Abstract 35

The Lite HEARTEN Study: How Exercise and Relaxation Techniques Affect Subclinical Markers of Heart Disease in Women: Patterns of Change and Effect Sizes to Power Future Studies of Treatment Efficacy

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Background: Stress has been linked in epidemiologic studies to the development and progression of coronary artery disease (CAD). However the mechanism is elusive and methods to reduce the impact of stress on cardiovascular health are not well defined.

Purpose: This feasibility study was designed to assess the feasibility and potential efficacy of strategies to reduce the impact of life stress and improve cardiovascular health and function of women with heart disease.

Methods: An experimental three-group pretest/posttest randomized control group design was used to study the effects of aerobic walking exercise versus mindfulness-based stress reduction (MBSR) with support group versus control on measures of subclinical markers of heart disease. Female patients from one cardiovascular clinic, aged 18 years or older, who were stressed (per Holmes and Rahe Life Change, or Perceived Stress Scales [PSS]), with diagnosed CAD (history of stenosis ≥ 50% of one or more coronary arteries) were eligible to participate. Subjects (N = 25) were randomized to MBSR (n = 11), exercise (n = 9), or control (n = 5) groups for 12 weeks. An exercise stress test assessed exercise and aerobic capacity (peak MET). Measures at baseline and 12 weeks included vascular flow mediated dilation (FMD peak % dilation) as primary outcome; and reactive hyperemia peripheral arterial tone index (RHI) as a secondary outcome. Other secondary outcomes included blood biomarkers (pro-B-type natriuretic peptide, cortisol, and high-sensitivity C-reactive protein [hs-CRP]), psychosocial (depression [Center for Epidemiological Studies Depression Scale, or CES-D], perceived stress [PSS-14], mental function [12-Item Short-Form Health Survey Mental Component Score, or SF-12 MCS], life stress [Holmes and Rahe Life Change], control [Control Attitudes Scale-Revised, or CAS-R], anxiety [Brief Symptom Inventory, or BSI], social support [Enhancing Recovery in Coronary Heart Disease intervention, or ENRICHD]; health perceptions (SF-12), physical functioning (SF-12 Physical Component Scale, [PCS]), and 6-Minute Walk Test (6MWT). Patterns of change of variables within and between groups were examined and effect sizes generated to calculate sample size estimates for future investigations to determine treatment efficacy.

Results: Of 25 enrolled, 18 completed the study. Women completing were white, aged 36 to 81 years (mean, 64.8), all with some college education or degree. Eight were retired and 10 were employed full- or part-time; a majority were currently or previously married; a majority had family histories of CAD, and histories of hypercholesterolemia, hypertension, and previous myocardial infarction or stent; none were diabetic. The protocol was judged feasible, safe (no adverse events), and acceptable to participants despite variable adherence and some attrition. Analysis of patterns of change, from pre- to posttreatment for all variables for all subjects, then for selected variables by group, notably revealed trends for improvement in psychosocial variables (CES-D, PSS, CAS-R, BSI) in all groups. There were patterns for improvement in exercise capacity (peak metabolic equivalent [MET]), inflammation (hs-CRP), and social support (ENRICHD) in the MBSR group. There were trends for improvement in the FMD peak % dilation, Mental Component Score, and walking distance for women in the exercise group. The control also had patterns for improvement in several study variables. Effect sizes, calculated for selected variables to power future investigation for moderate effects of interventions (80% power to detect differences between groups), were examined for sample sizes (N = 20–90 women pre/post). Projecting these sample sizes, there would be sufficient power to detect improvements for MBSR in hs-CRP, peak MET, PSS, ENRICHD, and MCS for exercise; and, with n = 50 in each of the three groups, sufficient power to detect differences between groups for MCS, peak MET and RHI. A sample size of N = 157 per group would be required to detect improvement in FMD peak % dilation.

Conclusions and Recommendations: The study protocol was feasible as designed and implemented, and patterns of improvement were observed in stress and psychosocial variables, and in cardiovascular health and function. Future study with a larger sample size will extend the period of intervention and focus on adherence enhancement to explore effects of exercise and MBSR on biobehavioral outcomes of women with heart disease.

This study was funded by the Women's Heart Health Program of the Minneapolis Heart Institute at Abbott Northwestern Hospital and the Minneapolis Heart Institute Foundation, Minneapolis, MN.