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ORIGINAL CONTRIBUTION

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Mindfulness-Based Stress Reduction for Failed Back Surgery Syndrome: A Randomized Controlled Trial

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Context: Previous studies on the effect of mindfulness-based stress reduction (MBSR) therapy on chronic pain syndromes have been hampered by study design.

Objective: To evaluate short-term efficacy of MBSR therapy for improving quality of life in adults with failed back surgery syndrome (FBSS).

Design: A single-center, prospective, randomized, single-blind, parallel-group clinical trial.

Patients and Setting: Participants were recruited from a multidisciplinary spine and rehabilitation center in the greater Portland, Maine, area.

Interventions and Main Outcome Measures: Patients were randomly assigned at baseline to receive either MBSR therapy plus traditional therapy or traditional therapy alone for an 8-week period. Those receiving MBSR therapy completed weekly group sessions, and the control group continued with their traditional care as prescribed by their medical care providers. At study enrollment and at 12-week follow-up, all participants completed questionnaires on pain, quality of life, functionality, analgesic use, and sleep quality. Patients in the intervention group also completed questionnaires at 40-week follow-up.

Results: The final analysis included 25 patients with FBSS; 15 patients were in the MBSR intervention arm, and 10 in the control group. At 12-week follow-up, patients in the intervention arm had a mean 4-point increase (on an 18-point scale) in pain acceptance and quality of life on the Chronic Pain Assessment Questionnaire, a mean 3-point decrease (on a 24-point scale) in functional limitation on the Roland-Morris Disability Questionnaire, a mean 5-point reduction (on a 30-point scale) in pain level on the Summary Visual Analog Scale for Pain, a mean 1-point reduction (on a 4-point scale) in frequency of use and potency of analgesics used for pain and recorded on logs, and a mean 1-point increase (on a 5-point scale) in sleep quality on the abridged Pittsburgh Sleep Quality Inventory. These results were statistically and clinically significant compared to outcomes for the control group.

Conclusion: The results suggest that MBSR can be a useful clinical intervention for patients with FBSS.

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Mindfulness-based stress reduction (MBSR) is a clinical educational approach to treating patients with a variety of chronic illnesses that has become increasingly popular over the past 30 years. Research in MBSR has evolved from simple observational studies[1,2] to more standard clinical trials[3] during the past several years. With more than 600 MBSR practitioners in North America and Europe,[4] as well as the establishment of a professional training program for MBSR instructors,[5] the MBSR treatment approach warrants further investigation.

The primary goal of teaching MBSR is to help students develop the capacity to approach any stressful experience, including pain, with a quality of "mindfulness." This approach is said to help students self-manage their experience of stress, responding more effectively to stressful situations instead of automatically reacting to them.[6] Mindfulness can be described as the awareness where thoughts, emotions and physical sensations arise and are accepted as is. Proponents of MBSR also assert that students develop a greater capacity for sustained concentration and gain insight into how resisting their own experiences can worsen suffering.

Mindfulness training has developed within several religious traditions for more than 2500 years. With MBSR, mindfulness training is placed in a secular context and updates the training with a scientific understanding of stress physiology and stress hardiness, which is a clinical psychology construct that describes the set of personality traits possessed by those individuals who thrive in stressful environments.[7]

MBSR Chronic Pain Trials

A 4-year study[1] of 220 patients with chronic pain who received the MBSR intervention demonstrated an initial reduction in

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pain, but the improvement was no longer detectable after 6 months. The primary limitation of the study was the lack of a control group. In a secondary analysis,[2] a subsample of the aforementioned population was compared to a nonrandomized control group, and statistically significant reductions in pain were asserted. However, this change regressed to baseline 2.5 months after intervention. A functionality survey in this secondary analysis also asserted an increase in function, but the survey used was not a validated and reliable questionnaire.

In a smaller study of 78 patients with chronic pain followed up for 12 months with the McGill Pain Questionnaire, a statistically significant reduction in pain was noted in all follow-up phases. Data interpretation was again limited by lack of a control group.[8] Another larger, more recent uncontrolled longitudinal study[9] of 133 subjects with chronic pain demonstrated reduced pain intensity and increased levels of function. These clinical improvements varied according to the subjects' particular chronic pain diagnosis and adherence to their home meditation practice.[9]

A three-arm randomized control trial compared MBSR, massage, and standard treatment over 12 weeks. The study included 30 subjects with chronic pain. Ten subjects were assigned to the MBSR course and demonstrated no statistically significant change in self-reported pain. The Short Form-12 (SF-12) measure of function was not different between the two groups at 8 weeks but did become so by 12 weeks.[3] The study[3] may be limited by the lack of standardized MBSR instructor training.

Failed Back Surgery Syndrome

Failed back surgery syndrome (FBSS) is defined as back or leg pain that persists or recurs after one or more surgical procedures on the lumbosacral spine.[10,11] These operations include discectomy, microdiscectomy, laminectomy, and fusion. The etiology of FBSS remains challenging, though it may include a combination of foraminal stenosis, symptomatic degenerative disks, pseudoarthrosis, neuropathic pain, recurrent disk herniation, mechanical pain, and psychosocial factors.[12] This etiologic imprecision is common to many varieties of chronic pain, but subjects with FBSS do provide a more homogeneous population than commonly seen in many chronic pain studies.

About 300,000 operations treating patients with back and leg pain were performed in the United States in 1994, and this number rose to nearly 400,000 by 2000.[13] Although it is estimated that 60% or more of these initial surgeries are successful, many are not.[14,15] Pain from FBSS is often debilitating and recalcitrant to treatment.[16] The reoperation rate is between 10%[17] and 19%,[13] and approximately 25,000 to 50,000 new cases of FBSS occur per year, according to a 1985 study.[18] A 2008 study places the yearly incidence as high as 80,000.[19]

Many interventions have been researched in the treatment of patients with FBSS, including osteopathic manipulative treatment, manual therapy, physical therapy, reoperation, epidural lysis of adhesions, selective nerve root blocks, systemic analgesics, and spinal cord stimulation. These interventions have demonstrated various degrees of success, and management of FBSS remains challenging.[20,21] Noninvasive approaches such as MBSR may be effective in this patient population,[22] and evaluating the efficacy of MBSR was the primary goal of this study. We hypothesized that patients receiving MBSR therapy would demonstrate improved quality of life, function, and sleep, as well as decreased pain and analgesic consumption.

Methods

Patients

Study participants were recruited from a multidisciplinary spine and rehabilitation center in the greater Portland, Maine, area. Institutional review board approval was provided by Asentral, Inc IRB (Salisbury, Massachusetts). Two hundred twenty invitation letters were mailed to a random selection of patients who had persistent leg pain, back pain, or both despite a history of lumbosacral spinal surgery within the previous 2 years. Exclusion criteria included pregnancy, cognitive impairment, relapsed chemical dependency, and lack of effective transportation. A sampling of 25 participants was chosen arbitrarily to help establish the feasibility of a larger study. All participants provided written informed consent. Contact information for one of the investigators (J.B.) was provided to participants for study-related questions.

Patients were randomly assigned at baseline and either received the MBSR instruction (intervention) group or the control group. To improve patient retention in the control group, control patients were offered the MBSR course later. Patients from both arms of the study continued to receive their usual medical care throughout the study period. Patients who participated for 12 weeks were compensated $50, and those who completed the 40-week follow-up were compensated with an additional $50.

Instruction in MBSR

For 8 weeks, patients engaged in classroom learning once per week for 1.5 to 2.5 hours. During the other 6 days of each week they were encouraged to meditate for 45 minutes per day with the aid of guided meditation audiotapes. A series of required homework assignments also underscored mindfulness and its incorporation into daily living. The sixth week of training included a 6-hour session that was in addition to the weekly session. The MBSR course educated participants on the physiology of stress and stress hardiness and provided participants with strategies for coping with stressful life experiences

using their mindfulness skills. The primary strategy for coping with pain was to develop and refine the capacity to be mindful. Participants were encouraged to be present with their experience of pain and stress in particular. One intended benefit of this approach was to help students to resist their experience of pain less and thereby reduce the suffering caused by their resistance.

Participants were taught to perform daily mindfulness practices. These practices include gentle yoga, walking, and seated meditation. The practices were intended to help participants directly notice the sensory, cognitive, and emotional facets of their experience, including the experience of pain. The experience of performing the practices was enhanced by interaction with the course instructors, who helped students distinguish between pain's emotional, cognitive, and sensory components. This strategy of disentangling these aspects of pain was intended to help participants see an opportunity to relieve the cognitive and emotional suffering that accompanies their pain, even if the nociceptive sensation should persist. The MBSR courses were taught according to the curriculum established at the University of Massachusetts (UMass) Medical Center.[23]

To standardize instruction in MBSR, the two course instructors completed the MBSR Teacher Development Intensive (TDI) offered through UMass Medical Center. Prerequisites for the TDI included professional experience in healthcare, education, or social change; a longstanding meditation and body-centered (eg, yoga) practice; prior completion of an MBSR course; and participation in at least one 5- to 10-day silent, teacher-led meditation retreat. The focuses of the TDI were extensive education in the MBSR curriculum as well as its theoretical, pedagogical, and philosophical underpinnings. The TDI training supports relative uniformity of the MBSR instruction from one course to the next. For the present study, one instructor, Sue Young, has a master's degree in psychotherapy, and the other instructor (G.E.) is an osteopathic physician who is board certified in neuromusculoskeletal medicine. The 2 instructors co-taught the entire course and were both present for all aspects of course instruction.

Outcome Measures

A questionnaire was given to all participants at baseline to assess their characteristics. These baseline characteristics included occupation, exercise and dietary habits, clinical disease, depression, alcohol and caffeine consumption, complementary or alternative treatment, and history of workers' compensation.

The outcome measures in this study were chosen for their clinical relevance by assessing levels of pain, function, medication consumption, sleep, and quality of life. For the Roland-Morris Disability Questionnaire (RMDQ) and the visual analog scale (VAS), we used the established clinical significance measures. Because the other questionnaires have no established threshold for clinical significance, we used the thresholds accepted by our institutions.

The questionnaires were as follows:

- **Chronic Pain Assessment Questionnaire (CPAQ)[24]**—This 108-point questionnaire is a summation of 18 6-point Likert-scale surveys that assess pain acceptance and quality of life. Clinical significance was established as a 4-point increase.
- **RMDQ[25]**—This 24-item, 24-point, yes or no questionnaire assesses function related to back pain. Clinical significance was established as a decrease of 3 points.
- **Summary VAS for Pain[26]**—This 30-point questionnaire is a summation of three 10-point, Likert-scale surveys that rate average pain, worst pain, and comparison of pain present this week vs last week. Clinical significance was established as a 3.6-point reduction in the average of the treatment group vs the average of the control group.
- **Abridged Pittsburgh Sleep Quality Index[27]**—This 5-item, 5-point yes or no questionnaire was used to assess five aspects of sleep: sleep quality, insomnia medication use, time until onset of sleep, duration of nightly sleep, and restoration after sleep. Clinical significance was established as a 1-point increase.

An analgesic medication log was recorded at weeks 0 and 12 for both arms of the study. These logs were scored on a scale of 0 to 4 points (with 0 indicating no analgesic use, 1 indicating less than daily non-opioid analgesic use, 2 indicating daily non-opioid analgesic use, 3 indicating less than daily opioid use, and 4 indicating daily opioid use). Clinical significance for this measure was established as a 1-point reduction.

Both arms of the study completed the set of questionnaires at weeks 0 (baseline) and 12. Patients enrolled in the control arm were then offered the opportunity to take the 8-week MBSR course. At 40 weeks, patients from the intervention arm (the initial MBSR course) were again mailed the set of questionnaires (with the analgesic medication log excepted). Patients from the control arm did not receive the 40-week questionnaires, because many of them had completed an MBSR course by then. Control patients who completed the MBSR course did not complete a 12-week follow-up.

Statistical Analysis

Statistical analysis was performed by a statistician (J.B.), who was blinded to patient intervention status. Baseline characteristics between the intervention and control groups were compared using Fisher's exact χ^2 tests for discrete variables and t tests for continuous variables. Points for the 24 questions comprising the RMDQ were summed and then analyzed using standard unpaired t tests at baseline and at 12 and 40 weeks. The same approach was used for the CPAQ questions and the pain questions from the VAS for pain. The responses

from the analgesic medication logs were coded on a scale of 0 to 4 and analyzed as both continuous and ordinal variables. The abridged Pittsburgh Sleep Quality Inventory was coded and analyzed similarly to the analgesic medicine logs. The 12-week intervention data sets were analyzed with respect to the 12-week control data sets. The 40-week intervention data sets were analyzed in comparison to their respective 12-week intervention data sets. Mean alpha was set at .05. These analyses were completed using SPSS software, version 14.0 (SPSS Inc, Chicago, Illinois).

Results

Of the 46 patients who were eligible to participate in the study, 25 were included in the final analysis. Fifteen of these patients had been randomly assigned to the MBSR intervention arm, and 10 to the control arm (*Figure*).

Table 1 compares baseline characteristics in the intervention and control groups. Patients from the two arms of the study were statistically indistinguishable in terms of occupation, exercise and dietary habits, clinical disease, depression, alcohol and caffeine consumption, and complementary or alternative treatment. All patients were white. No patient reported any history of a workers' compensation claim.

The MBSR group demonstrated statistically significant improvements in all outcome measures relative to the control group at 12 weeks (*Table 2*).[28] The respective criteria for clinically significant improvements were also met for all outcome measures. Gains in the outcome measures of the MBSR intervention group were maintained from 12 to 40 weeks. The CPAQ results demonstrated an additional mean 2-point gain

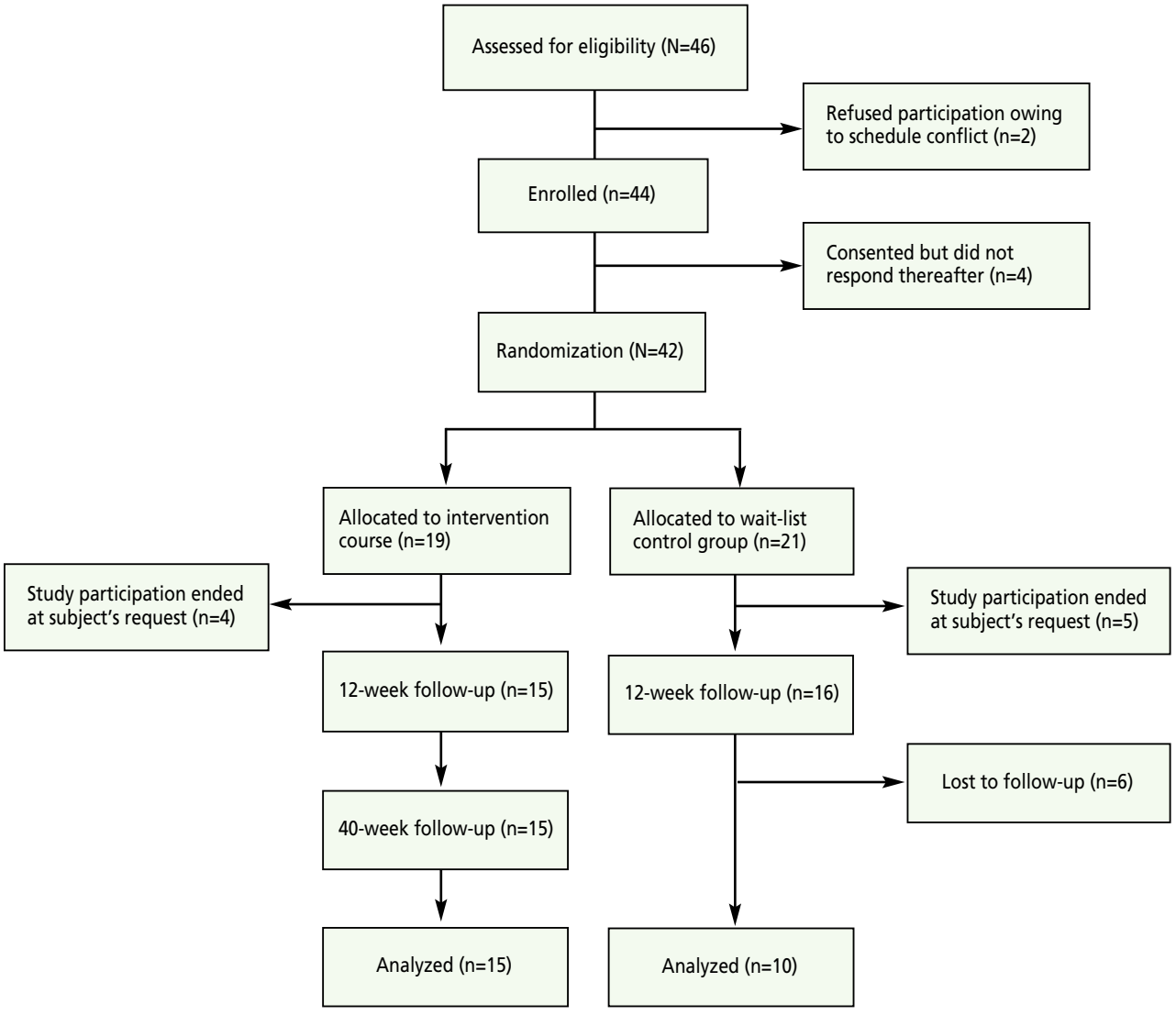

Figure. *Flow diagram of patients in the present report.*

Table 1
Mindfulness-Based Stress Reduction Therapy: Baseline Patient Characteristics in the Intervention and Control Groups*

Characteristic	Intervention Group (n=15)	Control Group (n=10)	*P* Value
■ **Age, y**	55.2 (11.2)	54.9 (9.5)	.94
■ **Height, in**	68 (3.5)	67 (3.2)	.48
■ **Weight, lb**	181 (41.8)	173 (39.2)	.62
■ **Sex**			
□ Women, No.	8	3	.54
□ Men, No.	7	7	
■ **Survey Score**			
□ Chronic Pain Acceptance Questionnaire	69.8 (7.1)	65 (5.6)	.10
□ Roland-Morris Disability Questionnaire	6.7 (5.1)	7.2 (5)	.83
□ Summary Visual Analog Scale for pain	23.2 (5)	24.3 (7.8)	.66
□ Abridged Pittsburgh Sleep Quality Index	2.4 (.8)	2.3 (.9)	.65

*All data are presented as mean (standard deviation) unless otherwise noted.

at 40 weeks—above the initial gain at 12 weeks.

Comment

The results of this study suggest that MBSR can be a useful clinical intervention for patients with FBSS. The results of the combined VAS for pain at 12 weeks are consistent with findings of previous MBSR chronic pain studies. The more durable results of the 40-week VAS for pain demonstrate a trend that has been seen with long-term follow-up in some, though not all, studies in the literature on the MBSR in chronic pain. This longer duration of benefit suggests greater clinical significance and merits further study.

Although the level of chronic pain is an important primary end point of the study, the CPAQ data underscore additional benefits of the MBSR. The CPAQ appears to capture a distinctive component of what transpires therapeutically with this intervention in terms of managing pain. The MBSR is said to help develop the capacity to embrace all varieties of experience, including unpleasant, painful states. The point is not to promote resignation to pain but rather to help people cope with pain when it is an inevitable aspect of living. One statement from the CPAQ reads, "I am getting on with the business of living no matter what my level of pain is." In this respect, the CPAQ captures the skillful coping component of the MBSR intervention, over and above any reductions in pain symptoms. Indeed, acceptance of chronic pain as measured by the CPAQ has been found to be inversely correlated with depression, physical and psychosocial disability, pain-related anxiety, and pain intensity while being directly correlated with increased daily activity and improved work status. These correlations with chronic pain acceptance were found to exist independent of perceived pain intensity.[17]

Moreover, a belief that pain indicates harm or disability has been shown to predict physical and psychosocial disability.[29] Therefore, it is reasonable to infer that acceptance of chronic pain in this population would contribute to improved function and decreased disability for patients with FBSS engaged in MBSR programs. Moreover, it is noteworthy that the CPAQ score continued to improve during the 28-week interval after the MBSR intervention was completed. This suggests ongoing clinical benefit and merits further longitudinal study.

The RMDQ results in the present study offer something new in terms of MBSR chronic pain research in that a validated, reliable measure of physical function demonstrated both statistical and clinical significance. Disability and functional limitations comprise a significant component of the disease burden of FBSS. Because functional status effectively demonstrates clinical benefit with associated quality of life and economic benefits, these data further underscore the benefit of this approach.

The sleep data are consistent with other MBSR studies that report improved sleep.[30] Improvement of sleep quality and reduction of insomnia medication consumption is particularly relevant for the FBSS population, where duration of pain correlates with poor sleep quality.[31] The reduction in the use of analgesic medications at 12 weeks is also important, because these medications have demonstrated adverse affects and financial cost.

In general, compliance with the MBSR curriculum has been found to be high; Kabat-Zinn[32] demonstrated a 70% program completion rate among 215 consecutive patients with chronic pain. Although 54% of the patients completed the study, the 11 patients who dropped out of the study were from the control group. This finding suggests an issue of patient retention as opposed to MBSR compliance. Because the patients were randomly solicited from a multidisciplinary pain clinic, there is less reason to believe they were uniquely inclined to begin and complete the MBSR curriculum.

The demonstration of statistical significance and clinical relevance for all primary outcome variables is new for research on MBSR and pain. The only other randomized controlled trial of MBSR in chronic pain, by Plews-Ogan et al[3] suggested a more limited benefit. In comparing MBSR data from different studies, the potential variability imposed by different instructors poses some methodological challenge. We attempted to address this concern by employing instructors who had completed a MBSR instructor training through UMass Medical Center.

Table 2
Mindfulness-Based Stress Reduction Therapy: Primary Outcomes for Intervention vs Control Groups*

Outcome Measure	Clinical Significance†	12-Week Follow-Up		*P* Value‡	Intervention, 40-Week Follow-Up (n=15)	Cohen *d* Effect§	Reference Range
		Intervention (n=15)	Control (n=10)				
Chronic Pain Acceptance Questionnaire	+4	7.0 (13.5)	-6.7 (11.0)	<.014	9.0 (8.4)	1.14	108-point scale (0, low pain acceptance/quality of life; 108, high pain acceptance/ quality of life)
Roland-Morris Disability Questionnaire	-3	-3.6 (3.4)	0.1 (1.9)	<.005	-3.4 (3.5)	1.28	24-point scale (0, high function; 24, low function)
Summary Visual Analog Scale for Pain	-3.6	-6.9 (6.9)	-0.2 (6.0)	<.021	-6.1 (8.3)	1.02	30-point scale (0, no pain; 30, worst pain imaginable)
Abridged Pittsburgh Sleep Quality Index	+1	2.0 (3.5)	-0.2 (1.7)	<.047	1.9 (3.3)	0.76	5-point scale (0, low sleep quality; 5, high sleep quality)
Analgesic Medication Log	-1	-1.5 (1.8)	0.4 (1.1)	<.001	NA	1.27	4-point scale (0, no analgesic medications; 2, daily nonnarcotic medications; 4, daily narcotic medications)

* Except where otherwise indicated, data represent mean differences (standard deviations) from baseline values. Negative numbers denote reductions in the scale relative to baseline values.
† Clinical significance of change in score was predetermined. For the Roland-Morris Disability Questionnaire and the visual analog scale, we used the established clinical significance measures. Because the other questionnaires have no established threshold for clinical significance, we used the thresholds accepted by our institutions.
‡ *P* values refer to comparison between intervention and control groups at 12 weeks.
§ Cohen *d* effect is calculated from *t* tests as the mean difference between groups divided by the pooled standard deviation, which results in a magnitude of difference expressed as a standard deviation rather than a mean difference.[27]

Abbreviation: NA, not available.

Conclusion

A randomized controlled study with a longer follow-up period is clearly needed for further investigation and replication. A demonstrated benefit over a prolonged period relative to a control group would more conclusively demonstrate clinical merit. The control group receiving standard medical care adequately represents the care that patients with FBSS typically receive, though an additional treatment arm employing a behavioral or educational intervention, or both, would help distinguish MBSR therapy from other health education interventions.

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