

Research Article

EFFECTIVENESS OF MINDFULNESS-BASED COGNITIVE THERAPY AS AN ADJUVANT TO PHARMACOTHERAPY IN PATIENTS WITH PANIC DISORDER OR GENERALIZED ANXIETY DISORDER

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Background: *Mindfulness-based cognitive therapy (MBCT) has been widely used to treat patients with depressive disorder to prevent relapse. The objective of this study was to examine the effectiveness of newly developed MBCT program as an adjuvant to pharmacotherapy in the treatment of patients with panic disorder or generalized anxiety disorder. Methods:* Forty-six patients with panic disorder or generalized anxiety disorder were assigned to either MBCT or an anxiety disorder education (ADE) program for a period of 8 weeks. The Hamilton Anxiety Rating Scale (HAM-A), Hamilton Depression Rating Scale (HAM-D), Beck Anxiety Inventory (BAI), Beck Depression Inventory (BDI), and Symptom Checklist-90-Revised (SCL-90-R) were used to assess the patients at 0 week and after the two programs had been running for 2, 4, and 8 weeks. **Results:** The MBCT group demonstrated significantly more improvement than the ADE group according to all anxiety (HAM-A, $p < 0.01$; BAI, $p < 0.01$; anxiety subscale of SCL-90-R, $p = 0.01$) and depression (HAM-D, $p < 0.01$; BDI, $p < 0.01$; depression subscale of SCL-90-R, $p < 0.01$) scale scores. The obsessive-compulsive and phobic subscales of the SCL-90-R also showed significantly more improvement in the MBCT group. However, no significant improvement was observed in the MBCT group versus the ADE group in terms of the somatization, interpersonal sensitivity, paranoid ideation, or psychoticism subscale scores of the SCL-90-R. **Conclusions:** MBCT may be effective at relieving anxiety and depressive symptoms in patients with panic disorder or generalized anxiety disorder. However, well-designed, randomized controlled trials are needed. *Depression and Anxiety 26:601–606, 2009.* © 2009 Wiley-Liss, Inc.

Key words: *generalized anxiety disorder; panic disorder; mindfulness-based cognitive therapy; mindfulness*

INTRODUCTION

Astin^[1] suggested that mindfulness meditation helps a person develop a stance of detached observation towards the contents of consciousness and that it may provide a useful cognitive behavioral coping strategy.

Several advances within the field of ‘third wave’ behavior therapy have led to the development of

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psychotherapeutic techniques based on mindfulness,^[2] such as mindfulness-based stress reduction (MBSR),^[3] dialectal behavior therapy,^[4] acceptance and commitment therapy (ACT),^[5] and mindfulness-based cognitive therapy (MBCT). MBCT was initially used to target cognitive vulnerabilities associated with the repeated relapse and recurrence of major depressive disorder.^[6,7]

Research into the use of MBSR has shown that a group mindfulness meditation training program can effectively reduce symptoms of anxiety and panic.^[3] Another study found that an intensive, but time-limited, group stress reduction intervention based on mindfulness meditation can have long-term beneficial effects in the treatment of patients with anxiety disorders.^[8] A research study of on ACT suggests that this approach is an acceptable and potentially effective treatment for social anxiety disorder.^[9] MBCT may also be used to improve immediate anxiety-related outcomes, which are specific to certain groups,^[10] as well as symptoms of depression. Furthermore, a recent study^[11] investigated the effectiveness of MBCT in patients with generalized anxiety disorder (GAD).

However, there is still some debate regarding MBCT as a treatment option, and studies of MBCT have been criticized for their methodology. MBCT studies have suffered from limitations such as small numbers of patients and problems with control groups.^[12] It is important to note that no controlled study of MBCT as a treatment for anxiety disorder has yet been reported. In a previous study, we assessed the effectiveness of a newly developed Korean mindfulness meditation-based stress management program in a group of panic disorder (PD) or generalized anxiety disorder (GAD) patients.^[13] The purpose of this study is to examine whether MBCT is more effective than a control therapy in patients with anxiety disorder.

METHODS

SUBJECTS

This study involved 63 patients with PD or GAD. Subjects were recruited by advertisement from among patients treated on an outpatient basis at the Department of Psychiatry, Pochon CHA University School of Medicine, between September 2006 to November 2007. Subjects were aged between 20 and 60 years, and fulfilled the DSM-IV criteria for GAD or PD with or without agoraphobia, as diagnosed by two psychiatrists using the structured clinical interview for DSM-IV (SCID), Axis I disorders.^[14,15] The psychiatrists were trained to conduct the psychological assessments by the Principle Investigator, and inter-rater reliabilities were confirmed for the Hamilton Depression Rating Scale (HAM-D) and Hamilton Anxiety Rating Scale (HAM-A) as 0.80 and 0.84 respectively. The assessors were blind to the patients' treatment assignments. Remission according to Ballenger's criteria^[16] had not achieved in any of the subjects after over 6 months of pharmacotherapy. Subjects without remission who continued to complain about their symptoms and did not show improvement from the baseline evaluation were included. Prior to commencement of the study, all

patients were treated with paroxetine (MBCT, mean \pm SD 21 \pm 5.8 mg/day; control, 22 \pm 5.3 mg/day), escitalopram (MBCT, 15 \pm 7.1 mg/day; control, 16 \pm 8.1 mg/day), or venlafaxine (MBCT, 150 \pm 73 mg/day; control, 160 \pm 84 mg/day) as antidepressants, and with alprazolam (MBCT, 0.52 \pm 0.28 mg/day; control, 0.48 \pm 0.25 mg/day) as an anxiolytic. There was no significant difference in the duration of medication use between the two groups (10.4 \pm 11.5 months for the MBCT group; 9.4 \pm 4.4 months for the control group). There were also no statistically significant differences between the two groups in terms of dosages and the numbers of selective serotonin reuptake inhibitors, venlafaxine and alprazolam. Psychiatrists confirmed that acute symptoms had stabilized and major symptoms had remained unchanged by clinical global impression^[17] for at least 2 months prior to commencement. Patient medications and dosages were not altered during the study. All patients were monitored for medication adherence by the use of checklists in an individual interview with assessors to confirm that the medication and dosages were actually being taken as prescribed. Exclusion criteria included any history of substance abuse or dependence, the presence of other psychiatric comorbidities (e.g. hypochondriasis, alcohol dependence, major depression), significant medical problems (e.g. diabetes mellitus, hypertension, tuberculosis, hepatitis, pheochromocytoma), and involvement in litigation or seeking compensation. We also excluded patients with PD or GAD with a comorbid major depression because we aimed to determine the effectiveness of MBCT in the treatment of a 'pure anxiety' disorder. All study procedures complied with Bundang CHA Hospital Institutional Review Board regulations and were conducted in accordance with the Declaration of Helsinki and the principles of Good Clinical Practice. Written informed consent was obtained after providing subjects with a full description of the study.

ASSESSMENTS

The 63 study subjects were initially assigned to undergo either MBCT ($N = 32$) or an anxiety disorder education (ADE) program ($N = 31$) consecutively. Subjects were contacted the day before the study started to encourage participation. Eight subjects in the MBCT group and nine subjects in the ADE group were excluded at baseline screening (two weeks before study commencement), and thus the data subjected to final analysis were obtained from 24 patients in the MBCT group (GAD = 5, PD = 19 at 0 week; GAD = 5, PD = 16 at 8 week) and 22 patients in the ADE group (GAD = 6, PD = 16 at 0 week; GAD = 6, PD = 15 at 8 week). Subjects in the MBCT group underwent weekly sessions of MBCT for 8 weeks, whereas ADE subjects received weekly sessions of general information on PD or GAD for 8 weeks. Both groups were assessed at 0, 2, 4, and 8 weeks using self-report measures, i.e. the Beck Depression Inventory (BDI),^[18,19] Beck Anxiety Inventory (BAI),^[20,21] and Symptom Checklist-90-Revised (SCL-90-R),^[22,23] and they were also assessed by a subject-blinded psychiatrist using clinician-rated scales, i.e. the Hamilton Depression Rating Scale (HAM-D)^[24] and the Hamilton Anxiety Rating Scale (HAM-A).^[25] Two psychiatrists assessed medication adherence, the homework checklist and dosages for each patient on a weekly basis.

MBCT PROGRAM

Two specialist psychiatrists with three years of MBCT education and training experience conducted the program. The programs were conducted in three separate groups. The number of subjects in each group was eight to twelve. The manual for the MBCT program was written in Korean in order to maintain treatment integrity. Since we could not have access to any of the information in the manual from the study published by Evans et al. in 2008, the MBCT program used

in the present study was devised for PD or GAD patients based on Segal et al.'s MBCT for depression^[7] and Korean mindfulness meditation.^[13] The MBCT training program used included mindfulness techniques (e.g. sitting meditation, body scan, walking meditation), cognitive approaches (e.g. observing thoughts and awareness), education about PD or GAD and cognitive distortions specific to PD or GAD, and homework to encourage the use of mindfulness in everyday life through regular practice. The duration of the weekly MBCT program was about 90 minutes, and a total of eight sessions were conducted. After finishing each session, the participants were given homework and an audio CD recorded in Korean by the authors. The participants were not permitted to engage in meditation or yoga on their own, nor were they allowed to attend regular psychotherapy. Program adherence based on weekly evaluations of the homework checklist was good (>80%) in every participant.

EDUCATION PROGRAM

The education program consisted of a presentation from a psychiatrist and education about the biological aspects of PD or GAD. The programs were conducted in three separate groups, and the number of subjects in each group was seven to eleven. Each session lasted for one hour, and was conducted weekly for eight weeks. Briefly, the course curriculum was as follows: weeks 1 and 2, 'A description of PD or GAD'; weeks 3 and 4, 'Symptoms and respiratory physiology of PD or GAD'; weeks 5 to 7, 'Biology, anatomy, and pharmacotherapy of PD or GAD'; week 8 'Group sharing and discussion'. Mindfulness and behavior therapy techniques for PD or GAD were not included.

DATA ANALYSIS

Categorical variables were presented as numbers and percentages, and were compared using chi-square. Continuous variables were expressed as mean \pm SD, and the Student unpaired *t* test was used for comparison. The effects of both programs were analyzed using mixed-effects model repeated measures (MMRM) approach, whereby two factors are considered to compare group performances. These factors were time main effect (which indicated whether changes to outcome variables occurred as a function of time, irrespective of the treatment received) and time \times treatment interaction (which indicated whether subjects in one treatment group changed more so than their counterparts in the other group over time). The outcome data for two treatment groups over time were analyzed using MMRM approach to handle the problem of missing data. The MMRM method is considered to provide better control of Type I and Type II errors than the traditional last-observation-carried-forward approach.^[26] SAS 9.1 was used for statistical analysis. All reported probability values were 2-tailed, with <0.05 considered statistically significant.

RESULTS

SOCIODEMOGRAPHIC CHARACTERISTICS

No significant differences were observed between the two groups in terms of sociodemographic characteristics, such as age (MBCT group, mean \pm SD = 40.8 \pm 7.3; ADE group, mean \pm SD = 38.1 \pm 9.7), gender [MBCT group, male/female = 14(58%)/10(42%); ADE group, male/female = 15(68%)/7(32%)], educational level (MBCT group, mean \pm SD = 13.7 \pm 2.0 years; ADE group, mean \pm SD = 13.5 \pm 2.4 years), marital status [MBCT

group, married = 15(62%); ADE group, married = 13(59%)], occupational status [MBCT group, employed = 12(50%); ADE group, employed = 12(54%)], or religion [MBCT group, religion declared = 12(50%); ADE group, religion declared = 17(77%)]. No significant differences were found between the two groups on any of the baseline anxiety or depression scale scores.

COMPARISON OF ANXIETY SCALE SCORES BETWEEN THE MBCT AND ADE GROUPS

Table 1 summarizes the effects of the two 8-week programs on anxiety scores. Analysis using the MMRM approach showed statistically significant decreases in anxiety scores over time in terms of HAM-A ($F = 118$, $df = 3,126$, $p < 0.01$), BAI ($F = 14$, $df = 3,125$, $p < 0.01$), and the SCL-90-R anxiety subscale ($F = 6$, $df = 3,126$, $p < 0.01$). MBCT group members showed larger anxiety score improvements than ADE group members, i.e. differences between the two groups remained significant even after considering the time \times treatment interaction [HAM-A ($F = 83$, $df = 3,126$, $p < 0.01$), BAI ($F = 10$, $df = 3,125$, $p < 0.01$), and the SCL-90-R anxiety subscale ($F = 4$, $df = 3,126$, $p = 0.01$)].

There was a significant difference in two measures of anxiety: HAM-A scale ($p < 0.01$) and BAI ($p = 0.04$) scores between groups effect, but there was no significant difference between the groups SCL-90-R anxiety subscale ($p = 0.07$).

DEPRESSION SCALE SCORES IN THE MBCT AND ADE GROUPS

Using the MMRM approach, the results presented in Table 2 show that both the 8-week programs produced statistically significant decreases in depression-scale scores over time: HAM-D ($F = 25$, $df = 3,125$, $p < 0.01$), BDI ($F = 17$, $df = 3,125$, $p < 0.01$), and the SCL-90-R depression subscale ($F = 10$, $df = 3,126$, $p < 0.01$). After taking time \times treatment interactions into consideration, the MBCT group was found to show significantly greater improvements in HAM-D scores ($F = 13$, $df = 3,125$, $p < 0.01$), BDI scores ($F = 8$, $df = 3,125$, $p < 0.01$), and scores on the SCL-90-R depression subscale ($F = 6$, $df = 3,126$, $p < 0.01$).

There was a significant difference between groups effect in patient scores for each of the three depression scales: HAM-D ($p < 0.01$), BDI ($p < 0.01$) and SCL-90-R depression subscale ($p = 0.02$).

SCL-90-R SUBSCALE SCORES IN THE MBCT AND ADE GROUPS

Analysis using the MMRM approach showed statistically significant decreases in the following scores as time progressed: the somatization subscale ($F = 18$, $df = 3,126$, $p < 0.01$), obsessive-compulsive subscale ($F = 4$, $df = 3,126$, $p < 0.01$), interpersonal sensitivity subscale ($F = 26$, $df = 3,126$, $p < 0.01$), phobic anxiety subscale ($F = 10$, $df = 3,126$, $p < 0.01$), paranoid idea-

TABLE 1. Scores on anxiety scales over time for patients with panic disorder or generalized anxiety disorder in the mindfulness-based cognitive therapy group and the education control group

	0 week Mean ± SD	2 weeks Mean ± SD	4 weeks Mean ± SD	8 weeks Mean ± SD
HAM-A ^a				
MBCT group (N = 24)	17.5 ± 4.5	11.6 ± 3.0	8.5 ± 2.6	3.4 ± 3.2
Education group (N = 22)	15.9 ± 5.6	16.0 ± 5.2	14.6 ± 5.7	14.9 ± 5.0
BAI ^a				
MBCT group (N = 24)	12.8 ± 10.2	6.2 ± 6.3	5.2 ± 4.8	5.2 ± 5.4
Education group (N = 22)	10.8 ± 6.3	10.5 ± 6.0	10.0 ± 6.1	10.3 ± 5.7
SCL-90-R anxiety subscale ^a				
MBCT group (N = 24)	8.1 ± 6.9	4.5 ± 4.7	3.4 ± 3.9	2.7 ± 3.3
Education group (N = 22)	6.9 ± 4.6	7.9 ± 7.4	6.6 ± 7.7	6.3 ± 6.6

HAM-A, Hamilton Anxiety Rating Scale; MBCT, Mindfulness-Based Cognitive Therapy; BAI, Beck Anxiety Inventory; SCL-90-R, Symptom Checklist-90-Revised; SD = standard deviation mixed-effects model repeated measures was used.

^aSignificant difference in the rate or magnitude of changes between the mindfulness-based cognitive therapy group and the education control group.

TABLE 2. Scores on depression scales over time for patients with anxiety disorder in the mindfulness-based cognitive therapy group and the education control group

	0 week Mean ± SD	2 weeks Mean ± SD	4 weeks Mean ± SD	8 weeks Mean ± SD
HAM-D ^a				
MBCT group (N = 24)	10.5 ± 5.8	6.7 ± 4.6	5.2 ± 4.1	5.3 ± 4.4
Education group (N = 22)	12.1 ± 3.2	11.5 ± 3.3	11.4 ± 3.5	11.0 ± 3.8
BDI ^a				
MBCT group (N = 24)	10.7 ± 6.2	6.8 ± 5.8	4.2 ± 3.4	4.2 ± 4.3
Education group (N = 22)	13.9 ± 5.8	13.7 ± 5.6	12.6 ± 5.4	13.1 ± 6.4
SCL-90-R depression subscale ^a				
MBCT group (N = 24)	11.7 ± 9.7	6.2 ± 6.6	3.7 ± 4.4	4.9 ± 6.6
Education group (N = 22)	10.8 ± 8.4	11.3 ± 7.6	10.0 ± 6.2	9.7 ± 6.3

HAM-D, Hamilton Depression Rating Scale; MBCT, Mindfulness-Based Cognitive Therapy; BDI, Beck Depression Inventory; SCL-90-R, Symptom Checklist-90-Revised; SD = standard deviation mixed-effects model repeated measures was used.

^aSignificant difference in the rate or magnitude of changes between the mindfulness-based cognitive therapy group and the education control group.

tion ($F = 10$, $df = 3,126$, $p < 0.01$) and psychoticism ($F = 10$, $df = 3,126$, $p < 0.01$).

According to these results and after considering the time × treatment interaction, subjects in the MBCT group showed greater improvements by the obsessive-compulsive subscale ($F = 5$, $df = 3,126$, $p = 0.01$) and the phobic anxiety subscale ($F = 3$, $df = 3,126$, $p = 0.02$). However, no significant differences were found for the other subscales (i.e. somatization, interpersonal sensitivity, paranoid ideation, psychoticism, and global severity index). Scores for hostility showed no significant change over time in either group.

There was a significant difference between groups effect in patient scores on the obsessive-compulsive ($p = 0.01$) and phobic ($p < 0.01$) subscales, but there was no significant difference between groups effect in patient scores on the other SCL-90-R subscales.

REMISSION RATE IN THE MBCT AND ADE GROUPS

Ballenger^[16] suggested that the remission of an anxiety disorder might be associated with HAM-D ≤ 7, HAM-A ≤ 7, freedom from panic attacks, no or mild agoraphobic avoidance, and no functional impairment. When patients were dichotomized according to these criteria on the basis of clinical interviews, 16 patients in the MBCT group and none in the ADE group were deemed to have remitted, and this difference was significant at 8-weeks (Fisher's exact test, $p < 0.00$).

DISCUSSION

The purpose of this study was to determine the relative merits of MBCT and educational sessions in the treatment of patients with PD or GAD. Our

findings revealed significantly greater decreases in anxiety-scale scores for patients in the MBCT group than for patients in the ADE group. These results are in agreement with those of previous studies, which indicated that MBCT can relieve anxiety in GAD^[11] and in bipolar disorder patients.^[10] Although the relatively small reduction in mean BDI scores (from 10.7 to 4.2) may not reflect a clinically significant outcome, the MMRM analysis of the scores on the other depression scales (HAM-D and SCL-90-R depression subscale) showed that the MBCT group had significantly more improvement than the ADE group, which is consistent with previous indications that MBCT can prevent depressive relapse in patients with depressive disorder.^[7,27] and bipolar disorder.^[10] Furthermore, these results suggest that MBCT reduces anxious and depressive symptoms in patients with PD or GAD by moderating worry and rumination.^[7,28]

In the present study, scores on the anxiety-related subscales of the SCL-90-R (obsessive-compulsive and phobic anxiety) were significantly reduced after the 8-week MBCT program, whereas scores on the other subscales assessed were not. These results are consistent with those of previous studies,^[28,29] which concluded that meditation can reduce phobic and obsessive-compulsive symptoms.

The present study had a number of limitations. Firstly, the assignment of patients to the two treatment groups was not properly randomized, and this may have led to a type I error. Secondly, the prescribed medication might have affected the result; delayed effects of the medication cannot be ruled out. Thirdly, we did not administer disorder-specific questionnaires (e.g. a panic disorder severity scale), and we could not perform separate analyses for each specific disorder due to the small sample size. Fourthly, the length of weekly sessions was longer for the MBCT program (1.5 hour/session) than for the ADE program (1 hour/session). This difference may have been responsible for the superior results for MBCT. Finally, we have so far been unable to conduct follow-up assessments on all patients in the study. Nevertheless, although we have six-month follow-up data on only 10 patients at the present time, the results obtained at the end of the eight-week treatment programs appear to have been maintained, and we plan conduct further long-term follow-up assessments in the future.

In conclusion, this study suggests that MBCT is more effective than education in the reduction of anxiety and depressive symptoms in patients with PD or GAD. However, our findings should be confirmed by better designed studies with larger numbers of patients before mindfulness-based cognitive therapy is considered for the clinical management of patients with PD or GAD.

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Conflict of interest

All the authors declare that they have no conflicts of interest.

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