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Effectiveness of Transcendental Meditation on Functional Capacity and Quality of Life of African Americans with Congestive Heart Failure: A Randomized Control Study

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Abstract

Objective— To evaluate the effectiveness of a Transcendental Meditation (TM) stress reduction program for African Americans with congestive heart failure (CHF).

Design— Randomized, controlled study

Participants and Intervention— We recruited 23 African American patients ≥55 years of age who were recently hospitalized with New York Heart Association class II or III CHF and with an ejection fraction of <.40. Participants were randomized to either TM or health education (HE) group.

Main Outcome Measures— Primary outcome measure was six-minute walk test; secondary outcomes were generic and disease-specific health-related quality of life, quality of well being, perceived stress, Center for Epidemiologic Studies Depression Scale (CES-D), rehospitalizations, brain natriuretic peptide, and cortisol. Changes in outcomes from baseline to three and six months after treatment were analyzed by using repeated measures analysis of variance, covarying for baseline score.

Results— For the primary outcome of functional capacity, the TM group significantly improved on the six-minute walk test from baseline to six months after treatment compared to the HE group (*P*=.034). On the secondary outcome measures, the TM group showed improvements in SF-36 subscales and total score on the Minnesota Living with Heart Failure scale. On the CES-D, the TM group showed significant decrease from baseline to six months compared to the HE group (*P*=.03). Also, the TM group had fewer rehospitalizations during the six months of followup.

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Conclusions— Results indicate that TM can be effective in improving the quality of life and functional capacity of African American CHF patients. Further validation of outcomes is planned via a large, multicenter trial with long-term follow-up.

Keywords

African Americans; Complementary Alternative Medicine; Congestive Heart Failure; Health Related Quality of Life; Stress; Transcendental Meditation

Introduction

Congestive heart failure (CHF) is a chronic, debilitating, and usually progressive disease that disproportionately affects African Americans.[1,2] Once diagnosed, this disease progresses more rapidly in African Americans than in Caucasians as evidenced by higher rates of initial and repeated hospitalizations and mortality.[2,3] Mortality and morbidity rates from CHF are higher for African Americans than the general population.[4] Studies indicate that progression of heart failure is largely influenced by neurohormone-, catecholamine-, and cytokine-mediated factors that may be amenable to interventions to decrease physiologic correlates of chronic stress.[5–8]

Stress is implicated in the pathogenesis and progression of heart failure. Stressful situations increase hospital readmissions in CHF patients.[8] Stress increases circulating catecholamines, activates the renin-angiotensin system, decreases ventricular fibrillation threshold, and increases blood pressure and heart rate.[5,8,9] Depression and stress are common in hospitalized CHF patients and lead to poorer outcomes and higher costs.[10] African Americans with depressive symptoms show elevated risk for hypertension and atherosclerosis, which are risk factors for CHF.[11] Congestive heart failure (CHF) patients frequently report depression, anxiety, and hostility that may be associated with impaired physical functioning due to CHF.[11–15] Psychosocial stress contributes to impaired quality of life in African Americans.[5,8–12] All of these factors are predictors of mortality, morbidity, and hospitalization.[12–15]

Mental stress appears to induce myocardial ischemia more frequently in those with low ejection fraction.[16] This finding confirms a mechanism whereby psychosocial stress may lead to CHF progression and related clinical events. While studies of psychosocial stress and CHF are few, they indicate that mind-body interventions that favorably modify neuroendocrine homeostasis may modify CHF progression. As a response, several programs have demonstrated that patient education with post-hospital followup lowers hospital readmission for CHF and enhances quality of life.[17–21] However, only a few of these models have addressed the beneficial effects of stress reduction through a complementary alternative approach.

Transcendental meditation (TM) is a widely used stress reduction program. Earlier studies (clinical and observational) have reported positive benefits of TM, such as reduction in breathing rate and plasma lactate and higher basal galvanic skin resistance.[5,8,9,12,13] Studies have shown beneficial effects of TM on cardiovascular risk factors and quality of life.[7,22] Transcendental meditation (TM) program had positive impact on the treatment of hypertension in Africans Americans.[9,12,23] Two randomized control studies of TM interventions in African Americans reported reductions in left ventricular mass and a regression of carotid atherosclerosis compared to controls.[5,12] Perceived stress was an independent predictor of new diagnosis of symptomatic CHF.[19] Lower stress-related catecholamine levels in plasma were observed after TM practice.[13] Significant reduction in ambulatory, inpatient, and health resource utilization in TM groups was observed compared to non-TM controls.[24,25]

The objective of our study was to implement the TM program as a secondary prevention tool and analyze its efficacy in improving clinical outcomes, Health-

related quality of life (HRQoL), and rehospitalization of African Americans with CHF.

Transcendental meditation (TM) has beneficial health effects; however, no studies specific to CHF in African Americans exist. Hence, the objective of our study was to implement the TM program as a secondary prevention tool and analyze its efficacy in improving clinical outcomes, Health-related quality of life (HRQoL), and rehospitalization of African Americans with CHF. We explored the effects of TM intervention on exercise tolerance as measured by the six-minute walk test, disease-specific and generic HRQoL, perceived stress score (PSS), the Center for Epidemiologic Studies Depression scale (CES-D), brain natriuretic peptide (BNP), cortisol level, and number of rehospitalizations, compared to a health education group at three and six months of followup.

Methods

Participants

We conducted a randomized, controlled trial comparing the TM program to a heart failure education (HE) program among African Americans ≥55 years of age who had New York Heart Association class II or III CHF and a left ventricular ejection fraction<.40. Study exclusion criteria were: 1) inability to verify heart failure diagnosis in medical record; 2) cognitive impairment; 3) inability/unwillingness to complete screening and intervention process; 4) enrollment in other trials on CHF; and 5) presence of another non-cardiac condition that reduced life expectancy to less than nine months. Participant identification and recruitment consisted of seven steps: 1) determining potential eligibility; 2) obtaining consent from patients' cardiologist or physician; 3) confirming eligibility; 4) screening; 5) obtaining informed consent; 6) baseline measurements; and 7) randomization. Recruitment and consent procedures were in accordance with Health Insurance Portability and Accountability Act (HIPAA) Standards for Privacy of Individually Identifiable Health Information. Our institutional review board approved the study, and all participants provided informed consent and HIPAA forms.

We identified 446 potential participants from the University of Pennsylvania Health Care System. Through medical chart review, this pool was reduced to 193 participants. Mean age of this group was 67.6 (SD=9.1) years, mean ejection fraction was .27 (SD=.10), and 47.8% were male. All received an invitation in the mail to attend a two-hour informal introductory session. Study investigators, a HE nurse instructor, and a TM instructor were present to discuss the study, answer questions, and assure the participants of the integrity of the research and privacy of their personal information. In total, 48 participants attended the two introductory sessions, and 31 provided informed consent (eight participants did not complete baseline measurements and were not randomized into the study). Twenty-three participants completed all baseline measurements and were eligible for randomization. Using a computer-generated random number, we randomly assigned each participant to either the TM or HE group. After randomization, 13 participants were in the TM group (n=13), and 10 participants were in the HE group (n=10). All investigators, data collection staff, and referring physicians were blinded to treatment assignment; a study coordinator notified the participants of their treatment assignment but was not involved in data collection. Participants were instructed not to reveal their treatment assignment except in case of an emergency.

TM and HE Interventions

Transcendental meditation (TM) is a behavioral intervention for stress reduction that is widely used and validated (http://www.tm.org/research/). It is a simple mental technique that is practiced for 15–20 minutes twice daily while sitting comfortably with eyes closed.[12] The TM program involves a seven-step course of 1.5-hour meetings over seven consecutive days,

including an introductory session, a personal interview, a personal instruction session, and followup in three small-group meetings. Follow-up refresher meetings consisted of a biweekly meeting for the first three months and a monthly meeting for the last three months. A certified instructor familiar with the sociocultural background of the participants provided TM intervention.

Participants in the HE program attended educational sessions that paralleled the time spent in TM training and practice. Health education (HE) was based on educational modules from the 2002 education program of the Heart Failure Society of America, available as downloadable modules from: http://www.abouthf.com/hf_education-materials.htm. A trained nurse conducted the HE program. Health education (HE) participants were instructed to listen to music or read for 20 minutes twice a day.

Participants from both groups were instructed to maintain a daily diary of their intervention compliance, change in food habits, and other usual activities. This diary was obtained from the participants at each follow-up meeting. Additionally, HE and TM instructors contacted the participants to confirm their compliance with the intervention. To overcome cross-contamination, participants were instructed to keep their group assignment confidential. Instructional sessions, follow-up meetings, and testings were held at different times of the day and week for each group so that they did not overlap.

Measures

Improvement in the six-minute walk test was the primary outcome measure.[6,26,27] The six-minute walk test is a practical measure of functional capacity. It is easy to administer, well tolerated, and reflective of activities of daily living.[6,26,27] To assess generic HRQoL, we used 36-item Short Form (SF-36) and Minnesota Living with Heart Failure Questionnaire (LHFQ) as heart failure-specific instruments.[28,29] The SF-36 is a self-administered questionnaire with a single, multi-item scale that assesses eight health concepts and has well-established reliability and validity.[29] The scores for each subscale range from 0% to 100%, and higher scores indicate better quality of life. The LHFQ consists of 21 questions to assess a patient's perception of how he or she is affected by heart failure, physically and emotionally. The validity, reliability, and sensitivity are established.[28] A total score is computed by summing the responses to the 21 items; higher scores indicate poorer HRQoL.

The Quality of Well-Being (QWB-SA) survey is a preference-weighted measure of general health status. It combines three scales of functioning with a measure of symptoms/problems to produce a point-in-time expression of well-being that runs from 0 (death) to 1.0 (asymptomatic full function). This self-administered survey had acceptable performance in older adults.[30,31] The PSS is a widely used instrument with excellent reliability and validity.[32] It is a 14-item self-report instrument with a five-point scale. The CES-D is a 20-item self-report depression scale developed to identify depression in the general population. It covers the major components of depression, with an emphasis on affective components: depressed mood, feelings of guilt and worthlessness, feelings of helplessness and hopelessness, psychomotor retardation, loss of appetite, and sleep disorder.[32,33]

Brain natriuretic peptide (BNP) is a biochemical marker associated with CHF. It predicts severity of heart failure and is associated with CHF hospital readmissions and outcomes.[6,34,35] Cortisol helps regulate blood pressure, cardiovascular function, and the use of proteins, carbohydrates, and fats. Secretion of cortisol increases in response to stress (physical or psychological).[8] To analyze BNP and cortisol, blood samples were drawn at baseline and at three and six months. Finally, number of readmissions during the follow-up period and primary diagnosis were obtained from a hospital administrative database. Outcome data were obtained at baseline and at three and six months after successful completion of intervention.

Statistics

The analyses of effects of treatment on outcome measures were based on an intent-to-treat analysis, ie, primary inferences were based upon randomization status and not on compliance status. Baseline assessment of comparability was performed between TM and HE groups. Continuous variables were compared between groups by *t* test. For dichotomous outcome variables, χ^2 tests or Fischer exact tests were used, as appropriate. Changes in primary and secondary outcomes from baseline to three and six months after the intervention were analyzed by repeated measures analysis of variance (ANOVA). All tests were conducted for α level of .05. To analyze the effect of TM on the six-minute walk test, we used two-way ANOVA with repeated measures in one factor (time), co-varying for baseline score by using PROC MIXED. We also tested the changes, over time, in PSS, generic HRQoL (SF-36) and QWB-SA, disease-specific HRQoL (LHFQ), and CES-D with ANOVA.

Results

Demographics of the study sample (*N*=23) are presented in Table 1. Most TM participants were men, had completed postgraduate education, and had higher income. Most HE participants had some college education and were more likely to be married. Both groups had a 95% compliance rate for all sessions and throughout the follow-up period. Both groups had comparable generic, HRQoL, QWB-SA, and CES-D scores at baseline (Table 2). Exercise tolerance was somewhat higher for the TM group than the HE group as measured by the six-minute walk test.

Using repeated measures analysis (PROC MIXED), co-varying for baseline scores, we found that the TM group had significant improvement in their six-minute walking test scores compared to the HE group (*P*=.034) after three and six months. Comparisons of mean changes in outcomes between baseline and three months and between baseline and six months are presented in Table 3 for both groups. Higher scores indicate better outcomes for QWB-SA and SF-36, while lower scores mean better outcome for PSS, CES-D, and LHFQ. In addition to the primary outcomes measure of the six-minute walking test, the TM group showed significant improvements compared to the HE on the SF-36 social function and the CES-D scales. The TM group reported a 37% reduction in total CES-D score after six months. The BNP and cortisol levels were comparable, and no other significant between-group effects were found.

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Over the six-month follow-up period, the HE group had six hospitalizations, while the TM group had three. Two CHF-related events were recorded in the TM group, compared to five in the HE group. Compared to HE groups, the relative risk for a CHF-related event in the TM group was .31. Mean length of hospital stay was 4.8 days for the HE group and three days for TM group.

Discussion

Current evidence indicates substantial opportunities to improve medical outcomes by adopting established complementary alternative medicine (CAM) techniques among practitioners, hospitals, health plans, and purchasers.[36] The results of our pilot test are encouraging.

Our results are consistent with those reported by other studies of TM as a secondary prevention tool for cardiovascular diseases.[5–9,12,13,22–25] Association of TM with lower blood pressure, enhanced quality of life, decreased health resource utilization, and decreased mortality has been shown.[5,7,9,12,13,22–25] A stress-management program for elderly CHF

patients reported positive changes in perceived stress, emotional distress, the six-minute walking test, and depression.[37]

In continuation with earlier mind-body intervention studies on TM, our study is the first to explore the effectiveness of TM as a secondary prevention tool in African Americans with NYHA class II or class III heart failure. However, several limitations should be mentioned. First, some of the comparisons should be interpreted with caution because of the small sample size. Second, we were able to compare only the demographic characteristics of those eligible patients who did not enter our study with those who participated in the study, and thus generalizability of our results is limited. Given the short followup, long-term effects of the intervention remain to be investigated. Nevertheless, our research yields information on the potential effectiveness of TM in improving HRQoL and physiologic outcomes for CHF in this high-risk population. A large, multicenter study is needed to further analyze and validate our findings.

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Table 1

Patient demographics

Variable	TM (*n*=13)	HE (*n*=10)	*P* value
Age in years (mean ± standard deviation)	64.4 ± 5.7	63.8 ± 8.9	.85
Sex (%)			.14
Male	53.85	20.00	
Female	46.15	80.00	
Education (%)			.25
8th grade	15.38	10.00	
High school	38.46	20.00	
Some college	15.38	50.00	
College graduate	7.69	20.00	
Completed postgraduate	23.08	.00	
Marital status			.07
Married (%)	39.00	78.00	
Income level (%)			
<$25,000	54.00	75.00	.36
≥$25,000	45.00	25.00	
Employment (%)			.22
Work part-time	16.00	.00	
Other (retired, disabled, or homemaker)	84.00	100	

TM=transcendental meditation; HE=health education.

Table 2

Comparisons of outcome measures at baseline (mean ± standard deviation)

Variable	TM (*n*=13)	HE (*n*=10)	*P* value
QWB	.62 ± .23	.61 ± .30	.89
PSS	32 ± 8.5	35.9 ± 7.5	.25
LHFQ			
Total	44.2 ± 16.3	52.2 ± 19.5	.29
Physical dimension	16.8 ± 6.9	18.3 ± 9.1	.65
Emotional dimension	9.2 ± 3.7	11.9 ± 5.5	.52
6-MWT (minutes) SF-36	254.02 ± 113.39	220.83 ± 131.4	.52
Physical function	39.6 ± 22.8	27.0 ± 16.7	.15
Role physical	57.7 ± 44.9	30.0 ± 32.9	.11
Role emotional	70.8 ± 37.9	61.1 ± 38.9	.63
Vitality	66.7 ± 14.9	56.3 ± 17.7	.24
Mental health	73.3 ± 28.9	71.7 ± 18.3	.90
Social function	68.8 ± 24.5	83.3 ± 18.8	.23
Bodily pain	67.8 ± 23.5	78.3 ± 24.8	.40
General health	35.4 ± 22.4	33.5 ± 23.5	.84
CES-D	14.8 ± 6.4	14.1 ± 12.1	.87
BNP (pg/mL)	311.9 ± 259	179.78 ± 215.19	.25
Cortisol (μg/dL)	17.7 ± 5.9	14.69 ± 5.06	.30

TM=transcendental meditation; HE=health education; QWB=Quality of Well-Being survey; PSS=Perceived Stress Scale; LHFQ=Minnesota Living with Heart Failure Questionnaire; 6-MWT=six-minute walk test; SF-36=36-question Short Form; CES-D=Center for Epidemiologic Studies Depression scale; BNP=brain natriuretic peptide.

Table 3

Comparisons of mean change in scores for TM and HE groups (Mean ± Standard Error)

Variable	Baseline – 3 months		Baseline – 6 months		*P* value		
	TM (*n*=13)	HE (*n*=10)	TM (*n*=13)	HE (*n*=10)	Between-Group Effect (Treatment)	Within-Group Effect (Time)	Treatment and Time Interaction
QWB	−.03 ± .13	.1 ± .11	−.1 ± .09	.02 ± .1	.51	.08	.95
PSS	.91 ± 2.1	.63 ± 2.8	3.0 ± 2.1	2.6 ± 1.7	.98	.06	.75
LHFQ							
Total	.64 ± 2.8	1.4 ± 2.3	4.5 ± 2.9	4.6 ± 4.1	.92	.10	.88
Physical dimension	.09 ± 1.5	.37 ± 1.5	2.2 ± 1.9	.25 ± 2.0	.60	.22	.51
Emotional dimension	1.1 ± .96	1.0 ± 1.9	2.1 ± 1.1	1.6 ± 1.2	.87	.28	.80
6-MWT (minutes) SF-36	−67.7 ± 24.7	−13.5 ± 15.4	−50.5 ± 25.1	6.2 ± 26	.03	.21	.84
Physical function	−.46 ± 5.2	9.4 ± 7.4	−1.0 ± 7.7	2.5 ± 6.5	.59	.86	.77
Role physical	2.7 ± 14.7	9.1 ± 15.5	−12.5 ± 11.9	9.4 ± 6.6	.81	.51	.03
Role emotional	−8.3 ± 8.2	8.3 ± 10.4	−25.8 ± 11.8	−14.3 ± 27.8	.85	.39	.39
Vitality	3.9 ± 2.8	5.5 ± 3.9	2.5 ± 4.3	1.8 ± 6.6	.48	.47	.82
Mental health	−5.0 ± 5.7	5 ± 5.8	−7.5 ± 6.1	.71 ± 5.5	.40	.92	.56
Social function	−12.7 ± 4.1	4.7 ± 3.2	−15.0 ± 6.1	12.5 ± 7.7	.01	.44	.12
Bodily pain	2.7 ± 10.6	1.25 ± 5.3	−2.5 ± 10.6	10.0 ± 3.9	.80	.44	.08
General health	.91 ± 4.4	.56 ± 4.4	−5.0 ± 5.9	−2.5 ± 4.0	.95	.22	.44
CES-D	7.7 ± 2.1	.87 ± 2.5	5.5 ± 1.5	−1.75 ± 3.6	.03	.24	.85
BNP (pg/mL)	−23.5 ± 17.1	−14.2 ± 9.8	−13.6 ± 42.9	−12.8 ± 9.9	.53	.26	.23
Cortisol (μg/dL)	−.4 ± 1.3	.91 ± 2.1	−.08 ± 1.7	−.3 ± 1.3	.77	.76	.57

TM=transcendental meditation; HE=health education; QWB=Quality of Well-Being; PSS=Perceived Stress Scale; LHFQ=Minnesota Living with Heart Failure Questionnaire; 6-MWT=six-minute walk test; SF-36=36-question Short Form; CES-D=Center for Epidemiologic Studies Depression scale; BNP=brain natriuretic peptide.