

Study Protocol Summary

Title: Plantar Heel Pain: Multisegment Foot Motion and Muscle Function, FFI Translation, and Evaluation of Treatments

ClinicalTrials.gov ID: NCT03161314

Date of the document: 30 December 2016 (Ethic approval date)

Study 1: Comparative Study of Gait and Foot Segment Motion Between Individuals with Plantar Fasciitis and Healthy Controls

Study Protocol

This study was designed to compare multisegment foot motion and gait between individuals with PF and healthy controls. All participants were fully informed about the study and gave their consent before participating in the study. The researchers recruited adults aged 20 to 80 years. Participants included people who had been experiencing foot pain related to PF for at least one month and showed tenderness in specific areas of the foot. Those with other serious health issues, such as arthritis or neurological problems, or with severe pain preventing walking, were excluded. The healthy control group included people without any foot pain or history of PF. The two groups were matched by age, gender, height, and weight to ensure fair comparisons.

Each participant had reflective markers attached to specific points on their pelvis, legs, and feet. Using a sophisticated motion capture system and force plates, researchers recorded how their feet and legs moved while standing still and walking at a comfortable pace along an 8-meter walkway. Multiple walking trials were recorded, and the two successive trials, with gait speed similar to the controls, were selected for detailed analysis. The data were processed to remove noise and standardized over the gait cycle, allowing for meaningful comparisons between participants.

Statistical Analysis Plan

To analyze the data, the researchers first checked whether the measurements followed a normal distribution. They then compared the demographics between PF and healthy controls to confirm that the groups were well matched. After that, the main analysis investigated how foot movements and gait differed among three categories: the symptomatic side of individuals with PF, the asymptomatic side of individuals with PF, and healthy controls. This comparison was done using ANOVA, which can detect whether any group differed significantly from the others. A p-value of less than 0.05 was considered statistically significant, meaning the observed differences were unlikely due to chance.

Study 2: Translation and Validation of the Thai Version of the Foot Function Index (FFI-Th)

Study Protocol

This study employed a cross-sectional design to adapt and validate the Foot Function Index (FFI) into Thai (FFI-Th). The translation process followed internationally recommended cross-cultural adaptation guidelines. Initially, two bilingual translators independently performed forward translations from English to Thai, which were then synthesized by an expert committee into a single version. This was back-translated into English by two native English speakers fluent in Thai to check for consistency. The pre-final Thai version was harmonized through consensus among health professionals, followed by cognitive interviews with 20 individuals to ensure clarity and cultural relevance. The final version was proofread by a linguist before use.

Participants included adults who could read and understand Thai and reported foot problems. A minimum sample size of 48 participants was determined based on prior reliability studies of similar FFI versions. Data were collected using the FFI-Th questionnaire, along with the EQ-5D-5L (a quality of life measure) and a pain visual analogue scale (pain-VAS).

Statistical Analysis Plan

Data analysis was conducted using SPSS software with significance set at $p < 0.05$. Descriptive statistics summarized demographic characteristics and questionnaire scores. The study examined floor and ceiling effects to identify items with extreme response patterns and noted the frequency of “not applicable” responses.

The reliability of the FFI-Th was assessed: internal consistency was evaluated using Cronbach's alpha, with values above 0.7 indicating acceptable consistency. Test-retest reliability was measured by the intraclass correlation coefficient (ICC) from repeated assessments one week apart, with ICC values interpreted as poor (<0.5), moderate (0.5–0.75), good (0.75–0.9), or excellent (>0.9).

Construct validity was explored through Principal Component Analysis (PCA) using varimax rotation, retaining factors with eigenvalues greater than 1 to confirm the underlying questionnaire structure. Criterion validity was assessed by correlating the FFI-Th scores with both the pain-VAS and EQ-5D-5L using Pearson's correlation coefficient. Correlation strengths were interpreted as weak (<0.3), moderate (0.3–0.5), or strong (>0.5), with positive or negative values indicating the direction of the relationship.

Study 3: Effects of Strengthening and Stretching Exercise Programs on Pain and Gait in Patients with Plantar Fasciitis: A Randomized Controlled Trial

Study Protocol

This study was a double-blind randomized controlled trial conducted at Physical Therapy Center, Mahidol University. It aimed to compare the effects of strengthening versus stretching exercises on individuals with PF.

Participants were diagnosed with PF based on clinical symptoms and ultrasound measurement, and then were randomly allocated into two groups: strengthening and stretching. Both groups initially received standardized conservative physical therapy (therapeutic ultrasound and manual therapy) twice a week for 4 weeks. Subsequently, they followed their assigned home-based exercise program three days a week for 4 weeks, continuing independently for 2 months after supervised intervention ended. Participants and the physical therapist who provided a conservative PT intervention were blinded to group allocation.

Outcome assessments, including pain intensity via visual analog scale (VAS) and gait parameters measured on a force distribution platform, were performed at five time points: Baseline, 2 weeks after the intervention, 4 weeks after the intervention, 1-month follow-up, 2-month follow-up

Statistical Analysis Plan

Data distribution was tested for normality using the Kolmogorov-Smirnov test. Outcome measures were analyzed using two-way repeated measures ANOVA to examine:

- Main effects of time (changes across assessment points),
- Main effects of group (differences between strengthening and stretching groups),
- Interaction effects (whether changes over time differed by group).

Post-hoc Bonferroni tests identified specific time points with significant differences. Independent sample t-tests compared groups at individual assessment times. Statistical significance was set at $p < 0.05$. SPSS software was used for all analyses.