

Statistical Analysis Plan

Data Analyses

The objectives of statistical analysis in this pilot study were to present data on (1) recruiting (e.g., the ratio of randomized participants to screenees, variability across time, etc.), (2) descriptive statistics on baseline characteristics, (3) rates of retention, adherence, dropout, and data completion, (4) rates of success by treatment group, (5) acceptability of the program to patients, (6) rates of adverse outcomes (deaths, MI, HF, other important events), and (7) costs of various aspects of the study (recruitment, determination of eligibility, retention, treatment, and evaluation of outcomes). Statistical methods were primarily descriptive, although logistic regression was used to quantify effects of intervention on success at 8 weeks and 6 months after the treatment period ends, controlling for stratum, baseline demographic variables and medical history. Analyses followed intention-to-treat principles. Statistical analyses was carried out by staff in the Biostatistics, Epidemiology and Research Design unit in the CTSI under the direction of Dr. Connett.