

# Prospective Feasibility Study of A Mindfulness-Based Program for Breast Cancer Patients in the Southeastern US

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## Research Article

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# Abstract

**Background:** Mindfulness interventions are effective at improving psychological distress and quality of life in cancer patients. Few mindfulness programs for cancer recovery exist in major cities throughout the Southeastern United States. The primary objective of this study was to assess the feasibility of a modified mindfulness-based stress reduction (MBSR) program for breast cancer patients in Birmingham, Alabama. The secondary objective was to estimate the effectiveness of the modified program by examining changes in patients' mindfulness skills and quality of life.

**Methods:** This study was a prospective, quasi-experimental feasibility study conducted over 10 months within a university hospital in Birmingham, Alabama. Feasibility was achieved if 80% of eligible patients screened chose to enroll in the study and 70% of enrolled patients attended all 8 program sessions. Program effectiveness was estimated by changes in mindfulness and quality of life indicators. These indicators were measured by validated scales administered at pretest, posttest, and 8-week follow-up and assessed with a non-parametric Friedman test. The program curriculum followed a modified version of Dr. Jon Kabat-Zinn's MBSR program. Program sessions included sitting meditation, hatha/restorative yoga, and a body-focused attention practice called body scan. There were 3 groups of 2-5 patients.

**Results:** The sample consisted of 12 patients. Forty-four percent (12/27) of eligible patients enrolled in the study, failing to meet recruitment success criteria of 80%; two out of 12 enrolled patients completed all 8 program sessions, resulting in 16.7% (2/12) retention, which fell below the retention success criteria of 70%. However, more than half (66.7%) of participants completed at least 7 sessions. Between baseline and 8-week follow-up, patients demonstrated statistically significant improvements in distress, general wellbeing, and fatigue-related quality of life.

**Conclusions:** Feasibility objectives were not achieved. However, a large majority of participants (66.7%) completed 7 of the 8 program sessions. Program effectiveness was promising for distress, fatigue, and wellbeing. Results warrant further research on MBSR programs for breast cancer patients in Alabama. Future programs should investigate how to increase overall recruitment numbers, focusing on introducing mindfulness concepts to inexperienced populations. Studies should consider hosting sessions in community locations or via telemedicine to improve accessibility.

## Background

Breast cancer is the most common non-cutaneous cancer among women in the United States.<sup>1</sup> Approximately 252,710 new breast cancer cases arise each year, and more than 3.5 million breast cancer survivors currently live in the US.<sup>2</sup> Breast cancer survivors remain at risk indefinitely for cancer recurrence, secondary cancers, and other chronic diseases.<sup>3,4</sup> Many breast cancer patients require endocrine therapies for 5 to 10 years after their initial active treatment. These treatments often have debilitating side effects resulting in poor adherence, early termination of treatment and reduced quality of life (QoL).<sup>5,6,7</sup> A robust focus on long-term survivorship care for breast cancer survivors is essential for

reducing the risk of cancer recurrence and development of secondary cancers as well as improving treatment adherence and QoL.

Complementary health practices – offered together with conventional oncological care – have demonstrated significant improvements in patients' health-related quality of life.<sup>8,9</sup> Complementary health practices are not generally part of conventional medical care and may have origins outside of usual Western practice.<sup>10</sup> These practices can range from practitioner-based approaches, like acupuncture and massage therapy, to self-care practices like dietary supplements, meditation, and yoga.<sup>11</sup> According to the National Center for Complementary and Integrative Health (NCCIH), an integrative health care approach “brings conventional and complementary approaches together in a coordinated way”, emphasizing “a holistic, patient-centered approach to healthcare and wellness – often including mental, emotional, functional, spiritual, social, and community”.<sup>10</sup>

Many cancer survivors turn to complementary treatments in search of palliation of cancer treatment side effects and to improve chances of living without recurrence.<sup>12</sup> Among those treated for cancer, breast cancer survivors have one of the highest utilization rates for complementary support modalities.<sup>13</sup> In one recent study, about 43.6% of individuals with breast cancer used a complementary health approach within the previous year.<sup>14</sup> High utilization of complementary supports is associated with improved health outcomes in breast cancer patients. Recent clinical reviews and meta-analyses of integrative and complementary therapies for breast cancer survivors indicate significant decreases in fatigue, anxiety, stress, and depression for participants practicing mind-body methods, particularly deep breathing, meditation, and relaxation techniques.<sup>15,16,17,18</sup>

Of the various mindfulness meditation curricula, the Mindfulness-Based Stress Reduction (MBSR) program is among the most practiced and studied.<sup>19</sup> MBSR is an 8-week stress reduction program based on intensive mindfulness training and includes weekly mindfulness sessions and a full-day mindfulness retreat. It was developed by Dr. John Kabat-Zinn and his colleagues at the University of Massachusetts Medical Center's Stress Reduction Clinic. Originally, MBSR was intended to help patients with chronic health conditions cope with the effects of pain and illness.<sup>20</sup> MBSR has been demonstrated to significantly improve psychological issues like anxiety, depression, and distress in breast cancer survivors while increasing quality of life. Systematic reviews also demonstrate improvements in physical symptoms like fatigue following MBSR.<sup>21,18,22,23</sup>

A recent report on breast cancer survivors and oncologists in Birmingham, Alabama found deficiencies in addressing quality of life issues after diagnosis. These unmet needs related specifically to psychological and physical problems due to cancer diagnosis and treatment.<sup>24</sup> While mind-body practices, like MBSR, have proven useful at improving such issues, exposure to and use of complementary health practices in the southeast are significantly low compared to the US overall.<sup>11,25,26</sup>

This pilot study aimed to assess the feasibility of an abridged MBSR program for breast cancer patients and survivors within the setting of an academic cancer center in the Southeastern, US. We designed a modified MBSR-like (MBSR-L) program that included the typical eight weekly MBSR sessions but excluded the full-day mindfulness retreat to better fit our patient population. The MBSR-L program also included two nutrition lectures. The goal of this pilot study was primarily to assess the accessibility and acceptance of the MBSR-L program among breast cancer survivors in Birmingham. Secondary goals were to estimate program effectiveness at improving mindfulness skills and quality of life and to evaluate the usefulness of the nutrition lectures.

## Objectives

### *Primary Objective:*

1. Assess the feasibility of the MBSR-L program in patients with breast cancer. Feasibility was determined by the successful recruitment and retention of patients to the study.

### *Secondary Objectives:*

1. Estimate MBSR-L program effectiveness by comparing participant reports of mindfulness, self-compassion, and spiritual wellbeing as well as health-related quality of life at three data collection visits: pretest, posttest, and 8-week follow-up.
2. Evaluate the usefulness of the study's nutrition lectures.

## Methods

### Trial Design

This pilot study had a single-arm, prospective, quasi-experimental design. Data was collected and compared at 3 timepoints: pretest, post-test, and 8-week follow-up. Initially, the study population was limited to early-stage estrogen receptor positive (ER+) breast cancer patients undergoing adjuvant treatment with aromatase inhibitors (AI's). As originally designed, participants would be post-menopausal women with early-stage breast cancer who would need to be treated anywhere from 5 to 10 years with AI's. However, due to low enrollment after the first cohort of patients completed the 8-week intervention, the study population was expanded to include breast cancer patients at any stage and on any treatment.

### Participants

To be eligible for the study, participants must have been diagnosed with and treated for breast cancer; willing and able to provide informed consent; and capable of committing to attend the weekly MBSR-L sessions. Patients must have scored a 4 or above on the National Comprehensive Cancer Network (NCCN) Distress Thermometer. Exclusion criteria included incarcerated patients, patients residing in nursing homes, patients unable to read or speak English, and patients with active psychosis.

Flyers advertising the study were sent to major breast cancer support groups throughout Birmingham, Alabama and were posted on advertising boards at the University of Alabama at Birmingham (UAB) Hospital and UAB's Kirklin Clinic, where oncology patients receive treatment. The study research coordinator also collaborated with UAB's breast cancer clinic nurses to identify potential candidates. Once identified, a nurse would administer the NCCN Distress Thermometer; self-referred patients called the research coordinator and were mailed an NCCN Distress Thermometer. Qualified participants received further information about the MBSR-L program and the time commitment required to participate. If the patient agreed to enroll in the program, the research coordinator obtained written informed consent from the patient before participation. Once consented, participants were assigned a unique study number, an MBSR-L group number, and were scheduled for an individual evaluation with the study psychologist. Evaluations were completed prior to participants starting the MBSR-L program and took place at one of UAB Hospital's clinics. Pretest data was collected from questionnaires completed at this evaluation.

## Intervention

### Program Structure and Content

Mindfulness meditation was proposed as a coping tool to improve patients' quality of life post-diagnosis. We designed the MBSR-L program as an 8-session weekly gathering of 8–10 women who were diagnosed and treated for breast cancer. Patients were evaluated for eligibility and assigned to a group on a first-come, first-served basis. There was a total of 3 groups of patients and each group underwent the 8-week mindfulness meditation program at different times over the course of the 10-month study. The second group started the program after the first group completed the program, and the third group started after the second group's completion. There was no temporal overlapping of group cycles.

Weekly sessions were held in UAB Hospital's Kirklin Clinic around 2 p.m. on weekdays and lasted 2–3 hours. The study's clinical psychologist was a certified MBSR teacher with over a decade of MBSR practice experience. The clinic psychologist acted as the group facilitator for each session, implementing mindfulness exercises and aiding group discussions. Emphasis was placed on increasing understanding of mindfulness techniques and key components including sitting meditation, hatha yoga/restorative yoga, and a sustained body-focused attention practice called body scan. The group setting encouraged participants to share experiences related to the rationale and implementation of mindfulness practices in program sessions.

MBSR-L deviated from the standard MBSR curriculum in two ways: first, the MBSR-L program did not include a full day meditation session due to logistical issues with patients and staff; second, two nutrition classes were added to the MBSR-L program. The content of the weekly intervention sessions is included in *Fig. 1. Weekly Intervention Content*, Figure Legend 1: This flowchart describes weekly content covered in each program session; content was based on the Mindfulness-Based Stress Reduction curriculum.

The deviation from the original MBSR protocol provided an opportunity to estimate the effectiveness of a less-time demanding mindfulness meditation program as well as a supplemental nutrition. The 30-

minute interactive nutrition lectures occurred during the sessions at week 3 and week 6. An oncologist, trained in integrative nutrition, led the lectures which covered basic nutrition recommendations for cancer patients promoted by the National Cancer Institute (NCI).

Study implementation and all materials related to study implementation, ethics, and participant consent was approved by the University of Alabama at Birmingham Institutional Review Board; all study methods were performed in accordance with the relevant guidelines and regulations set forth in the Declaration of Helsinki.

## Outcomes

Feasibility benchmarks were set a priori and were consistent with guidelines for behavioral intervention development.<sup>27,28,29</sup> The primary objective of feasibility would be achieved if 80% of qualifying patients chose to enroll in the study and 70% of enrolled patients attended all 8 program sessions. The study's research coordinator tracked all patients screened for enrollment and recorded session attendance for each of the 3 cohorts. Eligible patients who declined participation were asked to give the reason why.

Secondary objectives were to estimate program effectiveness at improving mindfulness skills and spiritual wellbeing as well as health-related quality of life measures. Mindfulness skills and spiritual wellbeing were measured with the Five Facet Mindfulness Questionnaire (FFMQ), Self-Compassion Scale (SCS), and the Functional Assessment of Chronic Illness – Spiritual Wellbeing, Expanded Version (FACIT-Sp-Ex). Health-related quality of life changes were determined by self-reported pain, fatigue, overall wellbeing, and distress scores. Pain, fatigue, wellbeing, and distress were measured by the Wong-Baker FACES Pain Rating Scale; the Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-Fatigue) scale; and the Functional Assessment of Cancer Therapy – Breast Cancer (FACT-B scale); and the NCCN Distress Thermometer, respectively. The study's principal investigator obtained permission from the FACIT organization to administer questionnaires to study participants. Research staff administered scales to patients at pretest, posttest, and 8-week follow-up.

## Mindfulness & Spiritual Wellbeing Measures

The 39-item FFMQ measures mindfulness skills across five factors (Observing, Describing, Non-reactivity to inner experience, Non-judging of inner experience, and Acting with awareness) and provides an empirically valid means of measuring mindfulness.<sup>30</sup> Recent studies suggest that the 4-factor model (excluding the Observing scale) is a better fit for non-meditating samples, so the Observing subscale was not included in the analysis of global mindfulness for the MBSR-L participants.<sup>31</sup>

The Self-Compassion Scale is a validated, 26-item instrument that gauges reactions toward the self during difficult times.<sup>32</sup> It is divided into six subscales that measure contrasting components: self-kindness versus self-judgment, common humanity versus isolation, and mindfulness versus over-identification. Mean scores from the subscales can be combined to yield a total score reflecting a global measure of self-compassion. The FACIT-Sp-Ex scale is another validated measure to determine

individuals' spiritual quality of life by measuring 3 components: meaning/peace, faith, and relational.<sup>33</sup> Patients rate their agreement with the scale's 23 statements on a 5-point Likert scale. The FFMQ and SCS are sensitive to change through mindfulness-based interventions and may, along with the FACIT-Sp-Ex scale, be effective in estimating the intervention's success at increasing mindfulness skills in participants.<sup>34</sup>

## Health-related Quality of Life Measures

The Wong-Baker FACES Pain Rating Scale is a validated ordinal scale consisting of 6 faces showing no pain (smiling face) to worst pain imaginable (grimace).<sup>35,36</sup> Pain ratings increase by twos from 0 to 10. The NCCN Distress Thermometer is a single-item distress tool that includes a graphic thermometer ranging from 0 (no distress) to 10 (extreme distress). It has been tested for its validity and reliability in measuring psychosocial distress in multiple cancer populations.<sup>37,38,39</sup>

The FACIT-Fatigue scale and the FACT-B scale are both validated and widely used instruments to measure fatigue-related quality of life and overall wellbeing, respectively.<sup>40,41,42,43</sup> The FACIT-Fatigue scale is a 13-item scale for which participants rate statements regarding their fatigue experience and its impact on their daily functioning. Statements are ranked on a 5-point Likert scale. Lower overall scores indicate greater fatigue. FACT-B is comprised of 4 subscales. Items are ranked on a 5-point Likert scale, and mean subscale scores are combined for an overall wellbeing score. Higher scores indicate higher quality of life.

Health-related quality of life results were supplemented by a follow-up questionnaire specifically tailored to the study and administered at the 8-week follow-up. Patients reported differences in the frequency of drug use, work attendance, and doctors' visits as well as changes in levels of pain, activity, stamina, wellbeing, and blood pressure as compared to before program enrollment. Answer choices were on a 6-point Likert scale of less/worse to more/better.

## Nutrition Class Evaluation

The pilot study also evaluated the usefulness of the 30-minute nutrition lectures delivered twice during the 8-week program. Participants completed a nutrition class evaluation at 8-week follow-up. The evaluation form gauges participants' overall assessment of the lectures on a 5-point Likert scale ranging from 1 (insufficient) to 5 (excellent). The evaluation form also determined participants' desire for more nutrition lectures, willingness to recommend the lectures, the usefulness of the lecture material, and the effectiveness of the lectures in changing diet; it included a short answer section for participants to describe its usefulness.

## Sample Size

The sample size goal was 30 participants referred by oncologists, other health care providers, or self-referred over a 10-month period. This number would allow for 3 groups of 8 to 10 participants for each 8-week program cycle. Small groups of no more than 10 participants would increase the likelihood of effective implementation of the MBSR-L program, which contains a large group sharing component. The

total sample number of 30 would be large enough to attest to the feasibility of a mindfulness meditation program for breast cancer patients in the Birmingham area. Thirty participants would also provide enough data to estimate effectiveness for the pilot study. During implementation, difficulties with participant recruitment and enrollment resulted in a much smaller sample size ( $n = 9$ ). Statistical analyses were adjusted to account for the small sample.

## Analytical Methods

Proportions were used to assess the primary feasibility outcome, which was determined by recruitment and retention. To evaluate whether the program achieved the 80% recruitment objective, the actual number of participants enrolled was divided by the total number of eligible participants screened. Likewise, the actual number of participants who completed all 8 program sessions was divided by the total number of participants enrolled to determine if the program reached the 70% retention objective.

To estimate program effectiveness, study staff analyzed data collected at pretest, posttest, and 8-week follow-up for each of the seven outcomes of interest. Staff first tested for normality in the data using the Shapiro-Wilk test for each variable. Because data was not normally distributed, staff used a non-parametric Friedman's test. For statistically significant results, we conducted post hoc Wilcoxon signed ranks tests to obtain pairwise comparisons. Alpha level for the Friedman's test was set at  $p = 0.05$ . A Bonferroni adjustment was used for pairwise comparisons to correct for the risk of type I errors, resulting in an alpha level of  $p = 0.017$  for Wilcoxon signed rank tests.

Analyses were conducted with the IBM SPSS Statistics Version 25 statistical software package. For statistically significant results, we included corresponding effect sizes measured with the Wilcoxon test  $r$  value. Effect sizes around 0.1 were considered small while effect sizes around 0.3 and 0.5 were considered moderate and large, respectively. Descriptive statistics (i.e., frequencies and percentages) were used to analyze answers from the follow-up questionnaire administered at 8-week follow-up. Results described participants' assessment of their quality of life post-MBSR-L and provided useful supplemental material to determine program effectiveness. Descriptive statistics were also used to examine responses from the nutrition evaluations. Results helped gauge the usefulness of the nutrition sessions and will inform future MBSR-L programs.

## Results

### Recruitment

Patient recruitment started in January 2018 for the first cohort and ended September 2018 for the last cohort. A total of 41 participants were screened for eligibility. Of those screened, 27 participants were eligible, and 12 participants enrolled in the study. Two participants left the study during the 8-week intervention due to time conflicts and cancer recurrence. One participant was lost to 8-week follow-up and was excluded from analysis for secondary outcomes. Thus, the analytic sample for secondary outcomes consisted of 9 subjects (See *Fig. 2. CONSORT Diagram of MBSR-L Recruitment and Retention*, Figure

Legend 2: This flowchart describes the number of patients screened and enrolled for each of the three groups in the MBSR program as well as attrition during the program; reasons for exclusion from study sample and for attrition are included).

## **Participant Baseline Characteristics**

The mean age of enrolled participants was 53 with a standard deviation of 9.3 years. Most participants were white (83.3%), married (66.7%), and relatively affluent, with most participants earning over \$50,000 per year (83.4%) and having completed at least some college (83.3%). A complete description of baseline demographic characteristics can be view in Table 1.

## **Feasibility & Estimated Effectiveness**

***Objective 1: Feasibility achieved if 80% of qualifying individuals chose to enroll in the study and 70% of MBSR-L participants completed all scheduled program sessions.***

Of the 27 eligible participants screened, 12 enrolled in the study, resulting in a 44.4% enrollment rate. This outcome fell well below the criteria for feasibility. Of the enrolled participants, 2 of the 12 (16.7%) attended all eight program sessions; however, 8 of the 12 (66.7%) attended at least 7 sessions. Thus, retention fell below the established criteria, but a large majority of participants (66.7%) attended 7 of the 8 program sessions.

Table 1  
Participant Demographics

<b>Participant Demographics (n = 12)</b>	
Age (y); mean $\pm$ SD	53 $\pm$ 9.5
Race; n (%)	
White	10 (83.3)
Black	1 (8.3)
Asian	1 (8.3)
Education; n (%)	
High School	2 (16.7)
Some college, no degree	4 (33.3)
Associate Degree	1 (8.3)
Bachelor's Degree	3 (25.0)
Advanced Degree	2 (16.7)
Income; n (%)	
< \$25,000	2 (16.7)
\$50,000 - \$74,999	2 (16.7)
\$75,000 - \$99,999	3 (25.0)
> \$100,000	5 (41.7)
Employment; n (%)	
Unemployed, not seeking	1 (8.3)
Unemployed, on disability	5 (41.7)
Full-time ( $\geq$ 40 hrs/week)	5 (41.7)
Retired	1 (8.3)
Marital Status; n (%)	
Single, never married	1 (8.3)
Married	8 (66.7)
Divorced	3 (25.0)

## ***Objective 2: Assess the effectiveness of the MBSR-L program at increasing mindfulness skills and improving the health-related quality of life in program participants.***

There was a statistically significant decrease in distress scores among pretest, posttest, and 8-week follow-up ( $\chi^2(2) = 9.813, p = .007$ ). (See Table 2.) There were also statistically significant increases in overall wellbeing, fatigue-related quality of life, and self-compassion scores among the three data collection points ( $\chi^2(2) = 7.6, p = .022$ ;  $\chi^2(2) = 10.889, p = .004$ ;  $\chi^2(2) = 6.222, p = .045$ ). Post hoc Wilcoxon signed rank tests for pairwise comparisons revealed statistically significant decreases in distress between pretest and 8-week follow-up ( $Z = -2.536, p = 0.011$ ) with a large effect size ( $r = 0.6$ ). Increases in overall wellbeing and fatigue-related quality of life were also statistically significant between pretest and 8-week follow-up ( $Z = -2.386, p = 0.017$ ;  $Z = -2.668, p = 0.008$ ). The effect sizes for these increases were also large ( $r = 0.6$ ;  $r = 0.5$ ). While a Friedman test indicated that self-compassion scores differed across the three time points, post hoc pairwise comparisons between pretest and posttest, and pretest and 8-week follow-up were not statistically significant.

Table 2  
Results from Analysis of Outcomes among Pretest, Posttest, and Follow-up with Friedman Test

	Pretest	Posttest	Follow-up	p-value <sup>a</sup>	Effect Size (r) <sup>b</sup>
Distress	<b>7.0</b> (5.5 to 8.0)	5.0 (4.0 to 7.5)	<b>2.0</b> (1.5 to 5.5)	0.007*	0.6
Wellbeing	<b>74.0</b> (66.5 to 92.0)	82.0 (71.5 to 107.0)	<b>105.0</b> (88.0 to 113.0)	0.002*	0.6
Fatigue	<b>19.0</b> (14.0 to 30.5)	29.0 (20.0 to 37.0)	<b>29.0</b> (24.0 to 24.0)	0.004*	0.5
Pain	2.0 (1.0 to 7.0)	4.0 (2.0 to 4.0)	2.0 (1.0 to 5.0)	0.898	
Mindfulness	84.0 (73.5 to 107.0)	100.0 (84.0 to 122.5)	119.0 (96.5 to 122.0)	0.105	
Spiritual Wellbeing	57.0 (53.0 to 76.0)	66.0 (61.5 to 82.5)	73.0 (61.0 to 80.0)	0.105	
Self-Compassion	3.0 (2.5 to 3.9)	3.4 (2.8 to 4.3)	3.7 (3.0 to 4.2)	0.045*	
<sup>a</sup> p-value from a non-parametric Friedman test with alpha level set at p = 0.05					
<sup>b</sup> Effect size calculated from significant results from post hoc Wilcoxon signed rank tests					
*Significant p-value from Friedman test (p < 0.05)					
Median scores in bold indicate significant p-values from pairwise comparisons with post hoc Wilcoxon signed rank test with a Bonferroni-adjusted alpha level set at p = 0.017					

Median scores for mindfulness and spiritual wellbeing at pretest, posttest, and 8-week follow-up indicated increases in both scores, however, these differences were not statistically significant. Similarly, median pain intensity scores increased slightly from pretest to posttest in our sample but returned to pretest score at 8-week follow-up. Changes were not statistically significant.

In the 8-week follow-up questionnaire, participants' assessments of their pain and overall quality of life post-intervention tended to be favorable. A large minority of patients (44.4%) indicated an improvement in the severity of pain episodes and either no change (44.4%) or a decrease in (33.3%) in the frequency of pain episodes. Further, patients reported their drug use for pain either stabilized (33.3%) or lessened (33.3%) after the MBSR-L program. A vast majority of participants (88.9%) reported an increase in activity after the program. A majority (55.6%) also indicated experiencing somewhat better energy levels, better overall wellbeing (66.7%), and either stabilized (55.6%) or improved (44.4%) blood pressure. Most patients (88.9%) visited the doctor at the same frequency after the program.

### Objective 3: Evaluate the usefulness of the nutrition class

Three enrolled participants missed the nutrition classes and did not complete a class evaluation; they were excluded from the analysis of the nutrition class. The sample size for the class evaluation was small (n = 6), but responses were favorable. Most participants (66.7%) rated the classes as “excellent” overall; found the class material helpful (66.7%); and reported that the classes helped change their diet (83.3%). All participants demonstrated a desire for more classes and a willingness to recommend the class to friends and family.

## Harms

There were no adverse events related to the study.

## Discussion

### Interpretation

Program feasibility criteria was set at 80% of eligible patients enrolling in the study and 70% of those enrolled completing all 8 program sessions. These parameters were not achieved. Recruitment outcomes fell below the feasibility criteria, and we did not meet our sample size goal of 30 participants. The intervention involved a significant time commitment and required travel to a single intervention site, which impacted recruitment numbers. Our program sessions took place at 2 PM on a weekday, and they were located at an urban hospital clinic with limited parking. These factors posed a significant barrier for many potential participants, particularly participants with full-time employment. Most ineligible patients were excluded from the study due to time conflicts, and many eligible patients who declined participation reported distance from the program site as the main reason for declining.

The low prevalence of mindfulness programs in southern states also may have affected study enrollment. An ecological study on MBSR availability by US state indicated that Alabama, along with other southern states, had very few certified MBSR teachers. Other studies on prevalence of mindfulness and complementary health practices in the US found that southerners are at significantly lower odds for use of complementary medicine and mind-body practices when compared to other geographic regions.<sup>11, 10, 23, 25, 26, 44</sup> Limited exposure to mind-body practices and their benefits could have made potential participants less willing to overcome barriers to participation.

Program retention, though falling short of feasibility criteria, was strong. Most participants (66.7%) attended at least 7 of the 8 program sessions, and a large majority of participants (83.3%) attended at least 5 sessions. According to recent MBSR studies, these attendance numbers can be considered successful.<sup>45,46,47</sup> One abridged MBSR program for breast cancer survivors demonstrated significant improvement in distress, anxiety, and fatigue severity after 6 weeks of mindfulness sessions.<sup>48,49</sup>

The trial demonstrated promising results for program effectiveness. Distress, wellbeing, and fatigue improved from pretest to posttest and continued to improve after the intervention. These changes were statistically significant from pretest to 8-week follow-up. These are consistent with the results found in

similar MBSR studies for breast cancer patients.<sup>50</sup> The corresponding effect sizes were large, suggesting clinically meaningful changes. Minimal clinically important differences (MCID) are defined as the smallest amount that an outcome must change to be meaningful to patients; it is a patient-centered concept often included in patient-reported outcomes in which the clinical significance of a change may not be apparent.<sup>51</sup> Improvements in wellbeing and fatigue far exceeded the MCID for these measures, indicating that changes in these outcomes were significantly meaningful to participants at 8-week follow-up.<sup>52</sup> Distress fell below the cutoff of 3 for clinically elevated distress scores at 8-week follow-up, which again suggests meaningful change for participants post MBSR.<sup>53</sup>

Self-compassion increased among pretest, posttest, and 8-week follow-up. These changes were statistically significant with the Friedman's test; however, the post hoc analysis with the Wilcoxon signed rank tests yielded no significant results. This discrepancy is most likely due to the Bonferroni adjustment in the post hoc analysis, which resulted in a more conservative alpha level for the Wilcoxon signed rank tests.

Mindfulness and spiritual wellbeing followed similar trajectories: increasing steadily from pretest to posttest and to 8-week follow-up. However, changes were not statistically significant. This increase is consistent with a recent review and other studies exploring MBSR's effects on spirituality and mindfulness.<sup>54,55,56</sup> It is possible that the lack of significance is due to our limited sample size.

Pain scores increased from pretest to posttest, but scores returned to pretest level at 8-week follow-up, and the changes were not statistically significant. These results are corroborated by a recent meta-analysis on MBSR studies for breast cancer patients in which pain scores did not change meaningfully post-intervention.<sup>50</sup> Differing stages of disease can impact the pain experience. For example, one MBSR study with metastatic breast cancer patients demonstrated very mild effects on pain.<sup>57</sup> Our sample consisted of patients with variable stages of disease.

## Limitations

To our knowledge, this study is unique in its focus on the feasibility of a mindfulness program for breast cancer recovery in a region with low prevalence of mind-body and complementary support use. However, results of this study must be interpreted with caution due to several limitations. Generalizability is limited due to the small sample size and the lack of a control arm. We did not control for participants' breast cancer stage, type of treatment, or location in the treatment process, so a causal relationship between the intervention and improvements cannot be strictly inferred.

## Lessons Learned and Future Research

Study staff will apply preliminary data from this feasibility study to develop a fully powered clinical randomized control trial (RCT). The future RCT will incorporate findings from this pilot trial to improve recruitment and determine the effectiveness of the program at improving quality of life in non-meditating

breast cancer patients in the Southeastern US. Further research is needed to confirm the consistency of study results in larger, more diverse samples.

The time and location of the program sessions resulted in a small sample size that was relatively homogeneous demographically. The lack of diversity in mind-body interventions like MBSR tends to be a widespread issue.<sup>58,59,60,61</sup> Future programs should consider incorporating some community-based participatory research methods to inform the structure and delivery of the MBSR program. Future studies should also offer sessions at varied times. Evening or morning sessions could improve program recruitment. For example, one MBSR study for parents of individuals with developmental disabilities employed community-based participatory research methods to develop the program. Based on input from potential participants, times varied (morning or evening) and program sessions took place at suggested locations within their community. A large majority of potential participants enrolled, completed program sessions, and demonstrated significant improvements in mindfulness, stress, and psychological wellbeing.<sup>62</sup>

Virtual mindfulness-based interventions may also greatly improve accessibility while maintaining efficacy. A recent meta-analysis of 1149 participants in 15 online mindfulness-based interventions indicated significant improvements in distress, anxiety, depression, wellbeing, and mindfulness post-intervention.<sup>63</sup> While data is limited for virtual mindfulness programs with cancer patients, available studies on such interventions indicate similar efficacy at improving distress and quality of life as in-person programs when compared to treatment as usual.<sup>64,65</sup> Patients with cancer may also be more receptive to interventions offered remotely.<sup>66</sup> Considering the increasing shift to telemedicine following the novel coronavirus pandemic, further investigation into virtual supportive cancer care interventions like mindfulness-based stress reduction is both warranted and needed.

Future studies should include a control arm. If the inclusion of a control arm is not possible, future MBSR-L studies should include only patients at a stage in their treatment where the natural history and occurrence of relevant variables is well understood. Controlling for those variables with more stringent inclusion criteria could limit the potential for bias in the results and increase the certainty that improvements can be attributed to the intervention.

There was a very low rate of referrals from local breast cancer clinics, may be due to a lack of understanding about MBSR at referring sources. Study referrals increased after study staff provided more resources on MBSR to breast cancer clinics. Few studies have investigated the reasons for geographic unevenness in complementary support use. Qualitative studies on perceptions of mindfulness practices in southern regions would be instrumental to informing effective recruitment and enrollment strategies for MBSR programs in southern cities. There was a very low rate of referrals from local breast cancer clinics, likely due to a lack of understanding about MBSR at referring sources. Study referrals increased after study staff provided more resources on MBSR to breast cancer clinics.

## Conclusions

Despite the study's limitations, the effect sizes and minimal clinically important differences related to improvements in participants' distress, fatigue, and wellbeing suggested sizeable positive effects, and retention of study participants was strong. The MBSR-L program was inexpensive and non-invasive with a low risk of potential harm. These benefits warrant further research into similar MBSR-L programs to improve psychosocial and physical symptoms in breast cancer survivors in the southeastern US.

Future programs may consider a qualitative component to inform effective and culturally relevant recruitment and enrollment strategies. Future programs may also consider hosting sessions within a community or virtual setting convenient to participants. Inclusion of nutrition classes to the MBSR program would also be well-supported by participants.

## List Of Abbreviations

**MBSR:** Mindfulness-based stress reduction program

**MBSR-L:** Mindfulness-based stress reduction-like program

**QoL:** Quality of life

**UAB:** University of Alabama at Birmingham

**FFMQ:** Five Facet Mindfulness Questionnaire

**SCS:** Self-Compassion Scale

**FACIT-Sp-Ex:** Functional Assessment of Chronic Illness – Spiritual Wellbeing, Expanded Version

**FACIT-Fatigue:** Functional Assessment of Chronic Illness Therapy – Fatigue

**FACT-B:** Functional Assessment of Cancer Therapy – Breast Cancer

**NCCN Distress Thermometer:** National Comprehensive Cancer Network Distress Thermometer

**CONSORT:** Consolidated standards of reporting trials

**MCID:** Minimal clinically important differences

**RCT:** Randomized controlled trial

## Declarations

### Ethics approval and consent to participate

The study protocol and all materials related to study implementation, ethics, and participant consent was approved by the University of Alabama at Birmingham Institutional Review Board. Informed consent was

obtained from all study participants prior to involvement in the intervention.

### **Consent for publication**

Not applicable

### **Availability of data and materials**

The datasets used and/or analyzed during the current study are available from corresponding author on reasonable request.

### **Competing interests**

The authors declare that they have no competing interests

### **Funding**

Funding for study received from the Breast Cancer Research Foundation of Alabama

### **Authors' contributions**

**C.S.** led the conception and design of the research study, including developing study protocols; contributed substantially to the writing and reviewing of the study manuscript.

**P.M.** led the implementation of study intervention, including the evaluation of study participants and data collection; reviewed the study manuscript.

**T.H.** contributed substantially to the development of study protocol, managed the recruitment, screening, and implementation of study protocols; reviewed the study manuscript.

**V.M.** managed participant data; led the statistical analysis and development of study manuscript, including figures and tables.

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Gregory Pavela, PhD: reviewed study manuscript

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# Figures

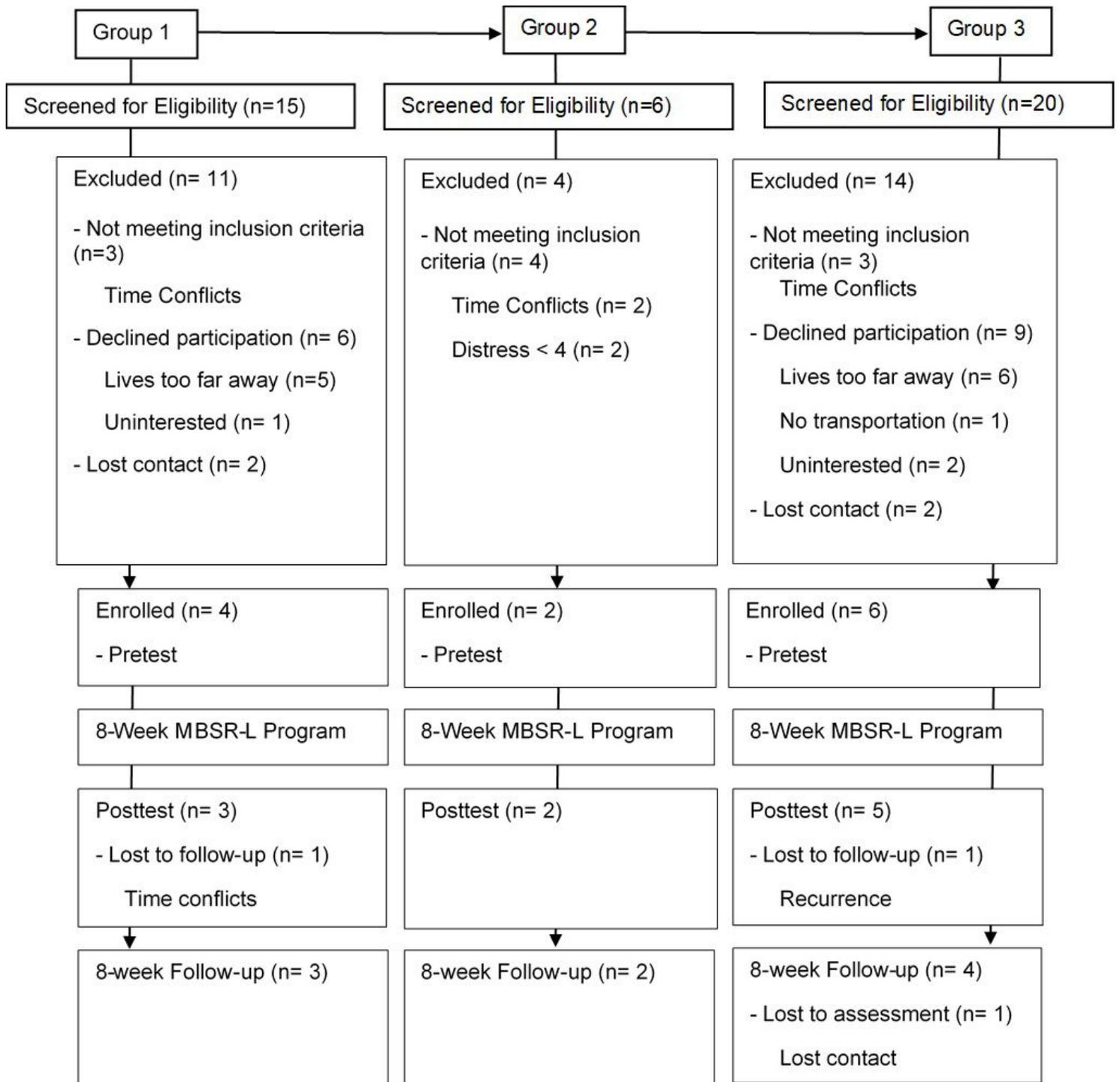
**Baseline Assessment with Group Facilitator**

<b>Week 1</b>	<ul style="list-style-type: none"> <li>• Welcome, review of guidelines, and introduction by group facilitator</li> <li>• Individual introductions, personal goals, expectations</li> <li>• Introduction to mindfulness: raisin-eating mindfulness exercise</li> <li>• Mindfulness of breathing, body scan exercise, observations</li> <li>• Homework exercise to reinforce utility of mindfulness</li> </ul>
<b>Week 2</b>	<ul style="list-style-type: none"> <li>• Perception and creative responses</li> <li>• Body scan followed by small and large group discussion</li> <li>• Emphasize universality of undisciplined minds; mindfulness as a new way of learning</li> <li>• Discuss homework</li> <li>• Introduce sitting meditation with awareness of breathing</li> <li>• Homework exercise: mindfulness of feeling journal including pleasant/unpleasant events, task-specific mindfulness</li> </ul>
<b>Week 3</b>	<ul style="list-style-type: none"> <li>• Appreciation, slowing down to observe what we already have</li> <li>• Mindful yoga, with discussion of how to incorporate yoga and sitting meditation into daily practice</li> <li>• Sitting mindfulness meditation</li> <li>• Review of homework, including pleasant events calendar</li> <li>• Homework: incorporating mindfulness into daily activities, questions about obstacles to mindfulness</li> <li>• Interactive nutrition lecture</li> </ul>
<b>Week 4</b>	<ul style="list-style-type: none"> <li>• How to notice being stuck and getting unstuck in your life; sitting meditation</li> <li>• Mindful yoga</li> <li>• Review of homework, incorporating yoga and sitting meditation, dealing with stress and pain, how many cope by escape activities</li> <li>• Definitions of stress and stressors – what is most stressful to participants, discussion of reaction vs. response</li> <li>• Homework: awareness of feeling stuck/blocked, etc.</li> </ul>
<b>Week 5</b>	<ul style="list-style-type: none"> <li>• Role of emotional reactivity in health and illness</li> <li>• Discussion of status of group – this is half-way point in MBSR-L group; guided sitting meditation</li> <li>• Discussion of meditation and yoga homework; observation of reacting to stressful events during the week, including life changes and their relationship to health</li> <li>• Reacting and responding to stress</li> <li>• Problem-focused and emotion-focused coping strategies and the role of mindfulness in both</li> <li>• Homework: sitting meditation, body scan, and/or yoga; fill out difficult communications calendar, answer questions</li> <li>• Bring awareness to moments of reacting impulsively and explore options for responding with greater mindfulness</li> </ul>
<b>Week 6</b>	<ul style="list-style-type: none"> <li>• Stressful communication: assertiveness, effective expression of feelings</li> <li>• Sitting meditation; mountain/lake meditation</li> <li>• Review of homework: difficult communications calendar</li> <li>• Maintaining your center in interpersonal relationships role play</li> <li>• Homework: mindful eating; information on diet and nutrition</li> <li>• Interactive nutrition lecture</li> </ul>
<b>Week 7</b>	<ul style="list-style-type: none"> <li>• Looking at situations from different perspectives</li> <li>• Sitting meditation – choiceless awareness, using the breath as an anchor as necessary</li> <li>• Discussion of solitary meditation/yoga practice</li> <li>• Loving kindness meditation</li> <li>• Homework: review and practice loving kindness meditation as part of sitting practice</li> </ul>
<b>Week 8</b>	<ul style="list-style-type: none"> <li>• Body scan followed by sitting meditation</li> <li>• Review of initial motivations for coming to group, sacrifices made to attend, what were the obstacles, how to work with strategies to not get stuck</li> <li>• Review of resources</li> <li>• Closing ceremony with emphasis on being whole and part of a larger whole</li> </ul>

**Exit Interview and Posttest Data Collection with Group Facilitator**

**Figure 1**

Weekly Intervention Content. Legend 1: This flowchart describes weekly content covered in each program session; content was based on the Mindfulness-Based Stress Reduction curriculum.



**Figure 2**

CONSORT Diagram of MBSR-L Recruitment and Retention. Legend 2: This flowchart describes the number of patients screened and enrolled for each of the three groups in the MBSR program as well as attrition during the program; reasons for exclusion from study sample and for attrition are included.

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [SupplementaryInfoFile1.pdf](#)
- [SupplementaryDatasetFile1.xlsx](#)
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