Statistical Analysis Plan

Heart Failure Medication Adherence

Date: July 19, 2018
Version: 1
NCT Number: NCT03402750

Data Analysis Plan

Statistical Assumptions. It is necessary to confirm the assumptions of the statistical tests that will be used in this study (ANOVA, repeated measures ANOVA, and chi-square). For repeated measures ANOVA, the assumptions are multivariate normality (a normal distribution to higher dimensions), homogeneity of the covariance matrices (that these be similar across groups), and independence of the variables. Multivariate normality will be tested using Mardia's multivariate kurtosis (Yuan, Lambert & Fouladi, 2004). Homogeneity of the covariance matrices will be tested with Mauchly's sphericity test (Mauchly, 1940). There is no statistical test for independence, but the randomized design of the study supports this assumption. ANOVA has similar assumptions, which will also be tested. Chi-square will be used if assumptions are violated. For the chi-square test, the assumptions are that the data is categorical and that the groups are independent. These assumptions will be met as a result of the study design and appropriate sample size.

Hypotheses

Hypothesis 1. Participants in the intervention group will have better medication adherence than the control group.

Hypothesis 1A. Medication adherence (calculated with medication possession ratio) of participants in the intervention group will be higher than those in the control group at 30 days.

Hypothesis 1B. Self-reported medication adherence among participants in the intervention group will be higher than those in the control group at 30 days.

These hypotheses will be tested using ANOVA.

Hypothesis 2. The Meds to Bed intervention will have strong feasibility and acceptability.

Hypothesis 2A: The Meds to Beds intervention will have at least 90% successful deliveries of medication before discharge.

Hypothesis 2B: Participants in the Meds to Beds condition will report a better experience obtaining hospital discharge medications than those in the control group.

Hypothesis 2C: Participants in the Meds to Beds condition will report a better experience overall in the study than those in the control group.

Hypothesis 2A will be tested with a proportion in the intervention condition. Hypotheses 2B and 2C will be tested using ANOVA.

Hypothesis 3. Participants in the intervention group will have lower deterioration in physical health from baseline to 30 days after discharge than the control group.

This hypothesis will be tested using repeated measures ANOVA.

Hypothesis 4. Participants in the intervention group will have a lower proportion of readmissions and deaths than the control group.

Hypothesis 4A. The intervention group will a lower proportion of readmissions at 30 days than the control group.

Hypothesis 4B. The intervention group will have a lower proportion of deaths at 30 days than the control group.

These hypotheses will be tested using a chi-square test.

Hypothesis 5. Participants in the intervention group will have lower increases in mechanisms of action variables 30 days after discharge than the control group.

Hypothesis 5A. The average length of time (in 0-30 days) before beginning a prescription medication regimen for participants in the intervention group will be lower than among those in the control group.

Hypothesis 5B. Participants in the intervention group will report lower increases in Personal Inconvenience (*Patient Factor* of belief that medications will be difficult to obtain) than those in the control group.

Hypothesis 5C. Participants in the intervention group will report a higher score in in Immediacy of Benefit (*Therapy-related factor)* than those in the control group.

Hypothesis 5D. Participants in the intervention group will report lower increases in Fatigue (*Condition-related Factor*) than those in the control group.

Hypothesis 5E. Participants in the intervention group will report lower increases in Family Inconvenience (*Social/economic factor* of reduced family support) than those in the control group.

Hypothesis 5F. Participants in the intervention group will report lower increases in Prescription-related Paperwork (*Health care team / health system factor*) than those in the control group.

Hypotheses 5A-5F will be tested using ANOVA or repeated measures ANOVA, depending on the number of times the outcome is assessed.