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

NCT Number: TBD

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Statistical Analysis Plan

Statistical analyses will be performed by an independent statistician. Means and standard deviations will be calculated for each outcome measure and baseline demographic characteristic. Baseline demographic data (e.g. age, body mass index, disease severity) will be examined for between-group differences using unpaired two-tailed t-tests. For all statistical analyses, alpha will be set to 0.05. Any multiple pairwise comparisons will be adjusted using the Bonferroni correction method.

Data will be assessed for sphericity, homoscedasticity, and normality using Mauchley's test, residual versus predicted plots, and quantile-quantile plots. Homoscedasticity and normality assumptions will be confirmed using Levene's test and Shapiro-Wilk's test, respectively. Sphericity assumption violations will be corrected for using the Greenhouse Geisser approach. Violations of homoscedasticity will be corrected for by bootstrapped model parameters. If normality is not met, a non-parametric test will be used.

Primary Hypotheses:

Repeated measures analyses of variance (ANOVA) will be performed to examine the within-group changes in learning outcomes over the six-week intervention. Between-group differences will be examined using a two-way mixed ANOVA, with the repeated measure being the learning outcome (foot progression angle change from baseline during in-lab and at-home walking) and the between-subject factor being group assignment (SMOD vs AMAC).

Secondary Hypotheses:

Biomechanical (knee joint moments), clinical (NRS knee pain, KOOS pain, symptoms, and physical function scores), and difficulty (difficulty of performing the FPA modification) change scores will be examined using an analysis of covariance (ANCOVA) with significant between-group baseline demographic group differences and baseline outcome values included as covariates.