

Statistical Analysis Plan Document Cover Page

Official Title of the Study: Trial of Self-managed Approaches for Patellofemoral Pain Syndrome in Active Duty Military

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Trial of Self-managed Approaches for Patellofemoral Pain Syndrome (PFPS) in Active Duty Military

Statistical Analysis Plan for PFPS Study

Data Analysis: The primary goal of the analysis is to compare changes over time in the three treatment groups and a usual care control group.

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 percentiles for categorical variables. Baseline Group Differences. ANOVA and Fisher Exact Test 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, rank and gender). Group inequities will be controlled in the analyses by using covariates or other appropriate statistical methods. Time Differences. Linear mixed effects regression models will be used to examine differences in time trends for the outcome variables among controls and those in the treatment groups. Random effects for subject will be included, and time will be examined. Our previous experience has been that for this type of intervention we find little variance explained by a random effect for time. The primary determination of group by time differences will use time as a continuous variable. 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. Secondary analyses will include time as a factor to examine responses at individual time points.

Specific Aim I: To determine whether the treatment regimens are significantly more efficacious than standard HEP, using linear mixed effects models, as described above, we will estimate separate models for each of the following dependent variables: knee strength for flexion and extension, energy expenditure, time to complete a step down test, steps walked per day, distanced walked in 6 minutes, and number of times to complete the chair rise.

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

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. 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 the mixed effects regression models.