

Official Title: Foot progression angle modification: an exploratory six-week telerehabilitation intervention in people with knee osteoarthritis.

NCT Number: TBD

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1.1 Statistical Analysis

Statistical analyses will be performed by an independent statistician (to be determined). Means and standard deviations across all participants will be calculated for each outcome measure and baseline demographic characteristics. Baseline data will be presented as descriptive data using measures of central tendency. Alpha will be set at 0.05 for all testing.

The primary focus of this study is the feasibility of the intervention. The use of a delayed-control design will be implemented to secondarily assess the efficacy of the intervention. Feasibility outcomes will be reported via summary statistics with a focus on the primary outcomes listed above.

1.1.1 Primary Statistical Testing:

Performance of the modification at the primary end point (6-week follow up) will be examined as outlined in comparison 1 below. All other outcomes measured at baseline, follow up and retention will also be examined using the comparisons below but are considered secondary to the feasibility and performance outcomes.

The statistical comparisons for laboratory-measured outcomes in descending order of priority:

- 1) Between group change at week 6 and week 10 (Delayed Group Secondary Baseline vs Immediate Group Follow up) assessed using an analysis of covariance for the difference in follow-up values while adjusting for baseline values.
- 2) Within-subject comparison of the Delayed Group intervention period, using the Delayed Group as their own control (Delayed Group Follow up vs Delayed Group Secondary Baseline) assessed using a mixed effects model with the participant as the random effect to account for the within-subject nature of the data.
- 3) Within-subject comparison of both groups' data from the intervention (excluding the Delayed Group control period) assessed using a repeated measures analysis of variance across baseline, follow up, and retention timepoints.

1.1.2 Exploratory Prediction of KAM and Optimal Modification Direction

First, bivariate Pearson correlation coefficients will be calculated for the relationship between each clinical measure and each KAM outcome. Next, a mixed stepwise linear regression will be performed for each KAM outcome (early stance peak, late stance peak, and impulse). An alpha threshold for retaining and removing the predictor will be set to 0.05 and 0.10, respectively. Significant predictors will be entered into sequential multiple linear regression models for determining the amount of KAM outcome variance explained by the individual predictors. Possible predictors will include body mass, tibial alignment, walking speed, categorical FPA and continuous FPA. We will then use logistic regression analyses to predict the optimal direction of FPA modification, defined as the FPA direction (toe-in or toe-out) which produced the largest reduction in KAM impulse at 10° of change from natural FPA, as measured during the screening test.