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Feasibility and effectiveness of a brief meditation-based stress management intervention for patients diagnosed with or at risk for coronary heart disease: A pilot study

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Extensive research has led to the development of a psychobiological model of cardiovascular disease. This model suggests that psychological factors such as depression, anxiety, hostility, and stress may affect the development and progression of coronary heart disease (CHD). Recent studies have also demonstrated that meditation-based stress reduction programs are useful interventions for patients with various medical and psychological symptoms. The objective of this pilot study was to gather preliminary information regarding the feasibility of implementing a brief meditation-based stress management (MBSM) program for patients with CHD, and those at high risk for CHD, at a major metropolitan hospital that serves a predominately non-local patient population. The secondary aim of this study was to investigate the possibility that such an intervention might reduce depression, as well as perceived stress, anxiety, and hostility, while improving general health scores. The overall feasibility results indicate that this MBSM intervention was highly feasible with regard to both recruitment and retention of participants. In fact, 40% of patients requested further training. In addition, after completion of the 4-week intervention, participants reported significant reductions in depression and perceived stress. In conclusion, the present study demonstrated that the brief meditation-based stress management program was well-received by patients and can successfully be used as a supportive program for patients at risk or diagnosed with CHD.

Keywords: meditation; cardiovascular disease; stress; anxiety; depression

Introduction

Heart disease is the number one cause of mortality in both men and women in the US (American Heart Association, 2008). An increasing number of programs are being developed for disease prevention and early detection. Despite these new primary and secondary prevention programs, there will be an increasing numbers of patients diagnosed with coronary heart disease (CHD) as the population ages.

A strong body of research has led to the development of a psychobiological model of cardiovascular disease. This model suggests that psychological factors such

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as depression, anxiety, hostility/anger, and stress may affect the development of and ultimately the progression of CHD. There have been several reviews of the literature that support this model in a more thorough way than is possible here (Rafanelli, Roncuzzi, Ottolini, & Rigatelli, 2007; Rozanski, Blumenthal, & Kaplan, 1999; Rozanski, Blumenthal, Davidson, Saab, & Kubzansky, 2005).

Psychological factors, CHD, and cardiac events

Depression

Numerous studies have shown that depression is extremely prevalent in patients with CHD. Prevalence estimates range from 14% to as high as 47% in patients with CHD (Lett et al., 2004), with higher prevalence rates typically found in patients with unstable angina or in patients awaiting CABG surgery. This high prevalence of depression in patients with CHD suggests that depression may contribute to the development of CHD. Several prospective studies' findings have confirmed that depressed individuals are more likely to develop CHD than non-depressed individuals (Lett et al., 2004). In addition, depression has been shown to be predictive of outcomes in patients with CHD. Patients with CHD with depression have a significantly increased risk of cardiac death and adverse cardiac events (Lett et al., 2004). Carney et al. (1995), identified depression as the best predictor of any cardiac event (myocardial infarction, death, CABG surgery, or angioplasty) independent of the extent of CHD, smoking status, and left ventricular ejection fraction. Patients with depression were found to be 2.2 times more likely to experience a cardiac event than non-depressed patients (Carney et al., 1995).

Anxiety

Although there have been fewer studies investigating the relationship between anxiety and CHD, there is evidence that suggests that anxiety may also impact the development of CHD in healthy individuals (Booth-Kewley & Friedman, 1987; Pignay-Demaria, Lesperance, Demaria, Frasure-Smith, & Perrault, 2003; Weissman, Markowitz, Ouellette, Greenwald, & Kahn, 1990). Likewise, there is some evidence that supports the hypothesis that anxiety may influence outcomes in patients with CHD (Gullette et al., 1997; Pignay-Demaria et al., 2003). Specifically, phobic anxiety has been found to be a risk factor for sudden cardiac death (Rozanski et al., 2005).

Hostility/anger

Numerous studies have explored the link between hostility and chronic anger and CHD. Positive studies have shown an association between chronic anger/hostility and cardiac events, specifically in regards to the progression of atherosclerosis during serial coronary angiography/carotid ultrasonography (Rozanski et al., 1999, 2005). Other studies have demonstrated that type A behavior (characterized by hostility) may double the risk of CAD and increase the risk of myocardial infarction (MI) fivefold over an 8.5-year follow-up (Rozanski et al., 1999). Anger levels have also been linked to the frequency of recurrent cardiac events (Rozanski et al., 1999).

Chronic stress

Research has shown that chronic stress plays a significant role in the development of heart disease. Exposure to chronic stress may negatively affect cardiac health directly through neuroendocrine mechanisms or as a result of its link to unhealthy behavior and other risk factors, such as high blood pressure, smoking, and physical inactivity (Macleod et al., 2002). Additional research is needed in order to clarify the mechanism by which chronic stress acts as a risk factor for cardiovascular disease.

Various life stressors can lead to chronic states of stress, such as work stress, socioeconomic status (SES) marital stress, and caregiver stress. Work-related stress has been extensively researched due to its frequent causal relationship to CAD. Studies have shown that this type of stress is related to an increased frequency of adverse cardiac events (Rozanski et al., 1999, 2005).

Behavioral and integrative interventions in heart disease

In a meta-analysis of cardiac related psycho-educational programs, 37 studies were reviewed that utilized interventions such as health education and stress management (Dusseldorp, van Elderen, Maes, Meulman, & Kraaij, 1999). The programs reviewed demonstrated a 34% reduction in cardiac mortality and a 29% reduction in recurrence of myocardial infarctions. In addition, a number of clinical trials have investigated the impact of interventions specifically targeting depression in cardiac patients. The results of the well-known SADHART (Glassman et al., 2002) and ENRICHD (Jaffe et al., 2006) trials have demonstrated the benefits of using selective serotonin reuptake inhibitors (SSRIs) in treating depression in patients with cardiac disease.

Research investigating the use of integrative therapies in cardiac patients is dominated by the studies of Ornish et al. (1998). Ornish investigated the effectiveness of a lifestyle program which includes meditation training, a low-fat vegetarian diet and exercise, and has demonstrated beneficial outcomes for participants (Gould et al., 1995; Ornish et al., 1998). Further research is needed to isolate the effectiveness of meditation alone in addressing the psychological risk factors associated with cardiac disease.

Mindfulness-based stress reduction

Mindfulness-Based Stress Reduction (MBSR), developed by Jon Kabat-Zinn at the Stress Reduction Clinic of the University of Massachusetts Medical Center (Kabat-Zinn, 1990), is one of the most well studied meditation and stress management programs. MBSR is a clinical behavioral medicine program that provides systematic mindfulness meditation training to a population with a wide range of chronic medical and stress related disorders (Bowen et al., 2006; Grossman, Niemann, Schmidt, & Walach, 2004; Kabat-Zinn, 1982; Kabat-Zinn, Lipworth, & Burney, 1985; Kristeller, 1999; Miller, Fletcher, & Kabat-Zinn, 1995). The standard program is comprised of eight weekly group sessions that meet for two and a half hours. These sessions consist of mindfulness meditation and gentle Hatha yoga training, as well as psycho-educational discussions about stress and coping. Homework assignments are given each week to incorporate mindfulness practice into everyday life (Kabat-Zinn, 1990).

Research suggests that Mindfulness-Based Stress Reduction programs are useful interventions for patients with various medical and psychological symptoms

(Grossman et al., 2004). Various institutions have adapted the MBSR model to create effective population-specific interventions for the treatment of depression, anxiety, chronic pain, substance abuse, and eating disorders (Bowen et al., 2006; Kabat-Zinn, 1982; Kabat-Zinn et al., 1992; Kristeller, 1999; Miller et al., 1995). Numerous controlled and uncontrolled studies have demonstrated the efficacy of MBSR-based interventions for a broad range of chronic disorders and conditions (review articles: Baer, 2003; Bishop, 2002).

Although there have been numerous studies that have investigated the cardiac specific physiological impact of various forms of meditation, to date there has only been one randomized trial that has investigated the effectiveness of MBSR in improving psychological outcomes in a cardiac population. Tacon, McComb, Caldera, & Randolph (2003) conducted a very small trial of a full 8 week MBSR program with female cardiac patients and found a significant post-intervention reduction in anxiety. No improvements were found in health locus of control or a measure of coping.

Method

Objectives

The objective of this pilot study was to gather preliminary information regarding the feasibility of implementing an abbreviated Mindfulness-Based Stress Management program for patients with CHD, and those at high risk for CHD, with regard to patients' level of interest, and availability. A secondary aim was to investigate the possibility that such an intervention might reduce depression, as well as perceived stress, anxiety, and hostility, which may themselves be risk factors for other adverse cardiac events. Kabat-Zinn's MBSR protocol was used as a model for our Meditation-Based Stress Management (MBSM) program, but for the purposes of this study (a non-local patient population), we have shortened and adapted it to a 4-week course. The abbreviated intervention covered all of the same material of the longer course but in less detail, allowing for shorter time spent on each skill taught.

Participants

The study population was drawn from patients at Columbia University Medical Center. All patients were adults who had been diagnosed with CHD or who were at high risk for CHD. Diagnosis of CHD included such diagnoses as coronary artery disease, chronic heart failure, history of myocardial infarction, coronary artery bypass graft surgery (CABG), valve repair or replacement, heart transplant, and/or aneurysm. Patients at high risk for CHD were defined as having any two of the following empirically established risk factors: male > 45, female > 55, family history of CHD, current cigarette smoker, hypertension, elevated total cholesterol with low HDL and/or high LDL, and diabetes. Other eligibility criteria included: ability to give informed consent, English speaker, and no active psychosis or dementia.

Procedure

Participants were recruited through advertisements posted in the cardiology suites at the Columbia University Medical Center. Cardiologists were also asked to inform

their patients about the study. Patients who contacted the study coordinator were evaluated for eligibility and given a detailed description of the study obligations. Patients who were interested and eligible gave informed consent in accordance with Institutional Review Board (IRB) guidelines. Baseline demographic information was collected prior to the beginning of the intervention. Study measures of depression, anxiety, stress, hostility, medical symptoms, and overall quality of life were also completed. Participants completed this battery of measures again at the completion of the intervention (4 weeks). Because of the pilot nature of this study no physiological data were collected.

Depression was assessed using the Center for Epidemiologic Studies-Depression Scale (CES-D) (Radloff, 1977). This self report scale has been found to have excellent internal consistency in patient samples ($\alpha = 0.85$). In the current sample, a Cronbach α of 0.72 was found.

State anxiety was assessed by using the State-Trait Anxiety Inventory (STAI) (Spielberger, 1983). The state anxiety version of the STAI assesses situational feelings of anxiety. The STAI has demonstrated good convergent validity and internal consistency. In the current sample, a Cronbach α of 0.76 was found.

Perceived stress was assessed by using the Perceived Stress Scale (Cohen, Kamarck, & Mermelstein, 1983). This is a 10 item, psychometrically sound, global measure of perceived stress. The PSS has adequate internal consistency and is highly correlated (0.52–0.076) with symptomological measures. A Cronbach α of 0.62 was found in the current sample.

Hostility was assessed by using the MMPI based, Cook-Medley Ho Scale (Cook & Medley, 1954). This scale has been widely used in research investigating the health consequences of hostility and has been shown to have good internal consistency ($\alpha = 0.8$) and construct validity (Smith & Frohm, 1985). A Cronbach α of 0.87 was found in the current sample.

Medical symptoms were assessed by using the Medical Symptom Checklist (MSCL-90), a list of 115 possible medical symptoms a respondent might have experienced as bothersome. The score is the total number of symptoms checked. While the reliability and validity of the MSCL have not been evaluated, it has been widely used in studies of MBSR and significant reductions on the MSCL have been found (Kabat-Zinn, 1985; Kabat-Zinn et al., 1985). A Cronbach α of 0.8 was found in the current sample.

Overall health was assessed by using the SF-36, a self report general health measure (Ware, Snow, Kosinski, & Gandek, 1993). It yields an overall health index score as well as psychometrically based physical and mental health summary scores. This widely used measure has reported reliability estimates from 0.7 to 0.9. A Cronbach α of 0.7 was found in the current sample.

In addition to these outcomes, information concerning the amount of time spent on meditation practice was also collected. Participants filled out weekly diaries indicating the time spent on various meditation practices.

Intervention

All participants attended the 4-week long Meditation-Based Stress Management Program at the Columbia University Medical Center. The program was taught by an MBSR instructor trained by the Kabat-Zinn team at the University of Massachusetts, Center for Mindfulness. The intervention involves intensive training

in mindfulness meditation and its application in daily living. During the program itself, participants were introduced to three formal meditation techniques: (1) a guided sitting meditation; (2) a guided body scan meditation; and (3) mindful Hatha yoga, which involves a range of body postures.

In addition to the formal mindfulness practices, informal mindfulness practices were also introduced. Informal practices include awareness of different aspects of daily life experience such as breathing, walking, driving, cooking, eating, cleaning, showering, talking, listening, working, parenting, and playing. Informal mindfulness practices also include awareness of emotional states, thoughts, and perceptions during daily activities, as well as bringing awareness to particularly stressful situations, to options for responding to them mindfully, and to the tendency to react automatically and unconsciously, especially when under stress. Group discussion focused on the meditation practices and their potential relevance to situations or stressors in daily life. For homework, all patients were required to practice meditation daily for at least 20 min per session. Guided meditation audiotapes and a cardiac yoga video were provided during the course and were optional tools provided to assist participants with their home practice. The time, date, and duration of each meditation session was recorded in the meditation diary, along with any comments regarding the practice. The meditation instructor was available by phone to answer patients' questions or concerns regarding any of the practices throughout the duration of the intervention. During the final class, the meditation instructor worked with patients to develop strategies for continuing their meditation practices at home. Patients completed post-intervention measures after the final class.

Results

The primary aim of this exploratory study was not to test hypotheses about the intervention's efficacy, but rather, to determine the feasibility and promise of utilizing a brief Meditation-Based Stress Management program within this population. Accordingly, data analysis regarding the primary aim was essentially descriptive.

Feasibility

The overall feasibility results indicate that this intervention was highly feasible. Fifty patients were evaluated for eligibility and 35 consented for participation. Only 4 participants dropped out of the intervention before its completion. Three of these four participants dropped out after the first class and cited scheduling conflicts as their reason for dropping out. Of the 35 who consented to participate in the study, 29% were male and 71% were female. The age of participants ranged from 34 to 76 years with a mean age of 55.89 years. Forty percent (40%) of the participants were diagnosed with CHD and 60% of the participants were at high risk for developing CHD, as defined above in the eligibility criteria. See Table 1 for the details of the sample demographics.

Adherence

Overall, participants were very adherent to the intervention and to the home practice. Eighty-six percent (86%) of the participants attended all 4 of the MBSM classes and reported that they practiced at least one of the meditation practices

Table 1. Demographics.

<i>N</i> = 35	<i>n</i>	%
Gender		
Female	25	71.4
Male	10	28.6
Ethnicity		
Caucasian	24	68
African-American	2	6
Hispanic	7	20
Asian/Pacific Islander	1	3
Other	1	3
Education		
Less than high school grad	1	2.8
High school grad	1	2.8
Post high school education	5	14.2
College grad	13	37.1
Post-graduate/professional degree	14	40
(missing)	1	2.8
Employed		
Yes	24	68.6
No	11	31.4
Household income		
Less than 10,000	2	5.7
10,000–29,000	5	14.2
30,000–49,000	6	17.1
50,000–69,000	3	8.5
70,000–89,000	8	22.8
More than 90,000	9	25.7
(missing)	2	5.7
Marital status		
Married	20	57.1
Single	4	11.4
Divorced	9	25.7
Separated	1	2.9
Living with someone	1	2.9
Cardiac history		
MI	3	8.6
CAD	1	2.9
Angina	1	2.9
Stent/angioplasty	3	8.6
CABG/valve repair	6	17.1
Contributing risk factors for CHD		
Hypertension	18	51.4
High cholesterol	13	37.1
Age (> 65)	7	20
Diabetes	5	14.3
Family history of CAD	29	82.9
Current Smoker	4	11.4
History of depression	17	48.6

throughout the course. The amount of home meditation practice ranged from 20 to 487 min per week. On average, participants practiced meditation at home a total of 147 min per week. Forty-three percent (43%) of the participants took part in an optional full day retreat which occurred after the study period.

Effect on psychological and physical outcomes

The secondary aim of this study was to assess the capacity of the meditation intervention to positively affect psychological and physical outcomes in patients with CHD and those at high risk for CHD. The following outcomes were assessed using a mixed model repeated measures analysis: perceived stress, anxiety, hostility, depression, and general health scores as measured by the PSS, STAI, Cook-Medley, CES-D, SF-36, and MSCL respectively. Age, gender, history of depression, and average weekly meditation practice were entered into the model as covariates. The PROC MIXED procedure for SAS, was utilized for these analyses. PROC MIXED is considered to be a better procedure than MANOVA as it does not delete cases with missing observations; mixed models uses all available data whereas traditional models can exclude a substantial proportion of data. Also, mixed models estimate the variance as well as the mean. Estimates of the regression parameters achieve higher precision when the best-fitting variance is used. Lastly, mixed models tend to be more parsimonious than traditional models as they estimate only the essential number of parameters and therefore make better use of the available degrees of freedom. See Table 2 for the descriptive statistics of these measures.

Of the above mentioned outcomes, depression ($t = -2.12$, $p = 0.04$) and perceived stress ($t = -2.22$, $p = 0.03$) were significantly reduced after the intervention. Effect sizes were calculated for these findings. There was a moderate effect size for both depression (Cohen's $d = 0.54$) and perceived stress (Cohen's $d = 0.68$), suggesting that a future randomized controlled trial with 80% power would be highly feasible, requiring approximately 80–100 subjects. There were no significant differences found between baseline and post-intervention on the measures of anxiety, hostility, medical symptoms, or overall health.

Discussion

The primary aim of this study was to test the feasibility of implementing a brief Meditation-Based Stress Management program for patients with and at risk for CHD in an acute care setting. Many of the patients receiving medical treatment at

Table 2. Psychological and physical outcomes.

	PRE			POST			<i>p</i> -value
	<i>N</i>	Mean	Std. Dev	<i>N</i>	Mean	Std. Dev	
Anxiety ^a	35	40.486	11.001	30	36.433	11.605	NS
Medical symptoms ^b	35	22.771	11.617	30	21.2	13.273	NS
Stress ^c	35	20.314	5.764	30	17.167	6.046	0.031
Depression ^d	35	19.314	7.741	30	14.4	8.783	0.039
Mental Function ^e	35	17.086	3.543	30	18.6	4.157	NS
Physical Function ^f	35	26.486	5.643	30	26.233	3.626	NS
Hostility ^g	35	17.143	8.640	30	16.533	8.665	NS

^aState Trait Anxiety Inventory (STAI).^bMedical Symptoms Checklist (MSCL-90).^cPerceived Stress Scale (PSS).^dCenter for Epidemiologic Studies Depression Scale (CES-D).^eMental Functioning Health Measure (SF-36).^fPhysical Functioning Health Measure (SF-36).^gHostility Measure (Cook-Medley).

the University Medical Center have to travel significant distances due to the fact that they live in the greater Metropolitan area and beyond. Thus, it is imperative to address feasibility issues when attempting to create an on-site intervention at a predominantly commuter hospital. At the conclusion of the pilot, it was evident that the MBSM program was well-received by patients and was highly feasible. The four classes were attended by both local NYC residents and by those who resided outside of the NYC area and received primary care at other hospitals. Several of the non-local patients were willing to travel up to 2 h per day to attend this program. Patients enrolled in this MBSM study demonstrated higher rates of attendance than had been seen in other interventions offered at the Columbia University Integrative Medicine Program.

This pilot study shortened and adapted the standard 8-week Mindfulness-Based Stress Reduction intervention to a 4-week program to encourage commuter patients to attend. When participants were asked their opinion about the length of the program, they initially stated that a longer commitment would have been a deterrent. However, after completing the 4-week series, a great majority of the patients expressed that they would have been interested in continuing. These reports indicated that in acute care settings, clinicians may attract more patients with shorter introductory programs (i.e. 4-week interventions) that lead into more comprehensive, in-depth clinical programs.

Although the current study demonstrates good feasibility with regard to enrolling and retaining participants, longer programs may be found to be more effective in reducing stress and other psychological variables, as mindfulness practice is a way of living which is cultivated through consistent long-term practice.

The secondary aim of this study was to investigate whether a Meditation-Based Stress Management intervention could reduce depression, as well as perceived stress, anxiety, and hostility, which may themselves be risk factors for adverse cardiac events. As this pilot was not an RCT, there are limitations to the conclusions one can make about the effectiveness of the intervention; however, the results did demonstrate significant pre-post intervention reductions in stress and depression. Both perceived stress and depression were significantly reduced after the intervention. These findings therefore suggest that this intervention has the potential to positively impact psychological well-being and could perhaps subsequently affect the progression of CHD. As stress and depression are largely ignored in acute cardiac hospital settings, these findings are extremely important in regards to future research and standard of care.

The findings of the current study did not show any statistically significant reductions in state anxiety scores. These results were unexpected as depression, stress, and state anxiety scores are often highly correlated. With additional meditation practice, and longer term follow-up, it is expected that anxiety might ultimately be reduced as were depression and stress levels.

The results of this study did not demonstrate any significant changes in hostility scores. These data were also unforeseen as meditation practice is often seen within the traditional Indo-Tibetan Buddhist context to be an intervention utilized to regulate destructive emotions such as anger and frustration. One explanation of this finding may be that only 4-weeks of MBSM training is insufficient in inducing attitudinal changes sufficient to ameliorate hostility scores. The initial goal of an MBSM intervention is to teach individuals to attain mental stability and clarity fostered through attentional training which can be applied in both their meditation

practice and their daily lives. The next goal of an MBSM intervention is to help individuals gain perspective and implement distance between themselves and their psychological experiences, such as thoughts and emotions. This type of perspective taking offers the distance necessary to experience emotions, including hostility producing triggers, without overreacting or exacerbating feelings of anger. Over time, as individuals improve this ability to gain perspective and distance, it is expected that hostility levels would be reduced. As mentioned, however, it is likely that these findings/effects were limited by the time and practice constraints of our study. It is possible therefore that in a longer-term MBSM program, or in a later follow-up assessment, hostility may be found to be a CHD risk factor amenable to change.

There are limitations regarding whether the findings can be attributed to the intervention itself as this pilot study was not an RCT. However, the results of this study do show that meditation-based interventions could successfully be used as preventative and supportive programs for patients dealing with various psychological and medical conditions, particularly CHD. While comprehensive, longer-term MBSM programs might lead to more significant lifestyle and behavioral changes, the abbreviated intervention highlighted in this paper is an appropriate program for an acute medical population, such as a cardiac-surgery care center. The 4-week intervention we have developed could serve as a model for inpatient care centers nationwide.

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