

Original Research

Clinical Significance of Stress, Depression, Anxiety, and Worry Symptom Improvement Following Mindfulness-based Stress Reduction

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Abstract

Mindfulness-based stress reduction (MBSR) teaches mindfulness meditation to reduce stress, anxiety, depression, and related forms of distress among a variety of patients. Much research has documented statistically significant reductions across a variety of self-report measures following MBSR, but researchers rarely assessed and reported the clinical significance of MBSR symptom reduction in accordance with specific criteria famously established by Jacobson and Truax [1]. Patients reporting symptoms of anxiety, depression, and/or other stress-related concerns received MBSR in an outpatient mental health clinic. In order to assess the clinical significance of reported symptom reduction, specific criteria to determine reliable clinical improvement and recovery were applied to the data from each patient across the main symptom outcome measures. This secondary clinical significance analysis was conducted with all 23 patients who completed MBSR and completed assessment measures both before and after the intervention in the original open trial. A reliable change index and a cutoff point for outcome measures of worry, depression, anxiety, and stress were obtained so that reliable clinical improvement and recovery on each measure could be assessed for each patient. The proportion of patients who were elevated in the clinical range above the cutoff before the intervention was determined, as well as the proportion of those reporting symptom reduction,



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the proportion showing reliable improvement, and the proportion recovered at the final MBSR session. Clinical significance analyses revealed that over half of the patient sample scored in the clinical range on each measure before MBSR. At the end of the intervention, the vast majority of these patients reported symptom reduction, and depending on the measure, 45-69% of patients who were clinically elevated initially and reported symptom reduction following MBSR exhibited reliable clinical improvement. Furthermore, 29-50% of those patients showing reliable clinical improvement also met criteria as recovered at the conclusion of the MBSR program. These results suggest that the symptom reduction observed following MBSR is substantial and clinically meaningful for many patients – an outcome that cannot be determined with statistical tests of significance alone. Clinical significance criteria, such as those applied in this study, could be implemented in randomized controlled trial protocols to supplement conventional tests of statistical significance and shed light on how clinically meaningful obtained changes on outcome measures are for patients.

Keywords

Mindfulness; meditation; mindfulness-based stress reduction; clinical significance

1. Introduction

Mindfulness-based stress reduction (MBSR) is an eight-week public health education course originally designed for medical patients presenting with an array of symptoms and concerns. Over the course of this 30-hour curriculum, MBSR instructors teach formal mindfulness meditation and movement practices, as well as ways to implement mindfulness in daily life, week to week. MBSR has been widely studied and effectively reduced stress, anxiety, and depression for a range of physical and psychological problems with medium to large effect sizes [2-4]. MBSR is currently listed in the Substance and Mental Health Services Administration (SAMHSA) National Registry of Evidence-based Programs and Practices (NREPP).

MBSR also appears promising in the treatment of stress, worry, anxiety, and depression symptoms among patients seeking traditional outpatient psychiatric and psychological services. In one large study of adolescent psychiatric outpatients [5], patients who attended MBSR reported improvements in anxiety, depression, somatic distress, and sleep disturbance significantly more than control group patients receiving only treatment as usual. In another study, adults diagnosed with a mood disorder (either current or in the past) who received MBSR demonstrated superior improvements in depression, trait anxiety, dysfunctional attitudes, and rumination compared to a matched but not randomized waitlist control group [6]. Randomized control trials established the efficacy of MBSR for social anxiety disorder [7], for GAD [8], and for reducing anxiety, depression, and insomnia among a mixed sample of patients diagnosed with generalized anxiety disorder (GAD), panic disorder, and/or social anxiety disorder [9].

A growing body of research suggests that improved vagal regulation is an important physiological mechanism underlying these observed reductions in anxiety, sleep disturbance, and related distress following mindfulness intervention. For example, heart rate variability, a widely accepted index of cardiac sympatho-vagal balance, improved after completion of the full 8-week MBSR curriculum

[10]. This improved parasympathetic modulation of heart rate suggests better sensitivity to meet constantly changing environmental demands [11], and is considered a peripheral biomarker of emotion regulation because the prefrontal cortical activity associated with “top-down” emotion regulation also appears to produce inhibitory input to the sinoatrial node via the parasympathetic nervous system [12]. Thus, improved cardiac vagal regulation may reflect improved neurovisceral system regulation more broadly [13], with improvements in anxiety and sleep stemming from central vagal and autonomic nervous system brain regions such as the supraoptic chiasm. Furthermore, mindfulness meditation may improve overall health by protecting or increasing telomere length, increasing telomerase activity, and may impact telomere-related gene expression [14], suggesting the potential for epigenetic changes as well.

MBSR has much research support documenting statistically significant change in anxiety, depression, and other stress-related symptom measures following this intervention. However, changes in psychological symptoms following an intervention can reach statistical significance without necessarily reaching *clinical* significance. Clinical significance refers to the practical importance of the symptom reduction for each patient, reflecting how clinically meaningful the reduction in symptom measures obtained for that patient might be. For example, statistical significance might be reached in a study because enough patients reported symptom reduction, but the degree of symptom reduction for many patients might be too small to have a noticeable effect on the quality of their daily lives. Similarly, severe patients might report reliable change in their symptoms but still suffer from residual symptoms in the clinical range – an outcome which would not be detected by tests of statistical significance. Furthermore, statistical significance might be reached if enough patients report improvement, even if a large subset of patients fail to improve or worsen over the course of the intervention. For these reasons, Jacobson and Truax [1] operationalized the concept of clinical significance in their seminal article by outlining specific criteria to categorize patients as improved and/or recovered following treatment. A reliable change index can be calculated to determine whether the degree of improvement for a given patient is statistically reliable, and cutoff scores reveal whether a patient’s reduced symptoms fall within a normative range and therefore reflect true clinical recovery.

The purpose of this secondary analysis was to examine the clinical significance of symptom reduction found in a previous open trial of MBSR delivered in an outpatient psychological services setting [15]. Original analyses documented statistically significant reductions on measures of worry, anxiety, depression, and stress, as well as increased positive psychological factors, among the 23 patients completing MBSR. Although means and standard deviations obtained for these measures suggested that these improvements might be clinically significant as well, clinical significance criteria were not applied to individual patient data. Therefore, in this secondary analysis, a reliable change index and a cutoff score for each of the main outcome measures was obtained and applied to individual patient data to determine how many patients showed reliable improvement and recovered following the intervention.

2. Method

2.1 Participants and Procedure

All data for this secondary clinical significance analysis were obtained from patients who enrolled in a pilot MBSR clinical program at a university-based psychological services center. Please see the

previous publication of the larger study [15] for more detailed descriptions of this community mental health clinic setting, study procedures, and MBSR instructor background. Patients either were referred to the MBSR program by a mental health clinician for anxiety, depression, or other stress-related concerns or patients were self-referred after learning that the new MBSR program was available at the clinic. All patients who decided to enroll in the MBSR program were invited to participate in the research. This clinical pilot program was not delivered in the context of a clinical trial in which participants were prospectively recruited for research purposes. Therefore, diagnostic interviews were not conducted and no formal inclusion or exclusion criteria were applied prior to selection in the study. Instead, all patients who enrolled in the program chose to do so after an interview revealed that MBSR might be beneficial for them, and in some cases, after a referral from a previous clinician. Thus, data were collected for the purpose of evaluating this new service program. Patients who enrolled in the MBSR program were given the option of volunteering to allow their questionnaire data to be de-identified and used for later research purposes as approved by the University of Nevada, Reno Institutional Review Board (IRB). Self-report measures were completed during the first and the final MBSR sessions.

Thirty of these patients allowed their data to be de-identified and included in the research study. Of these, 23 patients completed the intervention and attended the final MBSR session to repeat the assessment battery. Of the seven patients who did not provide final data, four participants actively dropped out of the MBSR group and attended fewer than five sessions, and three participants attended at least five sessions throughout the eight-week period and did not drop out of the program but were unable to attend the final session due to illness or family emergency. Of the 23 patients who completed assessment measures at both time points, 17 were female and six were male. Nineteen patients self-identified as Caucasian/White, one patient identified as Latinx, one patient identified as African American/Black, and two patients endorsed multiple race and/or ethnic backgrounds. Patient ages ranged from 22 to 64 years old ($M = 42.17$, $SD = 12.38$).

All patients attended the 8-week MBSR curriculum delivered by the author in groups of six to ten patients per group. Self-report measures were completed at the beginning of the first MBSR session and before ending the final session.

2.2 Measures

Penn State Worry Questionnaire (PSWQ) [16]. The PSWQ is a widely used 16-item measure of trait worry with excellent internal consistency, good test-retest reliability, and demonstrated construct validity. Respondents rate each item, including five reverse-scored items, on a five-point Likert scale. Total scores range from 16 to 80 with higher scores indicating a greater tendency to experience excessive and uncontrollable worry.

Depression Anxiety Stress Scales 21-item Version (DASS21) [17]. All 21 items comprising the Depression, Anxiety, and Stress scales of the DASS21 were included. The DASS21 is a widely used measure assessing core symptoms of depression, anxiety, and stress-related tension. Respondents indicate how much each statement applies to them on a Likert scale ranging from zero to three, resulting in a separate score for each subscale. Good internal consistency, two-week temporal stability, and valid factor structure was demonstrated in clinical samples for all three scales [18].

2.3 Data Analysis

Clinically significant change on the PSWQ and DASS-21 measure scales was assessed with specific criteria indicating reliable clinical improvement and recovery on these outcome measures [1]. For the PSWQ, standardized clinical significance criteria included a reliable change index of 7 and a cutoff score of ≤ 47 , as previously calculated on large treatment samples [19]. Clinical significance criteria for the DASS-21 scales, also based upon large samples [20], included a reliable change index of 6.19 for the Depression scale, a reliable change index of 6.96 for the Anxiety scale and a reliable change index of 6.23 for the Stress scale. Cutoff scores to determine recovery included a score of 9.22 for the Depression scale, a score of 6.31 for the Anxiety scale, and a score of 12.42 for the Stress scale. Cutoff scores were applied to each patient's data to determine how many patients fell above the cutoff before the intervention. For those whose scores were elevated before the intervention, reliable change index criteria were applied to determine whether any symptom measure decrease was large enough to be considered reliable improvement. Finally, cutoff scores again were applied to each patient's scores after the intervention to reflect recovery.

3. Results

Clinically significant change on the PSWQ and DASS-21 measures was assessed for the entire sample of 23 patients. Specific criteria indicating reliable clinical improvement and cutoff scores reflecting recovery on these measures were applied to determine the proportion of improved and recovered patients at the final MBSR session.

3.1 Worry Measure

For the PSWQ, standardized clinical significance criteria included a reliable change index of 7 and a cutoff point of ≤ 47 as previously calculated on large treatment samples [19]. Only five of the 23 patients scored at or below the PSWQ cutoff point of 47 before the MBSR intervention, leaving 18 patients scoring in the clinical range pre-intervention. Of these remaining 18 patients, sixteen reported some degree of reduction on the PSWQ following MBSR, with one patient reporting no change and one patient reporting an increase. When the reliable change index of 7 was applied to PSWQ scores post-intervention, 11 of the 16 participants (69%) exhibited reliable clinical improvement with PSWQ score reductions greater than 7. In addition, eight of these 16 patients (50%) also met criteria for recovery, falling below the cutoff point of 47.

3.2 Depression Scale

Clinical significance criteria for the DASS-21 [20] included a reliable change index of 6.19 and a cutoff score of 9.22 for the Depression scale. Of the 23 patients, 13 scored above the cutoff point on the Depression scale before the MBSR intervention. Of these 13 patients, 11 reported reduced depression following MBSR. Of these 11 patients reporting decreased depression, five patients (45%) both exhibited reliable clinical improvement (with reductions greater than 6.19) and met criteria for recovery with post-intervention scores falling below the cutoff. Of the six remaining patients, five also scored below the cutoff post-intervention suggesting recovery, but the magnitude of change was not large enough to meet the reliable improvement criterion. One patient reported no change and one additional patient reported increased depression post-MBSR.

3.3 Anxiety Scale

Clinical significance criteria for the DASS-21 scales [20] included a reliable change index of 6.96 and a cutoff score of 6.31 for the Anxiety scale. Of the 23 patients included in the study, 13 scored above the Anxiety scale cutoff point before the MBSR intervention. Of these 13 patients, 12 reported some degree of reduction on the Anxiety scale. Of these 12 patients, seven patients (58%) exhibited reliable clinical improvement (with reductions greater than 6.96), five of whom (42%) also scored below the cutoff meeting criteria for recovery post-intervention. Of the remaining five patients who did not meet criteria for reliable improvement, two patients did fall below the cutoff after the intervention but these changes were not large enough to meet the reliable improvement criterion. One patient reported an increased Anxiety scale score after the intervention.

3.4 Stress Scale

Clinical significance criteria for the DASS-21 scales [20] included a reliable change index of 6.23 and a cutoff score of 12.42 for the Stress scale. Of the 23 patients included in this analysis, 14 patients scored above the Stress scale cutoff point before the MBSR intervention. Of these 14 patients, nine (64%) exhibited reliable clinical improvement, four of whom (29%) also recovered by falling below the cutoff post-intervention. Of the three remaining patients whose changes were not large enough to meet the reliable improvement criterion, one patient did score below the cutoff post-intervention. One patient reported no change and one additional patient reported increased stress post-MBSR. The individual patient who reported increased stress post-MBSR was the same individual who reported increased anxiety and increased depression on the DASS-21. At the end of the intervention, this patient explained that increased feelings of stress, anxiety, and depression were an acute reaction to a medical situation with a close family member, and the patient expressed concern that scores on the questionnaires completed in the final session might not reflect their perceived benefit from the program.

4. Discussion

Clinical significance criteria were applied to individual patient data to determine the proportion of patients who scored in the clinical range on a given outcome measure before the intervention, how many of those patients reported symptom reduction, and how often this symptom reduction met criteria for reliable clinical change and recovery. Results revealed that over half of the patient sample scored in the clinical range on each measure before MBSR. At the end of the intervention, the vast majority of these patients reported some degree of symptom reduction. Depending on the measure, 45-69% of patients who were clinically elevated initially and reported symptom reduction following MBSR exhibited reliable clinical improvement. Thus, these patients demonstrated a large enough magnitude of change to meet stringent reliable clinical improvement criteria, suggesting that a substantial portion of patients who were clinically elevated on these measures before MBSR enjoyed meaningful improvement. When cutoff criteria were applied to investigate rates of recovery, 29-50% of those patients showing reliable clinical improvement also met criteria for recovery at the end of the intervention, falling below the cutoff and in the normative range. Many additional patients who scored above the clinical cutoff before the intervention also scored below the cutoff after the intervention – however, these patient scores often were not severely elevated

before the intervention, resulting in smaller magnitudes of change that failed to meet reliable clinical improvement criteria. The clinical significance of MBSR was most pronounced on the worry measure, with 18 of the 23 patients scoring in the clinical range before treatment, 16 of whom reported some symptom reduction, 69% of whom met criteria for reliable improvement and 50% of whom fell below the cutoff and in the normative range, indicating full recovery. Taken together, these results suggest that the statistically significant symptom reduction previously found in this MBSR intervention open trial also was associated with meaningful clinical change for a substantial portion of patients. The statistically significant symptom reduction documented in numerous MBSR clinical trials also might have reflected substantial and clinically meaningful change for many patients, if only clinical significance had been assessed.

Although a major strength of this study is its examination of the clinical significance of outcomes, a number of limitations must be considered. First, these data were not collected in the context of a clinical trial and there was no control group. The lack of a randomized control group leaves it unclear whether the MBSR intervention actually caused the observed changes or whether patients would have otherwise improved without intervention. Randomized controlled trials conducted with larger samples of patients should include not only conventional tests of statistical significance, but also examine clinical significance. Furthermore, this investigation only included outcome measures of worry, depression, anxiety, and stress. The clinical significance of MBSR on physical symptom measures of comorbid somatic symptoms, as well as direct measures of patient functioning, should be studied in addition to the usual anxiety and depression outcome measures. Finally, this study did not include physiological measures to examine any potential underlying physiological benefits of the intervention, such as improved vagal regulation.

Outcomes of clinical significance cannot be determined with statistical tests of significance alone and need to be assessed with individual patient data. Clinical significance criteria, such as those applied in this study, could be implemented in randomized controlled trial protocols when conventional tests of statistical significance show evidence of effectiveness. Clinicians and their patients would be encouraged to know that MBSR not only reduces symptoms across samples of patients to reach statistical significance, but also that such changes could likely be substantial and meaningful in patients' lives.

Author Contributions

The author did all the research work of this study.

Competing Interests

The author has declared that no competing interests exist.

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