

Dr. Jonathan Shaffer

The proposed K23 Career Development Award will enable Dr. Jonathan Shaffer to establish an independent research career with expertise in behavioral interventions for patients with heart failure (HF). Dr. Shaffer is a clinical psychologist whose long-term goal is to optimize a behavioral intervention to improve functional and cardiac outcomes for patients with HF, but further training is required to accomplish this goal. As such, he has assembled a multidisciplinary team of mentors to provide training in: (1) clinical trial design and conduct; (2) the pathophysiology, management, epidemiology, and exercise physiology of HF; (3) quantitative methods for dose estimation and randomized controlled trials (RCT); (4) clinical health psychology theories and practice; and (5) research dissemination. The career development plan includes completion of a Master's degree in Patient-Oriented Research from Columbia University. For his research project, Dr. Shaffer will conduct a dose-finding study and RCT of Problem-Solving Therapy (PST) for outpatients with HF and reduced quality of life (QoL). Previous research has shown that QoL is often severely diminished among HF patients, and that reduced QoL predicts mortality and morbidity. Given the mixed findings of previous trials, the minimal focus on QoL as a primary endpoint, and recommendations to consider QoL as part of high-quality clinical care, there is a need for new interventions to improve QoL for HF patients. Moreover, the complexity and financial burden of routine pharmacotherapy for HF suggest a need for new non-pharmacologic interventions. This proposal consists of two interrelated studies that together will determine the feasibility and patient acceptance of telephone-delivered PST for outpatients with stable HF and reduced QoL. Study 1 is a dose-finding study to determine the minimally effective dose (MED; in number of sessions) of telephone-delivered PST needed to produce a clinically significant QoL improvement over 8 weeks. PST will be administered to 48 participants in cohorts of 3, and the MED will be determined using the Continual Reassessment Method. Study 2 is a two-arm RCT of 44 additional participants who will be randomized in a 1:1 ratio to PST or Time Management. Study 2 is adequately powered to determine whether the MED of PST is associated with greater improvements in peak VO₂ over 8 weeks compared to Time Management. Study 2 will also evaluate the efficacy of PST versus Time Management with respect to QoL, self-efficacy, depression, daily physical activity, and distance walked during a 6-minute walk test (6MWT). A 6MWT and cardiopulmonary exercise testing will be conducted at baseline and at 8 weeks. QoL, depression, and self-efficacy will be assessed at baseline, 4, 8, and 12 weeks (and additionally at 16 and 20 weeks for Study 2). Actigraphy-assessed daily activity will be recorded throughout the intervention and follow-up period. Dr. Shaffer will use these data to design larger RCTs for subsequent R01 applications with power of 0.90 comparing PST to Time Management with QoL and cardiac outcomes as primary endpoints. These data will also inform his larger program of research on HF.
