Statistical Analysis Plan Document Cover Page

Official Title of the Study: Home-based Approaches for Subacute Low Back Pain in Active Duty: Randomized, Controlled Trial

NCT Number: NCT03502187

Date of Document: April 17, 2018

Statistical Analysis Plan for LBP Study

Data Analysis: The study will use a repeated measure design with measures at 4 time points. The primary goal of the analysis is to compare changes over time in the two treatment groups and a usual care control group. Potential covariates may include BMI, body weight, age, and other variables deemed to potentially confound the data.

Statistical Assumptions will be examined. For these analyses, we will use simple measures of central tendency (means, medians, and mode) and variability (standard deviations). Means and standard deviations will be calculated for continuous variables and percentages for categorical variables. Coefficient will be used to examine correlations between variables. Baseline Group Differences. ANOVA and chi-square will be used to test for differences in baseline characteristics by groups and groups will be compared for equivalence of potentially confounding variables (such as age, marital status, and gender). Group inequities will be controlled in the analyses by using covariates or other appropriate statistical methods. Time Differences. Since data collected over time tend to be correlated within an individual, a linear mixed effects model will be used to deal with individual subject differences at baseline and, if appropriate, over the course of the study. Longitudinal mixed regression models will examine differences in time trends for the outcome variables among controls and those in the treatment groups. In these regression analyses, the important primary measures will be expressed as a function of time, treatment group, and group-by-time interactions, while controlling for important covariates.

Specific Aim I: To determine whether the treatment regimens are significantly more efficacious than standard PCM, using the linear mixed effect method, as described above, we will estimate separate models for each of the following dependent variables: back strength for flexion and extension, energy expenditure, steps walked per day, number of push-ups in 2-minutes, number of push-ups in 2-minutes, distance walked in 6 minutes, and time to perform the lumbar trunk muscle test. We will construct linear contrasts to compare the rate of change in each treatment group with the rate of change in the usual care group.

Specific Aim II: To determine whether the treatments improve QOL, disability and symptoms of LBP significantly more than PCM, using the same linear mixed effect method as with Specific Aim 1, we will estimate separate equations for QOL, disability and LBP symptom dependent variables. Primary independent variables will be treatment group, time, and group-by-time interaction. We will adjust for pain medication.

Missing Data. Missing data rates and patterns will be assessed; in particular, missing data rates by treatment group will be examined. For the primary analysis, we will adjust for missing data by using an intent-to-treat analysis. All of the subjects in the study will be included in the analysis. The mixed effects model deals with missingness by weighting subjects based on the data actually collected. Treatment effects will be compared on the basis of the subject's original group assignment. In addition to the traditional intention-to-treat analyses, we will assess patterns of change both within and between groups using a mixed effects regression model for repeated measures data.