

## **STATISTICAL ANALYSIS PLAN**

**Official title: Reduction of Cardiac Steatosis and Improvement of Diastolic Function by Modulating Metabolic Health in Obese Individuals**

**NCT number: NCT03448185**

**Document date:1/6/2014**

## **Power Calculations**

Per protocol analysis will be performed and include only subjects who have completed at least 80% of the prescribed training. The primary outcome for this aim will be reduction in cardiac lipid content after intervention targeting visceral fat. Myocardial triglyceride content in obese subjects with metabolic syndrome is approximately 0.9% with a standard deviation of 0.4%. We anticipate a reduction of approximately 50% to 0.45% based on prior studies. In a 2x2 design with subjects randomized to HIIT or yoga and O3-PUFA or placebo, 60 subjects will need to be enrolled to detect an absolute reduction in mean TG content to 0.45% (from 0.9%) with a standard deviation of 0.4%, alpha of 0.05 and power of 80%. To analyze the cardiac effects of reducing visceral adiposity between groups, a mixed model repeated measures analysis will be used for continuous variables such as LV mass index, LV concentricity index, and diastolic strain adjusting for age, sex and hypertension. Descriptive statistics will be used to characterize changes in anthropomorphic parameters (e.g. BMI, lean body mass) and serum biomarkers (cTnT, NT-proBNP) using a 3 factor (time, exercise, drug) repeated measures analysis of variance between the four groups.