A Randomized, Wait-List Controlled Clinical Trial: The Effect of a Mindfulness Meditation-Based Stress Reduction Program on Mood and Symptoms of Stress in Cancer Outpatients

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Objective: The objective of this study was to assess the effects of participation in a mindfulness meditation–based stress reduction program on mood disturbance and symptoms of stress in cancer outpatients. **Methods:** A randomized, wait-list controlled design was used. A convenience sample of eligible cancer patients enrolled after giving informed consent and were randomly assigned to either an immediate treatment condition or a wait-list control condition. Patients completed the Profile of Mood States and the Symptoms of Stress Inventory both before and after the intervention. The intervention consisted of a weekly meditation group lasting 1.5 hours for 7 weeks plus home meditation practice. **Results:** Ninety patients (mean age, 51 years) completed the study. The group was heterogeneous in type and stage of cancer. Patients' mean preintervention scores on dependent measures were equivalent between groups. After the intervention, patients in the treatment group had significantly lower scores on Total Mood Disturbance and subscales of Depression, Anxiety, Anger, and Confusion and more Vigor than control subjects. The treatment group also had fewer overall Symptoms of Stress; fewer Cardiopulmonary and Gastrointestinal symptoms; less Emotional Irritability, Depression, and Cognitive Disorganization; and fewer Habitual Patterns of stress. Overall reduction in Total Mood Disturbance was 65%, with a 31% reduction in Symptoms of Stress. **Conclusions:** This program was effective in decreasing mood disturbance and stress symptoms in both male and female patients with a wide variety of cancer diagnoses, stages of illness, and ages. **Key words:** meditation, cancer, stress, mood, intervention, mindfulness.

ANOVA = analysis of variance; MANOVA = multiple analysis of variance; POMS = Profile of Mood States; SOSI = Symptoms of Stress Inventory.

INTRODUCTION

Emotional distress after receipt of a diagnosis of cancer is common (1–3). Doubts and fears about the future, changes in social roles, and physical symptoms or functional losses resulting from the disease or its treatment are among the precipitating factors. Compounding these difficulties, popular lore and equivocal scientific findings (4, 5) lead many patients to conclude that stress, including the very stress caused by their cancer experience, may contribute to recurrence or progression of their disease. As a consequence, persons diagnosed with cancer are increasingly seeking out supportive and complementary therapies as adjuncts to medical treatment in their efforts to cope with their illness and to promote healing. Growing interest in the use of these therapies reflects a desire for a more holistic approach to cancer treatment, which acknowledges our growing, albeit limited, understanding of the links between social, psychological, and physiological determinants of health (6, 7). A variety of psychosocial interventions that effectively ameliorate the distress or improve the quality of life of cancer patients have been developed (see Ref. 8 for a review).

Methods of promoting relaxation to self-regulate arousal and reduce distress, including various forms of meditation, make up one category of behavioral intervention of demonstrated utility across a spectrum of healthcare concerns. Derived from what were originally and primarily religious or spiritual practices, meditation has been adapted for secular purposes and is believed to bestow on its practitioners subjective benefits of personal transcendence, equanimity, and tranquility in addition to purported health benefits. Notably, Herbert Benson (9) coined and popularized the term "relaxation response" and advocated a simple form of meditation to moderate chronic sympathetic arousal and produce generalized beneficial health effects. There are several forms of meditation. Mindfulness meditation has roots in Buddhist Vipassana and Zen practices. It involves moment-by-moment, detached awareness and observation of the continually changing field of perception and its contents, and has been evaluated in a number of clinical settings.

Quasiexperimental studies suggest that mindfulness meditation may be useful in the treatment of anxiety disorders (10), chronic pain (11), and fibromyalgia (12). More recently, a randomized, controlled trial demonstrated improved lesion clearing rates in psoriasis patients under treatment who also received

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an audiotaped mindfulness meditation–based intervention during their phototherapy sessions (13). In a variety of samples of mostly healthy adults, the practice of meditation has also been associated with physical benefits, such as decreased heart rate (14, 15), slowed respiration (15), decreased blood pressure (16–18), lowered lipid levels (19), decreased levels of circulating stress hormones (16, 20–22), and enhanced immune function (23, 24). Psychological effects, including lower levels of anxiety and stress (20, 25–27), less substance abuse (28), and better overall psychological health (22, 25, 29), have also been reported. In a sample of medical students, those who underwent an 8-week mindfulness meditation–based stress reduction program had reduced state and trait anxiety, reduced overall distress (including depression), increased empathy, and increased scores on a measure of spiritual experiences compared with those in a wait-list control group (30).

We suspected that the practice of meditation and ancillary techniques could help cancer patients cope with their disease and treatment by providing a means of monitoring and regulating their own arousal, by allowing them to face and evaluate problems with greater emotional equilibrium, and by providing an avenue for them to assume an active role in pursuing personal health objectives. We began offering a pilot program that incorporated an evaluation component, revised the program on the basis of feedback from participants, and designed a clinical trial to evaluate the efficacy of our intervention. We hypothesized that a relatively brief meditation-based stress reduction program, delivered in a group format, would improve mood and reduce the stress experienced by cancer outpatients undergoing treatment or follow-up at our tertiary care cancer treatment facility.

METHODS

Subjects

A convenience sampling strategy was used to enroll patients in the study. Any patient who had a diagnosis of cancer at any time was eligible to participate. Clinical staff were informed of the study and invited to refer patients. Posters and leaflets announcing the study and inviting patient participation were posted in public areas of the clinic. Interested patients were requested to call or come to the departmental office. Patients' names and phone numbers were collected by the departmental secretary during each accrual period, which usually lasted 2 to 3 months.

One hundred nine patients initially enrolled in the study, but 19 of these patients dropped out before completing the intervention, leaving 90 patients who completed the study. Reasons for leaving the study included being too ill, hospitalization, or relapse (7); death before the completion of the study (2); and being too busy or working (4). Several participants gave no reason for dropping out (6). Demographics of those who completed the study and those who dropped out are presented in Table 1. Eighty-six women and 23 men were enrolled in the study. The dropout group consisted of 13 women and 6 men. The age of subjects ranged from 27 to 75 years (mean age, 51 years). In general, subjects were well educated, with a mean of 15 years of formal education. Patients with a wide range of types and stages of cancer were included in the study, as detailed in Table 2. Thirty-eight patients had breast cancer, making up the largest subgroup, which also is the largest group served at our center. The modal stage of participants was stage II, but all stages of cancer were well represented.

Instruments

The primary outcomes of mood and symptoms of stress were measured with use of the POMS (31) and the SOSI (32), respectively.

The POMS is widely used to study the psychological aspects of cancer. It is a 65-item adjective checklist designed to assess fluctuating affective states. The instrument provides a Total Mood Disturbance score and six factor-based subscale scores. It has acceptable test-retest reliability, has high levels of concurrent validity with related scales, and is sensitive to emotional changes within patient groups (33). Normative data are available for cancer populations (34, 35).

The SOSI was designed to measure physical, psychological, and behavioral responses to stressful situations. Respondents are instructed to rate the frequency with which they experience various stress-related symptoms on a five-point scale, ranging from "never" to "frequently," during a designated time frame selected by the investigator (in this case, the past week). The SOSI overcomes the limitations of checklist measures, which assume universally valid weightings of stressful events based on normative data, by focusing on manifest symptoms of stress and obviates the need for subjects to identify and rate all relevant stressful events occurring in their lives. Both predictive and concurrent validity have been demonstrated, and, in a mixed chronic-illness sample of patients with malignant melanoma and myocardial infarction, manifest symptom distress as

TABLE 1. Demographic Characteristics

Group	Gender (N)		Age (y)		Education (y)	
	Male	Female	Mean	SD	Mean	SD
Treatment						
Dropped out	2	6	46.7	14.2	14.9	2.0
Completed	7	46	54.9	10.5	15.7	2.9
Control						
Dropped out	4	7	53.1	9.3	14.3	3.8
Completed	10	27	48.9	13.2	15.0	2.7

TABLE 2.   Types and Stages of Cancer Diagnoses

Type of Cancer	Stage at Time of Enrollment (N)							
	Treatment Group				Control Group[a]			
	I	II	III	IV	I	II	III	IV
Completers								
Breast	5	15	1	4	5	5	2	2
Ovarian	1	3	2				2	1
Prostate		1		2			1	
Non-Hodgkins lymphoma	1	2					1	4
Melanoma		1	1					
Endometrial	1		1		1			
Colon	1		2					2
Cervical	1	1						1
Other		4	1	2	2	1	5	1
Dropouts								
Breast	1					2	2	1
Colon							1	1
Lung				1		1		2
Hodgkins lymphoma		1	1					
Other	2			2				1

[a] Staging information was unavailable for 1 control subject who completed the study.

measured by the SOSI was directly related to functional alterations due to disease and inversely related to cognitive adaptation and perceived quality of life (32).

Instruments created specifically for this study included a form for recording the duration of each participant's daily meditation practice and a demographic data collection form. Those instruments are available from the authors.

Procedure

When a sufficient number of participants were registered for randomization, all were interviewed individually 1 to 3 weeks before the start of the intervention. Informed consent was obtained at that time, and the baseline psychometric assessment was completed (time 1). Demographic and disease data were also collected and later verified by review of hospital charts. After all registered patients had been interviewed and assessed, they were randomly assigned to either the immediate intervention group (treatment condition) or a wait-list control group (control condition) using a fixed randomization scheme with assignment based on a table of random numbers. The treatment group started the program within 2 weeks of randomization while the control group waited. All patients were reassessed after the treatment group completed the program 7 weeks later (time 2). All between-group analyses were based on comparisons between these two groups. Subsequently, patients in the control group were given the opportunity to complete the program.

Intervention

Objectives. The objectives of the group program as described to the participants were 1) to provide an opportunity to examine and develop an understanding of one's personal responses to stress and a means to modify them, 2) to allow group members to take an active role in their healing process, 3) to teach options for self-care that promote feelings of competence and mastery, 4) to enhance feelings of well-being and wholeness through the practice of mindfulness meditation, and 5) to provide a safe and supportive group environment in which self-disclosure about the experience of cancer can take place in the service of learning new skills.

Structure. The intervention was provided over the course of seven weekly, 90-minute sessions. Didactic, inductive, and experiential modes of learning were used to implement the intervention and convey the informational content.

Components. The group stress reduction program was developed by the authors and is modeled on the work of Jon Kabat-Zinn (36) and colleagues at the Stress Reduction and Relaxation Clinic, Massachusetts Medical Center. We adapted and standardized the group intervention to the clinical context of our treatment center and on the basis of feedback received from patients in our pilot program. The intervention consists of three primary components: 1) theoretical material related to relaxation, meditation, and the body-mind connection; 2) experiential practice of meditation during the group meetings and home-based practice; and 3) group process focused on problem solving related to impediments to effective practice, practical day-to-day applications of mindfulness, and supportive interaction between group members. In addition, we produced a booklet containing information pertinent to each weeks instruction, including a bibliography for those wishing to pursue relevant themes in greater depth, and an audiotape with a sensate-focused relaxation induction on one side and a guided meditation on the other.

A fundamental principle unifying the program components is that purposive management of awareness (ie, mindfulness) affords multiple points of application in the recursive process of adapting to illness once experiential knowledge of key processes in the stress-response cycle is mastered. During program development, the clinical utility of incorporating multiple techniques was verified by patient feedback, which indicated that success and preference for various components differed among individuals.

Content

A week-by-week description of the program content follows.. Week 1.

Introductions and reasons for participation are shared. A rationale and overview of the intervention is presented. Didactic materials are distributed, and group rules (eg, confidentiality, regular attendance, home practice, and record keeping) are reviewed. Participants are led through an exercise focusing on full and relaxed breathing and guided awareness of bodily sensation while lying supine. Yoga mats are provided for in-session use. Home practice and record keeping are explained.

Week 2. A visualization exercise is used to demonstrate the interaction of mental imagery and bodily responses (a conditioned response of salivation is elicited through exposure to an imagined experience of tasting a lemon on a hot, dry day). Gentle yoga stretches are introduced. Principles and practices of meditation are further developed through a body scan exercise that systematically leads participants through a process of perceiving kinesthetic feedback from each area of the body.

Week 3. Group discussion and problem solving about home practice takes place. The body's response to stress, the relaxation response, and their physiological correlates are taught. Attentional processes as they relate to the practice of mindfulness meditation are outlined and illustrated through a guided meditation exercise using awareness of the breath as an anchor for attention. Mindful practice of gentle yoga stretches continues in this and all remaining sessions. Meditation using the breath as an anchor for attention is assigned for home practice.

Week 4. The reciprocal relationship between patterns of breathing and emotional response is explored through breathing exercises derived from yogic practices. A walking form of mindfulness meditation is introduced as a way of extending the practice into multiple contexts. Participants are encouraged to vary their home practice among the learned techniques.

Week 5. The relationship between cognition and emotion is explored. Application of mindfulness to the awareness of thought processes is taught to allow interruption and modification of habitual stress-inducing patterns of appraisal and thought. The nature of cognitive distortions and irrational assumptions and beliefs is explained. The tendency of the self to become identified with the contents of thought is highlighted and challenged. Homework includes self-monitoring of cognitive appraisal associated with stressful experiences and practice in challenging limiting beliefs.

Week 6. The self-monitoring assignment is reviewed, and problems encountered in application are addressed. Visualization and imagery as adjuncts to meditative practice are taught. Focusing awareness on a chosen image during guided meditation is used as a means to strengthen concentration and to experience imagery as a means to transform intention into action.

Week 7. Previously presented material is reviewed and integrated, highlighting meditation as a means to access wellness in multiple domains of experience. Each person is charged with the task of developing his or her own plan for continued well-being that uses insights derived from the program. The nature of the intervention as a starting point rather than a conclusion is reinforced. Resources in the community are discussed.

Analysis

Data and total scores on the POMS and SOSI were analyzed using one-way ANOVA to compare the treatment and control groups at each time period. If the overall ANOVA value was significant at the $p < .05$ level, post hoc independent-samples t tests were conducted on the subscales; Bonferroni's correction was used to adjust for the overall error rate. Change scores (from time 1 to time 2) were calculated and evaluated in the same manner. Demographic data were analyzed using independent-samples t tests to compare dropouts

and those who completed the study and to compare the treatment and control groups. Intent-to-treat analysis was conducted in the same manner and included all dropouts, whose time 2 (postintervention) scores were entered as unchanged. Categorical variables were compared using χ^2 analysis. Regression equations and correlations were performed to determine the impact of meditation home practice time and attendance on outcomes. Multivariate, repeated-measures ANOVA was used to analyze the main pre- and postintervention effects and interactions both between and within groups.

RESULTS

Subjects

Thirty-seven patients with early stage cancer (stages I and II) and 16 patients with late stage cancer (stages III and IV) completed the treatment program. The control group consisted of 14 patients with early stage cancer, 22 with late stage cancer, and 1 whose cancer stage had not been determined. A t test was used to compare the mean stage between groups; the difference was not significant ($t(87) = 1.94$, $p = .07$). Among the dropouts, four patients with early stage cancer and four with late stage cancer were originally assigned to the treatment group, and three with early stage cancer and eight with late stage cancer were assigned to the control group. These values were not different when analyzed by means of χ^2 analysis ($\chi^2 = 1.03$, $p = .37$). As well, there were no differences in the rate of dropping out between the treatment and control groups ($\chi^2 = 1.8$, $p = .21$), indicating that participants in the control group were not more likely to drop out than those in the treatment group.

When dropouts were compared with those who completed the study, dropouts were not more likely to have late stage cancer than those who completed the study. There were also no differences in age or years of education, but the dropouts attended an average of only 0.84 sessions (SD, 1.26), whereas those who completed the program attended an average of 6.04 of the 7 sessions (SD, 1.00) ($t(107) = 19.34$, $p < .001$). Among those who completed the treatment program, 26.4% of patients attended four to five sessions, and 73.6% of patients attended six or all seven sessions. All dropouts attended three or fewer sessions. There were no gender differences in the rate of dropping out ($\chi^2 = 1.5$, $p = .23$), indicating that both men and women were equally likely to complete the program.

When initial POMS scores of dropouts were compared with scores of those who completed the program using independent-samples t tests, the dropouts were found to have significantly more mood disturbance on the subscales of Anxiety ($t(107) = -2.00$, $p < .05$), Depression ($t(107) = -2.49$, $p < .05$), and Fatigue ($t(107) = -2.03$, $p < .05$) and on the Total Mood Disturbance score ($t(107) = -2.32$, $p < .05$). When

TABLE 3. POMS Scores: Times 1 and 2 and Change Scores

	Anxiety	Depression	Anger	Vigor	Fatigue	Confusion	Total Mood Disturbance
Time 1 (preintervention)							
Treatment							
Mean	9.7	14.1	9.6	13.5	11.7	5.5	37.1
SD	6.6	10.5	6.8	6.0	6.5	5.1	32.7
Control							
Mean	8.1	13.3	9.6	13.9	12.7	5.1	34.9
SD	6.3	9.4	6.9	7.1	6.9	5.1	35.0
Time 2 (postintervention)							
Treatment							
Mean	5.4	8.4*	6.1*	17.4	9.1	3.2*	14.7**
SD	5.8	8.9	5.1	7.4	5.4	4.8	29.8
Control							
Mean	7.9	13.0	9.5	14.5	11.4	5.6	32.9
SD	6.7	9.9	7.6	6.6	6.7	5.2	33.0
Change scores							
Treatment							
Mean	−4.8***	−6.2**	−3.9**	4.1**	−2.6	−2.5**	−24.1***
SD	5.6	8.3	4.8	6.8	5.7	4.2	25.1
Control							
Mean	−0.4	−0.4	−0.1	0.4	−1.4	0.3	−2.1
SD	5.2	9.5	7.1	4.6	6.0	3.9	28.6

* Less mood disturbance (or greater decrease in mood disturbance) in treatment group compared with control group, $p < .05$; ** $p < .01$; *** $p < .001$.

initial SOSI scores were compared, dropouts again exhibited more symptoms of stress on the subscales of Cardiopulmonary symptoms ($t(107) = −2.3$, $p < .05$) and Central-Neurological symptoms ($t(107) = −3.1$, $p < .01$).

Mood Scores

POMS scores at times 1 and 2 and POMS change scores for all subjects (treatment and control) who completed the study are presented in Table 3. Change scores were calculated by subtracting time 1 scores from time 2 scores. Therefore, negative change scores indicate a decrease in mood disturbance across assessments, whereas positive scores indicate more mood disturbance at time 2 compared with time 1. Only scores of those who completed the program ($N = 90$) are included because time 2 scores were not available for dropouts. Dropouts were eliminated from all subsequent analyses. There were no differences between the control and treatment groups at time 1, indicating that randomization had resulted in groups initially matched on mood disturbance.

At time 2 (after the treatment group had completed the 7-week program), POMS scores on the subscales of Depression ($t(88) = −2.27$, $p < .05$), Anger ($t(88) = −2.53$, $p < .05$), and Confusion ($t = −2.22$, $p < .05$) and the Total Mood Disturbance score ($t(88) = −2.69$,

$p < .01$) were significantly higher in the control group, indicating greater mood disturbance. When change scores were calculated and assessed with independent-samples t tests, the difference between the two groups was even more clear, with significantly more change in the direction of reduced mood disturbance in the treatment group on the subscales of Anxiety ($t(88) = −3.73$, $p < .001$), Depression ($t(88) = −3.02$, $p < .01$), Anger ($t(88) = −3.10$, $p < .01$), Vigor ($t(88) = 2.96$, $p < .01$), and Confusion ($t(88) = −3.20$, $p < .01$) and on Total Mood Disturbance ($t(88) = −3.80$, $p < .001$). The treatment program resulted in a 65% reduction in Total Mood Disturbance as measured by the POMS; the reduction in the control group was only 12%. The negative scores in Table 3 indicate improvements in mood in the treatment group, except on scale 4 (ie, Vigor), on which positive change scores indicate more Vigor, whereas scores in the control group did not change significantly from time 1 to time 2.

Repeated-measures general linear models MANOVA was also performed on the pre- and postintervention scores, comparing group and time effects and interactions between group and time. Not surprisingly, significant time effects were found across both groups on all variables, indicating that regardless of group membership, scores improved from time 1 to time 2. However, the interactions between group and time were also significant overall according to an omnibus mul-

tivariate test of all variables ($F(17,78) = 1.90$, $p < .05$). Individually, group-by-time interaction effects were found on scores for the subscales of Anxiety ($F(1,78) = 14.05$, $p < .001$), Depression ($F(1,78) = 8.60$, $p < .01$), Anger ($F(1,78) = 10.40$, $p < .01$), Vigor ($F(1,78) = 9.83$, $p < .01$), and Confusion ($F(1,78) = 8.63$, $p < .01$) and on the Total Mood Disturbance score ($F(1,78) = 13.72$, $p < .001$). This indicates that the improvements over time were significantly greater in the treatment group than in the control group.

An intent-to-treat analysis, a more conservative estimate of the effects of the program (including the 19 dropouts), was also performed. Scores of the dropouts were entered as unchanged from time 1 to time 2. With the inclusion of the unchanged scores of the dropouts (8 in the treatment group and 11 in the control group), postintervention scores on the POMS subscales and total mood disturbance were no longer significantly different between groups. Mean Total Mood Disturbance scores were 24.4 in the treatment group and 33.0 in the control group when dropouts were included. However, when change scores were compared (entering a change of zero for all dropouts), results were similar to those found without the dropouts. Significantly more improvement occurred in the treatment group than the control group on the POMS subscales of Anxiety ($t(107) = -3.84$, $p < .001$), Depression ($t(107) = -2.95$, $p < .01$), Anger ($t(107) = -2.99$, $p < .01$), Vigor ($t(107) = 2.77$, $p < .01$), and Confusion ($t(107) = -2.93$, $p < .01$) and on Total Mood Disturbance ($t(107) = -3.57$, $p < .001$). This indicates that even with use of the conservative intent-to-treat analysis, improvements over time were still significantly higher in the treatment group than in the control group.

The average total daily meditation time in the treatment group during the 7-week program was 32 minutes. This indicates that the participants did indeed change their behavior and complied with homework assignments. When meditation time was entered into a regression to predict POMS change scores, the result was significant ($F(2,43) = 3.94$, $p < .03$) and accounted for 15.5% of the variance in mood improvement. Number of minutes of practice significantly predicted change in Total Mood Disturbance ($t(81) = 2.73$, $p < .01$). As well, the Pearson product-moment correlation between total meditation time (in minutes) and change in Total Mood Disturbance was significant ($r = -0.393$, $p < .01$). Group attendance was not a statistically significant predictor of change in mood disturbance, perhaps because of the restricted range of attendance scores.

Stress Scores

Scores for the treatment and control groups on the SOSI at times 1 and 2 and SOSI change scores are presented in Table 4. At time 1, there were no differences between the two groups on any score, again indicating that the groups were initially matched on stress symptoms. At time 2, the control group scored higher, indicating that control patients had more stress symptoms than patients in the treatment group on several subscales, including Cardiopulmonary symptoms of stress ($t(88) = -3.05$, $p < .01$), Gastrointestinal symptoms ($t(88) = -2.32$, $p < .05$), Habitual Behavior Patterns ($t(88) = -2.97$, $p < .01$), Depression ($t(88) = -2.32$, $p < .05$), Emotional Irritability ($t(88) = -2.06$, $p < .05$), and Cognitive Disorganization ($t(88) = -2.62$, $p < .01$), and on the Total Stress Score ($t(88) = -2.80$, $p < .01$).

Change scores were calculated by subtracting time 1 scores from time 2 scores on each subscale; negative numbers again represent a decrease in stress symptoms. When the control and treatment groups were compared using independent-samples t tests, greater decreases in stress occurred in the treatment group on the subscales of Upper Respiratory tract symptoms ($t(88) = -2.11$, $p < .05$), Habitual Patterns ($t(88) = -3.01$, $p < .01$), and Emotional Irritability ($t(88) = -2.32$, $p < .05$) and on the Total Stress Score ($t(88) = -3.07$, $p < .01$). Overall, there was a 30.7% reduction of total stress symptoms in the treatment group, compared with an 11.1% improvement in the control group.

Results of the repeated-measures MANOVA indicated time effects across conditions on all subscales except Central-Neurological and Cognitive Disorganization symptoms, indicating that on most scales symptoms of patients in both groups improved over time. Interaction effects between group and time were found, however, on the Total Stress Score ($F(1,78) = 7.76$, $p < .01$) and on the subscales of Habitual Patterns of Stress ($F(1,78) = 9.07$, $p < .01$) and Emotional Irritability ($F(1,78) = 7.19$, $p < .01$), indicating greater improvements over time in the treatment group compared with the control group.

An intent-to-treat analysis including the dropouts (entering the same scores for all dropouts at times 1 and 2) still showed significant differences using independent-samples t tests after intervention on the subscales of Habitual Patterns of Stress ($t(107) = -2.64$, $p < .01$) and Cardiopulmonary symptoms ($t(107) = -2.87$, $p < .01$) and on the Total Stress Score ($t(107) = -2.27$, $p < .05$). Analysis of the intent-to-treat change scores (entering a change of zero for all dropouts) again resulted in findings similar to those of patients who

TABLE 4.   SOSI Scores: Times 1 and 2 and Change Scores

	Time 1		Time 2		Change Scores	
	Treatment	Control	Treatment	Control	Treatment	Control
Peripheral Manifestations						
Mean	7.6	8.1	4.9	6.6	−2.2	−1.4
SD	5.2	6.6	4.1	4.8	4.6	4.2
Cardiopulmonary						
Mean	12.1	14.4	7.6**	13.4	−4.1	−0.8
SD	7.6	15.6	7.3	10.3	6.9	9.9
Central-Neurological						
Mean	1.9	2.1	1.4	2.1	−0.4	0.0
SD	2.0	2.7	1.8	2.1	1.5	2.2
Gastrointestinal						
Mean	8.9	10.6	5.9*	8.7	−2.6	−1.6
SD	5.3	6.7	4.8	6.3	4.7	4.3
Muscle Tension						
Mean	12.7	12.3	8.5	10.4	−4.2	−2.1
SD	7.0	8.8	6.5	7.9	6.3	4.1
Habitual Patterns						
Mean	19.8	21.3	14.4**	20.5	−5.2**	−0.6
SD	9.3	9.7	8.7	10.2	7.4	5.9
Depression						
Mean	9.8	11.4	5.5*	8.8	−4.2	−2.4
SD	5.8	6.4	5.0	7.9	4.6	7.4
Anxiety/Fear						
Mean	11.4	11.9	7.9	9.6	−3.4	−2.0
SD	6.1	7.5	5.6	7.1	5.2	5.1
Emotional Irritability						
Mean	9.6	9.8	6.1*	8.3	−3.7*	−1.2
SD	6.2	6.8	4.1	5.6	4.8	4.6
Cognitive Disorganization						
Mean	8.1	9.4	6.8**	9.2	−1.3	−0.3
SD	4.2	6.5	4.2	4.3	3.6	6.2
Total Stress Score						
Mean	101.8	111.1	68.9**	97.6	−31.3**	−12.3
SD	43.7	59.6	40.4	54.0	32.4	30.2

* Fewer symptoms of stress (or greater decrease in stress symptoms) in treatment group compared with control group, $p < .05$; ** $p < .01$.

completed the program. Using independent-samples t tests, greater decreases in stress were observed in the treatment group on the subscales of Cardiopulmonary symptoms ($t(107) = -2.45, p < .05$), Habitual Patterns of Stress ($t(107) = -3.17, p < .01$), Muscle Tension ($t(107) = -2.07, p < .05$), and Emotional Irritability ($t(107) = -2.53, p < .05$) and on the Total Stress Score ($t(107) = -3.05, p < .01$).

Regression equations and correlations indicated that the best predictor of improvements in stress symptoms was number of sessions attended, which accounted for 13.2% of the variance in total change scores ($F(2,43) = 3.11, p < .05$). The correlation between attendance and change in stress symptoms was significant ($r = 0.30, p < .05$), and the correlation between meditation time (in minutes) and decreases in stress symptoms also showed a trend toward significance ($r = -0.253, p < .10$).

DISCUSSION

These results provide evidence that a relatively brief mindfulness meditation–based stress reduction program can effectively reduce mood disturbance, fatigue, and a broad spectrum of stress-related symptoms in cancer patients, consistent with other investigations of similar interventions with different populations (10, 11, 13). Those who attended the sessions and who meditated more had better outcomes than those who did not. It is reasonable to conclude that even greater benefits may accrue to participants who continue to practice over time and become more adept. Indeed, in other studies, experienced meditators were shown to have not only psychological benefits from meditation but also enhanced biochemical and physiological functioning when compared with nonmeditators (22–24).

The recruitment and randomization processes resulted in two groups whose equivalence was confirmed by analysis of demographic factors and preintervention test scores. Dropout rates in the two groups did not differ. One potential threat to the validity of the comparison is the possibility that those assigned to the control group felt disappointment and may not have improved as much spontaneously over time as they would have otherwise. Being assigned to the wait-list group may have mitigated against their participation in other beneficial psychosocial activities during the 7-week period, even though such participation was not discouraged. However, given their interest in meditation, it is equally likely that the effect of the program may be underestimated in this sample because of contamination of the control group, the members of which would have been able to avail themselves of meditative experiences through the use of books and tapes available in our library or by enrolling in community-based programs.

Two additional factors preclude making definitive cause-and-effect attributions between meditation per se and measured outcomes. A number of common factors, including expectancy effects and trust in the instructors, undoubtedly played a role. Indeed, in a multicomponent intervention such as this, it is difficult to isolate the mechanisms of action or specific techniques that may account for the improvements seen. Other aspects of the group besides the meditation, such as relaxation, the opportunity to take an active role in their own care, social support, or cognitive techniques, may have been beneficial. Other interventions integrating some similar techniques have also proven beneficial (37, 38), but again the specific components that are most beneficial have been difficult to determine (for reviews, see Refs. 8 and 39).

Compared with other studies that have used the POMS to assess improvement after group interventions, our patients improved as much as, or more than, patients in those other studies. Fawzy et al. (38) found a reduction of 26 points (42%) on the POMS Total Mood Disturbance score in melanoma patients after they participated in a 6-week multimodal group psychosocial intervention. Cunningham and Tocco (40) found a similar postintervention improvement in breast cancer patients; the 26-point change found by these investigators represented a 71% improvement because initial distress levels were lower in their sample than in ours. A more recent study of a 12-session cognitive-behavioral intervention for patients with metastatic breast cancer found only a 9.4-point improvement in the total mood disturbance score, but because initial scores were lower than in our sample, that change still represented a 41% improvement from

baseline (41). Thus, our finding of a 65% (24-point) reduction in total mood disturbance compares favorably with results of previous research.

Future comparative or dismantling studies may provide some clarification of active or essential components of group psychosocial intervention programs. However, on the basis of the cumulative evidence, it has been argued that variance due to treatment differences among bona fide treatments (those fully intended to be therapeutic) is small, that it is difficult if not impossible to identify specific program elements that mediate outcomes, and that such efforts are misdirected (42). From a pragmatic standpoint, our participants were able to acquire and practice a set of interrelated skills with mindfulness meditation at its core, which effectively alleviated their distress within a practical clinical setting.

The program we offered proved beneficial overall, even though participants had a variety of diagnoses and differed in severity of illness and age. This suggests that population heterogeneity does not preclude use of this intervention, an important point to note at a time when homogeneity of support groups is becoming more the norm (43, 44). However, self-selection of participants in our study likely resulted in a sample of cancer patients who were well motivated to pursue new learning and to adhere to practice recommendations. Thus, the generalizability of the findings may be limited with respect to motivational factors, but the results show that the program can be beneficial in those who express a desire to participate.

Our population exhibited higher levels of mood disturbance at the time of enrollment than a large sample of outpatients diagnosed with cancer an average of 1 year earlier (Total Mood Disturbance score, 36 vs. 20, respectively) (35). After the intervention, total mood disturbance in our sample was somewhat lower than those norms (14 vs. 20). This may indicate that patients who are experiencing higher-than-average distress are motivated to seek help, which led them to the meditation program. We also noted that patients who dropped out of the study initially experienced higher levels of distress than those who completed the program. This may indicate that our program alone is not sufficient to treat patients with more serious disturbance, who may benefit more from individualized attention to deal with specific symptoms. When compared with norms in the manual, however, our initial sample was substantially less distressed than psychotherapy patients (Total Mood Disturbance score = 77) and had slightly less overall mood disturbance than college students (Total Mood Disturbance score = 43). This further enhances the significance of the efficacy

of this intervention, illustrating that it effectively alleviated distress from a relatively low baseline level.

In summary, as evidenced by this study, this program of mindfulness meditation–based stress reduction effectively reduced Total Mood Disturbance and specific symptoms of Anxiety, Depression, Anger, and Confusion. This occurred in a diverse population of cancer outpatients with a variety of diagnoses and stages across a wide spectrum of ages among both genders. It also enhanced feelings of Vigor and decreased a wide variety of symptoms of stress in this population. More home practice predicted improvements in stress level and Total Mood Disturbance; better attendance was also associated with greater decreases in stress symptoms. Better attendance may have attenuated stress symptoms by allowing participants to benefit from the presence of others who were role models of good coping and stress-reduction skills. The diversity in the sample strengthens the generalizability of these findings. Future research should focus on pinpointing the most effective aspects of the intervention and further assessing the physical, biochemical, and physiological parameters that may be improved through use of this intervention.

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