 8 on the HADS depression scale were admitted to the trial provided they did not meet the trial exclusion criteria. Forty-one cases were excluded; 19 because they declined to participate; 9 because they did not meet the criteria for depression; and 13 for other reasons including having comorbid physical or psychological disorders, involvement in other psychological interventions and logistical reasons. Of the 117 cases who entered the trial, 60 were assigned to the MBCT group and 57 to the waiting-list control group. Thirty-four of 60 cases allocated to MBCT completed at least 3 sessions and were assessed at Time 2 (although completion of 3 sessions was not a requirement to be eligible for Time 2 assessment). Thirty-two of these cases were assessed at Time 3. Thirty-two of 57 cases allocated to the waiting-list control group were assessed at Time 2. Thirty of these were assessed at Time 3. A Consolidated Standards of Reporting Trials (CONSORT) diagram of the flow patients through the study is given in Figure 1 (Schulz et al., 2010). The drop-out rate was 47%, and 53% of cases completed assessments at Times 1, 2 and 3. T-tests for continuous variables and chi square tests for categorical variables showed that trial completers and dropouts from treatment and control groups did not differ significantly from each other on baseline demographic or clinical variables, indicating that completers were representative of all cases who entered the trial.

Demographic and clinical characteristics of the 62 trial completers are given in Table 1. Participants mean Time 1 HADS depression scores were between 11 and 12 and fell within the moderate depression range of 11-15 (Snaith & Zigmond, 1994). The statistical

significance of differences between the MBCT and control groups was determined with t-tests for continuous variables and chi square tests for categorical variables. From Table 1 it may be seen that trial completers in the MBCT group and the waiting list control group were very similar on demographic and clinical variables. They did not differ significantly in terms of gender distribution, age, socioeconomic status, number of children, number of patients taking antidepressant medication during the trial or number of patients who came off medication after the trial, and psychological adjustment as assessed by the HADS (Zigmond & Snaith, 1983), Brief Symptom Inventory (BSI; Derogatis, 2001), and Profile of Mood States (POMS; McNair et al., 1992). However there were significantly more married participants in the MBCT group. Also the mean score of the MBCT group was significantly higher than that of the control group on the total health-related quality of life index of the Psychosocial Adjustment to Illness Scale (PAIS; Derogatis & Lopez, 1986), and lower than that of the control group on the Mindful Attention Awareness Scale (MAAS; Brown & Ryan, 2003). Thus, the MBCT group showed more problems with health-related quality of life and less mindfulness than the control group.

Design

This was a controlled trial with MCBT and waiting-list control arms. Cases were assigned to MBCT and waiting-list control groups. All participants were assessed at baseline (Time 1), 8 weeks later (Time 2) and at 6 months follow-up (Time 3). Cases were not randomized to groups. Participants for whom it was convenient to attend scheduled treatment sessions were assigned to the MBCT group, and remaining cases were assigned to the control group, with the constraint that an attempt was made to minimize treatment and control group differences on demographic and clinical variables including age, gender, socio-economic status and antidepressant medication usage. As a result groups were very similar in terms of

demographic and clinical profiles as shown in Table 1, and described in the participants section below. Cases in the control group received no psychological intervention until Time 3, when they were offered MBCT.

Ethics

The trial was completed with ethical approval of involved institutions and informed consent of participants. Ethical approval was obtained from the Irish Health Service Executive Tallaght and Connolly Hospitals and University College Dublin. At the request of the research team, all participants signed consent forms.

MBCT programme

The MBCT programme included eight two-hour weekly sessions, and strictly followed Segal et al.'s (2002) protocol. In these sessions participants practiced a variety of mindfulness meditation exercises, learned how to use these exercises to cope with negative mood states and were helped to develop a conceptual understanding of mindfulness meditation and depression, using a cognitive behaviour therapy framework. Within this framework, negative mood states are viewed as deriving, not from life events, but from the way a person thinks about and interprets these events. From this perspective, negative moods may be altered by acknowledging that negative thoughts about challenging life events and related moods are not facts, but merely transient mental states to which people prone to depression react as if they were objective facts. Also mastery events, interpreted positively, promote positive mood states. In the first half of the programme participants learned how little attention they paid to their daily lives, how the mind flits form one topic to another, how to bring the mind back to a single focus including body parts and breathing, and how mind-wandering, can lead to negative thoughts, catastrophising and ruminating which causes low mood. Key exercises

learned early in the programme were the body scan meditation and mindfulness of breath meditation. In the second part of the programme participants learned to acknowledge and become aware of negative thoughts and feelings as transient contents of consciousness rather than facts, before returning awareness to their breathing, expanding attention to the body as a whole, and mindfully rather than impulsively deciding how to manage negative thoughts and feelings. In this context they were helped to identify high-risk situations in which to use mindfulness meditation as a relapse prevention skill. Participants were invited between sessions to complete daily meditation and mood management homework assignments, and this homework was reviewed in subsequent sessions. They were given audio-recordings and written material to guide them through meditation and mood management homework exercises. During some treatment sessions participants viewed a documentary on Jon Kabat Zinn's (1990) MBSR programme for chronic pain patients called *Healing from Within*, and read poems relevant to the practice of mindfulness.

The programme was run on 9 occasions at the hospitals from which participants were recruited, and participants attended the programme in groups of 4-7. On each occasion the MBCT programme was facilitated by the first author who is an experienced, registered psychologist who had completed a training programme in MBCT at the Centre for Mindfulness Research and Practice, Bangor University in 2006 and practiced meditation for 20 years. An assistant psychologist attended all sessions to manage practical aspects of the programme such as providing hand-outs and data collection. Of the 32 participants who completed Time, 1, 2 and 3 assessments, 29 or 90% completed 5 or more MBCT programme sessions. Where 2 or fewer sessions were attended, cases were classified as dropouts.

Measures

Participants were initially screened with the depression module of the SCID (SCID-D, First et al., 2002). If they met the criteria for a major depressive episode they completed the HADS (Zigmond & Snaith, 1983), BSI (Derogatis, 2001), a brief form of the POMS (McNair et al., 1992), a self-report version of the PAIS (Derogatis & Lopez, 1986) and the MAAS (Brown & Ryan, 2003). The SCID-D, HADS, BSI, POMS, PAIS and MAAS were also administered at Times 2 and 3.

All instruments in the assessment protocol (except the SCID-D) are relatively brief self-report questionnaires with well established psychometric properties, in which responses are given to items on 4, 5 or 6-point Likert scales. The 14-item HADS yields scores for depression and anxiety. The 18-item BSI contains depression, anxiety and somatization items and yields a summary global severity index reflecting overall psychological adjustment. The 30-item POMS covers a range of moods (tension-anxiety, depression-dejection, anger-hostility, fatigue-inertia, confusion-bewilderment, and vigour-activity) and yields a total mood disturbance index. The 46-item PAIS covers the domains of health care orientation, vocational environment, domestic environment, sexual relationship, extended family relationships, social environment, and psychological distress, and yields a total health-related quality of life index. The 15-item MAAS assesses dispositional mindfulness.

At Time 1 participants also completed a demographic questionnaire which included O'Hare et al.'s, (1991) socio-economic status scale and a 10-item short-form of the Marlow-Crowne Social Desirability Scale (MCSDS; Strahan & Carrese-Gerbasi, 1972) which was used to check the validity of responses to the clinical scales.

Cronbach alpha coefficients for the sample of 62 trial completers calculated at Times 1, 2 and 3 for the HADS depression and anxiety scales, and overall summary scores for the BSI, POMS, PAIS and MAAS all exceeded 0.7 indicating that for the present sample all scales showed acceptable levels of internal consistency reliability. Pearson product-moment

correlations between clinical scales and the MCSDS were all less than $r = 0.3$ indicating that responses on the clinical scales were not unduly biased by a social desirability response set.

After each session participants completed the Post-session Questionnaire (PQ; Llewelyn et al., 1988), in which they described the most significant event that had occurred in the session, and rated how helpful the event and the session were on 7-point Likert scales. At Time 2, MBCT programme participants completed the 8-item Client Satisfaction Questionnaire (CSQ; Larsen et al., 1979).

RESULTS

Data were analysed with SPSS Version 20.0 (IBM Corp, 2011). Cases were classified as improved at Times 2 and 3 if they no longer met the DSM IV criteria for depression and scored below the clinical cut-off score of 8 (Bjelland et al., 2002) on the HADS depression scale. At Time 2 the improvement rate in the treatment group (26/32, 81.3%) was significantly higher than that of the control group (15/30, 50%, Chi Square (1, $N = 62$) = 6.75, $p < .01$, using a one tailed test). Also at Time 3 the improvement rate in the treatment group (23/32, 71.9%) was significantly greater than that of the control group (15/30, 50%, Chi Square (1, $N = 62$) = 3.12, $p < .05$, using a one tailed test).

A series of 2 X 3, Group X Time, ANOVAs was conducted to examine the effect of treatment and control group membership and change over Times 1, 2 and 3 on HADS, BSI, POMS, PAIS and MAAS mean scores. Benjamini and Hochberg's (1995) procedure for controlling the false discovery rate and Type 1 error associated with conducting multiple tests was used. Means, standard deviations, effect sizes and ANOVA results are given in Table 2.

Statistically significant Group X Time interactions occurred for all dependent variables. These interactions are graphed in Figure 2 and tests of simple effects confirmed the impression given by these graphs. HADS, BSI, POMS and PAIS treatment group means

decreased to a significantly greater degree over Times 1, 2 and 3 than those of the control group, while MAAS mean scores increased significantly more in the treatment group than the control group. At Time 3 on all dependent variables treatment and control group means differed significantly from each other. Thus, significantly greater improvement in the MBCT treatment group occurred in terms of anxiety and depression on the HADS, global severity of psychological symptoms on the BSI, total mood disturbance on the POMS, health-related quality of life on the PAIS and mindfulness on the MAAS.

Effect sizes reflecting the extent of differences between means of treatment and control groups at Times 2 and 3 given in Table 2, show that at Time 2 moderate to large effect sizes (using Cohen's (1988) criteria) ranging from $d = 0.60$ to 0.82, were found for HADS anxiety and depression, POMS total mood disturbance, and MAAS mindful attention scales. Small effect sizes ($d < 0.2$) occurred at Time 2 for BSI global severity index and PAIS total health-related quality of life scales. However at Time 3, effect sizes for all dependent variables were moderate to large ranging from $d = 0.43$ to 1.0.

Ancillary analyses showed that baseline differences between treatment and control groups on marital status, PAIS-total health related quality of life and MAAS - mindfulness did not have a marked effect on outcome at Times 2 and 3 on dependent variables. ANOVAs in which marital status was included as an independent variable did not yield significant Group X Marital Status X Time interactions indicating that the effects of different numbers of married cases in treatment and control groups did not affect outcome on dependent variables. ANCOVAs in which Time 1 PAIS and MAAS scores were included as covariates yielded very similar results to the main analyses, indicating that the effect of differences between treatment and control groups in mean baseline PAIS and MAAS scores on dependent variables was also negligible.

An ancillary intent-to-treat analysis was conducted in which last observation carried forward values were imputed for missing values at Times 2 and 3 for cases who dropped out of the trial. For all dependent variables the pattern of mean scores was similar to that found in the main trial completer analysis, although because of the conservative nature of the intent-to-treat analysis, fewer statistically significant Groups X Time interactions occurred. Statistically significant Group X Time interactions occurred on the HADS anxiety scale and summary sales of the BSI, POMS and PAIS, but not the HADS depression scale or the MAAS.

To examine the relationship between improvements from Time 1 to 3 in mindfulness and improvements in psychological adjustment, Time 1 to 3 difference scores were first calculated for all dependent variables. Pearson product-moment correlations were then computed between MAAS difference scores on the one hand, and difference scores for the remaining dependent variables on the other, for 62 trial completers. Using these difference scores, and Benjamini and Hochberg's (1995) procedure for controlling the false discovery rate and Type 1 error associated with conducting multiple tests, the MAAS correlated r (60) = 0.27, p<.05 with HADS-Depression, r (60) = 0.34, p<.01 with HADS – Anxiety, r (60) = 0.61, p<.01 with BSI – Global Severity Index, r (60) = 0.55, p<.01 with POMS-Total mood disturbance, and r (60) = 0.29, p<.05 with PAIS- Total Health-Related QoL. Thus improvements in mindfulness on the MAAS was correlated with improvements in depression and psychological adjustment on all other dependent variables.

Participants were asked to complete PQs after each of the 8 MBCT programme sessions. With 32 cases in the eight-session MBCT programme, a complete data set would have included 256 PQs. However, because of session non-attendance and non-compliance with requests to return PQs after sessions, only 94 PQs were completed. A thematic content analysis was conducted on the 141 statements about significant therapeutic events

contained in these 94 PQs. The 141 statements were read by the first author, a coding scheme was developed based on the thematic content of the 141 statements, and each statement was assigned to a thematic category (Miles et al., 2013). Themes reflecting 12 significant therapeutic events and process, and frequencies with which these occurred in 141 PQ statements are given in Table 3. For 78% of the 94 PQs, the significant therapeutic events listed in Table 3 were rated as quite, very or extremely helpful. On a 7-point scale ranging from 1 = extremely unhelpful to 7 = extremely helpful, a mean rating of 5.97 out of 7 (*SD* = 0.82) was given, indicating that on average, significant therapeutic events were rated as very helpful. For 74% of the 94 PQs, therapy sessions were rated as quite, very or extremely helpful. On a 7-point scale ranging from 1 = extremely unhelpful to 7 = extremely helpful, a mean rating of 5.99 (*SD* = 0.88) was given, indicating that on average, MBCT sessions were rated as very helpful. From Table 4 it may be seen that on the 8 questions of the CSQ, 83-96% of participants evaluated the MBCT programme positively at Time 2.

DISCUSSION

This study is one of the first controlled trials to show that MBCT is an effective treatment for major depressive disorder in CHD patients. The study supported the main hypothesis it was designed to test and found that depressed CHD patients who completed an eight-session MCBT programme, compared with a waiting list control group showed significantly greater improvement rates in clinical depression, and improvements in mean scores on scales measuring depression, anxiety, psychological adjustment, mood, health-related quality of life and mindfulness. Effect sizes at six-months follow-up on these variables were medium to large by Cohen's (1988) criteria. The study also found support for a subsidiary hypothesis and showed that improvements increases in mindfulness were correlated with positive changes in depression, anxiety, psychological adjustment, mood, and health-related quality

of life. While this correlational finding cannot be taken as definitive evidence that increased mindfulness causes clinical improvement in depression and psychological adjustment, it does suggest that this is a reasonable hypothesis which was further supported by a thematic content analysis of qualitative accounts of treatment.

Participants in the trial identified a number of key events within MBCT sessions as particularly significant and helpful. The more frequently identified events and processes were learning meditation, breathing and relaxation skills; learning to be aware of the present moment; learning skills to focus, concentrate, detach from thoughts, and be mindful of the present moment; having conversations with others who have similar life challenges and feeling supported by them; learning that thoughts can affect mood, that thoughts are not facts, and negative thoughts can be accepted; and developing an optimistic outlook on the future. Thus, learning meditation, obtaining social support and developing optimism were perceived by participants as the ‘active ingredients’ of MBCT. Among trial completers, there was a high level of satisfaction with the MBCT programme as a whole, with each of the sessions, and with significant therapeutic events within sessions. However, there was also a high drop-out rate, and drop-outs may have been dissatisfied with the programme.

Our results are consistent with the results of previous studies of mindfulness-based interventions for a range of clinical populations generally (Bohlmeijer et al., 2010; Chiesa & Serretti, 2011; Grossman et al., 2004; Inga, 2011; Klainin-Yobas et al., 2012; Ledesma et al., 2010; McCarney et al., 2012; Piet et al., 2011, 2012; Vøllestad et al., 2012) and CHD patients specifically (Griffiths et al., 2009; Sullivan et al., 2009; Tacon et al., 2003). However, ours is the first published study of MBCT for CHD patients in which DSM IV major depression was an inclusion criterion. The effect size for depressive symptoms of $d = 0.77$ after treatment and $d = 0.60$ at six-months follow-up, compares very favourably with the effect size of $d = 0.31$ found for comprehensive cognitive behaviour therapy programmes in the meta-

analysis by Dickens et al. (2013), and the effect-size of $d = 0.33$ found for in a major trial for citalopram (Lesperance et al., 2007).

This study had two main limitations. There was a high drop out rate of 47% and cases were not randomly assigned to treatment and control groups. Drop-out rates from MBCT in 11 randomized controlled trials included in a recent systematic review (Galante et al., 2013) ranged from 4 to 58%, and the average drop-out rate was 20%. In a systematic review of 34 nonrandomized effectiveness studies of CBT Hans and Hiller (2013) found a weighted mean drop-out rate of 25%. In comparison with these drop-out rates, the rate found in our study was high. Compared with trial-completers who reported a high level of treatment satisfaction, drop-outs may have been dissatisfied with the MBCT programme. Our clinical impression is that the high attrition rate in our trial occurred because many patients referred to the trial were ambivalent about engaging, not just in MBCT, but in any form of psychological therapy (which is still associated with stigma in Ireland). However, dropouts probably attended an initial MBCT session or two to comply with their consultant cardiologist's advice. In future research, to address this issue, a careful preliminary screening process should be conducted to identify patients who have strong negative attitudes towards engaging in psychological treatment. Patients with positive attitudes towards psychological therapy may usefully be invited to participate in trials of routine MBCT as described by Segal et al. (2002). Those with negative attitudes probably require a preliminary motivation enhancement intervention before engaging in MBCT.

There was some evidence that the high dropout rate did not lead to attrition bias. A comparison of completers and dropouts on baseline demographic and clinical variables showed that they were very similar, so it may be assumed that trial completers were representative of all cases who entered the trial on demographic and clinical variables. Also, the results of an ancillary intent-to-treat analysis with last observation carried forward values

imputed for missing data points for dropouts, was consistent with results of the main analyses.

With regard to lack of randomization, statistical strategies were used to address the possibility of confounding due to selection bias. Baseline profiles of treatment and control groups were compared and found to be very similar. Ancillary analyses showed that baseline variables on which treatment and control groups differed had negligible effects on outcome.

The study had two further limitations which deserve mention. First, data on the number of previous episodes of depression were not collected. This information would have been valuable, since there is some evidence that MBCT is particularly effective for chronic relapsing depression (e.g., Segal et al., 2002). Second, it was not possible to determine the inter-rater reliability of thematic categories used to classify statements about significant therapeutic events given on the PQ, because PQ statements were classified by a single rater.

With regard to clinical implications, the results of our trial support the routine use of MBCT for CHD patients with secondary depression. A randomized controlled trial of MBCT for depression secondary to CHD is now warranted.

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Table 1. Demographic and clinical characteristics of trial completers in treatment and control groups

Variable		Group 1 Treatment Completers (N=32)	Group 2 Control Completers (N=30)	Chi Square or t-test
Gender+				
Male	f	19	22	1.00
	%	59.4	73.3	
Female	f	12	8	
	%	37.5	26.7	
Age in years				
	M	57.58	59.62	0.81
	SD	9.37	10.31	
	Range	35-80	39-77	
Relationship status				
Married	**f**	20	10	10.99**
	%	62.5	33.3	
Single	**f**	3	14	
	%	9.4	46.7	
Other or Unknown	**f**	9	6	
	%	28.1	20.0	
Socio-economic status+				
Managerial & Professional Occupations	f	13	8	2.51
	%	40.7	28.7	
Intermediate Occupations	f	4	3	
	%	12.5	10.0	
Small Employers & Own Account Workers	f	3	5	
	%	9.4	16.7	
Lower Supervisory & Technical Occupations	f	5	5	
	%	15.6	16.7	
Semi-routine & Routine Workers	f	5	8	
	%	15.6	26.7	
Number of children+				
	M	3.00	2.27	1.63
	SD	1.77	1.76	
	Range	0-8	0-6	
Clinical scales at Time 1				
HADS - Depression	M	11.12	11.13	0.01
	SD	3.36	2.40	
HADS - Anxiety	M	12.50	11.50	1.05
	SD	3.89	3.56	
BSI – Global Severity Index	M	27.44	20.97	1.90
	SD	13.81	13.66	
POMS-Total mood disturbance	M	43.97	34.97	1.53
	SD	23.81	22.13	
PAIS- Total Health-Related QoL	M	43.72	34.23	2.34*
	SD	16.54	15.34	
MAAS - Mindful Attention Awareness+	M	3.30	4.12	2.89*
	SD	1.20	0.99	
Antidepressant Medication				
On medication during the trial	f	10	8	0.16
	%	31.25	26.67	
Came off medication after trial	f	4	1	1.75
	%	12.50	0.33	

Note: HADS = Hospital Depression and Anxiety Scale. BSI = Brief Symptom Inventory. POMS = Profile of Mood Stats. PAIS = Psychosocial Adjustment to Illness Scale. MAAS = Mindful Attention Awareness Scale. M = Mean. SD = Standard deviation. *p<.05 + For gender and number of children, informaiton on one case was missing from treatment group completers. For socioeconomic status, data were missing from 2 treatment group completers and 1 control group completer. For the MAAS data were missing from 2 treatment group completers.

Table 2. Means of MBCT treatment group and waiting list control group trial completers at Times 1, 2 and 3, results of 2 X 3, Group X Time ANOVAs, and effect sizes for the Hospital Depression and Anxiety Scale, Brief Symptom Inventory, Profile of Mood States, Psychosocial Adjustment to Illness Scale and Mindful Attention Awareness Scale.

		MBCT Treatment Group (N=32)			Waiting List Control Group (N=30)			ANOVA		Treatment group-Control group Effect Size		
		T1	T2	T3	T1	T2	T3	Groups	Time	GXT	d at T2	d at T3
HADS - Depression	M	11.12	5.63	5.47	11.13	9.40	8.50	7.13	26.69**	5.52**	0.77	0.60
	SD	3.36	3.95	4.51	2.40	5.68	5.54					
HADS - Anxiety	M	12.50	7.13	6.47	11.50	9.87	8.83	2.65	29.94**	5.86**	0.60	0.52
	SD	3.89	4.24	4.68	3.56	4.93	4.38					
BSI – Global Severity Index	M	27.44	16.91	13.94	20.97	19.37	21.60	0.46	4.59*	6.19**	0.18	0.63
	SD	13.81	14.53	11.45	13.66	12.41	12.72					
POMS-Total mood disturbance	M	43.97	17.50	20.25	34.97	30.03	32.30	2.02	8.66**	6.55**	0.66	0.57
	SD	23.81	18.70	19.83	22.13	19.53	22.54					
PAIS- Total Health-Related QoL	M	43.72	33.47	22.81	34.23	36.13	40.97	2.04	3.69*	14.75**	0.14	1.00
	SD	16.54	15.75	14.84	15.34	21.86	20.78					
MAAS-Mindfulness⁺	M	3.30	3.22	4.52	4.12	4.12	4.04	3.19	6.65**	5.97**	0.82	0.43
	SD	1.20	1.20	0.92	0.99	0.99	1.30					

Note: HADS = Hospital Depression and Anxiety Scale. BSI = Brief Symptom Inventory. POMS = Profile of Mood States. PAIS = Psychosocial Adjustment to Illness Scale. MAAS = Mindful Attention Awareness Scale. Time 1 = baseline. Time 2 = 8 weeks after baseline. Time 3 = 6-months follow-up. M = Mean. SD = Standard deviation. *p<.05 **P<.01. Effect sizes are Cohen's d = (M1-M2)/(Pooled SD). ⁺For the MAAS data were missing from 2 treatment group completers.

Table 3. Significant therapeutic events and processes

	Themes	The most significant events in the MCBCT sessions were….	
1.	**Relaxation**	Learning meditation, breathing and relaxation skills	18%
2.	**Awareness**	Learning to be aware of the present moment	16%
3.	**Mindfulness**	Learning skills to focus, concentrate, detach from thoughts, and be mindful of the present moment	14%
4.	**Group support**	Having conversations with others who have similar life challenges and feeling supported by them	12%
5.	**Cognitive restructuring**	Learning that thoughts can affect mood, that thoughts are not facts, and negative thoughts can be accepted	12%
6.	**Optimism**	Developing an optimistic outlook on the future	10%
7.	**Positive experience**	Experiencing the group sessions, and life between sessions as positive experiences	8%
8.	**Self-confidence**	Developing confidence in the ability to practice mindfulness	4%
9.	**Goal setting**	Making a commitment to be mindful of daily tasks	2%
10.	**Communication**	Speaking out in the group setting	1%
11.	**Determination**	Developing determination to continue mindfulness	1%
12.	**Coping**	Learning that mindfulness skills are coping strategies that can be used to face future challenges	1%

Note: Percentages are based on 141 themes from 94 Post-session Questionnaires completed by 8-15 participants after each of 8 MBCT sessions.

Table 4. Ratings of 23 MBCT programme completers on the Client Satisfaction Questionnaire

	Question	Answer	Rate
Q1.	How would you rate the quality of the service you have received?	Good or excellent	91%
Q2.	Did you get the kind of service you wanted?	Yes, generally or definitely	96%
Q3.	To what extent has our programme met your needs?	All or most needs have been met	87%
Q4.	If a friend were in need of similar help, would you recommend our programme to him or her?	Yes, I think so or definitely	91%
Q5.	How satisfied are you with the kind of help you have received?	Very or mostly satisfied	91%
Q6.	Have the services you receive helped you to deal more effectively with your problems?	Yes, somewhat or a great deal	83%
Q7.	In an overall, general sense, how satisfied are you with the service you have received?	Mostly or very satisfied	91%
Q8.	If you were to seek help again, would you come back to our programme	Yes, I think so or definitely	96%

Figure 1. CONSORT diagram of flow of patients through the study

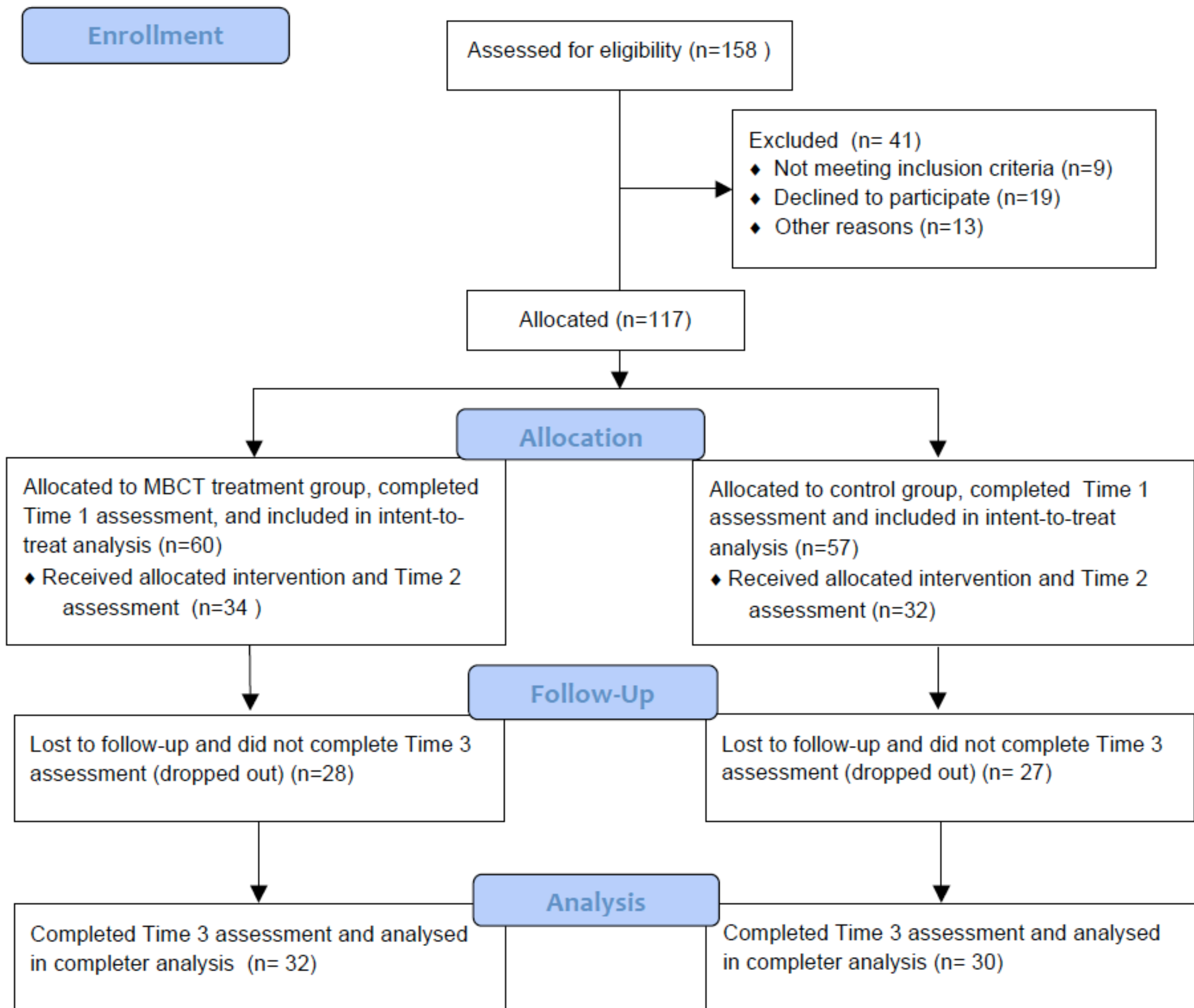

Figure 2. Mean scores of the MBCT treatment group and waiting list control group on dependent variables at Times 1, 2 and 3