# ORIGINAL RESEARCH

# HEALING THE HEART: A RANDOMIZED PILOT STUDY OF A SPIRITUAL RETREAT FOR DEPRESSION IN ACUTE CORONARY SYNDROME PATIENTS

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**Background:** Depression is associated with increased risk of cardiovascular morbidity and mortality in coronary heart disease. Numerous conventional and complementary therapies may address depression. Few involving spirituality have been tested.

**Objective:** The aim of this study was to compare the effects of a nondenominational spiritual retreat, Medicine for the Earth (MFTE), on depression and other measures of well-being six- to 18-months post acute coronary syndrome (ACS).

**Design/Setting:** A randomized controlled pilot study of MFTE, Lifestyle Change Program (LCP), or usual cardiac care (control) was conducted in Southeastern Michigan.

Participants: ACS patients were recruited via local and national advertising (n = 58 enrolled, 41 completed).

Interventions: The four-day MFTE intervention included guided imagery, meditation, drumming, journal writing, and nature-based activities. The four-day LCP included nutrition education, exercise, and stress management. Both retreat groups received follow-up phone coaching biweekly for three months.

Main Outcome Measures: Validated self-report scales of depression, spiritual well-being, perceived stress, and hope were collected at baseline, immediately post-retreat, and at three and

Results: Depression was not significantly different among groups (P = .21). However, the MFTE group had the highest depression scores at baseline and had significantly lower scores at all postintervention time points ( $P \le .002$ ). Hope significantly improved among MFTE participants, an effect that persisted at three- and six-month follow-up (P = .014). Although several measures showed improvement in all groups by six months, the MFTE group had immediate improvement postretreat, which was maintained.

**Conclusions:** This pilot study shows that a nondenominational spiritual retreat, MFTE, can be used to increase hope while reducing depression in patients with ACS.

**Key words:** Acute coronary syndrome, retreat, depression, hope, spiritual well-being, stress, psychological well-being

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#### INTRODUCTION

Each year, about 1.2 million Americans suffer initial or recurrent coronary events. Depression is among the psychological risk factors for the development of, as well as for morbidity and mortality associated with, coronary heart disease (CHD).

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Among individuals with established ischemic heart disease, depression is associated with a threefold to fourfold increase in risk of cardiovascular morbidity and mortality.<sup>2</sup> Depression in CHD patients has been linked to a number of specific outcomes, including impaired left ventricular function, cardiac autonomic dysfunction, coronary endothelial dysfunction, and poor health habits.3-5

Several studies have addressed the safety and efficacy of conventional antidepressants such as selective serotonin reuptake inhibitors in the treatment of depression in patients who have had a heart attack.<sup>2,6,7</sup> Nevertheless, a definite beneficial effect on cardiac end points has not been documented. Regarding psychological treatment of cardiac patients, although a small study found interpersonal therapy to be effective in achieving remission of depression in CHD patients,8 a larger trial found interpersonal therapy to have little benefit over simple cardiac clinical management for depression in CHD.9 However, the mortality benefit of psychological treatments (including cognitive-behavioral interventions and relaxation skills) was highlighted in a large meta-analysis of 9,856 cardiac patients.<sup>10</sup>

In the last decade, scientists have begun to study the effect of complementary and alternative medicine modalities on emotions, quality of life, and well-being of patients with CHD and

depression. Mind-body techniques such as meditation 11-16 and guided imagery, 12 as well as spirituality, 17 are among the complementary and alternative medicine approaches that may help patients with CHD. These approaches provide cardiac patients with nonpharmacologic tools that may prevent further coronary events. 18 Religion and spirituality have been further examined in recent reviews of their effects on depression and other mental health issues. Baetz and Toews<sup>19</sup> looked at social, psychological, and physiological mechanisms; while Hook et al<sup>20</sup> critically reviewed religious and spiritual intervention studies, finding several faith-based programs and 12-step programs to be efficacious. In addition, a variety of group-based behavioral and psychosocial interventions have been used to improve physical and psychosocial well-being among individuals with unstable angina or a history of heart attack.<sup>21-23</sup> However, no study was identified that examined the effects of these group-based programs on depression in individuals who have had unstable angina or a heart attack.

Medicine for the Earth (MFTE) is a retreat-based, nondenominational spiritual healing practice. <sup>24,25</sup> Medicine for the Earth uses techniques such as meditation, guided imagery, journal writing, drawing, and outdoor activities to help individuals reconnect with nature and their own understanding of an allencompassing spirit to improve physical, emotional, and mental health. Anecdotal evidence attests to the success of MFTE in reducing depression (personal communication, Sandra Ingerman and Sara L. Warber, February, 2004).

The purpose of this prospective randomized controlled pilot study was to compare the effects of a four-day MFTE program to a state-of-the-art, comprehensive Lifestyle Change Program (LCP) and usual cardiac care in patients recovering from acute coronary syndrome (ACS), defined as unstable angina or a myocardial infarction. Outcomes of interest included depression, psycho-spiritual well-being (stress, hope, gratitude, reflection, wholeness, and transmutation), health-related quality of life, and cardiovascular biomarkers (CRP, IL-6, IL-10, lipid profile). Our hypothesis was that MFTE and LCP would both have a positive effect, when compared with the control group, on depression, psycho-spiritual well-being, and health-related quality of life due to the group program and time spent in a natural environment. Further, we hypothesized that the spiritual healing practice, MFTE, would be more effective than the LCP program for depression and the psycho-spiritual outcomes; whereas the LCP program would be more effective than either MFTE or the control on the cardiovascular biomarker outcomes. Feasibility of the intervention was assessed by examining recruitment patterns and retention rates.

# **METHODS**

This study was conducted as a randomized controlled pilot study with three groups of individuals that had a history of unstable angina or myocardial infarction in the previous six to 18 months. All groups received standard evidence-based CHD care as specified by their individual physicians, including cardiac rehabilitation for the majority of participants. In addition to usual care, two groups of participants participated in either a four-day, retreat-based MFTE or LCP workshop. The random-

ization schedule was prepared by the biostatistician (B.W.G.) and administered by study personnel. Eligible participants were randomized to one of the three groups based on weights that helped to fill each workshop as it occurred. For example, the four-day MFTE retreat took place in February, whereas the LCP retreat took place in March. Randomization was weighted toward MFTE in a 3:2:1 ratio until just prior to the MFTE retreat. Following that, recruitment continued in a 0:3:2 ratio until the LCP retreat took place. Randomization was stratified by gender.

### **Population and Sample**

Women and men of any racial/ethnic group between the ages of 25 to 75 years with a history of unstable angina or a heart attack six to 18 months prior to the intervention were eligible for the study. The sample was recruited via advertising in various media in the state of Michigan, via web announcements to reach a national audience, and from the University of Michigan Cardio-vascular Medicine program beginning in the fall of 2004. Coronary artery disease status was confirmed by medical records from each individual's cardiologist. Prior to confirming eligibility status, participants completed the Beck Depression Inventory and the Brief Symptom Inventory so the study team could rule out major depression in any participating individuals.

# The Intervention: Four-Day Weekend, Retreat-Based Workshops

Both MFTE and LCP four-day workshops took place at Windrise Retreat Center in Metamora, Michigan, a beautiful rural setting located 50 miles north of Detroit. Participants and staff slept on-site for the duration of each workshop. All meals were prepared by the Windrise staff. Both four-day workshops adhered to similar schedules with equal time (19-20 hours) allotted to teaching/facilitation. Both workshops taught participants about techniques they could use upon returning home. For three months following each workshop, MFTE and LCP participants received biweekly telephone contact from a facilitator to encourage skill retention. From three to six months following the workshops, there was no contact between the research team and participants other than scheduling follow-up appointments for data and sample collection.

Medicine for the Earth is a spiritual approach that develops spiritual identity and allows for creation of a divine state of consciousness within each individual. Through this approach, positive transformation of one's personal health and well-being and global consciousness is achieved. The basic principle of MFTE is that humans are one with the creator and the web of life and have the power to transmute and transform both themselves and the world through their perceptions and spiritual practices. This approach emerged from Sandra Ingerman's passion and life's work to help heal environmental pollution and return this planet to a place that embraces the principles of love, harmony, beauty, unity, and peace.<sup>24</sup>

Central to this work is the concept of "connectedness" and the belief that a sense of disconnection leads to the unprecedented amount of physical illness, emotional illness, depression, suicide, and violence in the world. When people feel disconnected from themselves, their creator, and the web of life, they feel separate. This state of separation creates feelings of fear, anger,

Table 1. Techniques Used in Medicine for the Earth

MFTE Practice	Description	Comment	
Meditation	Breathe through the heart     Learn how to observe internal thoughts and	These first 4 practices are used to move the thinking/rational mind out of the way, allowing individuals to an within and connect with their	
	state of being  Detach from emotional triggers	individuals to go within and connect with their intuition and inner wisdom to find answers towards	
Guided imagery	<ul> <li>Imagine a healthy and happy life</li> <li>Discover one's personal story of creation</li> </ul>	achieving a state of health.	
Journaling	Take notes on internal reflections		
ooumaning	Record particular thoughts and words to focus		
	on throughout the day leading toward one's		
	desired outcome		
Drawing	<ul> <li>Draw an image of one's divine nature</li> </ul>		
	<ul> <li>Use this image as a symbol to meditate on</li> </ul>		
	throughout the day helping individuals		
	remember their true nature when challenged by life's path		
Nature activities	Spend time in nature		
Naturo donvinos	<ul> <li>Regain sense of well-being as individuals connected t</li> </ul>	o nature	
	<ul> <li>Reflect on how the earth, air, water, and sun give life</li> </ul>		
	<ul> <li>Sit down with a tree to destress and sense a connect</li> </ul>	ion with the heartbeat of the earth	
	<ul> <li>Take short walks in nature while appreciating the ways that earth, water, air, and sun give humans vitality to thrive</li> </ul>		
Nature imagery	<ul> <li>Imagine one's life as a plant in a garden</li> </ul>		
	<ul> <li>Reflect on thoughts or words that water one's internal</li> </ul>	I garden	
	<ul> <li>Sense that having a healthy life means planting seeds inspiration, and love</li> </ul>	s, with thoughts and words, in one's inner garden of hope,	

MFTE, Medicine for the Earth.

anxiety, depression, and hopelessness. Emotional and physical illness can be created from these negative internal states that come from feeling disconnected from the rest of life and nature itself. Medicine for the Earth helps individuals reconnect to the source of life.

Another of the fundamental principles taught in MFTE is that everything occurring in the outer world is a reflection of the individual's inner state of consciousness. Based on the spiritual principle that it is perception that creates reality, MFTE provides training and experiences that create deep changes in perception and spiritual awareness. The key to this change is the practice of transfiguration that helps each person to experience who they are beyond their body and mind; that is, we are spiritual beings, our true nature is light, and we are one with the source of life. In the MFTE work, transfiguration is practiced with a simple ceremony to imagine the self traveling deep into the body until it experiences its own inner spiritual light. Individuals then experience the flow of their spiritual light and radiate it out to the other members of the circle. In this way each individual experiences everyone in the circle in their divine perfection, thus feeding the health of each participant. When individuals practice experiencing their divine spiritual light daily or throughout the day they feel connected to the web of life dissolving their usual separated state of consciousness. This allows each person's healing energies and their radiant light to flow through every cell of their being and unlock the body's potential to heal and repair.

Individuals can then radiate that light into the world creating planetary healing and transformation.

In MFTE, participants learn how to transform their negative thoughts and emotions that come up throughout the day and how to create a healthy life for themselves. In the training, participants also learn how to reestablish their connection with nature and experience its healing power. Exercises use the techniques of guided imagery, meditation, drumming, drawing, journal writing, nature activities, and ceremony. See Table 1, for further description of practices used in MFTE. Shamanic journeying and guided imagery take one into an altered consciousness where one's brain waves change from beta waves, an ordinary state of consciousness, to theta waves. Being in a theta state is associated with improved problem solving and creativity as well as feeling relaxed and happy. 26,27 Also working in a supportive community is a form of social support that creates feelings of well-being that can support the process of healing.<sup>28</sup> The interested reader is referred to several books by Sandra Ingerman for more detail on the processes of the Medicine for the Earth work.24,29,30

The LCP is based on Dean Ornish's seminal work with cardiac patients<sup>21,31</sup> and a similar program developed at the University of Michigan called Coronary Alternative Treatment Study. The LCP is a whole-person approach to lifestyle change aimed at improving cardiovascular health. LCP emphasizes three critical areas of focus: nutrition, physical exercise, and stress manage-

ment. The workshop provides experiential learning through a mind-body-spirit model to help participants incorporate the practices into their daily lives.

As part of the nutrition component of LCP, a registered dietitian provides teachings on the specifics of a heart healthy diet, incorporating focus on portion size, healthy versus unhealthy fats, fluency in reading nutrition labels, balanced meal planning, and mindful eating. Delicious heart-healthy food is served throughout the four-day workshop.

Importance of physical activity to cardiovascular health is emphasized throughout the LCP. Daily exercise classes, taught by an exercise physiologist, are aimed at both providing physical activity and teaching individuals how to exercise properly and effectively on their own. Additionally, participants are encouraged to walk daily on the trails throughout the grounds of the retreat center.

In the LCP model, effective stress management is critical to cardiovascular health. A mindfulness-based approach to stress management, inspired in part by the work of Jon Kabat-Zinn, 32,33 is presented by a social worker who specializes in meditation education. Participants are taught the basics of mindfulness meditation and engage in various mindfulness exercises throughout the workshop.

Participants meet as a group with a cardiologist from the University of Michigan. Discussion is focused on general principles of cardiovascular health and disease, and time is provided for participants to direct their specific heart health-related questions to the physician.

## **Data Collection**

After the initial telephone screening, participants were mailed a packet containing two copies of the University of Michigan institutional review board–approved consent form and several self-administered questionnaires. Participants returned the Beck Depression Inventory and the Brief Symptom Inventory plus a signed consent document. Once eligibility was confirmed, participants were asked to complete and return the remaining questionnaires included in the packet.

Each workshop began with a baseline data gathering session. Participants came to the retreat having fasted for a minimum of eight hours and immediately had blood drawn for a lipid profile, high sensitivity C-reactive protein, IL-6, and IL-10. Blood pressure, weight, height, pulse, and respiratory rate were also measured. A study team member reviewed completed surveys and food records. Blood samples were transported on ice and stored frozen until analyzed. Control group participants submitted identical baseline data to researchers at the University of Michigan General Clinical Research Center.

The same set of questionnaires was completed on-site immediately following both four-day retreats, along with an evaluation form. The control group did not complete new questionnaires on day four; in all analyses, the baseline data was assumed to remain the same at day four.

Participants in all three groups completed the same set of self-administered questionnaires, clinical measurements, and blood samples three and six months following baseline data collection. Participants who lived too far away or were unable to come to the University of Michigan General Clinical Research

Center had no further blood draws or clinical measurements taken, but filled out the questionnaires and returned them by mail. Data collection was completed in January 2006.

#### **Outcome Measures**

**Primary outcome measure: depression.** We used two validated measures related to our primary outcome of depression, including the 21-item Beck Depression Inventory<sup>34,35</sup> and the 53-item Brief Symptom Inventory (BSI).<sup>36,37</sup> The BSI measures the number and severity of psychological symptoms and has been used extensively with medically ill patients.

**Secondary measures.** We used the following validated measures of psycho-spiritual well-being: the 14-item Perceived Stress Scale, <sup>38</sup> the six-item State Hope Scale, <sup>39</sup> and the six-item Gratitude scale. <sup>40</sup> The Short Form-36 was used to measure health-related quality of life. <sup>41,42</sup>

We used two new measures specifically to capture anticipated outcomes of the MFTE intervention: Irvine's spiritual well-being scale and a transmutation change questionnaire.

Irvine's spiritual well-being scale<sup>43</sup> measured spiritual well-being by using nine items that factor into reflective and sense of wholeness subscales. Each item was scored on a one-to-five Likert-type scale and items were averaged to calculate the subscale score. The reflective subscale consisted of two items (Cronbach alpha = .82), each of which addressed the issue of whether one has the time and mental space for contemplation. An example item is "you have time to listen to what is on your mind." Seven items formed the sense of wholeness subscale (Cronbach alpha = .85), where a high score reflects a high degree of peace and integration. Example items include "I feel at peace" and "I feel disconnected from what is important in life."

The transmutation change questionnaire (TCQ) was modified from a transmutation evaluation developed by Sandra Ingerman (personal communication, Sandra Ingerman and Sara L. Warber, August, 2004) to assess personal transformation after MFTE workshops. Six items of the TCQ were administered to both intervention groups immediately following their respective interventions. Each item is scored on a five-point Likert-type scale where zero represents no change and four represents significant changes.

**Lifestyle changes.** Since the LCP intervention focused on lifestyle changes and these are known to be useful in secondary prevention of cardiovascular disease, we attempted to assess physical activity and dietary intake. We used the Paffenbarger Physical Activity Questionnaire<sup>44,45</sup> to estimate the energy expenditure of usual and leisure activities, as well as four-day food records to be analyzed for total calories consumed; proportion of protein, carbohydrates, and fats; and quantities of fiber, saturated fats and cholesterol. Compliance with these questionnaires was not adequate to include in the analysis.

**Physical measures.** To assess the physical impact of our interventions we measured heart rate, blood pressure, weight, body mass index, lipid levels, and lipid particle size. We also measured

high sensitivity C-reactive protein that has recently been shown to correlate with depression in cardiac patients and is predictive of future cardiac risk. Biomarkers IL-6 and IL-10 (pro-inflammatory and anti-inflammatory cytokines, respectively) were measured to determine whether either intervention influenced the cytokine balance. Exercise and treatment of depression can increase IL-10 and lower IL-6.

## **Feasibility**

The numbers of research participants who completed the study compared with the number enrolled in each study arm were evaluated to determine feasibility of this type of intervention. Acceptability of the intervention was assessed through the postintervention program evaluations.

# **Statistical Analysis**

Baseline differences between groups were analyzed using chisquare tests for categorical data and analysis of variance for continuous data. Correlations between psychosocial variables were calculated using pooled results at all time points. Independent sample *t* tests were used to compare individual TCQ items between the two intervention groups. For all other outcome variables, we tested for treatment group effects, time effects, and treatment by time interactions by using a repeated measures analysis using the SAS mixed procedure. In this procedure, all data available for each group at each time point is included. Baseline values were included as covariates in these models. Least squares means, which adjust for any imbalance or missing data at a time point, were computed and used in plots of the data for each outcome. When the repeated measures analysis showed a significant difference between treatment groups, the time point slices were individually examined for significance. A significance level of .05 was used throughout.

#### RESULTS

Of 129 potential subjects screened, 58 were randomized to the study. Eleven randomized subjects declined to participate, citing schedule conflicts, disinterest in the group to which they were randomized, or inability to make the time commitment. The complete study schema and flow of participants is presented in Figure 1. The breakdown of data collection is as follows: 47 participants completed baseline data collection, 45 (96%) completed three-month data collection, and 41 (87%) completed six-month data collection, which included 22 of 23 (96%) from the MFTE group, 10 of 14 (71%) from the LCP group, and nine

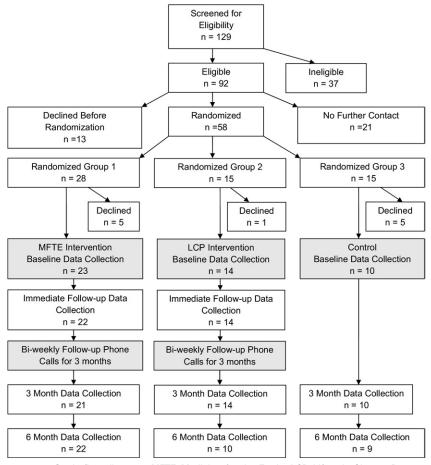


Figure 1. Study flow diagram. MFTE, Medicine for the Earth; LCP, Lifestyle Change Program.

Table 2. Group Characteristics at Baseline

Characteristic	MFTE	LCP	Control	P Value
Age, y, mean (range)	62 (39-75)	58 (44-69)	61 (38-78)	.302ª
Gender				
Female, No. (%)	10 (43)	7 (50)	2 (20)	.308 <sup>b</sup>
BMI, mean (range)	31 (23-50)	28.5 (19-39)	28 (22-36)	.346 <sup>a</sup>
Ethnicity, No. (%)				
White	17 (74)	13 (93)	10 (100)	.729 <sup>b</sup>
Hispanic	1 (4)	0 (0)	0 (0)	
African American	3 (13)	1 (7)	0 (0)	
Native American	0 (0)	0 (0)	0 (0)	
Asian	1 (4)	0 (0)	0 (0)	
Other	1 (4)	0 (0)	0 (0)	
Diagnosis, No. (%)				
CAD	2 (9)	1 (7)	2 (20)	.828 <sup>b</sup>
CAD, CHF	1 (4)	1 (7)	0 (0)	
CAD, bypass	2 (9)	1 (7)	2 (20)	
CAD, stent	3 (13)	2 (14)	0 (0)	
CAD, UA	6 (26)	6 (43)	3 (30)	
CAD, MI	9 (39)	3 (13)	3 (30)	
Antidepressant use, No. (%)				
Yes	3 (13)	4 (29)	3 (30)	.401 <sup>b</sup>
Scales at baseline, mean (range)				
Beck Depression Inventory	12 (2-36)	11 (2-36)	8 (0-19)	.376ª
Stress	36 (22-48)	37 (29-52)	35 (23-44)	.796ª
Gratitude	36 (24-42)	37 (28-42)	38 (31-42)	.703 <sup>a</sup>
Hope	36 (12-44)	34 (7-47)	35 (21-46)	.840 <sup>a</sup>
SWB reflective	3.9 (2-5)	3.8 (3-5)	3.7 (2-5)	.167ª
SWB wholeness	3.8 (2-5)	3.9 (2.5-5)	3.8 (2-5)	.809 <sup>a</sup>
SF-36 bodily pain	60 (30-90)	61 (10-90)	59 (30-90)	.953 <sup>a</sup>
SF-36 role emotional	81 (25-100)	71 (17-100)	83 (58-100)	.267ª
BSI positive symptoms	23.8 (3-47)	19.3 (3-47)	16.1 (0-35)	.259 <sup>a</sup>

MFTE, Medicine for the Earth; LCP, Lifestyle Change Program; BMI, body mass index; CAD, coronary artery disease; CHF, congestive heart failure; UA, unstable angina; MI, myocardial infarction; SWB, spiritual well-being; SF-36, MOS 36-Item Short-Form Health Survey; BSI, brief symptoms inventory.

of 10 (90%) from the control group. Eight participants (17%) did not complete portions of the follow-up. One participant left midway through the MFTE intervention due to perceived incompatibility with the program but completed three- and sixmonth data collection.

At baseline, all groups were statistically equivalent in terms of age, gender, ethnicity/race, cardiac diagnosis, and antidepressant use (Table 2). The groups were also statistically similar at baseline for depression, psychological symptoms, stress, gratitude, hope, spiritual well-being (reflectiveness, wholeness), and the SF-36 (bodily pain, role-emotional).

Across all participants, higher depression scores correlated with higher perceived stress and higher gratitude ratings correlated with heightened levels of hope. Gratitude and hope were inversely correlated with stress and depression. Each of these correlations was statistically significant (P < .0001 to .04).

The primary outcome variable was depression, as measured by the Beck Depression Inventory (Table 3 and Figure 2A). The range is 0 to 63, where scores ≥10 indicate a moderate probability of mild-to-moderate depression, and ≥40 a very high probability of severe depression. At baseline the group differences were not statistically different. The mean MFTE and LCP scores (12 and 11, respectively) were greater than 10, signifying mild to moderate depression. Immediately after the intervention, the mean of both groups was in the normal range (MFTE = 6, LCP = 7), representing a 50% (MFTE) and 37% (LCP) reduction from baseline. These reductions in depression persisted in the normal range at three and six months postintervention. The control group had lower scores at baseline (mean, 8), with a small nonsignificant reduction over time. The follow-up scores for the MFTE group when compared with baseline were significantly lower at all time points (P = .002, P = .002, and P < .001 for

<sup>&</sup>lt;sup>a</sup>One-way analysis of variance.

bChi-square test.

Table 3. Means of Outcomes by Group and Time Point

Scale	Time Point	MFTE <sup>a</sup> Mean (Range)	LCP <sup>b</sup> Mean (Range)	Control <sup>c</sup> Mean (Range)	P Value <sup>d</sup>
Beck Depression	Baseline	12 (2-36)	11 (2-36)	8 (0-19)	.2085
Inventory <sup>e</sup>	Post-retreat	6 (0-23)	7 (0-25)	NA	
	3 months	6 (0-21)	7 (0-26)	5 (1-12)	
	6 months	6 (0-18)	7 (0-40)	6 (1-13)	
Perceived Stress Scale <sup>f</sup>	Baseline	36 (22-48)	37 (29-52)	35 (23-44)	.0930 (P = .0488  for group)
	Post-retreat	30 (19-45)	33 (22-42)	NA	by time interaction)
	3 months	31 (17-46)	36 (20-51)	30 (22-39)	
	6 months	30 (19-48)	32 (23-54)	31 (19-40)	
Gratitude <sup>g</sup>	Baseline	36 (24-42)	37 (28-42)	38 (31-42)	.5954
	Post-retreat	39 (27-42)	39 (33-42)	NA	
	3 months	38 (16-42)	37 (24-42)	37 (30-42)	
	6 months	38 (29-42)	40 (36-42)	40 (38-42)	
State Hope Scale <sup>h</sup>	Baseline	36 (12-44)	34 (7-47)	35 (21-46)	.0137
	Post-retreat	41 (18-48)	37 (20-46)	NA	
	3 months	42 (33-48)	35 (11-48)	35 (13-45)	
	6 months	40 (30-48)	37 (13-46)	38 (16-48)	
SWB, reflective <sup>i</sup>	Baseline	3.87 (2-5)	3.79 (3-5)	3.30 (2-5)	.6344 ( $P = .025$ for group
	Post-retreat	4.34 (3-5)	3.85 (3-5)	NA	time interaction)
	3 months	4.18 (2.5-5)	4.04 (3-5)	3.95 (2.5-5)	
	6 months	4.09 (2-5)	4.13 (3.5-5)	3.83 (2-5)	
SWB, wholeness <sup>j</sup>	Baseline	3.78 (2.0-5.0)	3.95 (2.5-5.0)	3.88 (2.6-5.0)	.0924
	Post-retreat	4.13 (2.1-5.0)	3.93 (2.8-4.8)	NA	
	3 months	4.34 (2.1-5.0)	4.04 (2.9-5.0)	3.91 (2.4-5.0)	
	6 months	4.18 (2.5-5.0)	4.28 (2.6-5.0)	4.13 (2.5-5.0)	
BSI positive symptom	Baseline	24 (3-47)	19 (3-47)	16 (0-35)	.144 ( $P=.0225$ for group $ imes$
total <sup>k</sup>	Post-retreat	13 (0-42)	18 (2-38)	NA	time interaction)
	3 months	14 (0-38)	16 (1-36)	15 (0-29)	
	6 months	15 (1-36)	10 (0-38)	10 (2-21)	
SF-36: bodily pain <sup>1</sup>	Baseline	57 (20-90)	61 (10-90)	59 (30-90)	.0558
	Post-retreat	NA	NA	NA	
	3 months	71 (20-90)	64 (30-90)	70 (40-90)	
	6 months	70 (30-90)	70 (10-90)	74 (50-90)	
SF-36: role-emotional <sup>m</sup>	Baseline	81 (25-100)	71 (17-100)	83 (58-100)	.3474
	Post-retreat	NA	NA	NA	
	3 months	89 (25-100)	78 (17-100)	83 (58-100)	
	6 months	95 (25-100)	86 (25-100)	87 (50-100)	

MFTE, Medicine for the Earth; LCP, Lifestyle Change Program; SWB, spiritual well-being; BSI, Brief Symptom Inventory; SF-36, MOS 36-Item Short-Form Health Survey.

 $<sup>^{</sup>a}$ n = 23 at baseline.

 $<sup>^{</sup>b}$ n = 14 at baseline.

 $<sup>^{</sup>c}n = 10$  at baseline.

<sup>&</sup>lt;sup>d</sup>Repeated measures analysis. P value for treatment differences (2 df) based on repeated measures model adjusted for baseline value.

<sup>&</sup>lt;sup>e</sup>Range, 0-63; >10 = mild-moderate depression;  $\ge$ 40 = severe depression.

fRange, 14-70; higher score indicates greater perceived stress.

<sup>&</sup>lt;sup>g</sup>Range, 6-42; higher score indicates greater feelings of gratitude.

<sup>&</sup>lt;sup>h</sup>Range, 6-48; higher score indicates greater feelings of hope at the present moment (mean of normal population, 34).

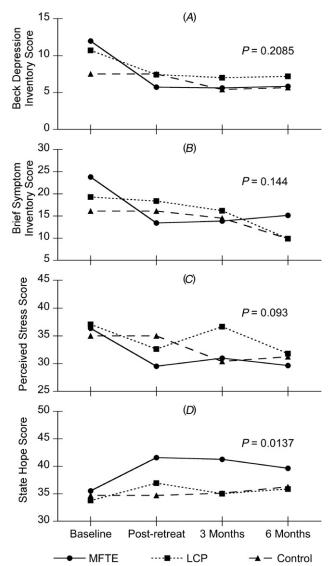
Range, 1-5; higher score indicates increased level of reflection.

<sup>&</sup>lt;sup>j</sup>Range, 1-5; higher score indicates increased sense of wholeness.

kRange, 0-53; count of all items with nonzero responses; reveals number of symptoms the respondent reports experiencing.

<sup>&</sup>lt;sup>I</sup>Range, 0-100; higher score indicates less bodily pain.

<sup>&</sup>quot;Range, 0-100; higher score indicates fewer problems with work or other daily activities as a result of emotional problems.



**Figure 2.** Primary results depicted using least squares means at all time points of (A) Beck Depression Inventory, (B) Positive Psychological Symptoms of the Brief Symptom Inventory, (C) Perceived Stress Scale, and (D) State Hope Scale. The P value is for the repeated measures analysis using baseline values as a covariate. *MFTE*, Medicine for the Earth; LCP, Lifestyle Change Program.

post-retreat, three months, and six months, respectively), although no statistical differences were found between groups after controlling for baseline and by using repeated measures analysis (P = .2085).

The Positive Symptom Total of the Brief Symptom Inventory (BSI) is the number of psychological symptoms reported, with scores ranging from 0 to 53. At baseline, groups were statistically equivalent (MFTE: mean 23.8, range 3-47; LCP: mean 19.3, range 3-47; control: mean 16.1, range 0-35). The repeated measures analysis did not show significant changes by group but did reflect an interaction of time and group (P = .023), with the significant time point being immediately post-retreat (P = .009).

Analysis of variance on the difference between baseline and post-retreat indicated that the number of symptoms experienced by MFTE participants significantly decreased immediately following the intervention (MFTE mean difference 10.3, range 5.0-15.7 vs LCP mean difference 0.9, range -4.1 to 5.9; P = .017). This change persisted over time (Table 3 and Figure 2B).

The Perceived Stress Scale measures how unpredictable, uncontrollable, and overloaded respondents found their lives during the last month, with possible scores ranging from 14 to 70 (higher scores denote more stress). Baseline Perceived Stress was quite elevated in all participants with group averages above 35 (in contrast to a smoking cessation sample where the mean score was 25; Table 3 and Figure 2C) The repeated measures analysis yielded a significant group by time interaction (P = .0488); observation of the graph shows that the LCP group felt more stressed at the three-month follow-up as they attempted lifestyle changes.

Scores on the State Hope Scale can range from six to 48, with higher scores indicating greater hope. All groups were initially near the population mean of 34 (MFTE 36, LCP 34, control 35). This measure significantly differed between the three groups over time (P = .0137). The MFTE group showed a marked improvement (mean > 40) in State Hope scores immediately after the retreat, and this persisted at both three and six months following the intervention (Table 3 and Figure 2D).

The Gratitude scale values ranged from six to 42, with higher scores reflecting more endorsement of thankfulness. Participants in all three groups reported normal amounts of gratitude at all measured time points (Table 3). Average ratings were near 38, median of a normal population. Repeated measures analysis showed no significant difference between the groups over time (P = .5954).

Irvine's Spiritual Well-being Scale includes a reflective subscale and a wholeness subscale (both one to five, higher is better). For the reflective subscale, the repeated measures group by time interaction was statistically significant (P=.025), particularly driven by the time point immediately after the retreat. At this time, participants in the MFTE had higher scores on average than did the LCP group or control group (P=.023; Table 3). For the wholeness subscale, although no statistically significant between-group differences were found using repeated measures analysis, all three groups had an improvement across the sixmonth study period (Table 3). Comparing all participants' scores from baseline to six-month, a significant increase in wholeness was seen (paired t test P=.0016; baseline mean 3.85, SD 0.77; six-month mean 4.19, SD 0.72).

The Short Form-36 is a frequently used measure of participants' perception of their health quality of life. It measures eight dimensions of health, including physical and social functioning, role-physical, mental health, vitality, and general health status. The participants had changes over time on two of the eight subscales, bodily pain and role-emotional. The SF-36 bodily pain subscale (0-100, national norm: mean 75.2+/-23.7) is scored such that a higher score indicates less pain. Repeated measures comparison of treatment groups approached significance (P = .0558); both MFTE and control groups experienced less pain at three-month follow-up than the LCP group (Table 3). The SF-36 role-emotional subscale (0-100, national norm: mean

**Table 4.** Transmutation Change Questionnaire: Results Immediately Post-retreat

Statement	MFTE Mean (SD)	LCP Mean (SD)	<i>P</i> Value
I have been feeling more connected to the web of life.	3.45 (0.67)	2.71 (1.27)	.028 <sup>a</sup>
I feel more connected to nature.	3.09 (1.02)	2.43 (1.34)	.102
My relationship to people has changed.	2.82 (1.18)	2.14 (1.51)	.143
I have the ability to transmute negative thoughts and beliefs.	3.41 (0.80)	2.57 (1.40)	.028 <sup>a</sup>
I can observe my emotional states instead of becoming lost in them.	2.86 (1.17)	2.79 (1.42)	.859
I pay attention to receiving the nurturance of the food I eat.	2.64 (1.26)	3.57 (0.85)	.020 <sup>a</sup>

MFTE, Medicine for the Earth; LCP, Lifestyle Change Program.

All items are scored on a scale from 0-4 (higher is better).

"Statistically significant difference on independent sample t test.

81.3+/-33.0) is scored such that a higher score indicates fewer to no problems with work or other daily activities as a result of emotional problems. In repeated measures analysis no significant group differences were seen (P = .3474; Table 3). However, analysis of baseline to six-month scores shows significant improvement in participants' emotional states over time (means 78.55, 91.25, respectively; paired t test P = .002).

The TCQ is scored from zero to four, with higher scores reflecting greater perceived changes (Table 4). The MFTE group felt significantly more connected to the web of life than did the LCP group post-retreat (P=.028). Participants in MFTE also felt a significantly greater ability to transmute negative thoughts and beliefs (P=.028). Conversely, participants in LCP paid significantly more attention to receiving the nurturance of the food they ate than did the MFTE group (P=.020). Both groups felt a greater connection to nature, changed relationships with other people, and had more of an ability to observe emotional states rather than becoming lost in them.

We measured several physical parameters at baseline, three, and six months, including heart rate, blood pressure, weight, cholesterol, high sensitivity C-reactive protein, IL-6, and IL-10. Using repeated measures analysis, no significant differences between groups were found for any of these parameters (see Table 5).

Subjects were given open-ended questions in which they could convey any untoward events associated with the interventions, but none were reported.

#### DISCUSSION

Our primary outcome variable, depression, was not significantly different among groups when evaluated using the prespecified repeated measures analysis. However, the MFTE group had the highest depression scores at baseline and had significantly lower scores at all postintervention time points. Hope, which has been shown to be conceptually linked with depression and spirituality in cardiovascular disease, <sup>46</sup> was markedly improved among MFTE participants, an effect that persisted for three and six months following the intervention. Previous observational studies have demonstrated an association of hope with positive cardiovascular outcomes, <sup>46</sup> whereas others have observed that hopelessness is common after ACS and predicts decreased exercise participation. <sup>47,48</sup> Our study is the first randomized clinical trial to demonstrate an intervention that positively effects hope in ACS patients.

Reflection and wholeness, parts of spiritual well-being, were also elevated immediately after the MFTE retreat. In addition, MFTE participants felt more connected to the web of life and had greater ability to transmute negative thoughts and beliefs following the retreat as would be expected based on the precepts of the program. This may explain why these participants were less depressed, more hopeful, and had fewer psychological symptoms (as measured by the positive symptoms scale of the BSI) after the retreat. Our results are consistent with a recent review of spiritual and religious interventions for depression that point to the efficacy of several forms of faith-based therapy to improve depression over an extended period of time.<sup>20</sup>

In short, it appears that the retreat-based MFTE experience jumpstarts a return to psycho-spiritual well-being, whereas other interventions achieve a similar end point more slowly. This observation in itself is important, as few interventions for depression would be expected to take effect in such a short period of time. The slower return to well-being was seen in measures of "sense of wholeness" and "emotional role," where all trial participants improved gradually over time. Similar to some MFTE and LCP activities, a recent review of relaxation education shows improvements of depression, anxiety, resting heart rate, anginal symptoms, and return to work in CHD patients.<sup>49</sup> Furthermore, psychological treatment effects are particularly pronounced in men with mental stress-induced myocardial ischemia, as shown in a 2002 study by Blumenthal et al<sup>50</sup> in 94 men with coronary artery disease (CAD). The authors found that stress management was associated with a significant reduction in clinical CAD events relative to usual care in both the short-term and longterm. In contrast, our findings highlight the usefulness of a nondenominational spiritual intervention in improving depressive symptoms and fostering hope. Our work adds an important spiritual voice to the current discussion on the importance of psychological well-being in the prognosis of CAD.

In addition to these positive findings, we found that MFTE is an acceptable intervention given that 96% of the participants completed the study, more than in either of the other groups. A weekend retreat format is also acceptable (18% decline). In addition, we learned from participant feedback that participants were eager for continued contact with other participants. This highlights a possibility for altering the intervention design in a future study. To accommodate this need for further contact, a reunion was held for the MFTE participants after the conclusion of the study. In addition, LCP and control group participants

Table 5. Physical Measures Outcomes By Group and Time Point

Measure	Time Point	MFTE <sup>a</sup> Mean (SD)	LCPb Mean (SD)	Control <sup>c</sup> Mean (SD)
Heart rate, beats/min	Baseline	70 (10.3)	65 (9.8)	63 (11.0)
	6 months	64 (10.0)	64 (11.5)	63 (11.6)
Systolic blood pressure, mm Hg	Baseline	128 (18)	126 (14)	133 (18)
	6 months	117 (16)	114 (11)	111 (13)
Weight, Ib	Baseline	199.0 (38.4)	180.9 (45.9)	188.7 (49.0)
	6 months	191.0 (20.5)	178.9 (61.3)	189.9 (46.4)
Triglyceride, mg/dL	Baseline	124 (59.8)	151 (106.1)	147 (61.7)
	6 months	131 (87.4)	173 (140.6)	102 (25.6)
VLDL and chylomicron triglyceride, mg/dL	Baseline	93 (60.6)	118 (107.0)	110 (53.4)
	6 months	97 (86.6)	142 (137.8)	66 (27.7)
HDL cholesterol, mg/dL	Baseline	50 (12.2)	53 (13.3)	41 (9.3)
	6 months	33 (7.9)	43 (8.9)	46 (11.2)
Hs-CRP <sup>d</sup>	Baseline	2.73 (1.9)	2.64 (2.8)	3.15 (2.5)
	6 months	3.52 (3.8)	2.32 (3.7)	6.36 (11.2)
IL-6 <sup>e</sup>	Baseline	<5 (0)	<5 (0)	<5 (0)
	6 months	<5 (0)	<5 (0)	<5 (0)
IL-10 <sup>f,g</sup>	Baseline <sup>f</sup>	6.15 (6.2)	3.45 (0.7)	3.86 (1.6)
	6 months <sup>g</sup>	<3.6 (0)	<3.6 (0)	<3.6 (0)

MFTP, Medicine for the Earth; LCP, Lifestyle Change Program; Hs-CRP, high sensitivity C-reactive protein; VLDL, very low density lipoprotein; HDL, high density lipoprotein; IL-6, interleukin-6; IL-10, interleukin-10.

were offered a one-day workshop to learn techniques presented in MFTE and many chose to attend.

Although this study is limited by its small sample size, several statistically significant results were nonetheless identified. Another drawback was that, overall, participants were only mildly depressed at baseline. Excluding patients with normal scores on the depression scales may have produced a more robust effect for the interventions. Unfortunately, one of the two MFTE follow-up facilitators was unable to perform the semimonthly phone follow-ups as planned. However, analysis did not show any significant difference in the outcomes for that subgroup compared with the other subgroup of MFTE participants. Follow-up blood results and physical measures were not available for participants who lived too distant to return for sample collection or measurement, thus reducing our ability to quantify significant differences on these important cardiovascular outcomes. In addition, the LCP group had the lowest response rate at the six-month follow-up point, which may have reduced our ability to quantify a more robust effect for that program over

Overall, this study provides encouraging evidence that supports teaching nondenominational spiritual practices that can be incorporated into the daily lives of people who have a history of ACS. A major benefit of this training is the establishment of hope. Clinically, these preliminary findings are provocative. Healthcare providers know intuitively that hope is necessary for

healing. We are cautioned to not take away hope nor to provide false hope. However, in our medical training we are rarely presented with tools to increase hope. One participant identified the greatest impact of MFTE quite simply: "There is hope." Another would recommend the program to other heart patients "because it changes the view on life and lifts the burden of stress to let your heart be free and shine to heal itself." We conclude that MFTE is worthy of a larger clinical trial that may further elucidate its effects and place in the clinical care of ACS patients.

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 $<sup>^{</sup>a}$ n = 23 at baseline.

<sup>&</sup>lt;sup>b</sup>n=14 at baseline.

cn=10 at baseline.

dReference range, 0.0-3.5.

<sup>&</sup>lt;sup>e</sup>Normal value <5.

fNormal value <15.5.

 $<sup>^{</sup>m g}$ Normal value <3.6; reference range changed between testing dates, but all values in normal range.

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