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Is Mindfulness-Based Cognitive Therapy Effective for Preventing Relapse of Depression in
Adults?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

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ABSTRACT

Objective: The objective of this selective EBM review is to determine whether or not mindfulness-based cognitive therapy is effective for preventing relapse of depression in adults.

Study Design: Review of three English-language randomized controlled trials published between 2014 and 2015.

Data Sources: Three randomized controlled trials published in peer-reviewed journals comparing mindfulness-based cognitive therapy to comparable treatment options found via PubMed.

Outcomes measured: Outcome measured was presence or absence of relapse of major depressive episodes in adults determined by the Structured Clinical Interview for DSM-IV.

Results: Kuyken et al. found that there was not a statistically significant difference in the incidence of relapse of depression in adults between those using MBCT and those on maintenance anti-depressant therapy ($p=.43$ *Lancet*. 2015;386(9988):63-73. doi: S0140-6736(14)62222-4 [pii]). After further analysis, the NNT for this study of 33 indicated a small treatment effect. Similarly, Shallcross et al. again found no difference between groups receiving MBCT and those participating in an active control condition ($p=.91$ *J Consult Clin Psychol*. 2015;83(5):964-975. doi: 10.1037/ccp0000050 [doi]). Again, after analysis there was a small treatment effect (NNT=-45). Finally, Williams et al. again showed no significant difference in relapse rates between groups receiving MBCT combined with TAU and those using TAU alone ($p=.13$ *J Consult Clin Psychol*. 2014;82(2):275-286. doi: 10.1037/a0035036). However, upon further analysis their treatment effects were found to be the largest of the three studies evaluated in this review (NNT=14).

Conclusion: This review showed that there is no difference between MCBT and control conditions in successful prevention of depressive episodes in adults. It was determined that MBCT is a viable treatment option for those with MDD, but it was not shown to be superior to other known treatment modalities such as antidepressant therapy or psychotherapy.

Key words: mindfulness-based cognitive therapy (MBCT), major depressive disorder

INTRODUCTION

Major depressive disorder (MDD) is a chronic and incapacitating disease affecting approximately 6% of adults worldwide each year.¹ Additionally, about one in five people will meet diagnostic criteria for MDD throughout their lifetime.¹ Major depressive disorder is characterized by at least one discrete depressive episode lasting two weeks or longer, involving some or all of the following signs: clear-cut changes in mood, interests, pleasure, cognition and vegetative symptoms.¹ The exact pathophysiology of MDD is unknown, but there are many hypotheses that genetic and environmental factors, such as disordered reuptake of serotonin and adverse childhood events respectively, are involved in the development of this condition.¹ It is known that the condition affects patients' quality of life by impairing cognition, disrupting social and occupational functioning, and increasing patients' suicide risk and overall mortality rate.¹ In addition to affecting patients' mental health, major depressive disorder has also been associated with increased risk of developing other physical illnesses such as diabetes mellitus, heart disease, and stroke.¹

According to the National Ambulatory Medical Care Survey performed by the CDC, there were approximately 11 million healthcare visits for depressive disorders, excluding bipolar depression, in the year 2016 in the United States alone.² In 2013, \$71 billion was spent treating depression in the US, 53% of that being in an ambulatory care setting. It was the sixth most costly condition to treat overall, and the number one most expensive mental disorder to treat.³ Typical management of major depressive disorder combines psychotherapy and pharmacologic anti-depressant therapy, such as selective serotonin reuptake inhibitors (SSRI) among others.¹ Because MDD is a complex disorder, no single treatment has been found to be a cure-all, and relapses are common for patients with this condition.¹ This information, combined with the

statistics presented above, demonstrates the necessity for healthcare resources to be allocated toward treating MDD, and also that new approaches to treatment continue to be developed and researched.

Mindfulness-based cognitive therapy (MBCT) is a manualized, group therapy that combines the attentional training of mindfulness meditation with the activation and psychoeducation elements of cognitive therapy.⁴ Mindfulness itself is the process of learning to be aware of and wholly present in the moment at hand. It encourages the practitioner to avoid judgment of any bodily sensations, thoughts, and surrounding environmental stimuli, in an effort to practice being open, accepting, and curious.⁵ In the setting of MDD, the goal of mindfulness is that the patient will learn to recognize a worsening of their mood, without reacting to and judging themselves for the change.⁵ The overarching theoretical premise of mindfulness-based interventions is that, by practicing mindfulness, individuals will become less reactive to unpleasant internal phenomena, and more reflective, which in turn will lead to positive psychological outcomes.⁵ This paper evaluates three randomized controlled trials (RCTs) comparing the efficacy of MBCT as a means to prevent relapse of depression in adults with other therapies.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not mindfulness-based cognitive therapy is effective for preventing relapse of depression in adults.

METHODS

All research was completed by the author of this review using the PubMed database. Key words used in searches included “major depressive disorder” and “mindfulness-based cognitive therapy.” Articles were selected based on their relevance to the author’s question and if the

outcomes measured were patient-oriented outcomes, or POEMs. All articles were published in peer-reviewed journals and written in the English language. Inclusion criteria were studies published within the past ten years at the time of the search, and studies structured as a randomized controlled trial. Studies were excluded if they were published before the year 2008. The statistics reported and used included p-value, confidence interval, experimental group event rate (EER), and control group event rate (CER).

The population evaluated in the selected studies was adults with a history of at least one major depressive episode. The studies selected for this review were three randomized controlled trials using mindfulness-based cognitive therapy as the experimental intervention for MDD, with comparable control conditions. Those comparison control groups included maintenance antidepressant therapy⁶, active control condition lacking a mindfulness component⁷, and treatment as usual.⁸ The outcomes measured by all studies were the presence or absence of a relapse of depressive episodes, measured by the Structured Clinical Interview for DSM-IV (SCID). Below, Table 1 provides a summary of the demographics and descriptions of the studies evaluated in this review.

OUTCOMES MEASURED

The outcome measured in this selective EBM review was the presence or absence of relapse of major depressive episodes in adults determined by the Structured Clinical Interview for DSM-IV (SCID) performed by trained assessors.

RESULTS

In this selective EBM review, three studies comparing mindfulness-based cognitive therapy to a comparative treatment option were evaluated in adults who had been previously diagnosed with major depressive disorder and achieved remission before the start of the trial.

Table 1. Demographics and Descriptions of Included Studies

| Study | Type | #Pts | Age (yrs) | Inclusion Criteria | Exclusion Criteria | W/d | Interventions |
|--------------------------------|------|------|-------------|--|---|-----|--|
| Kuyken (2015) ⁶ | RCT | 424 | >18 | -dx of recurrent major depressive disorder (MDD) in full or partial remission -on therapeutic dose of maintenance anti-depressant drugs | -current episode of MDD -comorbid diagnosis of substance use -organic brain damage -current or past psychosis including bipolar disorder | 58 | -Eight 2.25 hour group sessions of MBCT, weekly for 8 consecutive weeks with four refresher sessions every 3 months for 1 year |
| Shallcross (2015) ⁷ | RCT | 92 | >18 and <65 | -minimum of 1 prior MDD episode -current remission from MDD for at least 1 year | -substance dependence -current suicidal ideation -current diagnosis of other psychiatric conditions (schizophrenia, Bipolar d/o ect) | 51 | - 2.5 hour group classes of MBCT weekly for 8 consecutive weeks |
| Williams (2014) ⁸ | RCT | 164 | >18 and <70 | -at least 3 prior episodes of MDD -current remission from MDD for at least 8 weeks | -history of other psychiatric conditions (schizophrenia, substance abuse ect.) -current psychotherapy counseling -regular meditation practice | 12 | -Eight weekly classes of MBCT lasting 2 hours each |

Kuyken et al. recruited participants from primary care practices in the UK who had at least three prior episodes of MDD and were currently on therapeutic anti-depressant medications.⁶ Further inclusion and exclusion criteria can be found in Table 1. The study randomly assigned 212 patients to the control group continuing on maintenance anti-depressant medication, and 212 patients to the experimental group who participated in an eight-week MBCT course with support to taper or discontinue their anti-depressant medications during the course of treatment.⁶ The researchers determined the experimental and control groups were of similar composition at the start of the trial and did not note any known biases. The participants were made aware of their group assignment; however, the raters of this study were blind to the assignments. The follow-up of patients was sufficiently long at 24 months after the start of the trial. The researchers evaluated patients at six different times throughout the two year period: one month after the MBCT course ended (equivalent time for control group), and at 9, 12, 18, and 24 months.⁶ At that time 366 of the 424 participants remained in the trial, meaning losses to follow-up were less than 20%. A worst-case analysis was not performed on the subjects lost to follow-up, but the remaining patients were analyzed with an intention-to-treat analysis. The study used an intention to treat analysis hazard ratio to measure the time to relapse for both the experimental and control groups.⁶ They found that there was no significant difference between the experimental and control groups, and that both treatment modalities were similarly effective at preventing relapse of depressive episodes. (Hazard ratio 0.89, 95% CI 0.67-1.18, $p = 0.43$)⁶

This review further analyzed the data presented in the study performed by Kuyken et al., using the raw data of relapse rates of depression. Success was considered absence of relapse of depressive episodes, and failure was considered at least one relapse of depressive episodes over the course of the 24-month study. It was reported that 44% of the experimental group (EER) and

47% of the control group (CER) experienced a relapse in depressive episodes. The relative risk reduction (RRR), absolute risk reduction (ARR), and numbers needed to treat (NNT) were calculated based on the number of patients who relapsed in each group and the data is summarized in Table 2 below.

Table 2. Treatment effects for Kuyken et al.⁶

| EER | CER | RRR | ARR | NNT |
|-----|-----|------|-----|-----|
| .44 | .47 | .064 | .03 | 33 |

Shallcross et al. recruited participants from the urban areas in the Rocky Mountain West section of the United States through referrals from mental health centers based in the community and advertisements. From over 1000 applicants, 92 participants were selected to be involved in the study, with inclusion and exclusion criteria detailed in Table 1. The experimental group received an 8-week MBCT course, and the control group participated in what this study describes as an active control condition. This included classes involving physical activity and movement, music, and nutrition, with no mindfulness components.⁷ The study made in-class time and out-of-class homework equal for both groups.⁷ There were 46 participants randomly allocated to both the experimental and control groups, and they were determined to have similar composition. As in the research conducted by Kuyken et al., the participants in the study were not blind to their group assignment, but the interviewers conducting SCID to determine relapse of depression were masked to the assignments.⁷ Follow-up was sufficiently long, with patients being evaluated over a 60-week time period. This study performed an intention to treat analysis with the results yielding hazard ratio=.945, 95% CI .364-2.45, p=.9. Similar to the study

described above, Shallcross et al. did not find a statistically significant difference in relapse rates between the MBCT group and the active control group.

Again, this review further investigated the incidence of relapse of depressive episodes, using the same parameters for success and failure as noted above. With 32.6% of the experimental group (EER) and 30.4% of the control group (CER) relapsing, the RRR, ARR, and NNT were calculated and displayed in Table 3 below.

Table 3: Treatment effects for Shallcross et al.

| EER | CER | RRR | ARR | NNT |
|------|------|-------|-------|-----|
| .326 | .304 | -.007 | -.022 | -45 |

Williams et al. conducted a randomized controlled trial with three arms: MBCT with treatment as usual, cognitive psychological education with treatment as usual, and treatment as usual (TAU) alone as the control group. The researchers conducted separate analyses comparing each of the two experimental arms to the control condition, so this review only took into account the experimental arm using MBCT and the control group, as they are most similar to the other studies considered in this analysis. The study recruited participants through advertisements and referrals from primary care and outpatient mental health clinics in the UK.⁸ A total of 164 participants comprised the arms evaluated by this review, with 108 participants randomly allocated to the MBCT with TAU experimental group and 56 to the TAU control group. More comprehensive inclusion/exclusion criteria and intervention description is detailed in Table 1. Like the studies previously described, participants were aware of their group assignment, but assessors were blind to that information. All participants were encouraged to continue TAU, which included their current medication regimen, psychotherapy, or other services used to reach

remission prior to the start of the trial, and it was determined “there was no significant differences between groups in pharmacological or psychiatric/psychological treatment received.”⁸ Follow up was sufficiently long, as patients were assessed immediately after treatment course was completed (equivalent time frame for control group) and then at 3, 6, 9, and 12 months.⁸ Losses to follow-up were 7.3%, and there was no mention of a worst-case analysis. An intention to treat analysis was performed with a Cox regression for time to relapse yielding the following results: hazard ratio= 0.68, 95% CI 0.42-1.12, and p=.13.⁸ Williams et al. also determined there was not a statistically significant difference between the MBCT and control groups.

As with the other studies, this review analyzed the relapse rates from the experimental and control groups, again using the same criteria for success and failure. Of the 108 participants in the experimental MBCT group 46% relapsed, while 53% of the TAU control group relapsed. RRR, ARR, and NNT were calculated and presented in Table 4 below. Of the three studies presented, this analysis shows the study performed by Williams et al. had the largest treatment effect with NNT being the lowest of the three.

Table 3: Treatment effects for Williams et al.

| EER | CER | RRR | ARR | NNT |
|-----|-----|-----|-----|-----|
| .46 | .53 | .13 | .07 | 14 |

DISCUSSION

Major depressive disorder is a complicated condition with many factors contributing to its development that can make the presentation, symptoms, and severity of the disease variable from patient to patient. For that reason, there are a variety of treatment options available and

much of the approach to treatment is trial and error to discover what works for each individual. Because the exact pathophysiology is unknown and is most likely a combination of factors rather than one etiology, it is common for patients to utilize multiple treatment approaches. MBCT has been suggested as a treatment option for depression to help patients be less reactive to negative internal thoughts and feelings, in an effort to improve their overall disease course and risk of relapse.⁵ An interesting correlation noted by both Kuyken et al. and Williams et al., was that a subgroup in their respective studies who reported a severe history of childhood trauma had a drastically lower rate of relapse in the MBCT groups as compared to those allocated to the control conditions.^{6,8} This was in contrast to the overall results of each study which demonstrated no significant difference between groups. The researchers theorized that those who have a known history of severe childhood trauma might have developed a learned reactivity to negative stimuli as a child that may respond more drastically to MBCT, because it is directly targeting that process as a means of treating their depression. Further research is warranted to investigate the most effective place in therapy of MBCT for patients with a known history of extensive childhood trauma at the time of diagnosis.

There are some factors that may limit the applicability of these studies to the general population. The first to consider is that most patients in these trials were recruited from either primary care or mental health clinics, and all participants were required to be in remission from MDD to be entered into the trials.^{6,7,8} This implies that the participants were patients that had reliable access to care and were compliant with their prior treatment plans. Additionally, the participants in the experimental groups completing MBCT were able to commute to and from sessions and commit multiple hours of their day once a week, for eight weeks to the treatment^{6,7,8} This level of access and commitment may not be feasible for all those diagnosed with MDD.

There have been some electronic delivery methods of MBCT developed, but its effectiveness compared to in-person group therapy sessions is unknown.⁵ Finally, two of the three studies were conducted in the UK where all citizens have insurance coverage under the National Health Service. The remaining study was done in the United States, but as mentioned above, all patients had demonstrated remission through their prior treatment courses, implying reliable medical coverage. The out-of-pocket cost of MCBT for those without insurance coverage is unknown and not a focus of this review, but it is a factor that must be considered for implementation of this therapy.

CONCLUSION

The results examined in this review demonstrated that mindfulness-based cognitive therapy was not a superior treatment of major depressive disorder when compared to other treatment modalities such as maintenance anti-depressant medication, active control conditions, and patients' treatment as usual. The evidence garnered after calculating treatment effects was slightly conflicting. Two studies showed MBCT having a relatively small treatment effect requiring 33 and 45 people respectively, be treated with MBCT to prevent one person experiencing a relapse.^{6,7} However, one study exhibited a much larger treatment effect, only requiring the treatment of 15 people to prevent one relapse.⁸ Although the data are not overwhelmingly convincing, considering the millions of people worldwide affected by MDD each year, this review determined that MBCT is moderately effective at preventing relapse of depression in adults, and should not be ruled out as a treatment option.

What remains unknown after this analysis is the exact place in therapy for MBCT. Further study is warranted to determine if patients with MDD would be best served using MBCT as an adjunct therapy, only after being stabilized on other treatment regimens as in the studies

examined in this review, or if it is a viable option to begin at the time of diagnosis. It is also warranted to investigate whether a history of trauma and abuse has any bearing on the effectiveness of the therapy.

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