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Article

The feasibility and effectiveness of mindfulness-based cognitive therapy for mixed diagnosis patients in primary care: a pilot study

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ABSTRACT

Background Mindfulness-based cognitive therapy (MBCT) is an intervention developed for the prevention of recurrent depression which is now being applied to widening numbers of clinical populations. Despite evidence for its effectiveness in preventing relapse in depression, less is known about its efficacy within routine clinical practice for groups of patients with more varied mental health problems, despite this being a potentially promising context for its application.

Aims This pilot study aimed to investigate whether MBCT would be feasible and effective when delivered in a primary care context for patients who are vulnerable to recurrent depression and anxiety.

Results Attrition from the programme was low and both attendance and engagement with home practices (during and after the intervention) were comparable with or higher than those observed in the existing literature. Improvements in self-reported depression, anxiety, rumination, self-compassion and well-being were evident over the 8-week programme and at 6-month post intervention follow-up.

Conclusions Despite limitations in terms of sample size and the absence of a control group, the results demonstrate that the promising research results of MBCT for depression are transferable from a research to a practice setting, and demonstrate that it may be an effective and feasible intervention when delivered in a primary care setting for a range of mental health problems.

Keywords: depression and anxiety, MBCT, primary care

Introduction

Mindfulness-based cognitive therapy (MBCT) is a manualised 8-week group intervention which focuses on developing attentional skills and cultivating an attitude of non-striving through meditative practices.[1] MBCT is an integration of mindfulness-based stress reduction (MBSR), with elements of cognitive therapy to enable it to meet the specific aim of targeting the psychological vulnerabilities underlying depression.[2] MBSR was developed to alleviate stress and emotional suffering associated with a range of physical and psychological health problems.[2–4] MBCT has been shown to reduce relapse rates in individuals who have suffered three or more episodes of depression (and are therefore highly vulnerable to future episodes) by around 50%, and is comparable with continued antidepressant medication in preventing relapse over a 15-month follow-up.[5–7] Based on current research, MBCT is recommended as a key priority for implementation in the UK health service by the National Institute for Health and Clinical Excellence (NICE) guidelines for individuals who have experienced three or more episodes of depression and are currently in remission.[8]

Whilst the current research on MBCT for the prevention of depressive relapse offers gold standard evidence of its efficacy, to date there has been limited dissemination of this evidence into everyday clinical practice.[9] A handful of areas offer MBCT within the UK health service and, with the exception of Finucane and Mercer, there has been little research exploring the feasibility of MBCT for mixed diagonosis groups in primary care.[10] There are a range of factors which may be impeding the implementation of MBCT within routine National Health Service (NHS) care including a lack of trained therapists, current service delivery structures and lack of awareness of the potential of the approach.[9] The transferability of evidence to practice may be further challenged by the strict inclusion and exclusion criteria employed within research trials. Evidence has to be interpreted and translated to ensure its applicability on the ground.[11]

The maladaptive patterns which MBCT aims to address in relapse prevention, specifically rumination and experiential avoidance, are also likely to be implicated in maintaining depression.[12] A number of small-scale studies suggest that MBCT may indeed be effective in reducing symptoms in currently depressed patients, and in those previously considered resistant to treatment.[10,13,14] Change in diagnostic status and reduction in depressive symptoms have also been reported in a small-scale randomised controlled trial (RCT) for patients with chronic recurrent depression.[15] Despite indicating positive changes from pre- to post-intervention symptomology, none of these small-scale studies employ a longer-term follow-up point, so it is unclear whether improvements are maintained.

Although MBCT was developed with the aim of preventing relapse in depression, there is a theoretical rationale for extending its use to a broader range of mental health problems. Anxiety disorders may be particularly suitable for treatment with mindfulness-based interventions (MBIs). Mindfulness practices encourage a present-centred non-judgemental awareness and an attitude of approach rather than avoidance of experience. This enables a disengagement from the maladaptive patterns of intrusive negative thinking, often based in fear of future situations, and a reduction in the urge to avoid, control or suppress aversive thoughts, emotions and body sensations which are characteristic of anxiety disorders.[16] Although there is not yet enough evidence in the form of large-scale RCTs to draw any firm conclusions, preliminary research suggests that MBIs may indeed be helpful in the treatment of anxiety disorders.[17–20] Improvements in levels of anxiety, depression and fatigue have also been found in patients with chronic fatigue syndrome (CFS).[21]

Furthermore, there is a growing evidence base for the closely related MBSR programme in successfully working with groups of participants with a wide range of psychological challenges including general anxiety, panic disorders, obsessive compulsive disorder (OCD) and mild to moderate depression.[17,22–24]

Given this potentially broader range of applicability of MBIs, there is support for expanding the criteria for eligibility for MBCT, and evaluating the feasibility of this in an NHS primary care setting. This model of MBCT implementation in the primary care context may have some distinct advantages over the tighter inclusion criteria currently recommended by the NICE guidance of individuals with three or more episodes of depression currently in remission.[8] First, patients vulnerable to depression but in remission are less likely to be in contact with primary care services. Second, MBCT may have a role to play in primary care in treating mixed groups which include: (1) patients with co-occurring depression and anxiety; and (2) patients who are vulnerable to depression and anxiety, either because of a chronic physical health challenge or because of a previous history of depression and/or anxiety. Third, preliminary evidence indicates that MBCT as a short-term, preventive and group intervention has the potential to be cost-effective.[7]

The current study aimed to address two related questions. First, whether MBCT is a feasible intervention when delivered in a primary care setting with general practitioner (GP) referral; and second,

whether MBCT could be effective, in terms of reducing symptomology and improving positive affect and well-being, for patients with a broader range of mental health problems than is currently recommended in the NICE guidelines, extending the inclusion beyond individuals who have had three or more episodes and currently in remission, to those with current mild to moderate depression, anxiety disorders and CFS.

Methods

Intervention participants

Participants were selected to take part in the trial based on their referral and acceptance onto an 8-week MBCT intervention delivered through a GP surgery. There were no inclusion criteria to take part in the research, but participants had all been referred to the MBCT intervention by local GPs if they were vulnerable to depressive relapse, were experiencing mild to moderate symptoms of depression, anxiety disorders or CFS. Seventeen of the 21 patients taking the MBCT class consented to taking part in the research. The sample consisted of 5 males and 12 females ranging in age from 33 to 60 years (mean = 48; SD = 8). Fourteen of the participants reported having experienced a past episode of depression, six reported having experienced anxiety disorders and five reported CFS. Of the participants who had experienced depression, the number of past episodes ranged from 2 to 20 (mean = 6.2; SD = 6.9) with the length of the worst episode ranging from 2 to 36 months (mean = 11.1; SD = 10.4). Age-of-onset of depressive episode ranged from 8 to 44 years (mean = 28.4; SD = 12.7). Time since the last depressive episode was calculated by deducting age of last episode from current age. Although this was not accurate to the month, the majority of participants had experienced an episode within the last year (range 0–4 years; mean = 0.75; SD = 1.3). Nine of the participants were currently taking medication for depression or anxiety, and the three who were not currently taking medication had taken it in the past. Twelve participants had received psychological treatment for their depression in the past.

Survey participants

Eleven of 52 GPs practising within the districts local to the research site returned the postal survey and were therefore included in the study.

Design

This is a single-site non-randomised trial using a single factor repeated measures design. All consenting participants received the MBCT intervention, and assessments took place pre/post intervention and at 6-month post-intervention follow-up.

Measures

Demographic data

A brief questionnaire developed for the study was used to gather demographic data. This included age, gender, marital status, occupation, present and past medication, and history of psychological and emotional disorders (including past treatment).

Anxiety and depression

The Hospital Anxiety and Depression Scale (HADS) is a 14-item questionnaire originally developed to assess depression and anxiety in physically ill patients.[25] Anxious and depressive symptomatology is measured across two separate 7-item subscales. The subscales appear to assess independent factors even when strongly intercorrelated and good internal consistency has been demonstrated.[26,27]

The Patient Health Questionnaire 9 (PHQ-9) is a 9-item questionnaire with each item corresponding to one of the nine diagnostic criteria for major depressive disorder in the *Diagnostic and Statistical Manual of Mental Health Disorders* (DSM-IV).[28] The PHQ-9 has been demonstrated to be both reliable and valid in measuring the severity of depression.[28]

Rumination

To measure rumination we used the short version of the Ruminative Response Scale (RRS).[29] The RRS comprises of three factors; brooding, reflection and depressive symptoms.[29] As this study already contains measures of depressive symptoms, only the 5-item brooding and 5-item reflection subscales were used in order to minimise the burden on participants. The RRS is a reliable and valid measure of rumination.[30]

Well-being

The World Health Organisation (WHO) (Five) Well-being Index (WBI-5) is a 5-item measure of well-being. Each item refers to a positive feeling and participants rate the degree to which they have experienced that feeling in the past two weeks on a 6-point Likert scale (5 = *all of the time*; 0 = *at no time*).

The scale has demonstrated good internal and external validity.[31]

Self-Compassion

The Self Compassion Scale (SCS) is a 26-item self-report scale assessing an individual's propensity to have a compassionate stance towards the self.[32] The scale measures three dimensions of self-compassion: self-kindness vs. self-judgement; common humanity vs. isolation; mindfulness vs. over-identification. The scale has good internal consistency (r = 0.92) and test–retest reliability, as well as demonstrating convergent validity in terms of significant negative correlations with depression and trait anxiety.[32]

Participant feedback

At T1 and T2, individuals were asked to estimate the level of mindfulness practice they had engaged in and to rate how important the programme has been to them. Participants were invited to comment on their reasons for this rating.

GP survey

A survey was developed in conjunction with a local GP. The survey contained questions about GPs' attitudes towards MBCT as a treatment approach, and about its suitability for delivery within the context of primary care. Response involved circling different options and allowed space for comment.

Intervention

MBCT is an 8-week group-based intervention combining training in mindfulness meditation with psychoeducation in relevant cognitive processes. In addition to the eight sessions, patients receive an individual pre-class screening interview with the MBCT teacher and a group-based orientation session. Participants are asked to engage with formal and informal mindfulness practice for about 45 minutes for 6 days each week. Formal practice included guided meditations on CDs and informal practices involved incorporating mindfulness into daily life aided by choosing routine activities to bring attention to. The home practice was supported by reading materials. The intervention was delivered by an experienced MBCT teacher and co-led by a GP, based in the local surgery where the classes were held, who has trained in mindfulness. The surgery was in a small town in a rural area.

All MBCT participants received an intervention screening and orientation interview prior to commencing the course. They were screened for suitability for the intervention including ability and willingness to engage with the course material and structure, ability to work within a group setting and absence of recent trauma (in the previous 6–12 months).

Procedures

During the intervention screening interview, patients were given information on the research and informed written consent was obtained from all participants prior to inclusion in the study.

Consenting participants completed self-report questionnaires before, immediately after the 8-week intervention (T1; responses ranged from one to four weeks) and 6 months following completion of the 8-week intervention (T2; responses ranged from 1 to 8 weeks). The GP survey was sent to all GPs in the two districts local to the surgery in which the intervention was delivered.

Analysis strategy/data preparation

Feasibility

The feasibility of delivering MBCT within the context of primary care was addressed by both the survey of GPs' opinions towards implementing MBCT, as well as its acceptability to patients. Acceptability was addressed by reviewing attrition rates from the MBCT intervention as well as attendance rate taken from the register, participant's ratings of how important the intervention had been to them at T1 and T2, and the extent to which they engaged with meditation practices during treatment and their continuation of these at follow-up.

Effectiveness

The study employed both a Per Protocol (PP) and an Intention To Treat (ITT) analysis. Two of 17 participants who completed measures at T0 did not complete at T1 or T2 so their responses were carried forward for the ITT analysis. Missing data were dealt with by replacing the missing value with the mean scale score for cases where < 10% of data was missing. Systematic missing data were evident in two cases. At T0 one participant had omitted items from the SCS and at T2 one participant had omitted the second page of the HADS and these data were excluded from analysis.

All measures with the exception of the WBI-5 showed good internal consistency consistent with those of other studies (Cronbach's α HADS = 0.89,

SCS = 0.86, RRS = 0.77, PHQ-9 = 0.80). Cronbach's α for the WBI was the lowest of the scales at 0.51.

The significance of outcomes based on ITT between T0 and T1, and T0 and T2 were assessed using paired sample *t*-tests with the PHQ, the SCS and the RRS. Shapiro–Wilks tests and observation of QQ plots revealed both the WBI-5 and the HADS were not normally distributed, and were therefore analysed using the Wilcoxon signed rank test as the non-parametric equivalent.

In order to determine the clinical impact of the MBCT intervention, scores on the HADS (PP) were used to assess caseness. Scores on the individual depression and anxiety subscales of 7 or less are regarded as within the normal range, scores from 8 to 10 are regarded as possible cases and scores of 11 or higher are regarded as probable cases.[25] The approach employed by Demyttenaere *et al* was adopted in order to take into account combined subscale ratings.[33] In this way, five different case categories were used: non-casesness, non-case on both anxiety and depression subscales or possible case on just one of the subscales; mixed anxiety–depression (subthreshold depressive and anxious symptomology), possible case on both anxiety and depression subscales; casesness of depression, probable case on depression subscale and non-case or possible case on anxiety subscale; caseness for anxiety, probable case on anxiety subscale and non-case or possible case on depression subscale; and caseness for comorbid anxiety depression, probable case on both depression and anxiety subscales.[33] The breakdown of case categories at each time point as well as the percentage of participants meeting caseness at T0 who reached remission or maintain caseness at T1 and T2 can then be reported.

Results

Feasibility

All but one of the 17 participants attended five or more of the eight MBCT sessions (range 3–8; mean = 6.8; SD = 1.4). The mean scores for the number of days per week during the intervention that participants engaged with the mindfulness practices ranged from 4.4 to 5.8 (CD, 4.5; breathing space regular, 5.8; breathing space coping, 4.4; and routine mindful activity, 5.1). At the T2 follow-up, 20% of participants reported still practising mindfulness 3–5 times per week, 33.3% once or twice per week, 33.3% once or twice per fortnight and 13.3% less than once per month. Participants rated out of 10 how important the intervention had been to them, ranging from 6 to 10 (mean = 9; SD = 1.3) and at T2 also ranging from 6 to 10 (mean = 8.8; SD = 1.3).

The results of the GP survey revealed that the majority of GPs believed that MBCT could be helpful (64%) or very helpful (9%) for preventing relapse in recurrent depression with the remaining GPs unsure. A similar trend was evident for MBCT as a treatment for anxiety disorder (45% helpful, 9% very helpful, 45% not sure). Almost all GP respondents reported that primary care was the most suitable setting for delivering MBCT (91% yes, 9% no). When asked their views on putting more emphasis on preventative approaches such as MBCT for mental health, even if this requires a shift in funding priorities, GPs were either very positive (27%) or quite positive (73%). The number of patients seen by individual GPs per year that they felt might benefit from MBCT ranged from 6 to 30 (mean = 14.7%; SD = 10.5%). Ninety-one per cent of GPs identified counsellors as being the most suitable group to deliver MBCT assuming the best level of training, with 9% not having written a response to this question.

Effectiveness

Mean scores and standard deviations for each of the outcome measures at T0, T1 and T2, and effect sizes between T0 and T1 and T0 and T2 are reported in Table 1.

Intervention outcomes

t-Tests revealed significant ($P < 0.01$) changes in all of the outcome measures between the T0 and T1 time points (Table 1). Levels of anxiety (HADS), depression (HADS and PHQ-9) and rumination (RRS) significantly decreased and levels of well-being (WBI-5) and self-compassion (SCS) significantly increased. The Cohen's *d* effect sizes for changes in the primary outcomes of depression and anxiety both measured by the HADS were medium ($d > 0.5$) and approaching medium (0.47), respectively. Medium or approaching medium effect sizes were also evident for depression (as measured on the PHQ-9), self-compassion (SCS) and well-being (WBI-5) (Table 1). The effect sizes for the brooding and reflection subscales of the RSS as well as the total score rumination (RRS) were small (< 0.2).

Long-term outcomes

For overall change (T0–T2) *t*-tests revealed significant ($P < 0.01$) reductions in anxiety (HADS), depression

Table 1 Means, standard deviations and intervention and follow-up effects

Measure	Intention to treat (n = 17) Mean (SD) T0	T1	T2	Intervention change (T0–T1) t (z)	d	Overall change (T0–T2) t (z)	d
HADS Depression	8.53 (4.37)	4.24 (2.86)	4.81 (4.52)	(3.45)**	0.59	(3.42)**	0.42
HADS Anxiety	12.00 (5.07)	7.65 (4.26)	9.00 (4.98)	4.17**	0.47	3.97**	0.30
PHQ_9	12.47 (5.30)	7.53 (5.06)	9.47 (6.87)	3.54**	0.47	2.10	0.25
SCS†	2.48 (0.50)	3.29 (0.71)	3.01 (0.67)	3.87**	0.67	2.95**	0.45
RRS brood	13.53 (3.54)	10.76 (2.84)	12.06 (3.54)	2.97**	0.43	1.82	0.21
RRS reflect	10.76 (2.86)	9.35 (2.78)	9.82 (2.63)	2.45*	0.25	1.50	0.17
RRS total	24.29 (5.01)	20.11 (4.46)	21.89 (4.83)	3.42**	0.44	2.08	0.24
WBI‡	9.25 (3.77)	13.62 (5.89)	11.87 (6.36)	(2.80)**	0.45	(1.82)	0.26

* $P < 0.05$; ** $P < 0.01$. † n = 16 for intention to treat. ‡ n = 16 for intention to treat, n =14 per protocol.

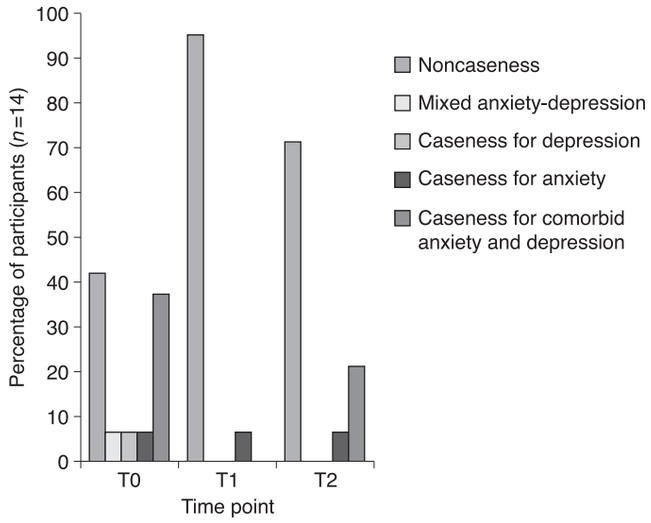

Figure 1 Categories of caseness at each time point

(HADS) and significant increases in self-compassion (SCS) (Table 1). Decreases in depressive symptoms as measured on the PHQ-9 were approaching significance (P = 0.052). A positive trend was evident for well-being (WBI-5) but this was not significant (P = 0.07). Small effect sizes were evident across all measures with the exception of the reflect subscale of the RRS.

Caseness (clinical significance)

Figure 1 reports the percentage of participants who met criteria for caseness as scored on the HADS. Of the 14 participants who completed the HADS at all three time points, 57% scored clinically significant cases at T0. Comorbid anxiety and depression was the most common category (36% of participants), with an even spread of 7% of participants for depression, anxiety and mixed anxiety–depression. At T1, a clear shift in caseness was evident with only 7% of participants meeting caseness, this being anxiety.

At T2 a reversal of this trend was evident with 28.5% meeting caseness (comorbid anxiety and depression 21.5% and for anxiety 7%). Of the participants who met criteria for caseness at T0, 87.5% had reached remission at T1 and 12.5% maintained caseness. At T2, 50% were in remission, with 50% experiencing caseness. Of the participants who did not meet criteria for caseness at T0, 100% maintained non-caseness at both T1 and T2.

Discussion

The results from this pilot study suggest that MBCT is both feasible and effective when delivered to mixed diagnosis patients in a primary care context. This strengthens the argument for extending the application of MBCT to a broader range of mental health issues and provides evidence that primary care may be a promising context for this model of delivery.

Impact on symptom reduction

A key finding of this study was the demonstration of a positive outcome for participants on a range of psychological measures. Baseline scores for anxiety and depression revealed a reasonably high level of symptomology within the group and significant reductions both in terms of mean scores and the percentage of individuals meeting clinical caseness were evident over the intervention period. These results support the preliminary body of research suggesting that MBCT may be effective in reducing symptoms for individuals currently suffering from depression and anxiety, as well as for those in remission as a preventative approach to relapse.[10,13,34,35] Significant reductions in rumination were also evident following the MBCT intervention. Rumination is widely accepted to be implicated in perpetuating and intensifying depressed mood and this has been supported by cross-sectional longitudinal and experimental studies.[36] As well as predicting the risk of relapse in previously depressed patients,[37] ruminative response style has also been found to significantly predict the onset of new depressive episodes.[38] Evidence also suggests that rumination may be as strong a predictor of symptoms of anxiety as of depression.[38] The reductions in rumination reported here are therefore encouraging and could be an indicator of vulnerability for future episodes. A noteworthy finding of this study was the increase in symptoms of anxiety, depression and rumination scores between post intervention and 6-month follow-up. This may have some important implications for how MBCT services are delivered. MBCT programmes aim to teach participants an ongoing method of self-regulation through continued home practice, but additional follow-up support may be of benefit to participants and help them to maintain changes. This theme emerged in Finucane and Mercer's study in which participants reported that they felt the course was too short and some form of follow-up is essential.[10] A recent trial of MBCT for recurrent depression and suicidality offered two follow-up classes to participants, one 6–8 weeks following the intervention and another at 6 months, as survival curves from previous research indicate these to be the most vulnerable times for relapse.[39,40] Within the context of primary care, if regular courses were delivered, some form of ongoing practice sessions accessible to all past course graduates may be an alternative model of continued support.

Impact on positive affect

Alongside symptom reduction, this study aimed to assess the impact of MBCT on positive affect. Significant improvements in both self-compassion and well-being were evident over the course. The improvements in self-compassion over the intervention period are consistent with previous research on individuals with recurrent depression currently in remission, which identified self-compassion as a key mechanism of change in MBCT, mediating the effects of MBCT on depressive symptomology at 15-month follow-up.[41] The findings in the current study therefore give an encouraging indication of longer-term benefits in terms of reducing depressive symptomology. In line with the trends for symptomology, there was a slight reversal of the intervention gains at the 6-month follow-up period both for well-being and self-compassion which again could indicate the need for follow-up support.

Feasibility

A key question posed by the study was whether MBCT would be feasible within this population in a primary care context both in terms of acceptability to patients and the process of referral and support from GPs. Attendance during the MBCT intervention was high, and attrition rates were low; both of which are noteworthy given the rural geography and some participants were relying on public transport. The level of self-reported engagement with home practice was high both during and following the course. Along with high attendance rates, the participants' ratings of how important the course

had been to them both immediately following and 6–8 months after the intervention also indicates that MBCT is an acceptable intervention for the patients referred in this study. Feedback given by GPs in the survey revealed that they could refer a considerable number of patients per year if such classes were routinely available, and that they supported a shift to more preventative methods for addressing mental health problems. This is an encouraging finding in support of the utility and feasibility of evidence-based third-wave interventions in primary care, and is especially pertinent within the UK where GPs are given greater commissioning powers in service provision for their patients.[42]

Study limitations and future research

Although the findings of this pilot study are encouraging the authors recognise a number of limitations. First, it was not within the scope of the study to recruit a matched control group. This indicates that, whilst findings were promising and aligned with existing literature on MBI's efficacy, observed change which occurred over the study period cannot conclusively be attributed to the intervention. Second, the sample size was small and despite being large enough to detect the scale of the effects, this reduces the generalisabilty of findings. A central aim of the study was exploring the feasibility of the intervention for patients with a mixed diagnosis and exploration of the referral process by GPs. A randomised controlled study would not have enabled investigation of these pragmatic questions. A third limitation is that the study only used one treatment group and so the extent to which the outcomes evident were influenced by factors which may have been unique to this group rather than MBCT in general is unknown. It was deemed appropriate, however, to first explore the practical aspects of delivering a group in this context in the first instance before rolling out further implementation. Further research in the form of an RCT with a larger sample size is recommended to address the methodological issues highlighted above. This should also include a cost-effectiveness analysis of delivering MBCT to this broader demographic within a primary care context taking into account service use and medication prescription.

Conclusion

Despite methodological limitations, the results of this study suggest that MBCT is an effective intervention when delivered in a primary care setting to individuals vulnerable to depression and anxiety disorders. The study supported its feasibility within this setting with high retention and acceptability to patients and referrers. The intervention also demonstrated effectiveness, in significantly reducing symptoms of depression anxiety and improving wellbeing and self-compassion. MBCT is a relatively new treatment. It is only 10 years since the MBCT manual was published, 8 years since the first evidence synthesis recommended MBCT and only 2 years since systematic approaches to MBCT teacher training and intervention integrity were published.[1,9,43,44] The next challenge for this emerging field is implementation.[9] This study tested the practical applicability of MBCT in a pragmatic primary care setting, and adds to the small but growing literature on the process of knowledge transfer from the university settings in which the MBCT evidence was created to the healthcare settings where it will be implemented.

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CONFLICTS OF INTEREST

None.

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