Testing a Dietary Intervention Called parts per thousand Pro-Heartt\textsuperscript{a} to Reduce Adiposity and Enhance Cardiac Structure, Functional Status, Lipid Profiles, Glycemic Control, and Quality Of Life in Obese, Diabetic Patients with Advanced Heart Failure

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Abstract

BACKGROUND: To date, no known clinical trials have been done to test the effects of high protein (HP) diets in obese, diabetic patients with heart failure (HF). The goal of this four-year study is to explicate the role of HP diets in delaying the progression of disease in 90 patients with HF, New York Heart Association class II and III, body mass index (BMI) ≥30 kg/m², and diabetes mellitus. We hypothesize that participants randomized to the HP diet compared to a standard protein (SP) diet will show greater reductions in adiposity (e.g. weight, waist circumference, percent body fat) and greater improvements in cardiac structure, functional status, lipid profiles, glycemic control, and quality of life following the 12-week intervention and that these changes will be maintained over time.

METHODS/DESIGN: Recruitment and enrollment in this prospective, two-group, randomized trial is on-going; participants are randomized to either a HP diet which consists of 30% protein (~110 g/day), 40% carbohydrates (CHO, ~150 g/day) and 30% fat (~50 g/day) or standard protein (SP) diet which consists of 15% protein (~55 g/day), 55% CHO (~200 g/day) and 30% fat (~50 g/day). Participants will complete an intensive 12-week
supervised weight loss intervention consisting of personalized nutritional counseling and support at baseline and asked to return at 2, 4, 8, and 12 weeks. After the intensive weight loss intervention, participants will be seen in clinic every 3 months for one year (6, 9, and 12 months) to monitor weight maintenance. Data will be obtained at baseline, 12 weeks (immediately after the intensive weight loss phase), and 15 months.

**DISCUSSION:** Data from the proposed study will provide researchers and clinicians with evidence for rational recommendations for weight loss modalities that can be integrated in HF management and treatment guidelines.