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ORIGINAL RESEARCH

Brief Mindfulness-Based Cognitive Therapy in Women With Myocardial Infarction

Results of a Multicenter Randomized Controlled Trial

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ABSTRACT

BACKGROUND Elevated perceived stress is associated with adverse outcomes following myocardial infarction (MI) and may account for poorer recovery among women vs men.

OBJECTIVES This randomized controlled trial tested effects of a mindfulness-based intervention on stress levels among women with MI.

METHODS Women with elevated stress (Perceived Stress Scale [PSS-4]≥6) at least 2 months after MI were enrolled from 12 hospitals in the United States and Canada and via community advertising. Participants were randomized to a remotely delivered mindfulness intervention (MBCT-Brief) or heart disease education, both 8 weeks long. Follow-up was 6 months. Changes in stress (PSS-10; primary outcome) and secondary outcomes (depressive symptoms, anxiety, quality of life, disease-specific health status, actigraphy-assessed sleep) were compared between groups.

RESULTS The sample included 130 women with MI (mean age 59.8 ± 12.8 years, 34% racial/ethnic minorities). In intention-to-treat analysis, PSS-10 scores declined in the MBCT-Brief arm (−0.52 [95% CI: −0.77 to −0.28]) but not the heart disease education arm (−0.19 [95% CI: −0.45 to 0.06]; group×time interaction $P = 0.070$). The effect was stronger in per-protocol analysis of participants who completed ≥4 intervention sessions ($P = 0.049$). There were no significant differences in secondary outcomes in intention-to-treat or per-protocol analyses. Within the MBCT-Brief arm, more frequent mindfulness practice was associated with greater reductions in stress ($P = 0.007$), depressive symptoms ($P = 0.017$), and anxiety ($P = 0.036$).

CONCLUSIONS MBCT-Brief was associated with greater 6-month reductions in stress than an active control among adherent participants. More frequent mindfulness practice was associated with greater improvements in psychological outcomes. Strategies to engage women with MI in mindfulness training and support regular home practice may enhance these effects. (JACC Adv. 2025;4:101530) © 2025 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

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ABBREVIATIONS AND ACRONYMS

CHD = coronary heart disease

CVD = cardiovascular disease

HARP = Heart Attack Research Program

HDE = heart disease education

MBCT = mindfulness-based cognitive therapy

MI = myocardial infarction

MI-CAD = myocardial infarction with obstructive coronary artery disease

MINOCA = myocardial infarction with nonobstructive coronary arteries

PSS = perceived stress scale

PHQ-9 = patient health questionnaire-9

PROMIS = patient-reported outcomes measurement information system

QOL = quality of life

SAQ-7 = seattle angina questionnaire-7

Heart disease remains the leading cause of death among women in the United States.[1] Women experience poorer recovery (ie, angina, physical functioning, quality of life [QOL]) and have higher rehospitalization and mortality rates after myocardial infarction (MI) compared with men, which are not fully explained by known sex differences in biological and behavioral factors and treatment.[2-5] Elevated psychosocial stress increases the incidence of coronary heart disease (CHD) and is associated with worse patient-reported outcomes and increased risk of nonfatal cardiovascular events and mortality in patients with stable CHD and acute MI.[6-9] These effects are independent of traditional risk factors and may involve both behavioral and physiological mechanisms.[6,10] Women report higher stress levels following MI than men,[11] which contributes to their worse recovery, even after accounting for medical history, MI presentation, and health status.[5,7] There is growing interest in psychosocial interventions for patients with MI and CHD.[12-14] However, prior studies testing psychosocial programs in patients with heart disease suggest they are more effective for men than for women.[15]

Mindfulness-based cognitive therapy (MBCT) is an evidence-based program that reduces stress and negative emotions in various chronic disease populations, including cardiovascular disease (CVD).[16-20] It targets key psychosocial risk factors affecting women (eg, rumination),[21,22] and recent findings suggest that women may experience greater improvements in psychological outcomes than men.[23-25] However, the intensive in-person format of traditional MBCT programs present a barrier for many who might benefit, including women with family and work obligations and those with acute or chronic illnesses. To address these limitations, we adapted MBCT for remote delivery.[26] The adapted program, MBCT-Brief, requires <50% of the time commitment of traditional in-person MBCT and delivery via teleconference improves access while preserving social support provided by the group format. Abbreviated and remotely delivered mindfulness programs have been shown to be feasible and effective.[27-29] The goal of this study was to test the efficacy of MBCT-Brief for improving perceived stress (primary outcome), depressive symptoms, anxiety, QOL, and sleep (secondary outcomes) in women with a history of MI. We hypothesized that participants randomized to MBCT-Brief would show greater 6-month improvements in perceived stress and secondary outcomes compared with those randomized to an active control group, telephone-based heart disease education (HDE). In exploratory analyses, we also examined changes in hypothesized intervention targets (ie, rumination, mindfulness, perceived social support).

METHODS

This trial was one of three studies comprising the NYU Women's Heart Attack Research Program (HARP), a center in the American Heart Association's Go Red For Women Strategically Focused Research Network.[30] Women were recruited for the trial from the HARP clinical study, a multicenter observational cohort study of women with acute MI. Due to slow enrollment, women with a history of MI were also enrolled via community advertising (ie, self-referrals). The study was approved by the Institutional Review Boards of NYU Grossman School of Medicine and all participating sites and was conducted from December 2016 to December 2020. The

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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trial was registered on ClinicalTrials.gov on September 26, 2016 (NCT02914483). Details of the study design and interventions were previously published.[26]

PARTICIPANTS. English-speaking women aged ≥21 years with a confirmed diagnosis of MI based on the Fourth Universal Definition[31] and a score of ≥6 on the 4-item Perceived Stress Scale (PSS-4)[8] at least 2 months post-MI (ie, following the acute recovery period) were eligible. Exclusion criteria were moderate or severe depressive symptoms (Patient Health Questionnaire-9 [PHQ-9] ≥15); active suicidal ideation (PHQ-9 item 9 ≥1); history or current diagnosis of psychosis; significant cognitive impairment noted in the medical record or evident during screening; and current participation in another behavioral trial. Women who were ineligible due to suicidal ideation were evaluated for safety and provided with a list of local mental health resources and/or treatment referrals. Referral to cardiac rehabilitation was per clinical routine.

SCREENING. Women with a diagnosis of acute MI were identified at or around the time of referral to cardiac catheterization and were approached in-person by a research coordinator for written informed consent for the HARP clinical study, which included consent to be contacted for the HARP Stress Management Trial. Those who declined or were ineligible for the clinical study were asked to provide written consent to be approached for the trial. Both groups of women were contacted ≥2 months after MI and completed screening and verbal informed consent for the trial by telephone. We also enrolled women with a history of MI (≥2 months prior; no upper limit) who contacted the research team in response to study advertisements (ie, self-referrals). These self-referred participants completed initial screening by telephone and written informed consent by mail. Their medical records were obtained to confirm MI and other eligibility criteria.

STUDY VISITS. Baseline assessments were completed in waves, after each cohort of 9 to 12 women had been enrolled. Participants completed self-report questionnaires and a research assistant reviewed the medical record and mailed an actigraph, sleep diary, and prepaid return mailer to participants who agreed to complete the sleep monitoring protocol. All assessments were repeated at post-treatment (~3 months) and 6-month follow-up visits.

RANDOMIZATION AND BLINDING. Following completion of baseline assessments for each cohort, participants were randomized 1:1 to one of the study programs: MBCT-Brief or HDE. The randomization scheme was created using the REDCap randomization module with stratification by coronary artery disease status, as an aim of the parent HARP program was to compare participants with MI with nonobstructive coronary arteries (ie, no stenosis ≥50% of any major epicardial vessel; MINOCA) vs those with MI with obstructive coronary artery disease (ie, stenosis ≥50% of any major epicardial vessel; MI-CAD).[32] Research coordinators collecting outcome data were blinded to intervention assignment. Participants, investigators, and intervention facilitators were aware of treatment assignments.

MEASURES. Baseline characteristics. Demographic and socioeconomic factors including age, race, ethnicity, marital status, education, employment status, financial strain (income covers needs poorly/not very well), and presence of children living at home were assessed via self-report. Medical history including CVD risk factors, current medications, participation in cardiac rehabilitation, and mental health treatment were collected at each time point via self-report and medical record review. Participants were classified as having MINOCA or MI-CAD based on results of clinically indicated invasive coronary angiography.

Intervention targets. Hypothesized targets of the MBCT-Brief intervention were assessed using validated measures, including the 12-item rumination subscale of the Rumination-Reflection Questionnaire,[33] the 15-item version of the Five Facet Mindfulness Questionnaire,[34] and the ENRICHD Social Support Inventory.[35]

Intervention adherence and satisfaction. Adherence was assessed by session completion (0-8 sessions) in both groups. In the MBCT-Brief arm, a 3-item measure of the frequency of continued practice (5-point scale from never to daily) of formal and informal mindfulness was administered at the 6-month visit. Intervention satisfaction was assessed by a single item which asked participants to rate the helpfulness of the program they completed on a 0 to 10 scale. Participants were also asked whether they would recommend the program to others (yes/no).

Outcome measures. Validated self-report measures were used to assess patient-reported outcomes, including perceived stress (primary outcome; PSS-10),[36] depressive symptoms (PHQ-9),[37] anxiety (Hospital Anxiety and Depression Scale-A),[38] general health-related QOL (Patient-Reported Outcomes Measurement Information System [PROMIS]-Global Health),[39] and disease-specific health status (Seattle Angina Questionnaire [SAQ-7]).[40] All enrolled participants were also asked to complete a sleep monitoring

protocol at each study visit, which entailed wearing a validated actigraph (wGT3X-BT, ActiGraph Corp) on the nondominant wrist and keeping a sleep diary for 1 week.[41] Sleep duration (hours/night), sleep efficiency (percentage of time in bed spent sleeping), and wakefulness after sleep onset (minutes/night) were calculated for each night and averaged across the week for each study visit that included a minimum of 3 nights of data.[42]

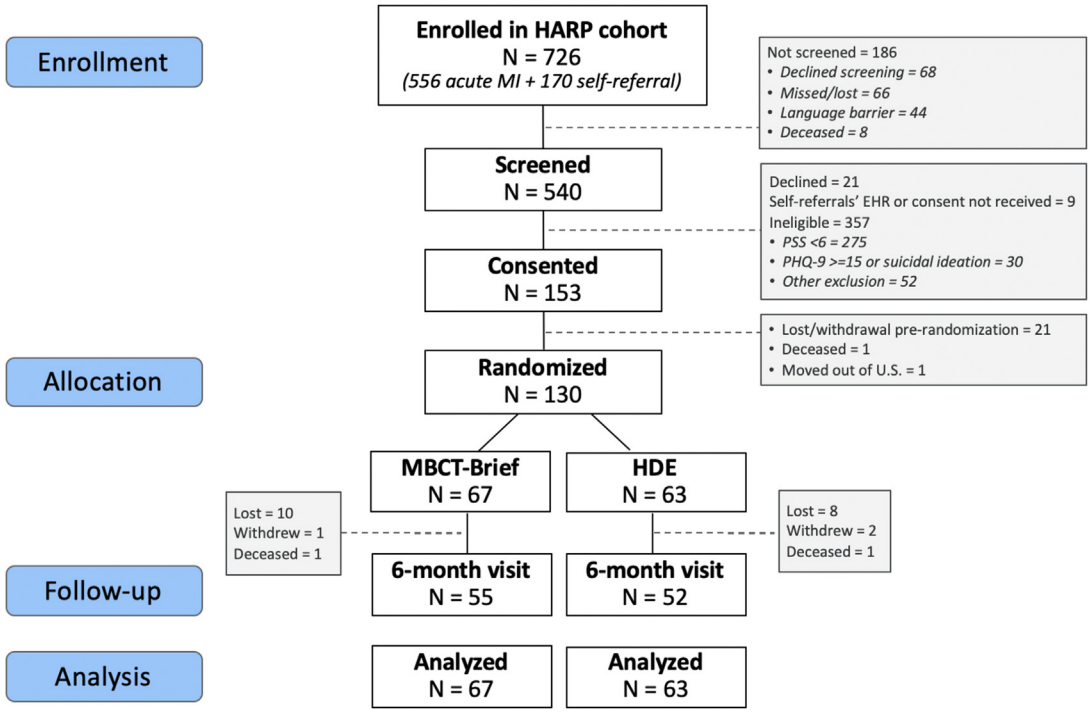
STUDY ARMS. Heart disease education. The control arm was an enhanced usual care condition designed to control for nonspecific effects of attention and treatment credibility, which has been identified as a limitation of prior trials of meditation-based interventions.[13] Participants in both study arms received a printed educational brochure developed by the American Heart Association: "Women, Heart Disease and Stroke." The HDE program entailed a review of the content of this brochure in 8 weekly individual 15- to 30-minute phone calls with a nurse or advanced nursing student trained in the study protocol. Topics included heart attack and stroke warning signs, CVD risk factors, and lifestyle behavior change to reduce CVD risk. The importance of managing stress was noted but no instruction was provided. Missed sessions were combined with subsequent sessions.

MBCT-Brief. This manual-based program was adapted from the original in-person MBCT program and combined mindfulness training and cognitive therapy skills.[16] Details of the session content have been described previously.[26] Participants completed individual orientation sessions with a trained MBCT-Brief facilitator by phone prior to the 8 weekly 1-hour group teleconference sessions. Groups included participants from any sites based on order of enrollment. Approximately 20 minutes/day of home practice was assigned between sessions, including formal (eg, body scan, mindfulness of breath) and informal (eg, mindfulness of daily activities) practices and the 3-minute breathing space (to cope with momentary stress). Audio guides were provided to support formal mindfulness practice. Individual make-up sessions (~20 minutes) were offered when participants missed a weekly group session. A certified MBCT instructor (P.V.) trained three intervention facilitators and provided ongoing group supervision. All sessions were audiotaped and 25% were reviewed to rate treatment fidelity using an adherence scale developed for MBCT-Brief.[43] Ratings were made by two research staff members after training, practice, and demonstration of acceptable inter-rater reliability. Of the 24 reviewed sessions (2 per cohort), the median treatment fidelity rating was 3 out of 3 (IQR: 2.5-3), indicating strong fidelity to the protocol.

STATISTICAL ANALYSIS. A power analysis using a two-sample *t*-test for independent means indicated that a sample size of 65 women per arm would provide 90% power to detect a difference of 4.0 in PSS-10 scores between the MBCT-Brief and HDE arms at 6 months at $\alpha = 0.05$. This represents a 25% reduction in PSS-10 scores from the expected mean baseline score, which is consistent with results of our single-arm pilot trial of MBCT-Brief in women with MI. We observed a medium-sized effect (Cohen's $d = 0.62$) in the pilot, similar to other trials using the PSS-10.[44] The target sample size of 144 (72 per arm) was based on a projected 6-month attrition rate of 10% given telephone follow-up and low mortality rates in the study time frame.

Sample characteristics were summarized by study arm using mean ± SD, median (IQR), and frequencies (percentages) where appropriate. Intervention adherence and satisfaction were compared between study arms and by sociodemographic factors and enrollment type (acute MI vs self-referred) using Fisher's tests for categorical variables and *t*-tests or Mann-Whitney U tests for continuous variables. Intention to treat was the primary analytic approach for testing intervention effects. We compared changes in the study outcomes across three time points (baseline, 3 months, 6 months) between the MBCT-Brief and HDE arms using mixed effects regression models with and without adjustment for demographic and clinical variables. Missing follow-up data were not imputed. Fixed effect terms included study cohort, recruitment site, time since MI, antidepressant medication use, and the group×time interaction. Participant ID was included as the random intercept. The group×time interaction was prespecified as the primary method to determine whether changes in outcomes over time differ significantly between the two groups.[26] To account for repeated measures within participants, we included a random intercept for each participant. The time variable was specified as continuous measure (0, 3, and 6 months) to capture linear trends over the study period. Missing follow-up data were not imputed. Per-protocol sensitivity analyses excluded participants who completed <4 MBCT-Brief or HDE sessions. Subgroup analyses examined the impact of age group (<65 vs ≥65 years), race and ethnicity

FIGURE 1 Consolidated Standards of Reporting Trials Diagram



EHR = electronic health record; HARP = Heart Attack Research Program; HDE = heart disease education; MBCT-Brief = adapted mindfulness-based cognitive therapy; MI = myocardial Infarction; PHQ = Patient Health Questionnaire; PSS = Perceived Stress Scale.

(non-Hispanic White vs other racial or ethnic group), MI type (MINOCA vs MI-CAD), recruitment type (acute MI vs self-referred), baseline depressive symptoms (PHQ-9<10 vs ≥10), and timing relative to the COVID-19 pandemic (outcomes assessed prior to vs after March 2020) on the results. We did not adjust for multiple comparisons in these exploratory analyses. Within the MBCT-Brief arm, univariate associations between frequency of home practice and change in outcome variables were examined using Spearman's correlations.

RESULTS

Figure 1 shows the CONSORT (Consolidated Standards of Reporting Trials) diagram. From December 2016 to March 2020, 540 women were screened for the trial, of whom 130 (24.1%) were eligible and enrolled. Due to the COVID-19 pandemic, enrollment was stopped in March 2020 at 130 participants (90% of the target sample size of 144). The 6-month retention rate was 82.3% and was similar across study arms (82.1%, MBCT-Brief; 82.5%, HDE; $P = 0.947$).

PARTICIPANT CHARACTERISTICS. Baseline characteristics are presented by treatment arm in **Table 1**. The median time between MI and enrollment was 93 days overall (IQR: 68-654 days); 77 days (IQR: 61-102 days) among the 86 participants approached around the time of acute MI and 1,072 days (IQR: 515-2,681 days) among the 44 self-referred participants with a history of MI. Characteristics of acute MI versus self-referred participants are shown in Supplemental Table 1.

INTERVENTION ADHERENCE AND SATISFACTION. **Table 2** shows measures of intervention adherence and satisfaction by study arm. MBCT-Brief participants completed a median of 7 of 8 sessions (IQR: 3-8 sessions) and 74.6% completed ≥4 sessions, considered the minimum effective dose of MBCT.[45] Within the MBCT-Brief arm, participants ≥65 years of age were more likely than those <65 years of age to complete ≥4 sessions (91.7% vs 65.1%, $P = 0.020$). Non-Hispanic White participants were more likely to complete ≥4 sessions than racial/ethnic minority participants (82.6% vs 57.1%, $P = 0.036$). Women with

TABLE 1 Baseline Characteristics by Randomized Treatment Arm

	MBCT-Brief (N = 67)	Heart Disease Education (N = 63)
Sociodemographic factors		
Age, y	60.2 ± 12.2	59.4 ± 13.5
Race and ethnicity		
Non-Hispanic White	46 (68.7%)	40 (63.5%)
Non-Hispanic Black	13 (19.4%)	15 (23.8%)
Hispanic (any race)	5 (7.5%)	3 (4.8%)
Other (eg, Asian, mixed race)	3 (4.5%)	5 (7.9%)
Education ≤ high school	13 (19.7%)	9 (14.5%)
Financial strain	29 (43.9%)	23 (37.1%)
Employed	31 (47.0%)	36 (58.1%)
Married/living with partner	30 (45.5%)	25 (40.3%)
Children living at home	24 (36.9%)	22 (35.5%)
Clinical factors		
Time from MI to enrollment, median (IQR) days	95 (70-734)	87 (68-454)
Recruitment type		
Acute MI	46 (68.7%)	40 (63.5%)
Self-referred	21 (31.3%)	23 (36.5%)
MINOCA	18 (26.9%)	16 (25.4%)
Antidepressant medication	16 (23.9%)	23 (36.5%)
Cardiac rehabilitation	10 (14.9%)	11 (17.5%)
Hypertension	40 (59.7%)	36 (57.1%)
Dyslipidemia	39 (58.2%)	30 (47.6%)
Diabetes	14 (20.9%)	16 (25.4%)
Current smoker	7 (10.4%)	10 (15.9%)

Values are mean ± SD or N (%)
MBCT-Brief = adapted mindfulness-based cognitive therapy; MI = myocardial infarction; MINOCA = myocardial infarction with no obstructive coronary arteries.

children living at home were less likely than those without children at home to complete ≥4 sessions (58.3% vs 87.8%, $P = 0.013$). None of these participant characteristics was associated with satisfaction with MBCT-Brief.

PERCEIVED STRESS (PRIMARY OUTCOME). PSS-10 scores by group and by time are shown in **Table 3**. In the intention-to-treat analysis, perceived stress declined in the MBCT-Brief arm ($P < 0.0001$) and did not change in the HDE arm ($P = 0.141$); the group×time interaction was not statistically significant ($P = 0.070$; **Table 4**). In the per-protocol analysis, limited to participants who completed at least 4 intervention sessions, MBCT-Brief was associated with a greater reduction in perceived stress compared with HDE ($P = 0.049$). There were no significant differences in treatment effects on perceived stress in any of the subgroup analyses. Within the MBCT-Brief arm, more frequent informal mindfulness practice was associated with larger 6-month reductions in perceived stress ($r = -0.42$, $P = 0.007$).

ANXIETY AND DEPRESSIVE SYMPTOMS. Hospital Anxiety and Depression Scale-A and PHQ-9 scores by group and changes over time are shown in Supplemental Table 2 and **Table 4**. In the intention-to-treat analyses, anxiety declined in the MBCT-T arm ($P = 0.007$); the group×time interaction was not significant ($P = 0.533$). There were no significant changes in depressive symptoms in either treatment arm over time. Results were similar in the per-protocol analyses. There were no differences in treatment effects on depressive symptoms or anxiety in by subgroup. Within the MBCT-Brief arm, more frequent informal mindfulness practice was associated with larger 6-month reductions in depressive symptoms ($r = -0.39$, $P = 0.017$), and more frequent formal mindfulness practice was associated with greater 6-month reductions in anxiety ($r = -0.34$, $P = 0.036$).

QUALITY OF LIFE AND DISEASE-SPECIFIC HEALTH STATUS. PROMIS-Global and SAQ-7 scores by group and changes over time are shown in Supplemental Table 2 and **Table 4**. In the intention-to-treat analysis, SAQ-7 ($P = 0.016$) and PROMIS-physical health scores ($P = 0.009$) improved in the MBCT-Brief group, and PROMIS-physical health scores improved in the HDE arm ($P = 0.011$) but without significant group×time interactions (SAQ-7, $P = 0.343$; PROMIS-physical health, $P = 0.964$) (**Table 3**). Results were similar in the per-protocol analysis. There were no differences in treatment effects on QOL or disease-specific health status by subgroup. Within the MBCT-Brief arm, there were no associations between frequency of continued mindfulness practice and 6-month changes in QOL or disease-specific health status.

SLEEP DURATION AND QUALITY. Sleep duration and quality by group and changes over time are shown in Supplemental Table 2 and **Table 4**. In the intention-to-treat analysis, sleep duration increased in the MBCT-Brief arm ($P = 0.038$) but did not change in the HDE arm ($P = 0.459$). There were no group×time interactions for sleep duration or quality (**Table 3**). Results were similar in the per-protocol analyses. In subgroup analyses, there were larger treatment effects (MBCT-Brief vs HDE) on sleep quality in racial/ethnic minority participants than in non-Hispanic White participants (wakefulness after sleep onset, −9.12 [95% CI: −14.81 to −3.17, $P = 0.003$] vs 2.65 [95% CI: −1.77 to 6.74, $P = 0.234$], interaction $P = 0.002$; sleep efficiency, 1.58 [95% CI: 0.61-2.61, $P = 0.003$] vs −0.42 [95% CI: −1.14 to 0.31, $P = 0.265$], interaction $P = 0.002$). With regard to the COVID

pandemic, there was a larger treatment effect on sleep duration after March 2020 (30.14 [95% CI: 6.60-54.28], $P = 0.021$) vs before (95% CI: 1.54 [−3.18 to 6.14], $P = 0.526$; interaction $P = 0.031$). Within the MBCT-Brief arm, frequency of continued mindfulness practice was not associated with 6-month change in sleep quality or duration.

INTERVENTION TARGETS (MINDFULNESS, RUMINATION, PERCEIVED SOCIAL SUPPORT). Five Facet Mindfulness Questionnaire-15, Rumination-Reflection Questionnaire, and ENRICHD Social Support Inventory scores by group and changes over time are shown in Supplemental Table 2 and **Table 4**. In the intention-to-treat analyses, mindfulness increased ($P = 0.011$) and rumination decreased ($P < 0.0001$) in the MBCT-Brief arm and did not change significantly in the HDE arm; the group×time interactions were not significant (mindfulness, $P = 0.382$; rumination, $P = 0.065$) (**Table 3**). Results were similar in the per-protocol analyses. There were no significant differences in treatment effects on mindfulness, rumination, or social support by any of the subgroups examined. Within the MBCT-Brief arm, more frequent formal mindfulness practice was associated with greater 6-month increases in mindfulness ($r = 0.36$, $P = 0.025$).

TABLE 2 Intervention Adherence and Satisfaction

	MBCT-Brief (n = 67)	Heart Disease Education (n = 63)	*P* Value
Session completion			
Sessions completed (0-8)	7 (3-8)	8 (8-8)	0.001
Completed 0 sessions, %	16.4%	9.5%	0.303
Completed ≥4 sessions, %	74.6%	85.7%	0.130
Satisfaction with intervention[a]			
Program helpfulness (0-10)	8 (6-10)	7 (4.25-8)	0.005
Recommend program to others, %	95.5%	75.9%	0.010
Continued mindfulness practice (at 6 months)[b]			
Formal mindfulness		N/A	N/A
≥ Once/week, %	47.6%		
≥ Once/month but < once/week, %	16.7%		
Never or rarely (< once/month), %	35.7%		
Informal mindfulness		N/A	N/A
≥ Once/week, %	61.0%		
≥ Once/month but < once/week, %	12.2%		
Never or rarely (< once/month), %	26.8%		
3-minute breathing space		N/A	N/A
≥ Once/week, %	52.4%		
≥ Once/month but < once/week, %	2.4%		
Never or rarely (< once/month), %	45.2%		

Values are median (IQR) or n (%). [a]N = 99 (87.6% of the 113 participants who completed ≥1 MBCT-Brief or heart disease education session). [b]N = 43 (76.8% of the 56 MBCT-Brief participants who completed ≥1 session).
Abbreviation as in Table 1.

DISCUSSION

In this randomized controlled trial of women with MI, MBCT-Brief was associated with greater 6-month reductions in perceived stress than HDE among participants who completed at least half of the program, with no difference between groups in this primary outcome on intention-to-treat analysis (**Central Illustration**). Within the MBCT-Brief arm, more frequent practice of mindfulness skills after the intervention concluded was associated with greater reductions in perceived stress, depressive symptoms, and anxiety. These findings are consistent with previous trials demonstrating small to moderate positive effects of mindfulness-based interventions on stress in patients with CVD.[13,17,20] Most prior studies have tested traditional in-person programs, which pose significant barriers to engagement and potential scale-up. Our study contributes to the growing evidence of the efficacy of abbreviated, remotely delivered mindfulness-based interventions.[27-29]

Overall, adherence to the MBCT-Brief and HDE sessions was fair to good and participants reported high satisfaction with both programs. Adherence was somewhat higher for HDE, likely due to the lower time commitment and individual versus group-based format, which made it easier to accommodate participants' schedules. While about 75% of MBCT-Brief participants completed at least 4 sessions, 16% completed no sessions. Within the MBCT-Brief arm, poorer adherence was associated with younger age, having children living at home, and being a racial or ethnic minority woman. These characteristics were not associated with satisfaction ratings, suggesting that logistical factors may have posed barriers to attending the weekly sessions. Still, cultural sensitivity in mixed groups may have also contributed to lower adherence among minority women. Strategies to further reduce burden (eg, shorter and/or fewer sessions, asynchronous training options), build motivation for self-care among women with MI, and

TABLE 3 Mean (SD) PSS-10 Scores Over Time by Study Arm

Time Point	MBCT-Brief	Heart Disease Education	*P* Value
Baseline (n = 129)*	18.3 (5.6)	18.2 (5.2)	0.438
3 months (n = 104)	17.0 (6.3)	16.3 (6.6)	0.275
6 months (n = 107)	15.3 (6.3)	16.2 (6.2)	0.229

Values are n (%). PSS-10 scores range from 0 to 40. *Baseline data for one participant was lost before entry; participant completed follow-up visits and is included in intention-to-treat analyses.
PSS = Perceived Stress Scale; other abbreviation as in Table 1.

TABLE 4 Intervention Effects on Primary and Secondary Outcomes

	MBCT-Brief	Heart Disease Education	*P* Value for Group×Time Interaction*
Perceived stress (PSS-10)			
Intention-to-treat	−0.52 (−0.77 to −0.28)	−0.19 (−0.45 to 0.06)	0.070
Per-protocol	−0.49 (−0.76 to −0.22)	−0.09 (−0.37 to 0.18)	0.049
Depressive symptoms (PHQ-9)			
Intention-to-treat	−0.15 (−0.34 to 0.02)	−0.16 (−0.34 to 0.02)	0.962
Per-protocol	−0.09 (−0.28 to 0.10)	−0.12 (−0.31 to 0.07)	0.811
Anxiety (HADS-A)			
Intention-to-treat	−0.23 (−0.39 to −0.06)	−0.16 (−0.33 to 0.01)	0.533
Per-protocol	−0.26 (−0.43 to −0.08)	−0.18 (−0.37 to −0.01)	0.571
Disease-specific health status (SAQ-7)			
Intention-to-treat	0.96 (0.19-1.73)	0.42 (−0.37 to 1.19)	0.343
Per-protocol	0.90 (0.10-1.73)	0.20 (−0.64 to 0.99)	0.230
Quality of life (PROMIS-mental)			
Intention-to-treat	0.26 (−0.01 to 0.54)	0.08 (−0.20 to 0.35)	0.350
Per-protocol	0.21 (−0.08 to 0.49)	0.03 (−0.26 to 0.31)	0.402
Quality of life (PROMIS-physical)			
Intention-to-treat	0.33 (0.09-0.58)	0.32 (0.08-0.57)	0.964
Per-protocol	0.28 (0.02-0.55)	0.26 (−0.01 to 0.51)	0.906
Mindfulness (FFMQ-15)			
Intention-to-treat	0.39 (0.09-0.69)	0.20 (−0.10 to 0.50)	0.382
Per-protocol	0.31 (−0.02 to 0.63)	0.20 (−0.12 to 0.53)	0.656
Rumination (RRQ)			
Intention-to-treat	−0.74 (−1.07 to −0.41)	−0.29 (−0.63 to 0.05)	0.065
Per-protocol	−0.65 (−1.02 to −0.28)	−0.28 (−0.65 to 0.09)	0.162
Social support (ESSI)			
Intention-to-treat	0.09 (−0.06 to 0.24)	0.06 (−0.09 to 0.21)	0.788
Per-protocol	0.13 (−0.03 to 0.29)	0.05 (−0.11 to 0.21)	0.514
Sleep duration			
Intention-to-treat	3.34 (0.29-6.48)	1.28 (−2.08 to 4.61)	0.377
Per-protocol	3.10 (−0.03 to 6.40)	0.82 (−2.58 to 4.24)	0.192
Sleep efficiency			
Intention-to-treat	0.04 (−0.35 to 0.46)	−0.42 (−0.86 to 0.02)	0.138
Per-protocol	0.05 (−0.34 to 0.49)	−0.35 (−0.80 to 0.08)	0.343
Wakefulness after sleep onset			
Intention-to-treat	0.12 (−2.34 to 2.38)	2.28 (−0.26 to 4.84)	0.227
Per-protocol	0.12 (−2.49 to 2.40)	1.93 (−0.60 to 4.55)	0.316

Values are mean change (95% CI). Intention-to-treat: Includes all randomized participants (n = 130). Per-protocol: Includes participants who completed ≥4 intervention sessions (n = 104). **P* values are for group×time interactions in the mixed effects regression models, adjusted for cohort, recruitment site, time since MI, use of antidepressant medication.

PHQ = Patient Health Questionnaire; HADS-A = Hospital Anxiety and Depression Scale-Anxiety subscale; SAQ = Seattle Angina Questionnaire; PROMIS = Patient-Reported Outcomes Measurement Information System; FFMQ = Five Facet Mindfulness Questionnaire; RRQ = Rumination-Reflection Questionnaire; ESSI = ENRICHD Social Support Inventory; other abbreviations as in Tables 1 and 3.

enhance cultural sensitivity are needed to improve engagement in future studies.

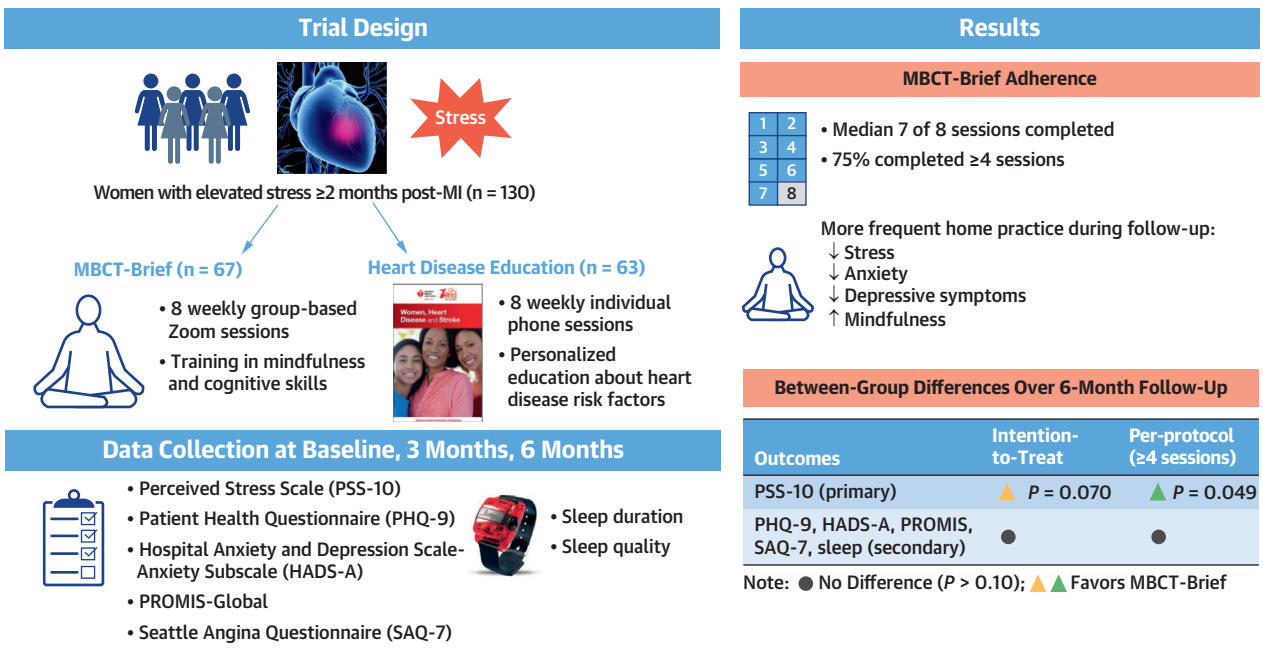
At the 6-month follow-up visit, 48% to 61% of MBCT-Brief participants reported engaging in the various mindfulness practices they were taught at least once per week. While it is encouraging to see some continued home practice following the eight weekly sessions, more frequent practice is likely needed to experience the full psychological benefits of mindfulness training.[46] This is supported by our finding that more frequent home practice was associated with greater reductions in perceived stress, depressive symptoms, and anxiety over 6 months. Incorporating strategies to support regular home practice (eg, smartphone apps, booster sessions) may enhance the efficacy of MBCT-Brief.

MBCT-Brief was also associated with small improvements in anxiety, QOL, disease-specific health status, and sleep duration over 6 months, while HDE was associated with improvement in QOL. However, the two groups did not differ significantly on any secondary outcomes. The absence of an effect on depressive symptoms, which differs from previous trials,[18] may reflect the fact that less than one-third of participants had elevated depressive symptoms at baseline. Expanding eligibility criteria to include depression may be worthwhile in future studies given the importance of this CVD risk factor and the fact that MBCT was originally developed to reduce depression relapse. It is also possible that comparing MBCT-Brief to usual care would have revealed additional positive effects of the program. A recently published Cochrane review of trials in patients with or at risk for CVD found that mindfulness-based interventions reduced stress more than active and nonactive comparators, but reduced depressive symptoms and anxiety only in trials with nonactive comparators.[47]

In subgroup analyses, MBCT-Brief was associated with larger improvements in sleep quality than HDE among racial/ethnic minority women vs non-Hispanic White women. To our knowledge, this is the first study to assess effects of a mindfulness-based intervention on objectively assessed sleep in patients with CVD. The observed increase in sleep efficiency and reduction in wakefulness after sleep onset might have resulted from a reduction in perceived stress, but it was not possible to test mediation in this study. Given disparities in CVD and the relationship between sleep and CVD outcomes,[48,49] future studies should examine whether these effects are associated with improved clinical outcomes. Previous studies testing other psychosocial interventions in cardiac patients have demonstrated reduced risk of recurrent cardiovascular events and mortality.[50-53] Larger studies with longer follow-up periods will be needed to evaluate whether the reductions in stress we observed with MBCT-Brief are sustained over time and are associated with improvements in clinical outcomes.

STRENGTHS AND LIMITATIONS. This study had a number of strengths, including the diversity of the

CENTRAL ILLUSTRATION **Effects of Mindfulness Training on Perceived Stress in Post-MI Women**



PROMIS = Patient-Reported Outcomes Measurement Information System; other abbreviations as in Figure 1.

sample (34% racial/ethnic minority women from 14 U.S. states and Canada) and the broad age range (29-93 years). The remotely delivered, group-based intervention likely enhanced participation, particularly among women with recent MI. Indeed, only 12% of eligible women declined to participate. In a trial testing an in-person, group-based psychosocial intervention in women with CHD, 39% of eligible women declined to enroll, most often due to inability to commit and inconvenience of the program.[53] The comparison condition, matched for weekly contact with a trained facilitator, was another strength. Lack of active controls was noted as a limitation of previous studies in the American Heart Association statement on meditation-based interventions to reduce CVD risk.[13] However, a usual care-only arm may have improved our ability to detect positive effects of MBCT-Brief.

The study also had several limitations. First, we had to close recruitment early due to the COVID-19 pandemic. Although we enrolled 90% of the target sample size, the retention rate was lower than projected, reducing statistical power. Furthermore, it was not possible to fully explore how the pandemic may have affected findings. MBCT-Brief was associated with larger improvements in sleep duration than HDE after the onset of the pandemic versus before. The frequency of working from home may have presented an opportunity for longer sleep, but mental health effects of the pandemic may have dampened potential psychological benefits of the intervention. Second, we added women with a history of MI to the planned sample of women with acute MI due to slow enrollment, which resulted in qualitatively distinct groups of participants. We also included participants with both MINOCA and MI-CAD. However, the primary analyses controlled for time since MI and CAD status, and subgroup analyses indicated that intervention effects did not differ between these groups. Third, while we controlled for recruitment site, this may not fully capture intersite differences and does not address neighborhood-level factors that could influence the degree of stress reduction observed. A fourth limitation is the high rate of missing data on home practice of mindfulness skills in the MBCT-Brief arm. Strategies to obtain home practice data in future studies are needed, as this could help explain variability in treatment response. Finally, while the PSS-

10 is a validated measure of perceived stress, there is no established cutoff for clinically significant change. Future studies would benefit from including stress biomarkers (eg, cortisol, inflammation) to supplement self-report data.

CONCLUSIONS

An abbreviated, remotely delivered mindfulness intervention reduced perceived stress more than HDE among women with MI who were adherent to the program but not in the overall study sample. Our findings suggest that strategies to increase engagement of women with MI in mindfulness training and support regular home practice may enhance the effects of MBCT-Brief. In addition, attention to barriers that may affect women's ability to participate in psychosocial interventions post-MI, even those delivered remotely, will help to ensure equitable access.

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PERSPECTIVES

COMPETENCY IN MEDICAL KNOWLEDGE: Mindfulness training was associated with greater 6-month reductions in perceived stress than heart disease education among women with MI who were adherent to the virtual, group-based intervention. Continued practice of mindfulness skills following the intervention was associated with greater improvements in psychological outcomes.

TRANSLATIONAL OUTLOOK: Remotely-delivered, group-based mindfulness training is a promising approach to reducing stress among women with MI. Further research is needed to identify strategies to support session attendance and home practice.

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KEY WORDS myocardial infarction, women, stress, mindfulness, clinical trial

APPENDIX For supplemental tables, please see the online version of this paper.