The Effects of Rehabilitation and Minimalist Shoes (FRAMES) on Pain, Strength, and Function in Adults with Plantar Fasciopathy

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of the Requirements for the Degree

Doctor of Philosophy

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by

Jennifer Xu

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ABSTRACT

Individuals with plantar fasciopathy (PF) can struggle with even the most simple of daily tasks due to their foot pain, leading to reduced physical activity, recurrent episodes, and an overall decline in quality of life. There are a host of deficits in physical function that can both cause and be a result of pain, including reduced intrinsic foot muscle (IFM) strength and size, poorer postural control, and compensations in gait mechanics, such as reduced impact forces on the painful limb. Combined with the increased levels of kinesiophobia and fear-avoidance that also often occur, individuals with PF can experience a cycle of reduced activity, poorer physical function, and increased fear of movement that hinders their recovery. The problem is that most individuals are recommended and pursue more passive interventions of rest, ice, orthoses, stiffer shoes, or more invasive corticosteroid injections. There are much fewer recommendations of implementing active, movement-based interventions in order to improve physical function, as a treatment for this disorder. Previous research has indicated that strengthening the IFM via exercises or through wearing minimalist shoes are an effective treatment to reduce pain and improve function. However, these studies have not observed other functional measures or psychological outcomes after these interventions.

The purpose of all 3 manuscripts was to assess the effects of implementing an 8-week routine of daily strengthening exercises and wearing minimalist shoes (FRAMES group), compared to only exercises (control), on the recovery of individuals with PF regarding pain, function, physical attributes and psychological measures.

The purpose of Manuscript 1 was to specifically asses the effects of this program on self-reported measures of pain, perception of recovery, and function at baseline, 4-weeks, and 8-weeks, assessed with patient reported outcomes. We found that individuals with PF who performed strengthening exercises for 8 weeks, with or without the addition of minimalist shoes, were able to significantly decrease their pain and increase their function. A greater percentage of individuals in the FRAMES group were also able to achieve a minimally clinically important difference in self-perceived function. However, the most important aspect of these findings is that strengthening exercises are effective in this population, and the addition of minimalist shoes did not take away from their ability to recover.

The purpose of Manuscript 2 was to assess the effects of this intervention on objective functional measures of foot morphology, IFM strength assessed via dynamometers, IFM size via diagnostic ultrasound, single-leg balance with a force plate, and gait kinetics using pressure-sensing insoles. We found that all individuals in the study were able to achieve significant increases in IFM strength, and that several IFM muscles achieved significant increases in only the FRAMES group, which were the flexor hallucis brevis and quadratus plantae. However, there were no significant changes in single-limb balance in either group or any changes in impact forces during walking gait.

The purpose of Manuscript 3 was to determine what baseline factors of self-reported pain, function, psychological beliefs, and physical attributes are the most important in achieving the best improvements in pain and function after undergoing the intervention. The secondary purpose was to determine the effect of the interventions on psychological variables of kinesiophobia, fear-avoidance belief, and pain self-efficacy.

We found that individuals with poorer baseline self-reported outcomes of lower function, higher pain, and higher kinesiophobia were associated with greater recoveries in pain and function, likely because of a larger margin for improvement. We also found that physical traits of stronger and larger IFM at baseline were associated with greater reductions in pain. However, first peak impact force during treadmill walking gait and center-of-pressure path length during single-limb balance were not associated with recovery of pain or function. It was also found that the total cohort was able to decrease their kinesiophobia and increase their self-efficacy after the intervention, although there were no changes in fear-avoidance belief and no differences between the groups.

These results show that implementing a short but daily strengthening intervention, with or without the use of minimalist shoes, can improve self-reported outcome measures of pain, function, and psychological beliefs, for individuals with PF. They are also able to significantly alter their physical function. Minimalist shoes can assist in improving IFM size over 8 weeks, however, and can increase self-reported function to a greater degree than the control group. This study is the first of its kind to assess physical function and psychological variables in individuals with PF after a movement-based intervention. These findings show that improving foot and total body function for this clinical population can be an effective treatment, and that minimalist shoes can potentially serve as an adjunct treatment.

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SECTION II: MANUSCRIPT I

PERFORMING A HOME EXERCISE PROGRAM AND WEARING MINIMALIST SHOES REDUCES PAIN AND IMPROVES FUNCTION IN ADULTS WITH PLANTAR FASCIOPATHY

ABSTRACT

Background: Plantar fasciopathy (PF) is a common condition that leads to foot pain, decreased function, and a poorer quality of life. Individuals with PF experience weakened and smaller intrinsic foot muscles (IFM), which importantly serve to support the foot in weight-bearing positions. However, most passive treatments involve rest, orthoses and stretching, or more invasive corticosteroid injections, which do not target this limitation and can lead to recurring PF episodes over the years.

Purpose: The purpose of this randomized controlled trial is to determine the effect of wearing minimalist shoes and performing therapeutic exercises (FRAMES) on self-reported pain and function assessed at baseline, at 4 weeks, and 8 weeks, compared to only performing exercises (control).

Methods: 37 individuals with PF were randomly allocated into FRAMES or control groups (FRAMES: n=19 (14 female), Control: n=18 (13 female)). Both groups completed 8-weeks of a strengthening protocol, which included a myofascial release with a massage ball, calf-raises with toes elevated on a rolled towel, and calf and plantar foot stretches. The FRAMES group wore a pair of minimalist shoes for 8 weeks, which started with a transition period and ended with them wearing the shoes for 8 hours everyday for the last 4 weeks. All participants wore Fitbits to track activity over the 8 weeks, and adherence was assessed via a daily text sent to the participant with a survey link. Self-reported pain and function measures were collected at baseline, 4-weeks, and 8-weeks, which were 3 separate Visual Analog Scales for pain (VAS1: average pain over the past week, VAS2: average first-step pain over the past week, VAS3: heel pain of the day), the Global Rating of Change (GROC), and the Foot and Ankle Ability Measure (FAAM) which had 2

subscales (Activities of Daily Living (ADL) and Sport). Repeated Measures analysis of variance (RMANOVA) tests assessed changes in pain and function by time and group. Percent change and percent of individuals who achieved MCID was also calculated.

Results: 34 participants completed the intervention (43.60 ± 11.5 years, 77.4 ± 10.8kg, 168 ± 9.56cm; 35.8 ± 11.4 years, 77.4 ± 15.5 kg, 165 ± 7.78cm), due to 3 dropouts (n=2 control and n=1 FRAMES), who were not included in analysis due to lack of follow-up which would not answer the research question. There were no between-group differences or group-by-time differences. However, there significant effects by time, as the total cohort reported significantly decreased pain for VAS1 ($p<0.001$, FRAMES 38.8±18.4 to 16.3±19.8; Control 50.8±19.6 to 28.9±20.73), VAS2 ($p<0.001$, FRAMES 49.0±15.4 to 26.5±19.6; Control 57.0±25.4 to 31.0±24.0), VAS3 ($p<0.001$, FRAMES 36.8±21.0 to 21.3±18.5; Control 54.5±19.9 to 27.3±19.7), and increased function for both ADL ($p<0.001$, FRAMES: 77.0±13.7 to 92.5±8.07; Control: 77.7±14.1 to 87.1±10.3) and Sport ($p<0.001$, FRAMES: 50.1±25.1 to 75.8±22.7; Control: 56.0±27.8 to 71.4±28.7) subscales after the 8-week protocol (3.82 ± 3.52 days after day 56 of protocol). A greater percentage of individuals in the FRAMES group achieved MCID for VAS1 (88.89% to 56.25%), FAAM ADL (77.78% to 50%), and FAAM Sport (88.89% to 56.25%) subscales. Percent change was greater in the FRAMES group compared to control for FAAM ADL (20.1% to 12.1%) and FAAM Sport subscales (51.3% to 27.5%). Adherence at 4 weeks was 75.4% ± 18.39 for the control and 84.1% ± 11.57 for FRAMES. Adherence at 8 weeks was 71.2% ± 21.59 for the control and 80.6% ± 12.93 for FRAMES.

Conclusion: Performing home rehabilitation exercises with or without the addition of minimalist shoes improved pain and function in adults with PF, although a greater percentage of individuals achieved meaningful changes in the minimalist shoe group, especially in self-perceived function. Importantly, the minimalist shoes did not exacerbate pain for any individuals and could provide an alternative treatment for PF.

Word count: 614

Key words: plantar fasciopathy, plantar fascia, intrinsic foot muscles, minimalist shoes, chronic pain

INTRODUCTION

Plantar fasciopathy (PF) is a common condition that leads to pain,[1] limited functional ability,[2] and decreased quality of life.[2] The plantar fascia, a broad band of tissue on the dorsal aspect of the foot, passively stiffens the arch upon weightbearing[3] and provides support to the medial longitudinal arch (MLA). PF occurs from a mechanical overload to the tissue,[3] due to a sudden increase in body mass, weight-bearing physical activity, or both, simultaneously.[4] Common signs are sharp or stabbing pain[1] that is worse immediately upon weightbearing in the morning after a long period of laying down or after a long period of sitting still, as the plantar fascia is in a contracted or relatively shortened state and stretches upon the first step.[5] The pain may lessen after beginning movement.[6] However, pain may also worsen following bouts of prolonged activity such as intense training sessions.[6,7]

Patients with PF report worse quality of life via the Foot Health Status Questionnaire compared to individuals without PF[8,9] in both foot-specific (i.e., foot pain, foot function, footwear, general foot health) and general health domains (i.e., lower physical activity, social capacity, and vigor). Further, worse levels of pain, function, and quality of life after 12 months of PF have been shown to be predicted by baseline psychological factors, such as depression and neuropathic pain.[10] Individuals with PF report reduced physical activity[11] and reduced energy to complete physical tasks.[9] The reduced activity and mobility due to pain could potentially lead to long-term consequences such as dissatisfaction with life and resulting negative emotions, weight gain, cardiovascular issues such as hypertension or coronary artery disease, and non-insulin dependent diabetes.[12]

Individuals with PF may attempt to treat the condition on their own, or simply push through the pain, which could be common among athletes or individuals who are on their feet in their occupation. They may delay treatment until their symptoms are considered chronic,[12] which is known to prolong PF symptoms,[13] and could have disastrous long-term consequences for general health and wellness.[2] However, even if individuals do pursue earlier treatment, there is a lack of consensus on best treatments for PF, as studies on PF treatments are plentiful, but findings and clinical implications are limited by heterogeneity of treatment administration and lack of consistent outcome measures.[4] These treatments include conservative measures such as night splints and rest,[14] manual therapy including joint and soft tissue mobilizations,[7] stretching, and more invasive procedures such as corticosteroid injections.[4] The risk of having PF is 45.6% at a mean 10 years after symptoms begin, even with multiple treatments pursued,[15] showing the difficulty of treating this condition to full resolution in the long-term for some individuals.

Performing rehabilitation exercises has been shown to be effective in nearly every randomized controlled trial for reducing pain and improving function, which includes extrinsic foot muscle exercises such as calf-raises[16,17] and intrinsic foot muscle (IFM) exercises such as the short foot exercise.[18–21] These findings are important as individuals with PF have decreased ankle and IFM strength.[2,22] Additionally, walking in minimalist shoes for 8 weeks leads to increased IFM strength and size in healthy individuals,[23] and using minimalist shoes improves pain and function in individuals with PF.[24,25] This is because PF is a mechanical disorder[3] due to the demand that is placed upon the plantar

fascia. The IFM assist the plantar fascia in propulsion[26] and strengthening the muscles may offload the tissue for some pain relief.

Individuals with PF self-report decreased function[24] and activity,[11] most likely due to pain. This lack of use could potentially lead to reduced IFM strength and place an even greater demand on the plantar fascia, as these components work in tandem for human function.[27,28] This could further contribute to the pain a patient experiences, creating a cycle of dysfunction. Interventions such as arch supports, heel cups, and supportive shoes have been recommended in the past, along with instructions to avoid thin and flexible footwear and the subsequent excessive stretching of the plantar fascia.[14,24,29] Therefore, it may seem counterintuitive to think that minimalist shoes may help because wearing highly flexible minimalist shoes increases the range of motion for the foot, especially in toe extension which would stretch the plantar fascia. However, it is known that wearing minimalist shoes can improve IFM strength in healthy individuals,[30] most likely because the lack of support from the footwear increases active IFM support for the foot arch.[31] Thus it is curious if the minimalist shoes can work to improve IFM strength and in turn, offload the plantar fascia[28] and improve an individual's self-perceived function in activities of daily living and athletic pursuits. Additionally, the increased foot flexibility during physical movements while wearing minimalist shoes could actually provide a stretch for the plantar fascia in every step, as opposed to just during stretching exercises which have been known to improve some symptoms.[4,7] Lastly, wearing minimalist shoes is shown to increase plantar load distribution,[32] which may spread out the demand placed on the foot and allow for other structures such as the IFM to assist in movement.

The purpose of this study is to determine the effect of wearing minimalist shoes and performing therapeutic exercises (FRAMES) on pain and function via patient-reported outcomes (PROs) assessed at baseline, at 4 weeks, and 8 weeks, compared to only performing exercises (control). A secondary aim is to determine if baseline levels of self-reported pain and function, along with number of months having experienced PF, can influence the degree of recovery in individuals with PF. We hypothesized that adults with PF who wear minimalist shoes and perform rehabilitation exercises for 8 weeks would reduce their pain and improve function to a greater degree than the control group who only performed rehabilitation exercises for 8 weeks.

METHODS

This was an 8-week randomized controlled trial where individuals with PF were randomized into either the control group, which consisted of rehabilitation exercises, or the foot rehabilitation and minimalist shoes group (FRAMES), which consisted of the same exercises and the use of minimalist shoes during daily activity. The study was approved by the University's Institutional Review Board for Health Sciences Research (HSR-230045).

Participants

We enrolled 37 individuals with PF from UVA and the surrounding community using advertisements on social media, in public buildings, and by running clubs, as well as by clinician referral. All participants were included if they were between 18-55 years old,[24] with first-step pain in the morning over the past week at a Visual Analog Scale (VAS) score between 30 – 70mm[8,33] and pain for at least a month with insidious onset.[18] Individuals were excluded if they self-reported other current lower extremity

neuromusculoskeletal injuries or within the past 3 months, previous history of foot and ankle fractures or surgeries, current participation in a formal rehabilitation program for PF, current pregnancy, and previous experience in minimalist shoes. All participants provided their informed consent prior to beginning any study procedures.

Procedures

Participants were initially screened by filling out an online form indicating their answers to the inclusion and exclusion criteria. Study data were collected and managed using REDCap electronic data capture tools hosted at the University of Virginia.[34,35] Then, participants were screened over the phone to confirm the criteria and allow potential participants to ask any questions they may have had about the study. Participants were then invited to attend a baseline session, where their PF was confirmed via evaluation by a trained clinician including questions about the pain and palpation on the heel; the thickness of the plantar fascia was also scanned using diagnostic ultrasound (Acuson Freestyle, Siemens, Munich, Germany) to observe if plantar fascia thickening was indeed present in these individuals, a common finding in individuals with PF.[36] The thickness was not a qualifying criteria, but it was important to understand characteristics of the participants at baseline as the thickness could potentially be related to their level of pain or dysfunction. The participant lay prone on a treatment table while an ultrasound probe was placed longitudinally along the foot at the insertion of the plantar fascia on the calcaneus,[37] and 3 images were taken at this site. (Figure 1a and 1b)

After these screening procedures, participants were randomized into either the control or FRAMES group. Participants were randomized via a computer-generated scheme set up using REDCap by another member of the study team (JH) who did not

interact with any patients. Participants were randomized to treatment group assignment using a block randomization scheme with a block size of 4 which was stratified for biological sex. Two other members of the study team (SS, CK) performed the randomization and discussed the requirements with the participants. The main assessor (JX) was blinded to group assignment.

Outcome measures: Patient-reported outcomes

Then, participants filled out a variety of patient-reported outcomes to indicate their levels of pain and function on REDCap, using the following set of surveys described below. The set of surveys was repeated at the 4 week mark via a survey link that was emailed to them, then completed again at the post-intervention session.

Visual Analog Scale (VAS): Participants indicated their pain levels on a VAS from 0-100 ("no pain", " worst pain imaginable") on 3 separate scales as detailed previously[8]: average pain over past week, first-step pain over past week, average heel pain on the day of. The VAS shows internal consistency as a measure[38] and has been previously used in PF research, especially involving those with shoe-based interventions.[24,25]

Global Rating of Change (GROC): This was only filled out at 4-weeks and 8-weeks, as participants indicated their perception of their overall recovery since the start of the study. This consists of a Likert scale from -7 to 7 ("a very great deal worse" to "a very great deal better"), allowing the individual to decide the meaningfulness of their changes in pain and function. It has high face validity and correlates highly with other PROs regarding disability for most musculoskeletal conditions. The importance of the GROC is that it allows the patient to determine which constructs of health and function

are important to them,[39] meaning individuals could indicate self-perceived recovery even without improvements in pain or function, or vice versa. The GROC has been used previously in patients with PF and was able to detect change.[40,41]

Foot and Ankle Ability Measure (FAAM): Participants indicated their ability to do activities of daily living, as well as sport, if applicable. The FAAM consists of 29 items across daily activity (ADL) and sport scales, rated 0-4 ("no difficulty at all" to "unable to do"), with a higher score indicating a higher level of function. This has high internal consistency and good reliability (0.87-0.89) for a variety of leg, ankle, and foot musculoskeletal disorders including PF.[42] The FAAM has previously been used in PF research and was able to detect change in those studies.[7,43]

Intervention Protocol:

All participants were instructed on their rehabilitation program at the end of the baseline assessment and received a handout detailing the protocol. Participants were instructed to complete the protocol every day over an 8-week time period. Protocol adherence was assessed with a daily survey sent to participants via text message using Qualtrics software (Seattle, WA). The survey asked only 3 questions:

1. What is the date?
2. Did you do your intervention today? (Yes, No)
3. Do you have any questions for the study team? (Yes, No)
    a. If Yes: when are you available in the next 48 hours for a phone call?

This survey served as a reminder to participants to perform their intervention, as well as a way to establish adherence in case that were to play a role in symptom changes. Additionally, question 3 served as a method for the participants to reach out about any

questions or concerns about the protocol, particularly if the participants were having excessive pain or wanted to leave the study. In that case, the individual was contacted by one of the study team members (SS, CK) in order to avoid un-blinding by the study assessor. Information about this was recorded on the REDCap online database.

The protocol for the exercises and the minimalist shoe intervention is described below. The prescribed sets and repetitions per week are detailed in Table 1, and images of the exercises are seen in Figures 2a-2e.

The protocol began with a myofascial release (MFR) routine[44] of ball rolling under the foot using a massage ball (Neuro Ball, Naboso Technology, Chandler, AZ). Although Lipa et al. (2022)[44] had clinicians perform the MFR, the use of home exercises in the present study required individuals to be able to perform their own MFR at home.

Participants also performed calf-raises, on a stair so that the heels could drop below the foot and create some extra tension.[16] A towel was placed on the stair and rolled up, with the toes extended at the metatarsophalangeal joints and placed on top of the towel. The participants were instructed to complete the calf raises with 3-s concentric, 3-s eccentric, and 2-s isometric phases. Although previous authors began with single-leg calf raises and instructed participants to add resistance by adding books or weights into a backpack,[16,17] it was necessary to ensure that individuals could work their way up to single-leg calf raises. Additionally, Rathleff et al. (2014)[16] completed the calf raises every other day, whereas individuals performed the protocol every day in the present study and additional load may have been excessive and potentially counterproductive. Although other authors used individual repetition maximums to guide their protocol, the sets and repetitions provided in this study ensured the ease of this protocol as it was entirely a

home program. Lastly, because this study also had a group that wore minimalist shoes, the overall load could not be excessive. The prescription of calf-rases were balanced so that the control group could still find relief, but would not overload the FRAMES intervention group.

Lastly, participants performed stretches, which included a lunge calf-stretch for the gastrocnemius muscles, a wall calf stretch with their knee bent for the soleus muscles,[18] and a plantar foot stretch.[16]

The minimalist shoes chosen for this study were the Xero HFS II (Xero, Broomfield, CO), pictured in Figure 3a-b. The shoe has a minimalist index of 86% (weight: 193g, heel thickness: 9mm, drop: 0mm, no technologies, 5/5 longitudinal flexibility, 4/5 torsional flexibility) according to a previously established rating system[45] where 100% is the most minimal shoe. A slow transition into minimalist footwear serves as a protective factor against injury,[46] meaning a slow transition would be just as important, if not more, for impaired individuals. In this study, minimalist shoes were meant to be worn for a set amount of daily hours each week, detailed in Table 1, in any weight-bearing activity such as walking or conducting chores and errands, but not running. The walking protocol slightly follows that of Campitelli et al. (2016)[47] who increased wear time by an hour every 2 weeks given their 24-week intervention, whereas our 8-week protocol increased at a faster rate to allow for a few weeks of relatively full-time wear.

Statistical Analyses

An priori sample size estimate indicated that 34 total participants would enable us to detect a moderate Cohen's d effect size (ES=0.5) between groups with 80% power and

a-priori α=0.05, moderate Cohen's d effect size (ES) of 0.5. [48] This estimate was based on a previous study which found a Cohen's d ES = 0.81 for pain on a patient-reported outcome measure (Foot Health Status Questionnaire) when investigating the effects of minimalist shoes for 6 months on individuals with PF.[24] However, our protocol was only 8 weeks and we are expecting a more conservative effect size to achieve adequate power, which explains the chosen effect size for this power analysis.

All statistical analyses were performed only on n=34 individuals due to 3 participants who dropped out after the baseline assessment and randomization. An intention-to-treat analysis was not performed because none of the dropouts completed any follow-ups. The research question specifically asked about changes in outcomes, thus it was important to only include those who completed the post-test. ANOVA testing also only allows for the use of complete data, but it would be inappropriate to impute all of their follow-up data as it would increase Type I error.[49] Lastly, baseline pain and function of the dropouts were statistically similar to the cohort of n=34.

Descriptive analyses were conducted using jamovi version 2.6.19 (Sydney, Australia) with independent samples t-tests to evaluate baseline differences between groups in age, height, weight, BMI, length of pain, and VAS and FAAM scores, with α set to 0.05 a priori. Repeated measures ANOVA (RMANOVA) tests were used to evaluate changes in VAS construct 1 (VAS1: average pain over past week), VAS construct 2 (VAS2: first-step pain over past week), VAS construct 3 (VAS3: average heel pain on the day of), FAAM ADL, and FAAM Sport scores by group and time. Within-group and total cohort p-values across time were also included. An RMANOVA test was used to evaluate changes in the GROC scores at 4-weeks and 8-weeks. For the

RMANOVA model, Y_{ij} is the score for subject i at timepoint j, μ is the grand mean, α_j is the fixed effect of time (level j), β_k is the fixed effect of group (group k), $(\alpha\beta)_{jk}$ is the interaction between time and group, s_i is the random effect for subject i, and ε_{ij} is the residual error. The model is: $Y_{ijk} = \mu + \alpha_j + \beta_k + (\alpha\beta)_{jk} + s_i + \varepsilon_{ijk}$, where $s_i \sim N(0,\sigma^2_s)$ accounts for the individual variability across subjects, and $\varepsilon_{ijk} \sim N(0,\sigma^2)$ is the residual error.

Cohen's d effect sizes were also calculated between groups with pooled SD at each timepoint, and calculated from baseline to 8-weeks with the baseline SD for each group. Box-and-whisker plots were used to show significant differences visually.

An analysis was conducted to determine how many individuals in each group achieved the minimal clinically important difference (MCID) as a percentage. Previous studies established MCID to be a decrease of 8mm on the 100mm VAS for VAS1 and 19mm for VAS2 for patients with PF.[50] MCID was 8 points for FAAM ADL and 9 points for FAAM Sport subscales, according to a previous validity study conducted with a variety of foot and ankle disorders that included PF.[51] Participants who exceeded the MCID at the 8-week session were categorized as responders. The percent change of pain and FAAM scores were calculated per group. Adherence at 4-weeks was calculated by dividing the number of "yes" answers to question 2 by 28, and dividing by 56 for adherence at 8-weeks. A RMANOVA was also conducted to assess differences in protocol adherence by time (4-weeks and 8-weeks) and group. Lastly, a correlation matrix was conducted for baseline VAS and FAAM scores.

RESULTS

34 individuals completed this study (n=2, 1 from each group, dropped out after the baseline session citing reasons of lack of time or unwillingness to complete the protocol; n=1 control group dropped out because of pain). Figure 4 indicates the flow of the study. The 4-week session of filling out patient-reported outcome surveys occurred 1.34 ± 1.73 days after the mid-point day in the protocol (day 28). The 8-week follow-up session was 3.82 ± 3.52 days after the end of the protocol (day 56).

Mean and SD of baseline demographics, as well as VAS1, VAS2, VAS3, FAAM ADL, and FAAM Sport scores are in Table 2, along with p-values indicating significant differences at baseline between groups. Only VAS3 scores (average pain on the day of) differed at baseline between groups ($p=0.017$) according to the independent t-test.

Table 3 reports the mean and the mean and SD of demographics, VAS1, VAS2, VAS3, GROC, FAAM ADL, and FAAM Sport scores for 4-week and 8-week sessions, alongside indications of significant main or interaction effects, p-values within group with Tukey's HSD corrections, and Cohen's d effect sizes between baseline and 8-weeks. Figures 5a-c, 6, and 7a-b show the changes visually. There were significant main effects of time for VAS1, VAS2, VAS3, FAAM ADL, and FAAM Sport ($p<0.001$ for all), meaning that the total cohort reported significantly decreased pain and increased function over time, at both the 4-week and 8-week sessions. There were no significant effects for group by time, and there was one between-group difference (VAS3, $p=0.019$). However, post-hoc testing with Tukey's HSD adjustments revealed no significant differences at any time point between-groups. The between-group difference indicates that the average of each group in total show differences, but the significant effects by time show that both

groups improved at a similar rate. Thus a normal RMANOVA test was still completed for this variable.

Table 4 shows the percentages of participants in each group who achieved MCID after 8 weeks, as well as the percent change in both groups across 8 weeks for pain, GROC, and FAAM scores. A greater percentage of individuals in the FRAMES group (88.89%) achieved MCID for VAS1 (8 points) compared to control (56.25%), similar for the FAAM ADL (8 points, 77.78% compared to 50%, respectively) and the FAAM Sport subscale (9 points, 88.89% compared to 56.25%, respectively), while VAS2 had more similar percentages between the groups. Additionally, the FRAMES group achieved higher percent changes for FAAM ADL (20.1%) compared to control (12.1%), similar for FAAM Sport (51.3% compared to 27.5%), while all 3 pain constructs showed similar percent changes between groups.

Adherence at 4 weeks was a 75.4% ± 18.39 completion rate for the control group and 84.1% ± SD 11.57 for FRAMES. Adherence at 8 weeks was 71.2% ± 21.59 for the control group and 80.6% ± 12.93 for FRAMES. There were no significant differences in adherence between-group, but there was by time ($p=0.003$) for the total cohort, as there was decreased adherence at 8 weeks compared to 4 weeks.

Table 5 shows the correlations of baseline pain and function. Out of all 3 pain measures, VAS1 was the most significantly related to both the FAAM ADL and Sport subscales ($r=-0.584$, $r=-0.448$, respectively), although there were still significant correlations between most pain and function scores, except for VAS2 and FAAM Sport.

DISCUSSION

The results of this study indicate that an intervention of home rehabilitation exercises that includes minimalist shoes is safe, well-tolerated, and led to significant improvement in pain and function over an 8-week time period, and in as little as 4 weeks. These results provide support for the use of strengthening interventions delivered as a home exercise program for PF.

Although both groups improved their pain and function, there was no significant difference between the improvement with the minimalist shoe intervention compared to the control group. Importantly, the total cohort showed significant decreases in pain. Potentially, the exercises and the minimalist shoes both could have improved IFM strength and size, which could reduce strain on the plantar fascia, though future research must determine if changes in IFM function are possible in this population. Most interestingly, individuals with PF are often told not to wear thin and unsupportive shoes[14,52] as each step would essentially strain and stretch the plantar fascia, which could lead to worsened pain. Despite the fact that most clinicians advise thick, supportive, and inflexible footwear for their patients in order to avoid increasing pain, the present study shows that individuals with PF who used these shoes alongside a rehabilitation routine were in fact able to decrease their pain. Minimalist shoes can be safely implemented and well-tolerated in some individuals with PF, which may point to allowing for greater freedom in footwear in this population.

The results also importantly show that a greater percentage of individuals in the FRAMES group achieved MCID of average pain over the past week (VAS2), as well as FAAM ADL and Sport scores. Further, percent changes in FAAM ADL and Sport scores

were higher in the FRAMES group, and the Cohen's d effect size of FAAM ADL and Sport scores were nearly double in the FRAMES group. The greater relative amounts of improvements in function for the FRAMES groups may indicate that adding minimalist shoes to an active intervention may be beneficial for improving function, but may not be as effective for pain in only 8 weeks. It may be worth noting that self-perceived pain and function scores may not be all that related in individuals with PF. Correlation between pain at its worst and the Lower Extremity Functional Scale (LEFS), which asked similar questions to the FAAM, is nonsignificant in individuals with PF ($r=-0.25$).[53] In the present study, all 3 baseline pain scales only had low to moderate correlations with both baseline FAAM subscales. This interesting disparity between self-reported pain and function scores may align with the consideration of PF as a self-limiting injury.[54] Meaning, individuals may experience pain but still continue to function relatively normally, whether due to high expectations from their occupation, shame and embarrassment about having PF,[55] or simply because they have been adjusting to the presence of the chronic pain.[2] Lastly, the FAAM questionnaire only asks about the difficulty of completing certain actions and does not involve the word "pain". This slight separation between pain and function with these specific patient-reported outcomes could potentially explain why individuals who wore the minimalist shoes felt they had larger magnitude improvements in function and not pain, when compared to the control group.

Again, individuals with PF are often told not to avoid minimalist shoes, yet participants in this study implemented minimalist shoes in their daily lives and were able to improve their function. To be specific, the improved function for ADLs involves lower intensity actions, including standing, walking on different surfaces and slopes, stepping

up or down, squatting, and walking for time. Potentially, they could have been more willing to explore some of the lower intensity movements in the minimalist shoes because of the novel sensation of the shoes, which could have piqued their curiosity. Perhaps some movements felt better, or not much worse than normal, allowing them to feel more confident about their ability to move. Participants also could have simply felt more functional because they were able to wear shoes that they were previously told to avoid. Although they were instructed not to wear the minimalist shoes during sporting activities, the improvements in function during ADLs could have allowed individuals to feel more comfortable performing the higher-intensity actions in the FAAM Sport subscale. Those questions revolved around higher intensity actions, including running, jumping, cutting, and acceleration/deceleration movements. It is curious if the minimalist shoes led to improvements in IFM strength or confidence in movement that could have then affected self-reported function, and could be investigated with future studies. Regardless, the use of minimalist shoes in this population of adults with PF appears to improve self-reported function to a greater degree than performing exercises alone. This could be beneficial for patients with PF who have goals of improving their function in either activities of daily living or sports, not just reducing pain.

Providing rehabilitation exercises to all participants in the study was necessary to employ a standard of care, so that the control group was actually receiving some type of treatment. Therefore, this study was focused on the additive effects of minimalist shoes, as it was also important for the FRAMES group to perform exercises to provide protection for their feet. Transitioning too quickly into minimalist shoes as a runner can lead to increased injury,[46,56] thus rehabilitation exercises are recommended while

transitioning into the shoes as runners,[46] and may also apply to individuals with PF who are already vulnerable to foot pain. It was also important in this study to select a protocol of exercises that were not too time-intensive, so that the FRAMES group was not overloaded with a program. The exercises were selected based on research that myofascial release combined with stretching,[44] as well as calf-raises with metatarsophalangeal joint extension combined with stretching,[16] could decrease PF pain. This short routine was also importantly chosen to potentially improve protocol adherence, in hopes that individuals would be more willing to complete it at home due to its low time-cost, compared to some more intensive strengthening interventions in previous studies.[18,20,21] The adherence in this study was on average 76% for all individuals across the 8 weeks, with no significant differences between groups, which is lower than the previous report of 85.9% from Ribeiro & Joao (2022)[24] who only had their participants wear minimalist shoes for 6 months, 6 hours a day. It is not possible to determine exactly why the adherence was slightly lower in this present study, though it is certainly likely that the addition of exercises on top of the minimalist shoes contributed. However, some individuals also may have ceased completing the protocol near the end if they were feeling less pain, or there could have been differences based on participant demographics. Regardless, this adherence rate still led to significant decreases in pain and increases in function.

Although previous foot and ankle-based strengthening interventions with more intensive protocols found improvements in pain and function,[18,20,21] several protocols required more in-person visits,[18,21] and another protocol dictated completing the exercises 3 times a day for 6 weeks,[21] which can be very time-consuming. However, it is important

that even a short routine of massage, calf-raises, and several stretches all performed at home in the present study could improve outcomes. The specific toe-extended calf-raises in the present study were based on a previous study by Rathleff et al. (2014),[16] who found that these calf-raises and stretching could lead to improved outcomes. Although those authors used external loading with weights, this was not done in the present study because the FRAMES group likely would have been overloaded and it was important to balance their protocol. Also, there were no specific IFM exercises such as the short foot exercise unlike previously mentioned studies[18,19] because the minimalist shoes were intended to improve IFM. This could potentially reduce the need to perform IFM exercises, which require a lot of effort and time to both learn and perform.[57] Future studies should certainly investigate if the use of minimalist shoes can actually improve the strength and size of the IFM, but these improved outcomes even without direct IFM exercises are still a positive result. Although it is possible that the addition of more strengthening exercises could have improved outcomes to a greater degree, it also could have reduced protocol adherence, thus it was important to balance these components. For the minimalist shoe wear time specifically, it was important to select an easily trackable method of progression in this completely remote intervention. Campitelli et al. (2015)[47] previously tracked minimalist shoe wear time by hours worn per day with a progression over 24 weeks, and we also chose to progress the hours worn per day over the 8 weeks as a safeguard for injured individuals. Ribeiro & Joao (2022)[24] implemented a 6-hour daily wear protocol 6 days of the week for 6 months, but we determined that with a slow progression and exercises to protect against further injury, we would go up to 8 hours per day. Although a longer time period or a faster progression could certainly allow for an

increase in the use of minimalist shoes (e.g., worn during all waking and ambulatory hours), there is the potential for worsened symptoms or decreased rates of recovery with too quick of a progression. However, this should be explored with future research to understand if continuing to increase beyond 8 hours per day is still as effective, or if doses need to be more personalized, such as using a percentage of a daily average step count.

In the present study, all individuals showed significant improvements in pain and function over time regardless of group, which is somewhat different from previous studies using minimalist shoes as an intervention for individuals with PF. Ryan et al. (2009)[25] found that performing a more active rehabilitation program while wearing minimalist shoes, which included some dynamic warm-up movements and balance exercises, was beneficial in reducing pain. However, completing the routine in minimalist shoes resulted in earlier pain relief compared to using conventional running shoes.[25] Ribeiro & Joao (2022)[24] conducted a 6-month study for women in Brazil with PF with individuals wearing minimalist shoes alone (shoe group), minimalist shoes with a custom insole in the shoes (combined intervention), and a control group of 10 healthy women. The combined intervention and the shoe group both improved in their Foot Posture Index (FPI) and the Foot Health Status Questionnaire-Brazil (FHSQ-Br) which evaluates foot health compared to the control group. The minimalist shoes with a custom insole appeared to perform better than only wearing minimalist shoes, though both protocols showed improvements.[24] This could simply be because minimalist shoes alone do not provide enough assistance to the foot, and individuals with PF are in need of some type

of support during the initial recovery process. The support could come from orthoses or strengthening exercises as seen in the present study.

Table 6 demonstrates the differences in protocols across the present study and the 2 previous studies evaluating minimalist shoe usage in individuals with PF. It is clear that these studies are all quite different regarding the shoes chosen, the protocol prescription and length of time, and even demographic differences and the location of the study, which could have influenced activity or function levels. However, all 3 studies reported pain reductions in individuals who wore minimalist shoes for daily activity and/or completed a home exercise program, or for a rehabilitation exercise program while wearing minimalist shoes, which is still a beneficial finding. The increased flexibility of the minimalist shoes in these studies was likely to be beneficial in improving arch flexibility and even toe strength, compared to thicker and stiffer traditional running shoes and shoes usually recommended for individuals with PF.[14] In the present study and the study by Ryan et al. (2009),[25] both control and intervention groups experienced pain reductions following the intervention. Groups who perform rehabilitation exercises, regardless of footwear, can reduce their pain in as little as 4 weeks, which points to the benefit of strengthening and active movement as a treatment for PF.

It is important to consider the fact that Ryan et al. (2009)[25] used Nike Free shoes, which are thicker and not zero-drop compared to more minimalist shoes (Table 6, Figures 5a-c). Additionally, the Nike Free shoes have a more tapered toe compared to the Xero shoes, which could considerably "interfere with natural movement of the foot", which is an important component of minimalist shoes.[45] Potentially, the exercises themselves in the present study and the Nike Free study overpowered the effects of the minimalist

shoes. Thus it is curious how using shoes with an even higher degree of minimalism may influence results, especially those used in previous research studies for interventions such as Vivobarefoot[58] or Vibram FiveFingers.[47] Both of those brands have higher minimalist indexes[45] than Nike Free shoes or the model used in the present study.

Limitations:

The VAS3 baseline score (average pain of the day) was significantly lower in the FRAMES group. This could certainly be because sessions were conducted anytime between 9am and 7pm and the time of day could influence pain levels. This could also alter how individuals recovered, as starting at a lower pain level meant they wouldn't be able to decrease as much compared to higher scores. There were certainly limitations in the protocol as well. Home exercise programs could have resulted in variation of effort and timing, and individuals may not have been as adherent as an in-clinic program. However, it is curious if adding the need to travel to a clinic could actually decrease adherence with home exercises. Exercise modifications due to pain or inability to perform were also difficult to handle remotely. Instructions to wear shoes for specific number of hours a day did not take into account hours spent sitting or standing. The actual activity completed during the hours wearing the shoes could have differed because of occupation and associated fashion and footwear needs, and random activities that deviated from an individual's normal routine. Participants were instructed to maintain their regular activity, but there may not have been a guarantee of similar activity between individuals in the FRAMES group, which could have affected results. This could be explored in the future by using step count as a metric instead of worn hours. Additionally, self-report of protocol completion may not have been fully accurate. Individuals in the

FRAMES group could not indicate separately if they had completed the exercises and worn the shoes, due to the necessity to blind the assessor throughout the program. Lastly, the dropouts may have impacted our findings. Although their means of baseline pain and function were not different, there may have been other factors at play that caused their dropouts, and their lack of inclusion could have altered our findings. One individual dropped out due to a decrease in pain after the initial phone screen and a lack of desire to be in the intervention (control), another individual simply did not want to be in the study (FRAMES), and one individual reported increased pain with the exercises (control). It is possible that the necessity of wearing minimalist shoes in the FRAMES group dissuaded that participant, and if she had participated, her adherence could have been very poor. However, it is important to capture these different characteristics in order to understand what types of individuals would most benefit from this intervention, such as those with high compared to poor adherence, or those who decrease their pain over 8 weeks, compared to those who end up with increased pain. This was not possible because of the lack of any follow-ups in these dropouts, not even at 4 weeks, which is a limitation. In this case, we captured only those who were willing and able to complete the intervention.

Researchers may consider performing longer interventions to pursue complete pain relief, as PF is multifactorial and some individuals may benefit from longer protocols to obtain complete pain relief. The length of the study was 8 weeks, however, there were only 5 weeks of "full" wear time, or 8 hours per day, and it may be curious what 8 weeks or longer of "full" wear time could do. Future research should also investigate physiological changes in individuals with PF after an intervention of wearing minimalist shoes and/or performing strengthening exercises. Minimalist shoes can impact

gait, IFM strength, and balance in healthy individuals, authors have reported investigating the use of minimalist shoes because of the potential for increased IFM strength as an adaptation to the lack of support in the footwear.[31]

CONCLUSION

The 8-week intervention with home exercises and minimalist shoes showed significant improvements in pain and function, even in as little as 4 weeks, which was no different than the control group that did home exercises alone. The standard of care treatment, which were the home rehabilitation exercises, were effective, but the addition of minimalist shoes led to earlier and larger magnitude increases in self-reported function. These results provide an alternative in the clinical perspective for minimalist shoes to be used as a treatment option for improving self-reported function. Physicians, podiatrists, and rehabilitation professionals may consider allowing for more freedom in shoe choices during the rehabilitation process.

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Table 1. Rehabilitation Protocol

Week	1	2	3	4	5	6	7	8
MFR (mins/day)	3	3	4	4	4	5	5	5
Calf-raises	Bilateral, 3x12	2-up-1 down, 3x12	1-leg, 3x8	1-leg, 4x8	1-leg, 3x8	1-leg, 3x8	1-leg, 3x10	1-leg, 3x10
Lunge calf-stretch	2 x 30 sec.	2 x 30 sec.	2 x 30 sec.	2 x 30 sec.	2 x 30 sec.	2 x 30 sec.	2 x 30 sec.	2 x 30 sec.
Calf-stretch, knee bent	2 x 30 sec.	2 x 30 sec.	2 x 30 sec.	2 x 30 sec.	2 x 30 sec.	2 x 30 sec.	2 x 30 sec.	2 x 30 sec.
Foot Stretch (set x rep, hold)	2 x 30 sec.	2 x 30 sec.	2 x 30 sec.	2 x 30 sec.	2 x 30 sec.	2 x 30 sec.	2 x 30 sec.	2 x 30 sec.
MS (hrs/day)	1	2	4	6	8	8	8	8

MFR, myofascial release; MS, minimalist shoes; hrs, hours

Table 2. Baseline characteristics by group

	Control (n=16)		FRAMES (n=18)		Different at baseline? (p)
Variable	**Mean**	**SD**	**Mean**	**SD**	
Sex	n = 11 female		n = 13 female		
Age	35.80	11.40	43.60	11.50	0.056
Height (cm)	165	7.78	168	9.56	0.381
Weight (kg)	77.40	15.50	77.40	10.80	0.990
BMI (kg/m^2)	28.40	5.21	27.80	4.73	0.709
Months pain	15.30	9.26	15.40	13.10	0.967
VAS1 (mm)	50.80	19.60	38.80	18.40	0.075
VAS2 (mm)	57.00	25.40	49.00	15.40	0.269
VAS3 (mm)	54.50	19.90	36.80	21.0	**0.017**
FAAM ADL	77.70	14.10	77	13.70	0.889
FAAM Sports	56.00	27.80	50.10	25.10	0.522
PF Thickness (cm)	0.40	0.14	0.44	0.10	0.374

SD, Standard deviation; BMI, body mass index; VAS1, average pain over past week; VAS2, average first-step pain over past week; VAS3, pain of the day; GROC, Global Rating of Change; FAAM ADL, Foot and Ankle Ability Measure Activities of Daily Living scale; PF, plantar fascia

Table 3. Change in pain and function across time, by group and for the total cohort

		Baseline (T1)		4-week (T2)		8-week (T3)		Within group p-value			ES:	95% CI	
		Mean	SD	Mean	SD	Mean	SD	T1–T2	T1 –T3	T2–T3	T1–T3	LL	UL
VAS1†	Control	50.8	19.6	36.4	17.2	28.9	20.73	0.055	**<0.001**	0.345	-1.09	-1.83	-0.34
	FRAMES	38.8	18.4	28.1	16.3	19.8	17.8	0.200	**<0.001**	0.192	-1.05	-1.75	-0.35
	All	44.5	19.6	32.0	17.0	24.1	19.5	**0.002**	**<0.001**	**0.010**	-1.04	-1.55	-0.54
VAS2†	Control	57.0	25.4	44.3	23.3	31.0	24.0	0.391	**<0.001**	0.131	-1.05	-1.79	-0.31
	FRAMES	49.0	15.4	33.8	17.1	26.5	19.6	0.166	**<0.001**	0.656	-1.28	-1.99	-0.56
	All	52.8	20.8	38.7	26.8	28.6	21.5	**0.011**	**<0.001**	**0.017**	-1.14	-1.66	-0.63
VAS3†‡	Control	54.5	19.9	41.2	15.9	27.3	19.7	0.232	**<0.001**	0.067	-1.37	-2.14	-0.60
	FRAMES	36.8	21.0	27.1	18.1	21.3	18.5	0.508	**0.014**	0.787	-0.78	-1.46	-0.11
	All	45.1	22.1	33.7	18.3	24.1	19.1	**0.020**	**<0.001**	**0.014**	-1.02	-1.52	-0.51
GROC (Week 4–8)	Control			3.00	2.99	3.19	2.64			0.995	0.07	-0.63	0.76
	FRAMES			3.39	2.25	3.61	1.69			0.990	0.11	-0.54	0.76
	All			3.21	2.59	3.41	2.16			0.700	0.08	-0.39	0.56
FAAM ADL†	Control	77.7	14.1	81.9	12.7	87.1	10.3	0.734	**0.045**	0.178	0.76	0.04	1.48
	FRAMES	77.0	13.7	87.6	10.1	92.5	8.07	**0.010**	**<0.001**	0.171	1.38	0.65	2.11
	All	77.3	13.7	84.9	11.6	90.0	9.46	**0.004**	**<0.001**	**0.004**	1.08	0.57	1.59
FAAM Sport†	Control	56.0	27.8	68.2	26.8	71.4	28.7	0.050	0.109	0.972	0.55	-0.16	1.25
	FRAMES	50.1	25.1	65.6	21.5	75.8	22.7	**0.004**	**<0.001**	0.118	1.07	0.38	1.77
	All	52.9	26.21	66.8	23.8	73.7	25.4	**0.001**	**<0.001**	0.062	0.81	0.31	1.30

* significant for interaction effect group by time, † significant for main effect time, ‡ significant for between group, bolded values indicate significance ($p<0.05$)

SD, Standard deviation; VAS1, average pain over past week; VAS2, average first-step pain over past week; VAS3, pain of the day; GROC, Global Rating of Change; FAAM ADL, Foot and Ankle Ability Measure Activities of Daily Living scale

Table 4. MCID and Percent Change results for pain and function

	MCID			Percent change	
		% exceed MCID			
Variable	**MCID value**	**Control**	**FRAMES**	**Control**	**FRAMES**
VAS1	8mm	56.25%	88.89%	43.1%	49%
VAS2	19mm	62.50%	61.11%	45.6%	45.9%
VAS3				49.9%	42.1%
GROC				1.8%	1.8%
FAAM ADL	8 points	50%	77.78%	12.1%	20.1%
FAAM Sport	9 points	56.25%	88.89%	27.5%	51.3%

MCID; minimal clinically important difference, VAS1, average pain over past week; VAS2, average first-step pain over past week; VAS3, pain of the day; GROC, Global Rating of Change; FAAM ADL, Foot and Ankle Ability Measure Activities of Daily Living scale

Table 5. Correlations between pain and function

	VAS1	**VAS2**	**VAS3**	**FAAM ADL**	**FAAM Sport**
VAS1					
VAS2	r=0.814 p<0.001				
VAS3	r=0.907 p<0.001	r=0.688 p<0.001			
FAAM ADL	r=-0.584 p<0.001	r=-0.461 p=0.006	r=-0.478 p=0.004		
FAAM Sport	r=-0.448 p=0.008	r=-0.257 p=0.142	r=-0.379 p=0.027	r=0.565 p<0.001	

VAS1, average pain over past week; VAS2, average first-step pain over past week; VAS3, pain of the day; GROC, Global Rating of Change; FAAM ADL, Foot and Ankle Ability Measure Activities of Daily Living scale

Table 6. Studies that have used minimalist shoes as treatment for PF

	Xu et al.	Ribeiro & Joao (2022)	Ryan et al. (2009)
Participant information	Individuals with PF (>1 month), from 18-55. Pain at origin of plantar fascia, worse in morning. Baseline averages: age 39.7, height 1.66m, BMI 28.1 kg/m^2, average weekly first-step pain 53/100mm	Only women diagnosed with acute PF age 30-55 years, healthy controls. Baseline averages: age 47.1 years, height 1.65m, BMI 27.3 kg/m^2, pain 7.55/10.	Individuals with PF (at least 6 months), from 18-60. Pain origin of plantar fascia, worse with activity or in morning. Baseline averages: age 40.5, height 1.69m, BMI 28.5 kg/m^2, pain approx. 65/100mm.
Location (author)	Charlottesville, VA, USA	São Paulo, Brazil	Vancouver, British Columbia, Canada
Purpose	Investigate effects of wearing minimalist shoes and performing exercises, to exercises alone, on pain and function in individuals with PF	Investigate effects of combining a custom insole with minimalist flexible shoes and the shoes alone, in a gait-training protocol on pain and function in women with PF.	Investigate effect of performing exercises in shoes with a soft and flexible midsole compared to conventional running shoes on pain in individuals with PF
Reasoning behind study	Minimalist shoes are known to increase IFM strength, and individuals with PF have decreased IFM strength. Interested in intervention that could be lower-cost in long-term, and decrease barrier to compliance.	Previous treatments do not target foot function. Mechanical treatment of minimalist shoes: accessible, lower chance of surgical complications. Reduce plantar overload – increased flexibility → improved pressure distribution,	Insoles and injections do not target strength and flexibility of foot, which is important
Shoe used	Xero Shoes HFS II (Broomfield, CO, USA) Men's or women's running shoe. Minimalist index: 86%	Shoes Moleca (Beira Rio S.A., Novo Hamburgo, RS, Brazil) Low-cost women's walking shoe: canvas, flexible, flat, zero drop,	Nike Free 5.0 (Beaverton, OR, USA) High flexibility: 8 cross-sectional, 3 longitudinal sole clefts. Approx. <1 cm midsole thickness, no heel counter.

	Weight: 193g, heel thickness: 9mm, 0mm drop, no technologies, 5/5 longitudinal flexibility, 4/5 torsional flexibility.	5mm rubber sole, 3mm internal wedge ethylene vinyl acetate) Mass between 91-182 g, depends on size	Reported: 232g at size 9, 23mm heel height, 9mm drop (Larson).
Groups	Minimalist shoes and rehab intervention (n=18), rehab intervention only (n=16)	Minimalist shoes alone group (n=12), minimalist shoes + custom insole (n=14), control (n=10)	Nike Free group (n=9), conventional running shoes [neutral or stability shoe] (n=12)
Protocol	**8 weeks:** Daily use of minimalist shoes and rehab intervention, 7 days a week. Filled out daily online survey sent out via text.	**6 months:** Daily use, 6 hours per day, 7 days a week (at least 42 hours per week). Filled out diary to ensure wearing.	**12 weeks:** Rehabilitation protocol in shoes, 4 times a week. Balance, ankle strengthening, calf and plantar fascia stretch. Weekly submission training log.
Pain measure	VAS (0 to 100mm):	VAS (from 0 to 10cm)	VAS (0 to 100mm): peak pain in previous 24 hours
Function measure	FAAM	FHSQ-Br (from 0 to 100), Foot Function Index (FFI)	N/A
Findings	Both groups showed improvements in their pain and function, but minimalist shoe use was not superior to the rehab-only group.	The combined intervention and the shoe group both improved in their Foot Health Status Questionnaire-Brazil (FHSQ-Br) compared to control. Both groups decreased their pain (control had no pain).	Significant pain reduction in both groups. Nike Free group: significantly lower pain scores during study period, but no interaction effect.

PF, plantar fasciopathy; BMI, body mass index; IFM, intrinsic foot muscles; VAS, visual analog scale; FAAM, Foot and Ankle Ability Measure; FHSQ, Foot Health Status Questionnaire

FIGURES

Figure 1.1. (a) Ultrasound scanning position for plantar fascia thickness, and (b) Plantar fascia thickness with measurement in ImageJ

(a)

(b)

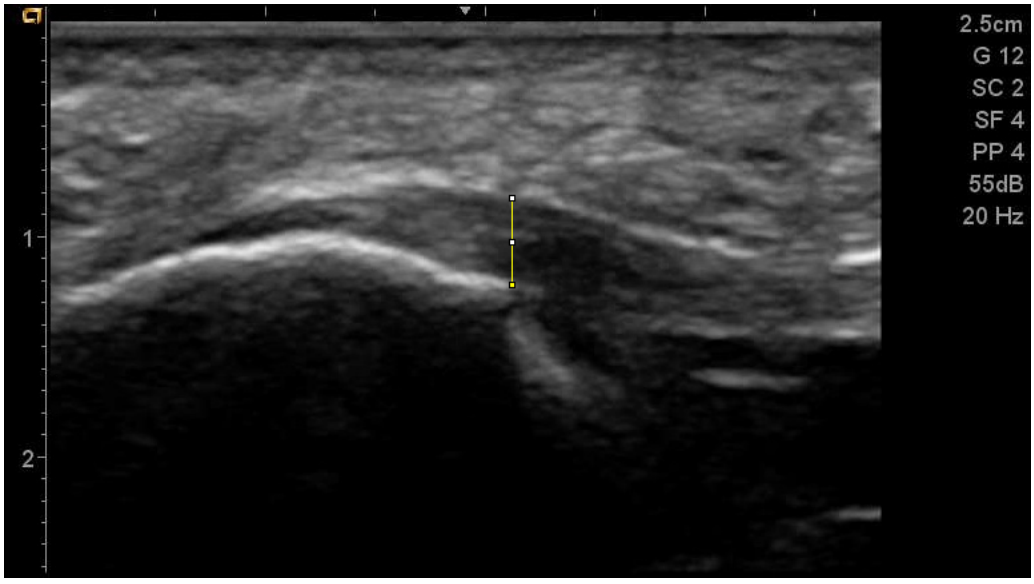
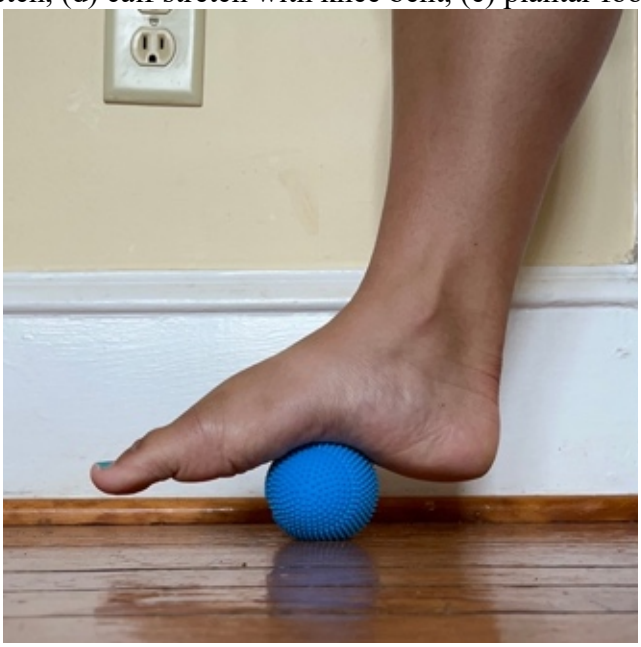


Figure 1.2. (a) Myofascial release on massage ball (Neuro Ball, Naboso Technology, Chandler, AZ), (b) Calf-raises on stair with toes elevated on towel roll, (c) lunge calf stretch, (d) calf stretch with knee bent, (e) plantar foot stretch.

(a) 

(b) 

(c) 

(d) 

(e) 

Figure 1.3. (a) Xero HFS II Women's and (B) Xero HFS II Men's Shoes chosen for this study

(a)

(b)

Figure 1.4. CONSORT diagram of study flow

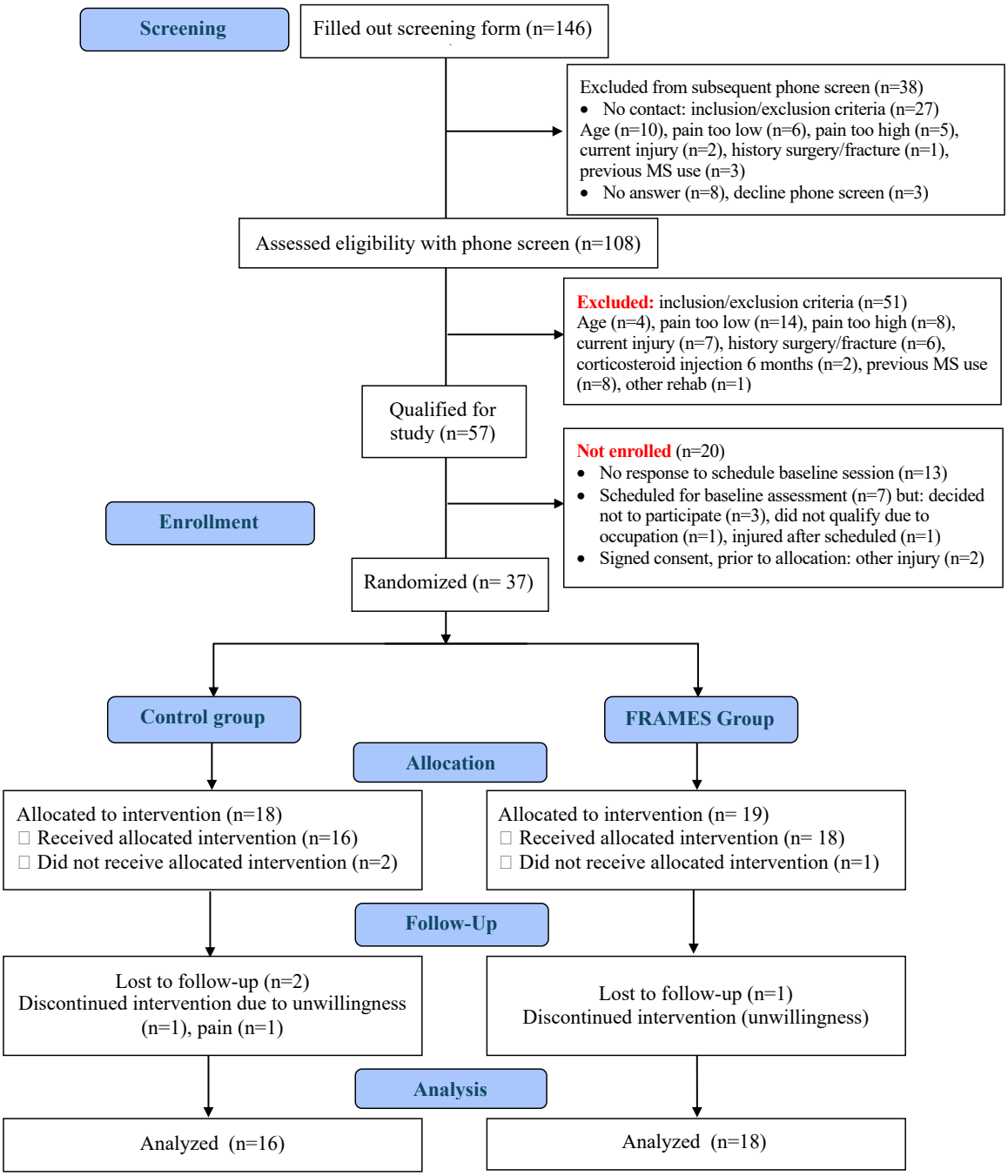
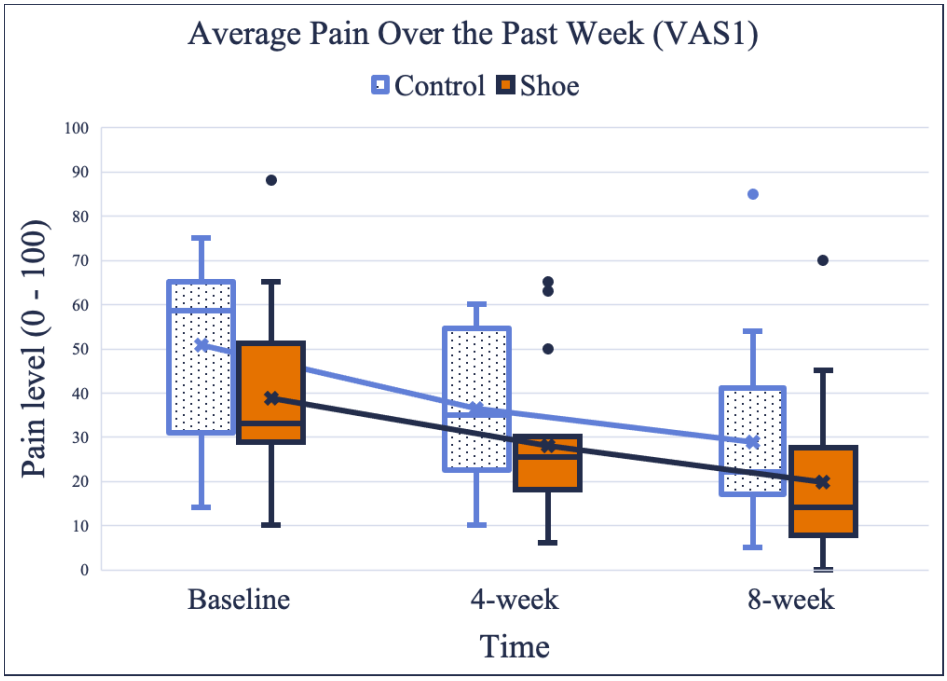
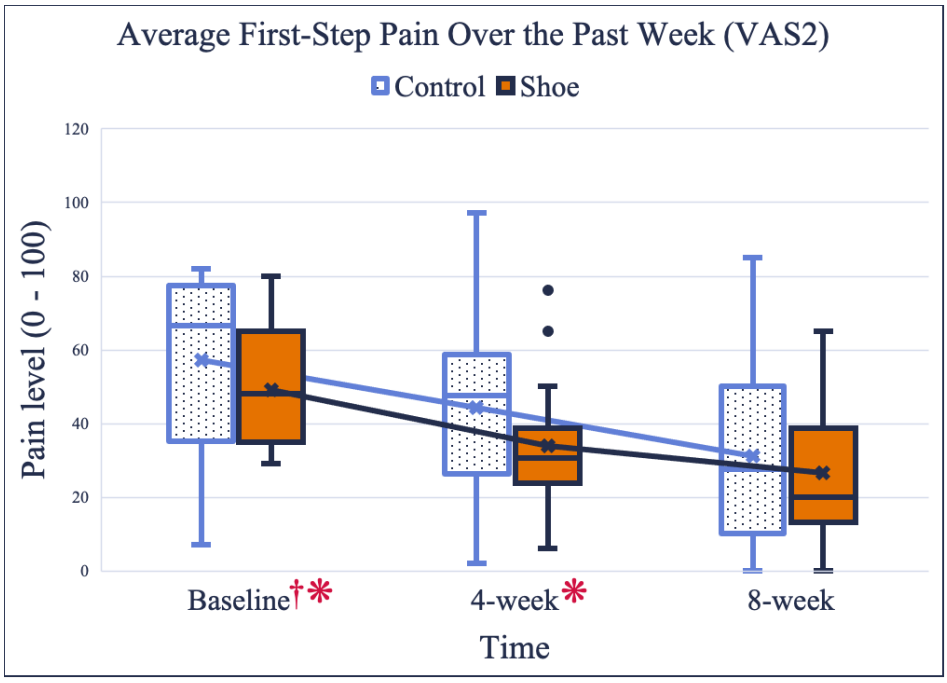


Figure 1.5. Change in pain levels across baseline, 4-weeks, and 8-weeks using the Visual Analog Scale (VAS) for (a) average pain over the past week, (b) average first-step pain over the past week, (c) heel pain of the day

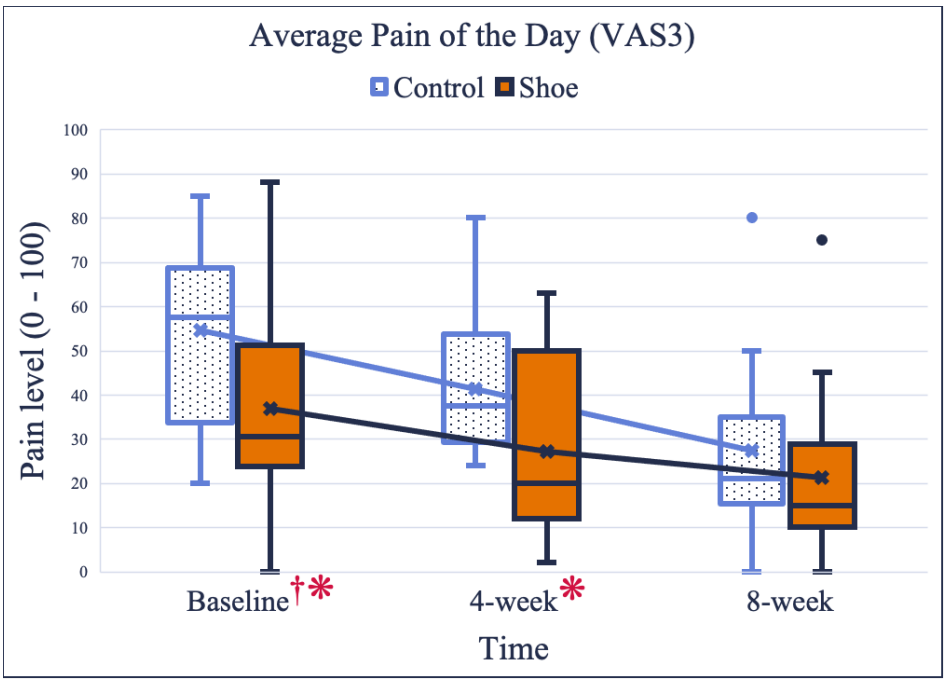
(a)



(b)

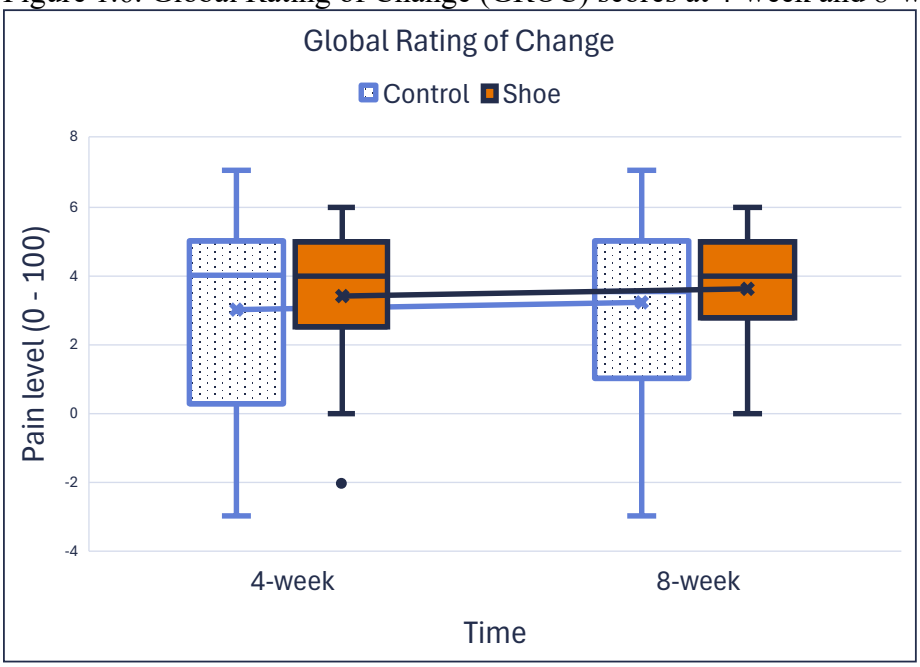


(c)



Caption: ✻ indicates significant difference from 8-week test session, † indicate significant difference from 4-week test session for total cohort. Round dots above or below boxes indicate outliers.

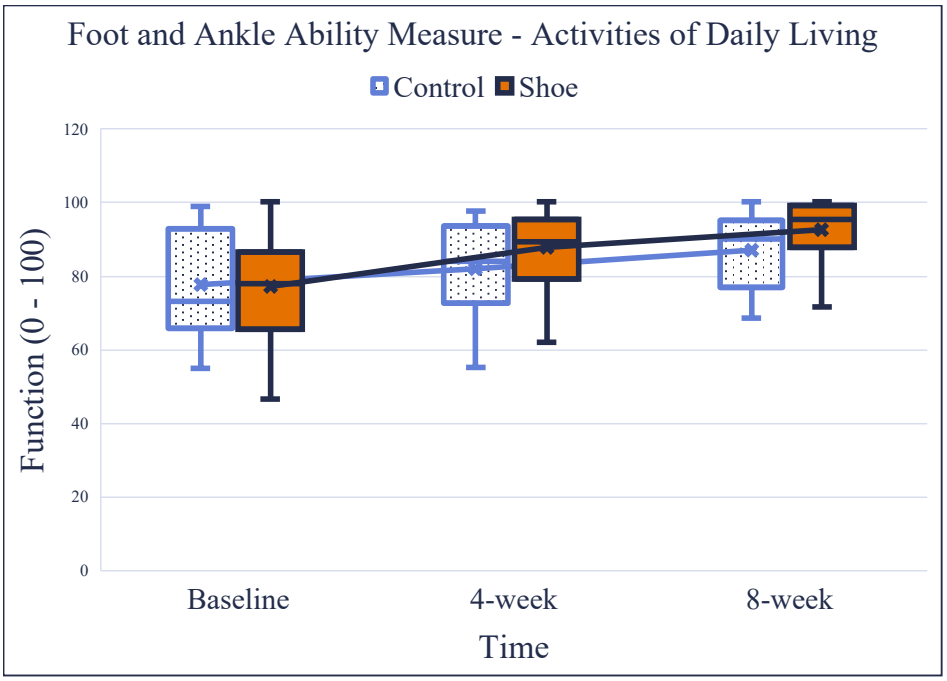
Figure 1.6. Global Rating of Change (GROC) scores at 4-week and 8-week timepoints



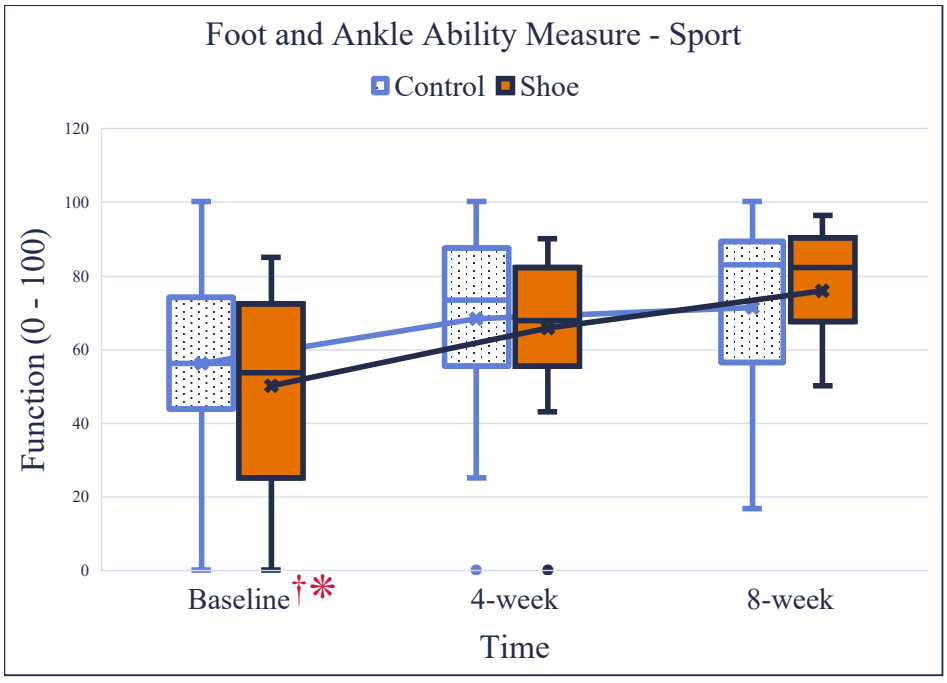
Caption: Round dots above and below boxes indicate outliers.

Figure 1.7. Change in Foot and Ankle Ability Measure (FAAM) scores across baseline, 4-weeks, and 8-weeks for (a) Activities of Daily Living subscale, (b) Sport Subscale

(a)



(b)



Caption: ✻ indicates significant difference from 8-week test session, † indicate significant difference from 4-week test session for total cohort. Round dots above or below boxes indicate outliers.

Figure 1.8. Comparison of shoe types used across studies using minimalist shoes as an intervention in individuals with PF: (a) Xero Shoes HFS II used in the present study, (b) Nike Free 5.0 Shoes (Ryan et al. (2009)), (c) Moleca shoes (Ribeiro & Joao (2022))

(a)

(b)

(c)

MANUSCRIPT II:

THE EFFECTS OF WEARING MINIMALIST SHOES AND PERFORMING REHABILITATION EXERCISES ON MORPHOLOGICAL & FUNCTIONAL OUTCOMES IN ADULTS WITH PLANTAR FASCIOPATHY

ABSTRACT

Background: Plantar fasciopathy (PF) is a commonly occurring condition that results in pain and is associated with a variety of physiological deficits, especially decreased intrinsic foot muscle (IFM) strength and size. The problem is that treatments for PF are often more passive interventions involving rest or stretching, as opposed to strengthening the lower limb and IFM to potentially intervene on some of these deficits. Minimalist shoes are one way of strengthening the IFM in healthy individuals, and have been shown to decrease pain and improve function in individuals with PF. However, it is unclear how this type of intervention could affect IFM strength and size and other functional tasks.

Purpose: The purpose of this study was to investigate the effects of wearing minimalist shoes and performing rehabilitation exercises, compared to only performing exercises, on functional measures of foot arch characteristics, IFM strength, IFM size. The secondary purpose is to examine changes in walking gait and static single-leg balance.

Methods: 34 individuals with PF were randomly allocated into the Foot Rehabilitation And Minimalist ShoES (FRAMES) group or control group (FRAMES: n=18 (13 female), 43.60 ± 11.5 years, 77.4 ± 10.8kg, 168 ± 9.56cm; Control: n=16 (11 female), 35.8 ± 11.4 years, 77.4 ± 15.5 kg, 165 ± 7.78cm). Both groups completed a strengthening protocol for 8 weeks. The exercises were a myofascial release with a massage ball, calf-raises with toes elevated on a rolled towel, and stretches for the calf foot muscles. However, the FRAMES group also wore a pair of minimalist shoes with a graded progression over the 8-weeks. All participants wore Fitbits to track steps throughout the intervention, and a daily survey was sent via text to participants to assess their adherence to the protocol. Outcome measures were collected at baseline and the post-test (8 weeks), which included

foot morphology (arch height standing, arch drop, arch height index), IFM strength with a handheld dynamometer (HHD) and novel dynamometer (ND) for the great and lesser toes separately on both feet, IFM size with diagnostic ultrasound in a weight-bearing position, single-limb balance with a force plate, and treadmill walking gait kinetics with pressure-sensing insoles. Repeated Measures analysis of variance (RMANOVA) tests assessed changes in functional measures by time and group, with Tukey HSD adjustments for post-hoc testing.

Results: Main effects of time were significant for great toes and lesser toes on both limbs on the HHD ($p<0.001$ for all), and great toes on the ND for the Non-PF ($p=0.035$) and PF limbs ($p=0.010$), showing that both groups improved IFM strength. There were significant main effects of time FHB MT Relaxed ($p=0.001$) and Resisted ($p=0.009$) with only significant increases in the FRAMES group for both conditions ($p=0.037$, $p=0.042$, respectively), and QP CSA Relaxed ($p=0.030$) and Resisted ($p<0.001$). There were no significant changes in single-leg balance ability in eyes open or closed. There were significant main effects by time for contact time both the non-PF ($p=0.003$) and PF limb ($p=0.003$), but only the control group achieved significant increases ($p=0.050$, $p=0.039$, respectively). There were also significant main effects by time for time to peak in both the non-PF ($p=0.012$, and PF limb ($p<0.001$), but only significant increases in the non-PF foot for the FRAMES group ($p=0.018$) and the PF foot for the control group ($p=0.007$). There were significant group by time effects for time to peak symmetry ($p=0.006$) with a significant increase only in the control group ($p=0.018$), and time between peak for the non-PF foot ($p=0.035$) and symmetry ($p=0.015$), showing an insignificant but diverging increase in the FRAMES group and a decrease in the control group for symmetry.

Conclusion: Individuals with foot pain who undergo a strengthening intervention with or without the addition of minimalist shoes can increase their IFM strength, but the addition of minimalist shoes led to increased size of several IFM. These are important findings when considering the potential use of minimalist shoes as a treatment to improve IFM function in healthy or clinical populations. The lack of significant changes in single-leg balance or impact forces in gait as hypothesized is likely because there were no postural control exercises or gait-retraining interventions, which could certainly be explored in the future.

Word count: 690

Key words: plantar fasciopathy, plantar fascia, intrinsic foot muscles, minimalist shoes, chronic pain, toe strength, gait, foot muscle size, postural control

INTRODUCTION

Plantar fasciopathy (PF) is a commonly occurring condition that results in pain,[1] decreased function,[2] and a large number of physiological decrements that may further contribute to dysfunction.[3] The plantar fascia is a band of tissue on the plantar side of the foot that supports the foot in weightbearing,[4] especially during propulsion in gait as it helps lift the medial arch[5] and stiffen the foot for a more efficient push-off.[4] PF occurs when the plantar fascia is mechanically overloaded,[4] and there are usually reports of unexpected increases in body mass or activity that increases strain to the tissue prior to the onset of pain.[6] Symptoms include pain that is usually worse upon weightbearing after a long period of rest or in the morning, or after bouts of prolonged activity.[7]

Notably, individuals with PF have weakened intrinsic foot muscles (IFM) compared to healthy individuals[8,9] and their uninjured limb.[8] There are also reports of decreased IFM volume[10–12] and cross-sectional area of several IFM[13] in the injured limb compared to healthy. This is significant as recent research has shown that the IFM importantly support the medial longitudinal arch (MLA) during load-bearing,[14] act as stabilizers in postural control tasks,[15] and play a large role in modulating force absorption and production at the foot during gait,[5,16] helping to offload strain on the plantar fascia.[5] Although it is not known if weakened IFM cause PF or is the result of the injury,[8] the overall problem is that weakened IFM cannot assist with movement as efficiently and likely places high demands on the plantar fascia tissue. Individuals with PF also have several impairments in functional tests compared to healthy controls, such as decreased vGRF during impact and propulsion while walking[17–19] slower walking speed,[20] and decreased dynamic and static balance ability.[20–22] The decreased IFM strength and size

likely play some role in the pathological gait and balance of adults with PF, which can subsequently affect an individual's activity and global function.

Treatments for PF are quite variable, though many have suggested more passive interventions such as rest, orthoses, or stretching.[23,24] These more passive interventions such as rest or insoles may certainly help in the short-term,[6] but resumption of activity may re-exacerbate the pain and push individuals to continue reducing activity, leading to a cycle of dysfunction. One intervention that has been shown to be successful is increase the strength of the IFM, likely because it de-loads the plantar fascia[5] to provide relief. The IFM can be strengthened with a variety of modalities, such as by performing IFM exercises[25] or by wearing minimalist shoes.[26] Minimalist shoes are highly flexible, thin, and light shoes with low heel-to-toe drop soles and no support, all with the intention of promoting natural movement of the foot.[27] The lack of support in the shoe places a demand on the foot to support itself, thereby increasing IFM strength.[28] Patients with PF who wore minimalist shoes as a treatment[29,30] have previously reported pain relief and increased function. However, no study has investigated subsequent changes in IFM strength, size, gait or balance, which are known to be negatively affected in individuals with PF.

The purpose of this study was to investigate the effects of wearing minimalist shoes and performing rehabilitation exercises, compared to only performing exercises, on functional measures of foot arch characteristics, IFM strength, IFM size. The secondary purpose is to examine how walking gait and static single-leg balance in individuals with PF will change over time after the intervention. We hypothesized that individuals with PF who both wear minimalist shoes and perform rehabilitation exercises will have greater

improvements in IFM strength and size, increases in impact forces during walking gait, and better single-leg balance compared to those who only perform exercises.

METHODS

The same number of participants (n=37) were recruited according to the same inclusion and exclusion criteria as Manuscript I. All participants provided informed consent prior to beginning any study procedures, and the study was approved by the University's Institutional Review Board for Health Sciences Research (HSR-230045).

The initial procedures of screening, assessment for PF, and randomization in the baseline session were the same as Manuscript I.

Instrumentation:

The following outcome measures were all assessed at baseline and at the follow-up session. All measurements were conducted by a board-certified athletic trainer with 8 years of experience and previous experience of using all data collection methods (JX).

Foot morphology: All measures of foot morphology were captured bilaterally. The Arch Height Index (AHI) tool (Jaktool Corporation, Cranberry, NJ) was used to measure foot length and arch height at the 50% of the foot length, (Figure 1a-c) which were used in the calculation of the Arch Height Index. The measurement was conducted in both sitting and standing positions. The test-retest and inter-rater reliability of the AHI tool is excellent in healthy individuals,[31] and has been used in individuals with chronic ankle instability but showed no differences compared to healthy.[32]

The Foot Posture Index (FPI-6) is a 6-item assessment of foot structure, with each component (3 each for the forefoot and rearfoot) rated on a scale from –2 to +2 to achieve a total score.[33] Positive values indicate more pronation and negative values indicate more

supination. Specifically, normal is 0 to +5, Pronated is +6 to +9, and highly pronated is 10+. Supinated is –1 to –4, and highly supinated is –5 to –12.

Forefoot measures included:

1) Presence of a bulge in the talonavicular joint (medial)

2) Congruence of the MLA with the floor

3) Abduction/adduction of the forefoot on the rearfoot

Rearfoot measures included:

1) Talar head palpation: palpating for the medial and lateral sides of the head of the talus

2) Curves above and below the lateral malleoli

3) Inversion and eversion of the calcaneus

The specific guidelines and the images used as reference are included in Appendix C, Additional Methods (Table C). The 6-item FPI is shown to be adequately reliable in a variety of clinical settings, with an ICC = 0.62 – 0.91),[33,34] and is recommended over the 8-item scale.[33] The FPI was validated against electromagnetic tracking software and was able to predict the variance in ankle kinematics more than other clinical measures previously reported.[33] The FPI has been used for risk factor identification, as a screening tool for foot posture type, and assessment of how foot posture is associated with injury or age.[35]

IFM strength: This was first assessed with a handheld dynamometer (HHD) [microFET2, Hoggan Scientific, Salt Lake City, UT, USA] according to previously established protocols.[31] This test has shown good-to-excellent reliability (ICC = 0.66 – 0.92) in measuring strength of the great toe and lesser toes for healthy individuals,[31] and

has been used in individuals with chronic ankle instability to successfully identify strength deficits.[32] 3 trials were collected per great toe and lesser toes of both feet. The participant was positioned hook-lying on a treatment table with the toe(s) hanging off the edge, and pushed down on the transducer without toe curl to perform the test (Figure 2a-c). The contraction was held for 3 seconds. The order of toe conditions was chosen in a Latin square formation, where the first participant tested would have their right great toe (condition 1) and left great toe (condition 3) tested, followed by the right lesser toes (condition 2) and the left lesser toes (condition 4), which would be the order "1324". Then, the second individual had the following order: 2413, and the third: 3142, the fourth: 4231, and then the order would start over again. This order simplified the testing procedure as the great toe and lesser toe tests used 2 different dynamometer attachments.

A second IFM strength assessment was conducted with a previously used handheld dynamometer (Human Locomotion, Massachusetts, USA), considered a "novel dynamometer" (ND).[36] The device has moderate to excellent intra-rater and inter-rater reliability (ICC – 0.73-0.95), and most of the strength tests on the ND and the HHD were within the 95% limits of agreement in healthy individuals.[36] 3 trials were collected per great toe and lesser toes (toes 2-5) separately, of both feet. Participants laid in a hook-lying position on the floor of an exam room with a low-pile carpet (Figure 2d), with knee flexion measured at 90 degrees. The card attached to the scale was placed under the great toe or lesser toe(s), and participants were instructed to press down with their toes as hard as they could after the assessor counted down "3,2,1, push". Then, over a count of 3 seconds (silently counted), assessors slowly pulled the handle of the device, so that the card slid out on "3". All toes on the same foot pushed regardless of the condition being

tested, and 30 seconds of rest were provided between contractions on the same foot. The order of the toe conditions were chosen in a Latin square formation again, where the first participant tested would have their right great toe (condition 1) and left great toe (condition 3) tested, followed by the right lesser toes (condition 2) and the left lesser toes (condition 4), which would be the order "1234". The order would then continue to alternate in order: "2341", then "3412", then "4123", and so on. At the baseline session, participants practiced each of the toe conditions once.

IFM Thickness and Cross-Sectional Area (CSA): This was assessed with diagnostic ultrasound using the Acuson Freestyle (Siemens, Munich, Germany) with a 3.8cm-wide and 8-Mhz linear transducer. The depth was set to either 3 or 3.5cm, depending on the size of the muscle in order to capture all borders, and gain could be adjusted by the assessor to visualize the image more easily. IFM size was assessed in a standing, weight-bearing position on a previously constructed staircase for weight-bearing IFM ultrasound measurements.[37,38] Individuals were instructed to place as much as of their weight as possible on the affected testing leg, with the other foot gently placed behind the testing foot to provide some stability (Figure 3a). In this position, the thickness (cm) and CSA (cm^2) of the abductor hallucis (ABH), flexor hallucis brevis (FHB), flexor digitorum brevis (FDB) and quadratus plantae (QP) were obtained. The measurement locations were in accordance with a previously established protocol in a supine position.[39] Although the present study performed the test in a standing, the locations were the same (Figures 3b-e).

The standing protocol shows excellent inter-rater reliability for muscle CSA, and fair to good for thickness, while intra-rater reliability ranged from fair to excellent in

healthy individuals.[38] Test-retest reliability in the supine position was excellent for resting thickness and CSA of the ABH, FDB, QP, and FHB (ICC = 0.76-0.98), and for resisted thickness and CSA of all 4 muscles (ICC = 0.75-0.92).[39] Although the testing positions differ, the reliability of IFM ultrasound measurements appears to be good to excellent overall.[40] Ultrasound is a valid and reliable alternative to MRI,[41] and shows consistently strong agreement[40] and high correlations[41] with MRI. MRI is more precise but ultrasound has a lower cost and is more accessible,[41] and has been reliably used in symptomatic populations, which can be more applicable to clinical practice.[40] Although MCID values have not been provided for ultrasound measurements of IFM in individuals with PF, minimal detectable change values for rest CSA were between 0.25-0.40 cm^2, and 0.14-0.24 cm for resting thickness measures across a variety of studies for asymptomatic individuals.[40]

3 trials of each resting and resisted muscle thickness were captured, along with one trial each of resting and resisted CSA. For ABH thickness, the center of the transducer head was placed longitudinally and directly below the navicular tubercle, on the thickest part of the ABH (Figure 3b). Some adjustments were made due to anatomical variations, including foot posture type and size of the muscle. Then, the transducer was rotated 90 degrees to capture ABH CSA at its largest point. This protocol was repeated with the participants abducting their great toe as hard as they could against the assessor's thumb, for resisted muscle measurements (Figure 3c).

For FHB thickness, the foot was positioned on the stair so that the ball of the foot was directly on the edge of the cutout, and the assessor placed the center of the transducer head under the first metatarsal (Figure 3d). Some adjustments were made to find the

thickest portion of the FHB. Then, the transducer was rotated 90 degrees to capture the FHB CSA at its largest point. This protocol was repeated with the participants performing isometric toe flexion (no curling) against the platform with all toes for resisted muscle measurements.

The FDB and QP were captured in the same image. The center of the transducer head was placed longitudinally in line with the third metatarsal head at 50% of foot length, which was previously established with the Arch Height Index measurements (Figure 3e). Adjustments were made to ensure both muscles were included in the image, with clear borders. The transducer was rotated 90 degrees to capture FDB and QP CSA at their largest points. This protocol was repeated with the participants performing isometric toe flexion (no curling) against the platform with all toes for resisted muscle measurements.

Single-leg balance: This was assessed with the AccuSway Optimized Balance and Sway Platform (AMTI Force & Motion, Watertown, MA, USA) The AMTI force plates have been used as a gold standard to validate other balance assessments[42] and are shown to have good to very good reliability in static conditions.[43]

Balance Clinic Software (AMTI, Watertown, MA, USA) processed the data which was sampled at 100 Hz. Participants performed a single-limb static balancing task barefoot on their injured limb with their hands on their hips, with their hip flexed to approximately 30 degrees and knee flexed to approximately 45 degrees. Three 10-second trials were collected of eyes both open and closed, (Figure 4a-b) with eyes open always collected first. If an error was committed, then the participant was tested again, up to a total of 10 times per eyes opened and closed each. Errors for this test included touching

down to the side, front, or back with the floating leg, the testing leg coming off the force platform, hands coming off hips, or eyes opening (where applicable).

Walking kinetics: A variety of kinetic variables were assessed during walking gait on a Biodex RTM600 treadmill (Biodex Medical Systems, Shirley, NY, USA) with a pair of loadsol® insoles (Novel Electronics, St. Paul, MN). The loadsol has been shown to be valid and reliable in healthy running and walking populations,[44] and has good-to-excellent agreement with instrumented treadmills and is reliable across sessions.[45] Although the loadsol has specifically not been used in patients with PF, it has been used to evaluate other clinical populations' gait asymmetries, such as individuals with ACL reconstruction surgery.[46]

After fitting the loadsol® insoles to the participant's shoes (Figure 5a), attaching the battery pack securely to the laces, and performing the procedure to zero the insoles, participants warmed-up at a self-selected pace for 5 minutes, to which they were blinded (Figure 5b). They selected a comfortable walking pace they could sustain for approximately 8-10 minutes, as if they were "walking to their car after shopping". They then walked on the treadmill for approximately 3 minutes, capturing four individual 30-second trials, with data sampled at 200 Hz. All participants wore the same pair of their daily comfortable shoes at both the baseline and follow-up sessions. Their instructions prior to the baseline session were to wear closed-toed shoes they could feel comfortable exercising in. Pictures were taken of their shoes at the baseline session so that participants could be reminded of which shoes to wear at the second session.

At the follow-up session, participants began with performing the 5-minute warm-up, but went through the process of self-selecting a comfortable pace again, while blinded

to the speed. Then, participants walked on the treadmill for approximately 3 minutes, capturing four 30-second trials. If this new self-selected speed was different than the baseline, participants walked at the baseline self-selected speed again for approximately 3 minutes, capturing four 30-seond trials.

Protocol

The rehabilitation and minimalist shoes protocols were the same as for Manuscript I.

Data Processing and Outcome Measures

Foot morphology: Calculation of the Arch Height Index was taken from a previous paper,[47] where it was calculated as: $(\text{arch height / foot length})_{\text{standing}} - (\text{arch height / foot length})_{\text{sitting}}$. Arch drop was calculated as: arch height standing – arch height seated. The other variables of interest were arch height only in the standing position and the FPI-6 scores. Symmetry between feet was also calculated for all measures except for the FPI-6 using the following formula: (injured limb/uninjured limb)*100.

Ultrasound: In order to blind the assessor who captured the initial images and was also completing the measurements (JX), a code written in R version 2024.09.1+394 (RStudio, Boston, MA) renamed each image with a random name of a string of numbers and letters, and the identifying subject number at the top was cropped out. The images were then measured using ImageJ version 1.53 (National Institutes of Health, Bethesda, MD) on a MacBook Air laptop (Apple Inc, Cupertino, CA) (Figure 6a-f). After measurement, another member of the study team (JH) de-scrambled the image names for data analysis. The average of 3 thickness values and the single CSA measurement for both resting and resisted conditions were analyzed. Activation ratio was also calculated

and analyzed, which is the contracted measurement divided by the resting measurement.[39]

Single-leg balance: Outcome measures include center of pressure distance and the 95% ellipse area. The anteroposterior (AP) and mediolateral (ML) directions will also include maximum and minimum velocity, as well as maximum and minimum displacement, and average deviation in the X and Y directions. The operational definitions for these terms are found in Appendix C, Additional Methods (Table C).

Gait kinetics: The data was processed via a processing code[48] written in Python (Python Software Foundation, Wilmington, DE). Outcome measures included contact time, time-between-peak (TBPeak), and time-to-peak (TTPeak). There was also first impact peak force (N) or initial contact, second impact peak force (N) or propulsion, mean impact force (N), loading rate (N/s), and impulse (Ns) which were normalized to bodyweight in Newtons for a unitless measure of bodyweights (BW).

Statistical analyses:

Means and standard deviations (SD) were calculated for each outcome measure.

Patient demographics were calculated per group at baseline to assess for any between-group differences using independent t-tests. Any between-group differences at baseline for all outcome measures were indicated on the respective table.

For foot morphology, repeated measures ANOVA (RMANOVA) tests were conducted per each foot condition (non-PF, PF, and symmetry) to assess changes by test session (baseline and post-test) with between-group comparisons. Post-hoc testing was conducted to show within-group changes with Tukey's HSD adjustments. α was set at 0.05 for this analysis and all the following RMANOVA tests.

IFM strength values were normalized to bodyweight in kilograms, and then RMANOVA tests were conducted for each of the greater and lesser toes on the HHD and ND, separately for each foot. Changes were assessed by test session (baseline and post-test) and between-groups. Separate RMANOVA tests were also conducted for symmetry between limbs of each variable, also by time and by group. For IFM muscle size, RMANOVA tests were performed for each of the CSA and muscle thickness measurements, by time (baseline and post-test), group (control and FRAMES). These tests were conducted separately for the relaxed and resisted conditions. Separate RMANOVA tests were conducted for activation ratio measures for each muscle, by time and group. For both IFM strength and size, p-values with Tukey's HSD adjustments and Cohen's d effect sizes for within-group changes were also reported from baseline to post-test.

For balance variables, separate RMANOVA tests were conducted for eyes open and eyes closed conditions, as not all individuals were able to complete the eyes closed balance tests. The tests were conducted by test session (baseline and post-test) and group. P-values with Tukey's HSD adjustments and Cohen's d effect sizes for within-group changes were also reported from baseline to post-test.

For gait kinetics, RMANOVA were conducted to compare outcome measures at baseline self-selected pace to the post-test walking at the same baseline pace between-groups. These were done separately for the non-PF limb, the PF limb, and symmetry. P-values with Tukey's HSD adjustments and Cohen's d effect sizes from baseline to post-test were also calculated within-group.

For the RMANOVA model, Y_{ij} is the score for subject i at timepoint j, μ is the grand mean, α_j is the fixed effect of time (level j), β_k is the fixed effect of group (group k), $(\alpha\beta)_{jk}$ is the interaction between time and group, s_i is the random effect for subject i, and ε_{ij} is the residual error. The model is: $Y_{ijk} = \mu + \alpha_j + \beta_k + (\alpha\beta)_{jk} + s_i + \varepsilon_{ijk}$, where $s_i \sim N(0, \sigma^2_s)$ accounts for the individual variability across subjects, and $\varepsilon_{ijk} \sim N(0, \sigma^2)$ is the residual error.

RESULTS

Patient characteristics for the full dataset are displayed in Table 1.

Means, SD, indications of significant main and interaction effects for foot morphology are displayed in Table 2, along with within-group p-values for the change by time. There are significant group by time effects for arch height on the PF foot (p=0.004), and significant between-group effects for the Δ Arch Height Index on both the Non-PF (p=0.013) and PF foot (p=0.037), and arch drop on the non-PF foot (p=0.016). The average values of the FPI indicate a foot with "normal" posture at baseline (FPI-6 score from 0 to 5), but there are no group-by-time interaction effects, and no significant changes within-group for FPI. For foot arch drop symmetry values specifically, 3 individuals were removed due to having a negative arch drop, which did not work with the symmetry calculation. Figures 7a-c show changes over time, by group and by foot in arch height while standing, arch drop, and arch height index.

Toe strength mean values and symmetry, with their respective SD, are displayed in Table 3 alongside any indication of significant main or interaction effects, Cohen's d effect size, and within-group p-values. There was one significant baseline difference between HHD GT Symmetry (p=0.010). Main effects of time were significant for the

total cohort for HHD GT Non-PF ($p<0.001$) and PF ($p<0.001$), HHD LT Non-PF ($p<0.001$) and PF ($p<0.001$), and ND GT PF ($p=0.034$). There was one significant between-group effect for HHD LT PF ($p=0.028$). Figures 8a-d show changes over time, by group and foot for HHD GT strength, HHD LT strength, ND GT strength, and NT LT strength.

Means, SD, and n are provided for the plantar fascia thickness and each IFM measurement in Table 4, along with indications of significant main or interaction effects, within-group p-values and Cohen's d effect sizes. There were several images that were unable to be measured due to blurriness or difficulty confirming borders, thus each analysis had varying numbers of participants. There were significant interaction effects for group-by-time for FDB CSA Resisted ($p=0.011$) and Activation ratio ($p=0.006$), and significant main effects of time for FDB MT Relaxed ($p=0.018$), FHB MT Relaxed ($p=0.001$) and Resisted ($p=0.009$), as well as QP CSA Relaxed ($p=0.030$) and Resisted ($p<0.001$). Figures 9a-e show the change across time by group and condition for FHB Muscle thickness, QP CSA, FDB CSA, FDB CSA Ratio, and ABH CSA.

For the balance testing, one individual in the control group did not complete any trials of eyes opened or closed in either session and was not included in either analysis. Additionally, 4 individuals in the FRAMES group could not complete eyes closed balance at the baseline session, and were excluded from the eyes-closed analysis. Balance analysis results are displayed in Table 4, with Mean, SD, Cohen's d effect size, and within-group p-values. Several variables had significant between-group effects for eyes open balance, which included lateral displacement ($p=0.014$), average X deviation ($p=0.017$), path length ($p=0.015$), and medial velocity ($p=0.018$). Post-hoc testing

revealed these to only be significantly different between-groups at baseline, as indicated on the table.

For all kinetic gait analyses, 2 individuals from the control group were excluded. For one participant, body weight was entered incorrectly during data collection and the trials could not be salvaged, and the other reported hamstring injury during the protocol, and displayed an antalgic gait that was most likely related to the injury. Table 5 indicates mean, SD, and within-group p-values and Cohen's d effect size for each foot and symmetry. Main and interaction effects for raw values and symmetry are also detailed in the table. Significant interaction effects for group by time are reported for time to peak symmetry ($p=0.006$), and time between peak for the non-PF foot ($p=0.035$) and symmetry ($p=0.015$). Significant main effects by time are reported for contact time for both the non-PF ($p=0.003$) and PF foot ($p=0.003$), time to peak on the non-PF foot ($p=0.012$) and PF foot ($p<0.001$).

DISCUSSION

This study is the first to observe foot morphology, IFM strength and size, single-leg balance, and gait kinetics with in-shoe pressure sensors after an intervention of minimalist shoes in individuals with plantar fasciopathy. There were several significant increases in IFM strength and size, which lines up with our hypothesis. However, there were no changes in impact forces during walking gait as hypothesized, although there were significant changes in some temporal variables. Lastly, there are no changes in balance performance, which was not expected in our hypothesis.

Foot morphology was initially assessed with the purpose of observing if adults with PF have an association between foot morphology and foot muscle strength, which

will later be reported in a separate study. Previous research shows that flexor strength of the lesser toes is associated with a decreased navicular drop (a smaller difference in navicular height between sitting and standing) in healthy adults.[49] Figures 7a-b in this present study show that the decreases in standing arch height and the increases in arch drop over time between limbs were more in parallel for the FRAMES group compared to the control group. The AHI score takes into account how the foot arch deforms upon weight-bearing, by also considering changes in foot length, to provide a more detailed description of how the foot changes over time,[47] which also showed more parallel decreases between limbs in the FRAMES group. (Figure 7c) Although these changes were not significantly different, these findings of parallel changes in the FRAMES group and not the control group are interesting. Implementing IFM strengthening, especially with the short foot exercise (SFE) to train the foot arch, has been shown to decrease navicular drop in healthy individuals[50] and individuals with CAI[51] or flat-feet.[52] In the present study, the use of minimalist shoes as an IFM strengthening mechanism[26] led to the opposite. However, this lines up with previous literature showing that habitual minimalist shoe wearers have a higher arch drop compared to conventional shoe wearers, potentially because minimalist shoes allow for a greater range of arch motion while walking[53] given the lack of arch support.[28] Native barefoot walkers are also reported to have lower medial arches than shod individuals, which could show that reduced arch support leads to more even pressure distribution across the foot.[54] In the present study, the FRAMES group was simultaneously able to achieve increased IFM strength over time and slightly decreased arch height, showing that their foot morphology aligned more with findings in healthy adults who wear minimalist shoes or no shoes at all.[53,54] Potentially,

the minimalist shoes intervened on both limbs for their arch characteristics, as opposed to the control group who only received an intervention on one foot.

Clinically, a pronated foot is promoted as risk factors for PF, yet research findings are mixed on PF rates across different foot types.[4] The dynamic control of pronation during gait is arguably more important in force absorption and weight acceptance, especially when considering injury risk.[55] However, even with the decreases of arch height and drop, these individuals were still able to maintain a normal foot posture according to the FPI and improve strength, pain, and self-reported function. This may lend credence to the idea that specific foot postures may not be "better" than others, but that IFM strength is important in the ability to control foot movement in a positive manner.[56] However, wearing minimalist shoes or decreasing shoe support to increase IFM strength may not automatically lead to increased arch height, so it likely needs to be trained with specific exercises if improved arch height is the goal.[50] Additionally, the participants only wore the minimalist shoes for 8 weeks, which may not be enough time for any significant morphological changes to develop in the foot arch. It would be curious if a longer study could potentially induce more changes.

Both groups importantly improved their IFM strength. The calf raises with the toes elevated on a rolled towel were previously used for patients with PF, as the MTP joint extension increases MTP joint moments[57] and stretches the plantar fascia, and led to significant decreases in pain compared to a stretching routine.[58] These results indicate that after performing 8-weeks of strengthening and stretching, with or without the addition of minimalist shoes, individuals simultaneously decrease their pain and increase their strength. Although the FRAMES group did not improve IFM strength to a greater

degree than the control group, wearing minimalist shoes still led to positive results. As most individuals with PF are recommended not to go barefoot, to wear stiffer orthoses and shoes, and avoid straining the feet,[23] it can certainly be difficult to implement a treatment of minimalist shoes in this population. There is quite a variety of publicly available information online for adults with PF to peruse,[59] which could influence an individual's willingness and adherence to this specific intervention. However, the individuals in this study completed the protocol and were able to improve their strength and decrease their pain.

Previously, the ND and HHD showed agreement when measured on the same day in healthy individuals,[26] but their ability to detect change across time in individuals specifically with PF appears to differ. The ND has not been validated to detect change in any populations previously, and testing with the ND may be more difficult for individuals with PF, given the lower relative strength outputs. Testing with the HHD on a more pliable treatment table could allow for variations in ankle plantarflexion angles and subsequent assistance from the long toe flexors during the contraction, or allow for some MTP joint extension at the MTP joint, thereby increasing force production.[57] Additionally, the reason for the more significant improvements for the HHD could be due to the calf-raises. The IFM assist in stabilization along with activation of the toe flexors through a range of MTP joint extension, and the placement of the phalanges on the stair for calf raises are more similar to the testing position for the HHD. The ND may be more difficult for participants to use because the toes are fully flat on solid ground, and there was no intervention that directly improved this specific type of isometric toe flexion. The decreased variation in ankle or MTP angles during the test may allow it to be a more

isolated instance of IFM strength. There may have been a learning effect that could have affected the findings as well, as the ND is likely more of a novel test compared to the HHD. Given the lack of significant changes in the ND, but significant changes in the HHD, more practice than 2 sessions 8 weeks apart may be warranted. Regardless, these results point to the importance of assessing IFM strength before and after a rehabilitation program, if possible.

Although the dynamometers provide a force output which can be useful and can be more clinically accessible than other assessments,[60] these devices cannot isolate the individual IFM. Diagnostic ultrasound is a valid and reliable method of assessing the muscle thickness and cross-sectional area (CSA) of individual IFM.[41,61] It can also provide some insight on IFM function when comparing images with and without muscle contraction.[39] As the IFM function mostly during weight-bearing activities,[14] it is important to perform the IFM assessments in a weight-bearing position,[37,38,62] which has excellent inter- and intra-rater reliability.[38] The present study completed weight-bearing ultrasound scans, although the participant's non-scanning foot could gently make contact with the platform to help the participant maintain their posture. They were instructed to place as much of their weight as possible on the affected limb, but allowing for contact with the other limb was for safety and patient comfort given the knowledge that individuals with PF have poorer balance.[20,21] This also allowed the muscle contractions to be easier when assessing resisted muscle thickness and CSA, as positions with greater postural demand increase IFM recruitment.[63]

The significant findings across the total cohort for increased FHB thickness in resting and resisted conditions, and resisted QP CSA show that an 8-week strengthening

protocol, with or without the addition of minimalist shoes, can lead to increased IFM size in individuals with PF. (Figure 9a-b). Hypertrophic gains are usually seen between weeks 6 – 8,[64] meaning we could expect the increased thickness to be due to hypertrophy, not just increased blood flow and swelling in the area from increased muscle usage. Additionally, although FDB CSA changes were not significant within-group, the effect sizes show that the control group had a decrease in resisted FDB CSA and the activation ratio, while the FRAMES group had medium to large increases in their resisted FDB CSA (d=0.58) and activation ratio (d=0.87) (Figure 9c-d). This could mean that while the muscle did not grow significantly in size in a resting condition, the ability to contract the muscle likely somewhat improved. Specifically in the FRAMES group, the relatively larger and positive effect sizes compared to the control group could be due to the increased demand of the minimalist shoes on the foot.[65,66] Previous research has shown that 8-weeks of walking in minimalist shoes (Inov-8 Bare XF 210 or 260 (Inov8, Crook, UK)) in healthy individuals can significantly increase FDB compared to a group performing only IFM strengthening exercises.[67] These similar findings in a population with PF may have significant clinical implications. Individuals with PF are often recommended more cushioned and supportive shoes[23,24] that restrict the natural movement of the foot[27] and reduce the need for great toe extension range of motion and strength during movement. However, introducing a thinner and more flexible shoe in this study means that the foot and especially the toes likely experienced an increased range of motion throughout each step[68] while walking and completing their usual daily activities. This likely demanded increased support from the IFM, which are involved in toe flexion and control of the MTP joint.[57]

Using minimalist shoes as a treatment may seem counterintuitive because PF is known as a mechanical injury, where increased load strains the tissue and causes pain.[4] However, increasing load to the foot via minimalist shoes in this case led to pain relief and positive muscular adaptations. Although the plantar fascia tissue supports the MLA in weight-bearing,[5] this is mostly during propulsion via the windlass mechanism which lengthens the plantar fascia to lift and stabilize the arch.[69] Otherwise, during early stance in walking gait, the plantar fascia is actually shortened and does not provide any support via the windlass mechanism,[70] and recent research has shown that the windlass mechanism is not as effective in dynamic tasks.[71] Conversely, the IFM are known to contribute to force absorption during both initial contact[5] and propulsion[5,57] in gait, and help to regulate foot stiffness depending on the force that the foot is experiencing. Secondly, abnormal pressure distributions on the foot can cause IFM hypertrophy.[66] This could have been achieved with walking in minimalist shoes without any previous experience, which typically leads to increased vertical ground reaction forces in the rearfoot and forefoot, allowing the IFM to adapt to the demand.[72] This is not to say that the plantar fascia would not experience strain with the minimalist shoes, but that the IFM might experience greater demands overall and through the full gait cycle, leading to these automatic regulatory adaptations[5,65] that could have overpowered some of strain on the plantar fascia. However, the increased mechanical strain on the plantar fascia that likely occurs may actually be beneficial, due to the increase in MTP joint extension[67] during gait in more flexible shoes that stretches the plantar side of the foot with each step. Stretching the plantar side of the foot is an important component in the rehabilitation of PF,[58] so it is curious if the minimalist shoes provided assistance in that area as well.

ABH was the only muscle that did not show any significant changes in muscle strength, although the raw data shows decreases in relaxed and resisted ABH CSA for the control group and increases for the FRAMES group (Figure 9e). In healthy individuals, walking for 8 weeks in minimalist shoes[67] and running for 10 weeks in Vibram FiveFingers (Vibram, Albizzate, Italy)[73] significantly improves ABH CSA. This disparity in findings is probably because running in general elicits greater forces than walking,[74] and healthy individuals may be more capable of improving their IFM compared to individuals who have PF. The ABH is also a unique muscle in comparison to some of the other flexor muscles, as contributes to the height of the MLA and assists in countering its deformation during weight-bearing.[14,75] Although one study evaluating IFM size in individuals with PF via ultrasound showed no difference in ABH size compared to healthy individuals, this was only in the resting position.[13] If the ABH contributes more to countering MLA deformation during gait which is in the early half of a stance cycle,[14] yet the plantar fascia is more active during the propulsive part of the gait cycle,[70] they potentially may not affect each other as much. Although PF can sometimes lead to arch pain,[1] it is unclear if it is due to weakness of the ABH or strain of the plantar fascia tissue. Further, the plantar fascia tissue overlays the toe flexor muscles and inserts into tendinous slips at the plantar forefoot, essentially inserting through the MTP joint over to the toes.[4] This may explain why more changes are seen in the FDB and FHB muscles, given their attachment sites and their more similar roles in gait when compared to the plantar fascia. Regardless, the lack of change in the ABH could be related to its role as a regulator of arch deformation, which was not actively intervened upon in this protocol. Potentially, specific exercises that improve both static and dynamic control of the arch[55]

could be implemented in a population like this in order to increase the size of the ABH and improve overall function. The SFE increases arch height and improves general arch mechanics in healthy individuals, even if flat-footed,[76] and is known to improve pain and function for individuals with PF.[77] However, further research must be conducted to observe if there are more functional and structural findings such as IFM strength, size, balance, and gait with IFM and arch-specific exercises.

When comparing IFM size via ultrasound between patients with and without PF, the QP CSA was actually shown to be increased in patients with PF,[13] theorized as a compensation to the significantly decreased CSA of the FHB. Historically, the QP has been regarded as an accessory flexor only for the flexor digitorum longus. However, more recent research shows that the QP also assists in foot stability during stance phase in gait by resisting extension of the toes through stabilization of the flexor hallucis longus (FHL) and flexor digitorum longus (FDL), as it inserts on those tendons.[78] Further, the QP shows significantly earlier onset of muscle activity while walking compared to the tibialis posterior, and during late propulsion, QP muscle activity levels persist while FHL and FDL activity decreases.[79] Certainly, the improvement in size of the QP for the FRAMES group could be due to the increased demand while walking, but it is curious if the calf-raises also elicited some more QP activation when trying to stabilize.

We hypothesized that improving IFM strength could improve balance, but that did not occur. Individuals with PF have a greater center of mass displacement during a single-limb balance test when tested with a force measurement platform compared to healthy controls.[20,22] However, it is unknown if the greater displacement is due to pain[21] or due to decreased plantar cutaneous sensation, which can happen from reduced physical

activity[80] and avoidance of being barefoot or wearing flat and thin shoes, according to some clinical recommendations.[23,24] When individuals wear minimalist shoes compared to other conventional or thicker shoes, they are reported to have better postural control and stability during standing, walking,[81] and jump landings.[82] This is likely because the thinner soles increase stimulus to the plantar cutaneous mechanoreceptors, which are important in maintaining postural control.[82,83] The reasoning behind our hypothesis was that the minimalist shoes would introduce more consistent exposure to increased stability in their daily lives, and could harness foot sensation to eventually improve balance ability. Additionally, we theorized that increased IFM strength would also contribute to balance ability, given the positive association in healthy individuals.[84] However, single-leg balance did not improve in either group, which were not concurrent with our positive results in IFM strength. This is likely because balance exercises were not prescribed at all in this intervention, which may mean that simply increasing IFM strength in individuals with PF is not enough to increase balance ability. However, implementing balance exercises could simultaneously improve postural control and increase IFM activation due to the increased postural demand.[63] Balance exercises could then potentially target two weaknesses in individuals with PF and should be explored as a potential treatment.

Most previous studies of gait in individuals with PF show decreased vertical ground reaction forces (vGRF) upon impact and propulsion while walking when compared to healthy people when using in-ground force plates,[17,19] somewhat corroborated by findings of reduced rearfoot and forefoot forces when using a pressure mat.[18] In the present study, force-sensing insoles were able to provide impact forces at initial contact (first peak impact force) and propulsion (second peak impact force), mean

impact force, loading rate, and impulse. However, there were no significant findings for any of these force variables after the 8-week intervention for either of these groups, which is not what was hypothesized. Interestingly, the full cohort at baseline shows no significant differences between feet for first peak impact force (p=0.237), second peak impact force (p=0.813), or mean impact forces (0.473). However, when observing symmetry for all force variables between-groups at baseline, the control group shows symmetry over 100% at baseline, indicating greater impact in the PF foot, yet this is opposite in the FRAMES group. (Figures 10a-c) Figures 11a-e show how the 2 groups differed at baseline, and then maintained their differences over time, showing that neither group altered their impact forces, loading rate, or impulse significantly

However, it may have been interesting to observe their gait patterns while wearing the minimalist shoes throughout the intervention, or to compare gait patterns in minimalist shoes both before and after the protocol. Individuals who are new to walking in minimalist shoes have increased vGRF at both the rearfoot and forefoot,[72] likely because of the reduced cushioning.[85] It is currently unknown how habituated minimalist shoe wearers alter their vGRF while walking, but habituated minimalist shoe runners are known to decrease their impact forces,[86,87] as they will adapt to the forces over time, gaining strength to attenuate said forces. However, it was not possible to know if participants in the FRAMES group were still experiencing increased impact forces from the minimalist shoes, or if they had already been considered “habituated” at the end of the study. The problem is that both individuals with PF and minimalist shoe wearers in general are known to have changes in their gait patterns compared to healthy limbs and conventional shoe wearers,[18,19,72,85] respectively, some of which counteract each other.

All of these potential differences may have played a role in the lack of changes observed after 8 weeks, or longer interventions may be needed. Additionally, our results show that 8 weeks of wearing minimalist shoes are not enough of a stimulus to alter gait patterns when being tested in conventional shoes again. It could take much longer to occur, as after 6 weeks of a running program to transition into minimalist shoes, the post-test session showed that running in conventional shoes led to increased impact peak forces at initial contact compared to the minimalist shoes.[86] Even though individuals in the present study were walking, it may be interesting to understand if minimalist shoes can alter gait patterns globally, across all footwear types, and at what time point that may occur. However, future studies should consider testing gait in minimalist shoes for both groups at the start and end of the study, to evaluate real differences.

There were significant findings by time for the temporal variables of contact time, time to peak, and time between peak. Contact time significantly increased in both feet for the control group, but there were no changes in the FRAMES group. The control group experienced significant increases in time to peak for their PF foot as well as for symmetry, while the FRAMES group experienced a significant increase in the non-PF foot. There were no significant within-group changes for time between peaks, although the control group did show a small increase in their non-PF foot, while other groups and conditions experienced decreases. (Figures 12a-c)

Previous research has shown no difference in total contact time in individuals with PF when compared to their asymptomatic limb or healthy controls, although there were differences by region such as increased midfoot and forefoot contact time.[19] There are currently no findings on time to peak or time between peak changes in individuals

with PF when compared to healthy individuals or the asymptomatic foot, although there is delayed time to mid-stance at the vGRF valley during walking gait.[19] While the reason for the changes in contact time is unknown, it is curious if these changes in the temporal variables could potentially be explained by pain. Potentially, individuals with a painful foot may have a longer contact time in order to remain stable, or because they step slower in order to reduce the pain they feel, which could also lead to a slower walking speed, a known characteristic in individuals with PF.[20] Authors have also suggested that individuals with PF de-load the painful foot, especially at the heel, as it can be painful to put pressure over it with PF.[18] In that case, they may land more anteriorly on the foot, thus decreasing their overall contact time. There is also the chance that landing more anteriorly on the foot may still be accompanied by a slower step because of pain or weakness, leading to an overall net balance of contact time. However, the increases in contact time and time to peak in this study are accompanied by decreased pain, as well as increased walking speed. This could indicate that after the intervention, individuals are more willing to take a full step by landing more towards the rearfoot, and can walk at a significantly faster speed, potentially because of their reduced pain or increased strength.

Many gait re-training protocols use metronomes and music to alter cadence and step length, in an attempt to alter spatiotemporal variables or vertical ground reaction forces.[88] When wearing minimalist shoes to walk, stride length initially decreases,[72] but is shown to increase again after 8 weeks of walking.[89] The initial decrease could be due to the thin-ness and flexibility of minimalist shoes that may cause some discomfort.[85] In this sense, minimalist shoes could potentially serve as a way of unconscious gait-retraining. The body will automatically react to the forces placed upon it, without having to

externally provide biofeedback to alter gait. Implementing minimalist shoes as gait-retraining for running gait should still involve some other type of gait retraining feedback[90] due to the high forces,[74] but it may be interesting to understand how these shoes can also provide positive effects for walking gait in impaired individuals, with or without additional external biofeedback. Given the lack of changes in these force-related variables, a combined intervention may be warranted to change those variables.

The other part of the consideration for using minimalist shoes in this study stems from the use of "toe-yoga" exercises that are isometric in nature. This type of contraction does not reflect how the IFM actually work in conjunction with the rest of the foot,[91] as the IFM operate more in weight-bearing and functional movements.[63,92] However, the use of minimalist shoes leads to strengthened IFM while individuals are performing those weight-bearing and functional movements.[26] It is also known that minimalist shoes can alter walking gait biomechanics[89,93,94] and postural control,[81,82] which may also have a positive effect for individuals with PF.

This study and several others show that simply spending daily activity in minimalist shoes can effectively improve outcomes for both injured[95,96] and healthy individuals,[67,97] in gait, IFM strength and size, and postural control. This study found that both groups were able to improve their strength, and there were increases in IFM size for the FRAMES group and not the control group. However, there were no improvements in postural control and more gait changes for the control group compared to FRAMES. While the strengthening intervention alone may be enough for some, there may be benefits to using minimalist shoes as an adjunct treatment for PF, along with other disorders that involve impairments in these areas. These shoes can provide a gait-

retraining, strengthening, or stabilizing intervention without needing other equipment, and individuals could complete the protocol simply by going through their daily activities. It could decrease an individual's time-cost when pursuing healthcare interventions, although clinicians should carefully consider how best to recommend using the shoes as an intervention. Warne & Gruber (2017)[98] published a guide for transitioning into running in minimalist shoes which may be beneficial to consult, even taking the same precautions for walking for these injured individuals. This includes being careful with volume of walking in the shoes, performing exercises to strengthen the feet alongside the shoes, and several other guidelines.

Limitations

For walking gait, both groups were tested in their conventional shoes after the intervention for these findings, and no one was tested in minimalist shoes at the baseline assessment, due to an inability to provide minimalist shoes for the control group to wear at the testing location. In the future, it may be important to consider testing gait in minimalist shoes for both groups at the start and end of the study, to evaluate real differences.

CONCLUSION

These results show that a combination of wearing minimalist shoes and performing a short daily strengthening routine can effectively improve IFM strength, and most notably, increase the size of the IFM. Although there were no improvements in postural control or gait in this specific intervention group, this may be due to the lack of specific balance-related exercise interventions or gait re-training. Future research could potentially focus on conducting balance exercises, or combining minimalist shoes with a

more specific gait re-training protocol. Additionally, future testing protocols for minimalist shoe interventions should involve assessments of IFM strength and size, and walking in minimalist shoes before and after the intervention for all individuals in the study. Clinically, wearing minimalist shoes alongside performing rehabilitation exercises are a minimally-invasive yet effective method of improving IFM strength and size in individuals with PF. Wearing minimalist shoes as a strengthening mechanism may decrease the time and energy spent learning and performing potentially difficult IFM exercises, and also serve as a more active, functional intervention. These improvements in functional testing occurred alongside a reduction in pain, which may point to stepping away from thick, cushioned, stiffer footwear for some patients.

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TABLES

Table 2.1. Baseline characteristics by group

	Control (n=16)		**FRAMES (n=18)**		Different at baseline? (p)
Variable	**Mean**	**SD**	**Mean**	**SD**	
Sex	n = 11 female		n = 13 female		
Age	35.80	11.40	43.60	11.50	0.056
Height (cm)	165	7.78	168	9.56	0.381
Weight (kg)	77.40	15.50	77.40	10.80	0.990
BMI (kg/m^2)	28.40	5.21	27.80	4.73	0.709
Months pain	15.30	9.26	15.40	13.10	0.967
PF Thickness (cm)	0.40	0.14	0.44	0.10	0.374

SD, Standard deviation; BMI, body mass index; PF, plantar fascia

Table 2.2. Foot morphology measures between control and FRAMES groups across baseline and post-test (8-weeks)

	Foot	Group	Baseline Mean		Baseline SD	Post-Test Mean		Post-Test SD	p-value
Δ Arch Height Index	Non‡	Control	-0.031	±	0.018	-0.027	±	0.007	0.571
		FRAMES	-0.018	±	0.009	-0.022	±	0.011	0.612
	PF‡	Control	-0.028	±	0.011	-0.030	±	0.009	0.912
		FRAMES	-0.023	±	0.005	-0.024	±	0.008	0.904
	Symm.	Control	69.2	±	95.39	113.3	±	31.41	0.984
		FRAMES	346.2	±	669.08	128.8	±	81.01	0.262
Arch Height (cm)	Non	Control	6.22	±	0.46	6.23	±	0.29	1.000
		FRAMES	6.15	±	0.32	6.11	±	0.38	0.932
	PF*	Control	6.25	±	0.35	6.17	±	0.29	0.105
		FRAMES	6.09	±	0.37	6.03	±	0.45	0.189
	Symm.	Control	100.6	±	4.27	99.0	±	2.99	0.428
		FRAMES	99.1	±	3.94	98.6	±	3.65	0.952
Arch drop (cm)	Non‡	Control	0.59	±	0.37	0.53	±	0.15	0.801
		FRAMES	0.36	±	0.20	0.43	±	0.19	0.685
	PF	Control	0.56	±	0.22	0.58	±	0.18	0.952
		FRAMES	0.46	±	0.10	0.47	±	0.14	0.959
	Symm.	Control	92.3	±	30.86	112.4	±	36.78	0.485
		FRAMES	123.1	±	43.06	128.7	±	61.39	0.999
Foot Posture Index	Non	Control	4.63	±	2.60	5.25	±	2.67	0.411
		FRAMES	4.11	±	2.65	4.39	±	2.03	0.881
	PF	Control	4.81	±	2.17	5.00	±	3.12	0.966
		FRAMES	4.56	±	2.73	4.89	±	2.00	0.815

Separate RMANOVA tests were conducted per limb, by time x group. Within-group p-values reported with Tukey's HSD adjustments.
* significant for main effect group x time, † significant for main effect time, ‡ significant for between-group differences.

Abbreviations: SD, standard deviation; Non, non-PF limb; PF, plantar fasciopathy; Symm, symmetry

Table 2.3. IFM strength measures assessed with handheld dynamometer (HHD) and novel dynamometer (ND) between control and FRAMES groups at baseline and post-test (8-weeks).

	Foot	Group	Baseline Mean		Baseline SD	Post Mean		Post SD	p-value	ES	95% CI (LL, UL)
HHD GT (BW)	Non†	Control	$12.55 * 10^{-2}$	±	$5.87 * 10^{-2}$	$15.98 * 10^{-2}$	±	$6.00 * 10^{-2}$	**0.016**	0.60	(-0.11, 1.31)
		FRAMES	$9.66 * 10^{-2}$	±	$4.88 * 10^{-2}$	$13.43 * 10^{-2}$	±	$6.25 * 10^{-2}$	**0.004**	0.61	(-0.06, 1.27)
	PF†	Control	$11.69 * 10^{-2}$	±	$6.18 * 10^{-2}$	$15.28 * 10^{-2}$	±	$5.95 * 10^{-2}$	**0.002**	0.68	(-0.03, 1.39)
		FRAMES	$9.87 * 10^{-2}$	±	$4.42 * 10^{-2}$	$13.14 * 10^{-2}$	±	$5.57 * 10^{-2}$	**0.003**	0.69	(0.01, 1.36)
	Symm.	Control	91.3[a]	±	14.7	94.9	±	18.2	0.816	0.01	(-0.68, 0.70)
		FRAMES	105.3[a]	±	14.9	99.8	±	15.9	0.487	0.53	(-0.13, 1.20)
HHD LT (BW)	Non†‡	Control	$10.09 * 10^{-2}$	±	$5.45 * 10^{-2}$	$13.64 * 10^{-2}$	±	$5.07 * 10^{-2}$	**0.003**	0.79	(0.07, 1.51)
		FRAMES	$8.26 * 10^{-2}$	±	$3.47 * 10^{-2}$	$10.80 * 10^{-2}$	±	$3.72 * 10^{-2}$	**0.033**	0.66	(-0.01, 1.33)
	PF†‡	Control	$9.97 * 10^{-2}$	±	$4.76 * 10^{-2}$	$12.98 * 10^{-2}$	±	$4.36 * 10^{-2}$	**<0.001**	0.94	(0.21, 1.67)
		FRAMES	$7.65 * 10^{-2}$	±	$3.53 * 10^{-2}$	$10.42 * 10^{-2}$	±	$4.17 * 10^{-2}$	**0.019**	0.71	(0.04, 1.39)
	Symm.	Control	101.0	±	15.9	97.0	±	13.2	0.806	0.40	(-0.30, 1.10)
		FRAMES	93.3	±	15.7	95.6	±	17.3	0.943	0.10	(-0.56, 0.75)
ND GT (BW)	Non	Control	$5.31 * 10^{-2}$	±	$3.06 * 10^{-2}$	$5.94 * 10^{-2}$	±	$2.73 * 10^{-2}$	0.514	0.21	(-0.48, 0.91)
		FRAMES	$4.80 * 10^{-2}$	±	$2.13 * 10^{-2}$	$5.37 * 10^{-2}$	±	$2.42 * 10^{-2}$	0.475	0.22	(-0.44, 0.88)
	PF†	Control	$5.09 * 10^{-2}$	±	$2.93 * 10^{-2}$	$5.87 * 10^{-2}$	±	$3.14 * 10^{-2}$	0.264	0.25	(-0.44, 0.95)
		FRAMES	$5.02 * 10^{-2}$	±	$2.55 * 10^{-2}$	$5.55 * 10^{-2}$	±	$2.88 * 10^{-2}$	0.198	0.33	(-0.32, 0.99)
	Symm.	Control	97.6	±	20.4	95.8	±	30.3	0.996	0.44	(-0.26, 1.14)
		FRAMES	110.8	±	59.5	113.4	±	63.4	0.986	-0.06	(-0.72, 0.59)
ND LT (BW)	Non	Control	$4.57 * 10^{-2}$	±	$2.32 * 10^{-2}$	$5.03 * 10^{-2}$	±	$2.40 * 10^{-2}$	0.419	0.23	(-0.46, 0.93)
		FRAMES	$4.26 * 10^{-2}$	±	$2.07 * 10^{-2}$	$4.18 * 10^{-2}$	±	$1.93 * 10^{-2}$	0.735	0.23	(-0.43, 0.89)
	PF	Control	$4.05 * 10^{-2}$	±	$2.37 * 10^{-2}$	$4.50 * 10^{-2}$	±	$2.43 * 10^{-2}$	0.773	0.34	(-0.36, 1.04)
		FRAMES	$3.85 * 10^{-2}$	±	$1.53 * 10^{-2}$	$4.05 * 10^{-2}$	±	$1.62 * 10^{-2}$	0.998	0.04	(-0.62, 0.69)
	Symm.	Control	83.7	±	20.5	91.7	±	32.1	0.777	-0.08	(-0.77, 0.61)
		FRAMES	103.0	±	38.7	106.7	±	40.3	0.965	0.00	(-0.66, 0.65)

Strength values reported in kg of force per kg body weight for a unitless measure of bodyweights (BW). P-value indicates within-group p-values across time.
* significant for main effect group x time, † significant for main effect time, ‡ significant for between-group differences.
Bolded values indicate significant p-values for within-group changes.

Abbreviations: IFM, intrinsic foot muscles; SD, standard deviation; ES, effect size; Symm, symmetry; HHD, handheld dynamometer; GT, great toe; LT, lesser toes; Non, non-injured foot; PF, plantar fasciopathy; ND, novel dynamometer; ES, effect size; CI, confidence interval; LL, lower limit; UL, upper limit

Table 2.4. IFM muscle thickness and CSA measured with ultrasound between control and FRAMES groups at baseline and post-test (8-weeks)

Condition		Group	Baseline Mean		SD	n	Post-Test Mean		SD	n	p-value	ES	95% CI (LL, UL)
Plantar Fascia Thickness (cm)		Control	0.44	±	0.10	16	0.38	±	0.14	16	0.368	-0.49	(-1.20, 0.21)
		FRAMES	0.40	±	0.14	18	0.43	±	0.10	18	0.998	0.25	(-0.41, 0.90)
ABH Muscle Thickness (cm)	Relaxed	Control	1.51	±	0.29	16	1.53	±	0.34	15	0.992	0.06	(-0.64, 0.77)
		FRAMES	1.49	±	0.21	18	1.55	±	0.29	18	0.603	0.24	(-0.42, 0.89)
	Resisted	Control	1.41	±	0.29	16	1.45	±	0.33	15	0.783	0.13	(-0.58, 0.83)
		FRAMES	1.46	±	0.29	17	1.48	±	0.26	18	0.729	0.07	(-0.59, 0.74)
	Activation ratio	Control	0.93	±	0.07	16	0.95	±	0.12	15	0.869	0.21	(-0.50, 0.91)
		FRAMES	0.97	±	0.12	17	0.96	±	0.11	18	0.946	-0.09	(-0.75, 0.58)
ABH CSA (cm^2)	Relaxed	Control	2.62	±	1.14	15	2.55	±	0.84	15	0.917	-0.07	(-0.79, 0.65)
		FRAMES	2.38	±	0.89	18	2.60	±	0.87	17	0.274	0.25	(-0.42, 0.92)
	Resisted	Control	2.64	±	0.99	15	2.42	±	0.87	15	0.799	-0.24	(-0.95, 0.48)
		FRAMES	2.46	±	0.95	18	2.54	±	1.05	17	0.997	0.08	(-0.58, 0.74)
	Activation ratio	Control	1.04	±	0.20	15	1.00	±	0.30	15	0.965	-0.16	(-0.87, 0.56)
		FRAMES	1.06	±	0.34	18	0.99	±	0.18	16	0.991	-0.25	(-0.93, 0.42)
FDB Muscle Thickness (cm)	Relaxed†	Control	0.86	±	0.14	15	0.94	±	0.14	15	0.266	0.57	(-0.16, 1.30)
		FRAMES	0.82	±	0.16	17	0.89	±	0.15	17	0.353	0.45	(-0.23, 1.13)
	Resisted	Control	0.90	±	0.15	15	0.96	±	0.15	15	0.368	0.40	(-0.32, 1.12)
		FRAMES	0.89	±	0.15	18	0.89	±	0.14	17	1.000	0.00	(-0.66, 0.66)
	Activation ratio	Control	1.05	±	0.08	15	0.97	±	0.32	15	0.653	-0.34	(-1.06, 0.38)
		FRAMES	1.10	±	0.19	17	1.00	±	0.12	17	0.470	-0.63	(-1.32, 0.06)
FDB CSA (cm^2)	Relaxed	Control	2.01	±	0.58	14	2.10	±	0.69	15	0.965	0.14	(-0.59, 0.87)
		FRAMES	1.77	±	0.63	17	1.86	±	0.66	18	0.969	0.14	(-0.52, 0.80)
	Resisted*	Control	2.13	±	0.64	14	1.96	±	0.63	15	0.529	-0.27	(-1.00, 0.46)
		FRAMES	1.70	±	0.58	18	2.07	±	0.69	18	0.073	0.58	(-0.09, 1.25)
	Activation ratio*	Control	1.08	±	0.20	13	1.02	±	0.47	15	0.275	-0.16	(-0.91, 0.58)
		FRAMES	0.97	±	0.18	17	1.14	±	0.21	18	0.090	0.87	(0.17, 1.56)

FHB Muscle Thickness (cm)	Relaxed†	Control	1.77	±	0.32	16	1.86	±	0.20	16	0.129	0.34	(-0.36, 1.04)
		FRAMES	1.76	±	0.21	18	1.87	±	0.24	18	**0.037**	0.49	(-0.18, 1.15)
	Resisted†	Control	1.87	±	0.29	16	1.95	±	0.18	16	0.649	0.33	(-0.37, 1.03)
		FRAMES	1.84	±	0.25	18	2.06	±	0.56	18	**0.040**	0.51	(-0.16, 1.17)
	Activation ratio	Control	1.07	±	0.10	16	1.05	±	0.05	16	0.408	-0.25	(-0.95, 0.44)
		FRAMES	1.05	±	0.06	18	1.10	±	0.17	18	0.866	0.39	(-0.27, 1.05)
FHB CSA (cm^2)	Relaxed	Control	3.19	±	0.85	15	3.22	±	0.93	13	1.000	0.03	(-0.71, 0.78)
		FRAMES	2.94	±	0.66	16	3.26	±	0.77	18	0.367	0.44	(-0.24, 1.13)
	Resisted	Control	3.22	±	0.69	15	3.33	±	1.05	13	0.908	0.13	(-0.62, 0.87)
		FRAMES	3.45	±	0.60	16	3.76	±	0.66	18	0.445	0.49	(-0.19, 1.17)
	Activation ratio	Control	1.08	±	0.36	15	1.08	±	0.17	12	1.000	0.00	(-0.76, 0.76)
		FRAMES	1.23	±	0.29	15	1.19	±	0.21	18	0.953	-0.16	(-0.85, 0.53)
QP Muscle Thickness (cm)	Relaxed	Control	0.93	±	0.22	15	1.00	±	0.26	15	0.723	0.29	(-0.43, 1.01)
		FRAMES	0.90	±	0.19	17	0.95	±	0.21	17	0.917	0.25	(-0.43, 0.92)
	Resisted	Control	0.95	±	0.19	15	1.04	±	0.22	15	0.950	0.44	(-0.29, 1.16)
		FRAMES	0.93	±	0.19	18	1.10	±	0.87	17	0.678	0.27	(-0.39, 0.94)
	Activation ratio	Control	1.05	±	0.25	15	1.10	±	0.38	15	0.995	0.16	(-0.56, 0.87)
		FRAMES	1.05	±	0.27	17	1.24	±	1.08	17	0.772	0.24	(-0.43, 0.92)
QP CSA (cm^2)	Relaxed†	Control	1.27	±	0.37	13	1.40	±	0.42	15	0.417	0.33	(-0.42, 1.07)
		FRAMES	1.19	±	0.37	16	1.38	±	0.51	17	0.344	0.42	(-0.27, 1.11)
	Resisted†	Control	1.26	±	0.51	14	1.66	±	0.56	13	**0.002**	0.75	(-0.03, 1.53)
		FRAMES	1.15	±	0.33	14	1.43	±	0.34	14	**0.008**	0.84	(0.06, 1.61)
	Activation ratio	Control	0.98	±	0.20	13	1.33	±	0.57	13	0.636	0.82	(0.02, 1.62)
		FRAMES	1.03	±	0.25	13	1.20	±	0.32	14	0.603	0.59	(-0.18, 1.36)

P-value indicates within-group p-values across time.

* significant for main effect group x time, † significant for main effect time, ‡ significant for between-group differences, [a] significant difference between contraction condition. **Bolded** values indicate significant p-values for within-group changes.

Abbreviations: IFM, intrinsic foot muscles; CSA, cross-sectional area; SD, standard deviation; ES, effect size; ABH, abductor hallucis; FDB, flexor digitorum brevis; FHB, flexor hallucis brevis; QP, quadratus plantae; ES, effect size; CI, confidence interval; LL, lower limit; UL, upper limit.

Table 2.5. Single-leg balance measures on the affected limb between control and FRAMES groups across baseline and post-test (8-weeks).

	Condition	Group	Baseline Mean	SD	Post-Test Mean	SD	p-value	ES	95% CI (LL, UL)
Lateral displacement (cm)	Eyes Open*	Control	1.18 ±	0.20	1.13 ±	0.24	0.828	-0.22	(-0.94, 0,49)
		FRAMES	1.44 ±	0.39	1.34 ±	0.26	0.227	-0.30	(-0.96, 0.36)
	Eyes Closed	Control	2.08 ±	0.28	2.18 ±	0.45	0.704	0.27	(-0.45, 0.99)
		FRAMES	2.22 ±	0.46	2.11 ±	0.33	0.671	-0.27	(-1.02, -0.47)
Medial displacement (cm)	Eyes Open	Control	1.22 ±	0.19	1.3 ±	0.24	0.670	0.37	(-0.35, 1.09)
		FRAMES	1.39 ±	0.45	1.37 ±	0.32	0.985	-0.05	(-0.70, 0.60)
	Eyes Closed	Control	2.07 ±	0.31	2.02 ±	0.28	0.886	-0.17	(-0.89, 0.55)
		FRAMES	1.92 ±	0.33	2.00 ±	0.25	0.748	0.27	(-0.47, 1.02)
Average X Deviation (cm)	Eyes Open*	Control	0.43 ±	0.09	0.43 ±	0.09	0.993	0.00	(-0.72, 0.72)
		FRAMES	0.56 ±	0.19	0.52 ±	0.14	0.507	-0.24	(-0.90, 0.42)
	Eyes Closed	Control	0.87 ±	0.13	0.90 ±	0.19	0.915	0.18	(-0.53, 0.90)
		FRAMES	0.92 ±	0.06	0.89 ±	0.16	0.934	-0.25	(-0.99, 0.50)
Anterior displacement (cm)	Eyes Open	Control	1.68 ±	0.39	1.76 ±	0.39	0.938	0.21	(-0.51, 0.92)
		FRAMES	2.17 ±	0.95	2.02 ±	0.73	0.562	-0.18	(-0.83, 0.48)
	Eyes Closed	Control	2.85 ±	0.65	2.91 ±	0.58	0.991	0.10	(-0.62, 0.81)
		FRAMES	3.02 ±	1.15	2.84 ±	0.77	0.791	-0.18	(-0.93, 0.56)
Posterior displacement (cm)	Eyes Open	Control	1.67 ±	0.44	1.82 ±	0.44	0.698	0.34	(-0.38, 1.06)
		FRAMES	2.21 ±	0.85	2.15 ±	0.95	0.966	-0.07	(-0.72, 0.59)
	Eyes Closed	Control	2.95 ±	0.67	3.04 ±	0.85	0.980	0.12	(-0.60, 0.83)
		FRAMES	3.48 ±	1.68	3.18 ±	0.73	0.597	-0.23	(-0.97, 0.51)
Average Y Deviation	Eyes Open	Control	0.63 ±	0.13	0.63 ±	0.14	1.000	0	(-0.72, 0.72)
		FRAMES	1.00 ±	0.20	0.98 ±	0.18	0.997	-0.11	(-0.82, 0.61)
	Eyes Closed	Control	0.74 ±	0.27	0.71 ±	0.20	0.855	-0.13	(-0.78, 0.53)
		FRAMES	1.07 ±	0.48	1.01 ±	0.27	0.839	-0.15	(-0.90, 0.59)
Path Length (cm)	Eyes Open*	Control	36.62 ±	6.86	39.79 ±	9.88	0.402	0.37	(-0.35, 1.09)
		FRAMES	51.72 ±	20.88	51.42 ±	17.61	0.998	-0.01	(-0.67, 0.64)

	Eyes Closed	Control	78.37	±	17.88	78.74	±	20.52	1.000	0.019	(-0.70, 0.73)
		FRAMES	87.25	±	33.30	87.82	±	24.65	1.000	0.02	(-0.72, 0.76)
Path Area (cm^2)	Eyes Open	Control	5.75	±	1.26	5.78	±	0.86	0.999	0.03	(-0.90, 0.74)
		FRAMES	5.75	±	1.04	5.98	±	1.23	0.756	0.20	(-0.45, 0.86)
	Eyes Closed	Control	4.43	±	0.59	4.35	±	0.63	0.966	-0.13	(-0.85, 0.59)
		FRAMES	4.60	±	1.11	4.72	±	0.58	0.918	0.14	(-0.61, 0.88)
Lateral velocity (cm/s)	Eyes Open	Control	10.49	±	2.65	11.23	±	3.63	0.965	0.23	(-0.49, 0.95)
		FRAMES	15.65	±	13.34	15.20	±	7.16	0.989	-0.04	(-0.70, 0.61)
	Eyes Closed	Control	22.13	±	4.63	21.62	±	6.33	0.995	-0.09	(-0.80, 0.62)
		FRAMES	26.43	±	13.25	26.13	±	10.66	0.999	-0.02	(-0.77, 0.72)
Medial velocity (cm/s)	Eyes Open*	Control	10.30	±	2.62	11.00	±	5.66	0.951	0.16	(-0.56, 0.88)
		FRAMES	15.80	±	6.71	13.22	±	4.25	0.165	-0.46	(-1.12, 0.20)
	Eyes Closed	Control	20.97	±	5.99	20.26	±	7.17	0.980	-0.11	(-0.82, 0.61)
		FRAMES	22.42	±	8.44	23.68	±	7.08	0.911	0.16	(-0.58, 0.90)
Anterior velocity (cm/s)	Eyes Open	Control	13.08	±	3.94	14.48	±	5.71	0.604	0.29	(-0.43, 1.00)
		FRAMES	14.44	±	4.57	14.26	±	4.19	0.998	-0.04	(-0.69, 0.61)
	Eyes Closed	Control	23.38	±	5.26	21.74	±	6.02	0.766	-0.29	(-1.00, 0.43)
		FRAMES	24.87	±	8.51	23.21	±	5.99	0.779	-0.23	(-0.97, 0.52)
Posterior Velocity (cm/s)	Eyes Open	Control	11.09	±	3.33	13.80	±	6.39	0.646	0.53	(-0.20, 1.26)
		FRAMES	18.56	±	15.86	15.20	±	7.87	0.397	-0.27	(-0.92, 0.39)
	Eyes Closed	Control	22.09	±	6.36	21.55	±	7.33	0.995	-0.08	(-0.79, 0.64)
		FRAMES	24.45	±	12.97	25.01	±	11.67	0.995	0.05	(-0.70, 0.79)
Ellipse Area 95%	Eyes Open	Control	7.64	±	2.84	7.72	±	2.75	1.000	0.03	(-0.69, 0.74)
		FRAMES	11.94	±	7.96	10.66	±	5.71	0.376	-0.18	(-0.84, 0.47)
	Eyes Closed	Control	24.15	±	7.59	24.66	±	8.85	1.000	0.06	(-0.65, 0.78)
		FRAMES	27.58	±	14.47	24.70	±	8.06	1.000	-0.25	(-0.99, 0.50)

* indicates significant difference between groups at baseline
Eyes Open: 18 shoe, 15 control. Eyes Closed: 14 shoe, 15 control.

Abbreviations: ES, effect size; CI, confidence interval; LL, lower limit; UL, upper limit.

Table 2.6. Treadmill gait kinetic measurements between control and FRAMES groups across baseline and post-test (8-weeks).

	Foot	Group	Baseline Mean		SD	Post-Test Mean		SD	p-value	ES	95% CI (LL, UL)
Contact Time (s)	Non†	Control	0.747	±	0.052	0.757	±	0.047	**0.050**	0.20	(-0.54, 0.94)
		FRAMES	0.747	±	0.067	0.753	±	0.066	0.256	0.09	(-0.56, 0.74)
	PF†	Control	0.746	±	0.049	0.758	±	0.044	**0.039**	0.26	(-0.49, 1.00)
		FRAMES	0.749	±	0.067	0.755	±	0.063	0.399	0.09	(-0.56, 0.75)
	Symmetry	Control	100.0	±	1.34	100.1	±	1.52	0.966	0.07	(-0.67, 0.81)
		FRAMES	100.3	±	1.63	100.2	±	1.45	0.986	-0.06	(-0.72, 0.59)
Time To Peak (s)	Non†	Control	0.203	±	0.018	0.205	±	0.020	0.857	0.11	(-0.64, 0.85)
		FRAMES	0.204	±	0.030	0.211	±	0.029	**0.018**	0.24	(-0.42, 0.89)
	PF†	Control	0.202	±	0.016	0.212	±	0.027	**0.007**	0.45	(-0.30, 1.20)
		FRAMES	0.206	±	0.027	0.211	±	0.027	0.307	0.19	(-0.47, 0.84)
	Symmetry*	Control	99.6	±	7.32	103.9	±	7.65	**0.018**	0.57	(-0.18, 1.33)
		FRAMES	101.4	±	5.00	100.3	±	7.65	0.796	-0.17	(-0.82, 0.48)
Time Between Peak (s)	Non*	Control	0.367	±	0.037	0.374	±	0.027	0.229	0.22	(-0.53, 0.96)
		FRAMES	0.360	±	0.030	0.356	±	0.029	0.671	-0.14	(-0.79, 0.52)
	PF	Control	0.366	±	0.028	0.365	±	0.019	0.992	-0.04	(-0.78, 0.70)
		FRAMES	0.360	±	0.034	0.359	±	0.028	0.997	-0.03	(-0.69, 0.62)
	Symmetry*	Control	100.1	±	7.06	97.8	±	5.82	0.083	-0.36	(-1.10, 0.39)
		FRAMES	98.0	±	9.09	100.8	±	4.59	0.690	0.39	(-0.27, 1.05)
Loading Rate (BW/s)	Non	Control	5.278	±	0.715	5.242	±	0.692	0.89	-0.05	(-0.79, 0.69)
		FRAMES	5.627	±	1.274	5.546	±	1.196	0.85	-0.07	(-0.72, 0.59)
	PF	Control	5.281	±	0.947	5.152	±	0.857	0.71	-0.14	(-0.88, 0.60)
		FRAMES	5.284	±	0.934	5.251	±	0.92	0.92	-0.04	(-0.69, 0.62)
	Symmetry	Control	101.5	±	12.06	98.7	±	13.48	0.780	-0.22	(-0.96, 0.52)
		FRAMES	95.1	±	13.21	96.3	±	14.20	0.970	0.09	(-0.57, 0.74)

First Peak Impact Force (BW)	Non	Control	1.042	±	0.098	1.038	±	0.085	0.91	-0.04	(-0.78, 0.70)
		FRAMES	1.122	±	0.108	1.126	±	0.102	0.91	0.04	(-0.62, 0.69)
	PF	Control	1.063	±	0.141	1.064	±	0.120	0.98	0.01	(-0.73, 0.75)
		FRAMES	1.069	±	0.091	1.072	±	0.091	0.92	0.03	(-0.62, 0.69)
	Symmetry	Control	101.2	±	7.88	102.5	±	7.78	0.944	0.17	(-0.58, 0.91)
		FRAMES	96.0	±	10.57	96.1	±	12.66	1.000	0.01	(-0.64, 0.66)
Second Peak Impact Force (BW)	Non	Control	1.102	±	0.085	1.095	±	0.070	0.81	-0.09	(-0.83, 0.65)
		FRAMES	1.134	±	0.105	1.154	±	0.114	0.59	0.18	(-0.47, 0.84)
	PF	Control	1.147	±	0.136	1.148	±	0.124	0.98	0.01	(-0.73, 0.75)
		FRAMES	1.091	±	0.090	1.107	±	0.096	0.61	0.17	(-0.48, 0.83)
	Symmetry	Control	103.2	±	8.72	105.0	±	10.73	0.890	0.18	(-0.56, 0.93)
		FRAMES	97.2	±	10.38	96.8	±	12.91	0.997	-0.03	(-0.69, 0.62)
Mean Impact Force (BW)	Non	Control	0.832	±	0.045	0.830	±	0.039	0.90	-0.05	(-0.79, 0.69)
		FRAMES	0.863	±	0.072	0.877	±	0.071	0.56	0.20	(-0.46, 0.85)
	PF	Control	0.852	±	0.079	0.855	±	0.069	0.92	0.04	(-0.70, 0.78)
		FRAMES	0.831	±	0.060	0.839	±	0.064	0.70	0.13	(-0.53, 0.78)
	Symmetry	Control	101.7	±	7.04	103.2	±	8.99	0.910	0.19	(-0.56, 0.93)
		FRAMES	97.2	±	8.74	96.3	±	11.37	0.968	-0.09	(-0.74, 0.56)
Impulse (BW*s)	Non	Control	0.624	±	0.046	0.627	±	0.039	0.85	0.07	(-0.67, 0.81)
		FRAMES	0.648	±	0.063	0.658	±	0.061	0.63	0.16	(-0.49, 0.82)
	PF	Control	0.640	±	0.067	0.647	±	0.056	0.77	0.11	(-0.63, 0.85)
		FRAMES	0.625	±	0.076	0.633	±	0.077	0.76	0.10	(-0.55, 0.76)
	Symmetry	Control	101.7	±	7.47	103.4	±	9.80	0.889	0.20	(-0.55, 0.94)
		FRAMES	98.1	±	8.4	96.6	±	11.62	0.997	-0.15	(-0.80, 0.51)

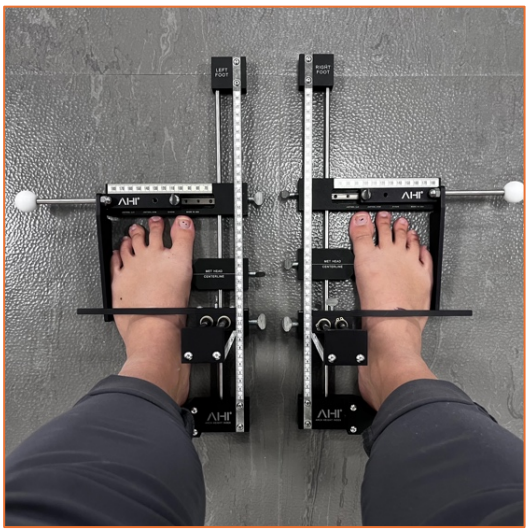
* significant for main effect group x time
† significant for main effect time
‡ significant for between-group differences
Bolded values indicate significant p-values for within-group changes.

RMANOVA tests with gait speed as a covariate were used for force-related variables (loading rate, first peak impact force, second peak impact force, mean impact force, and impulse) to report main and interaction effects, while within-group p-values were calculated from a two-tailed paired samples t-test.

Abbreviations: Non, non-injured foot; PF, plantar fasciopathy; ES, effect size; CI, confidence interval; LL, lower limit; UL, upper limit

FIGURES

Figure 2.1. (a) Measurement with Arch Height Index Tool (Jaktool Corporation, Cranberry, NJ), (b) AHI measurement seated, (c) AHI measurement standing

(a) 

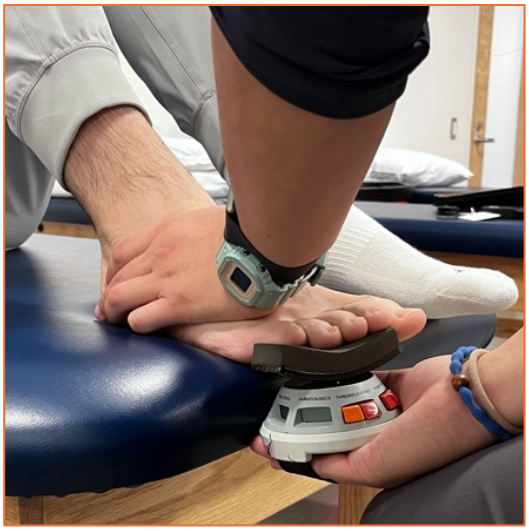
(b) 

(c) 

Abbreviations: AHI, Arch Height Index

Figure 2.2. (a) Testing position for IFM strength measurement with HHD (microFET2, Hoggan Scientific, Salt Lake City, UT, USA), (b) Measurement position of great toe strength, (c) Measurement position of lesser toe strength, (d) Measurement position for IFM strength with ND (Human Locomotion, Massachusetts, USA)

(a)  (b) 

(c)  (d) 

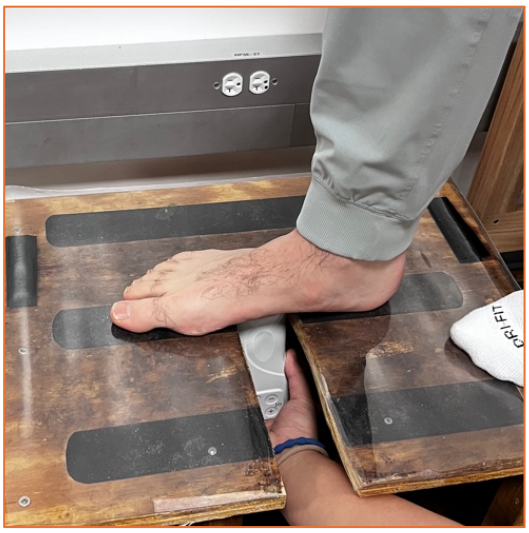
Abbreviations: IFM, intrinsic foot muscles; HHD, handheld dynamometer; ND, novel dynamometer

Figure 2.3. (a) Weight-bearing position on staircase for IFM ultrasound measurements, (b) Testing location for ABH muscle thickness, (c) Testing position for ABH muscle thickness resisted, (d) Testing location for FHB muscle thickness, (e) Testing location for FDB and QP muscle thickness

(a)

(b)

(c)

(d)  (e) 

Abbreviations: IFM, intrinsic foot muscles; ABH, abductor hallucis; FDB, flexor digitorum brevis; FHB, flexor hallucis brevis; QP, quadratus plantae

Figure 2.4. Using the AccuSway Optimized Balance and Sway Platform (AMTI Force & Motion, Watertown, MA, USA), (a) Testing position for single-leg balance protocol with eyes open, (b) Testing position for single-leg balance protocol with eyes closed

(a)  (b) 

Caption: (force plate is placed facing wall directly for test but was turned for the picture)

Figure 2.5. Walking on Biodex RTM600 treadmill (Biodex Medical Systems, Shirley, NY, USA) with loadsol insoles in shoes and folder blocking gait speed from participant

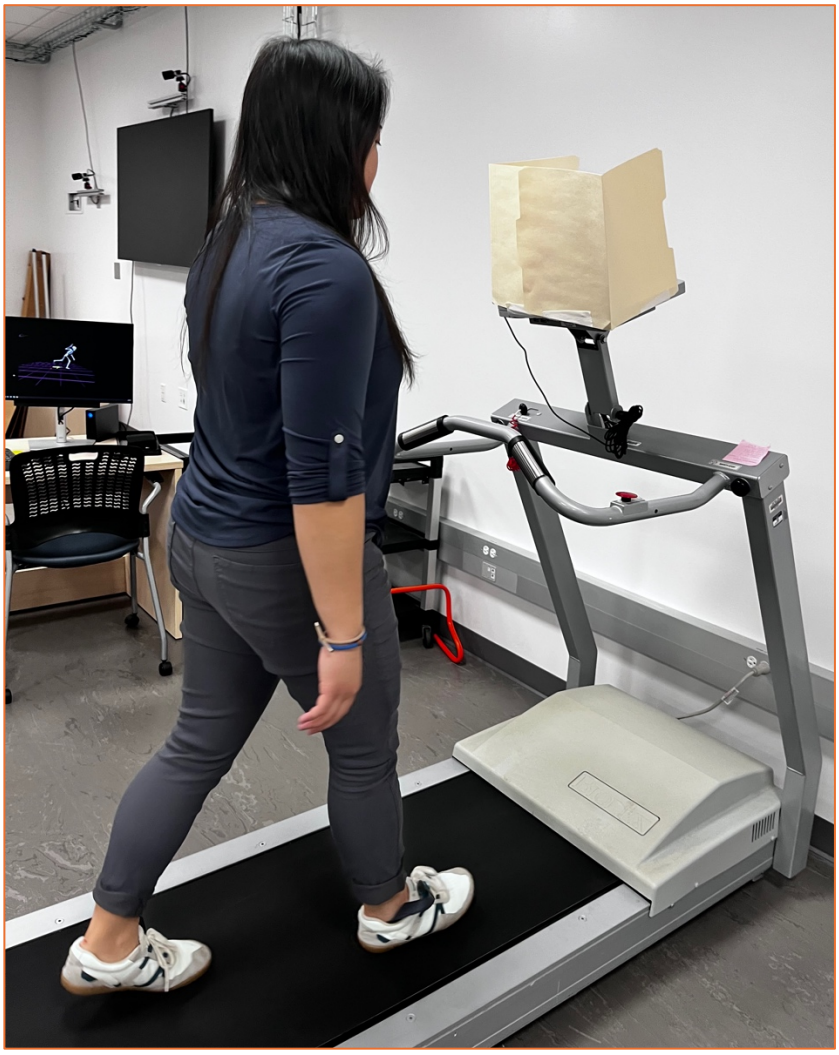
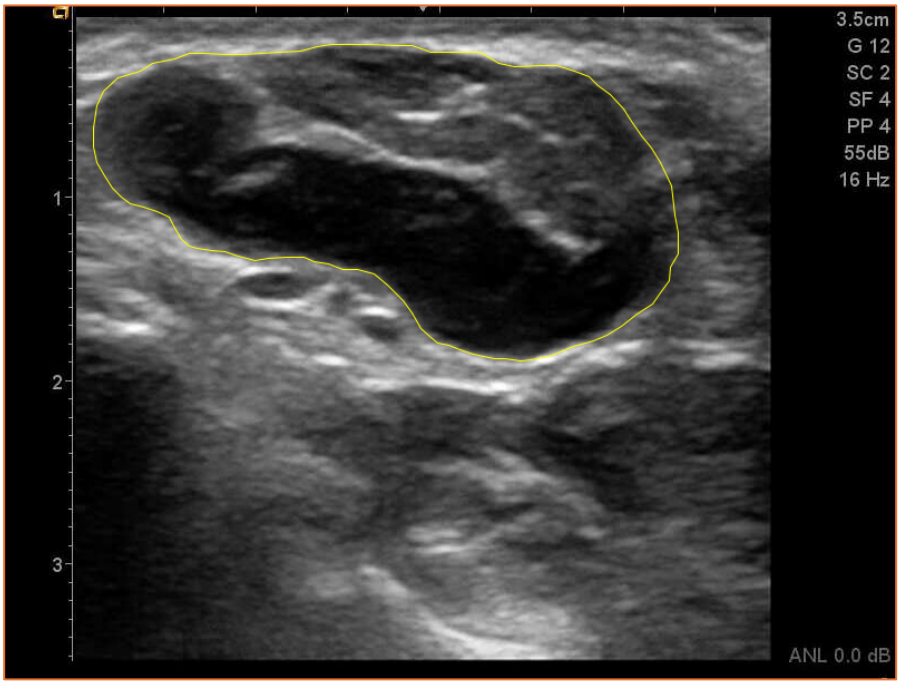
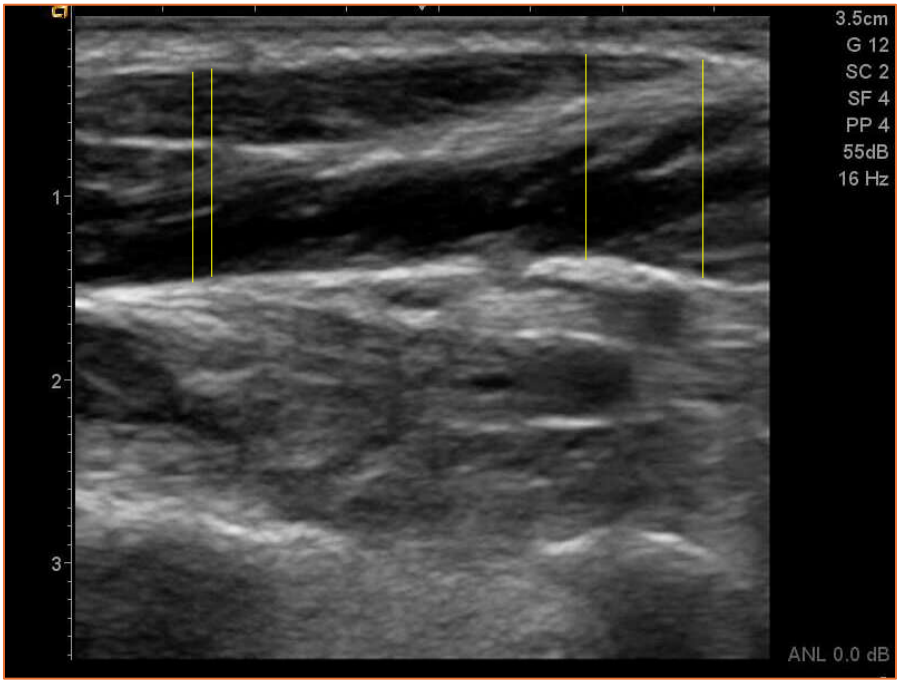


Figure 2.6. Using ImageJ version 1.53 (National Institutes of Health, Bethesda, MD) on a MacBook Air laptop (Apple Inc, Cupertino, CA) (a) Abductor hallucis (ABH) cross-sectional area (CSA) measurement, (b) ABH muscle thickness measurement, (c) FHB CSA measurement, (d) FHB muscle thickness measurement, (e) FDB and QP CSA measurement, (f) FDB (top) and QP (bottom) muscle thickness measurement

(a)



(b)



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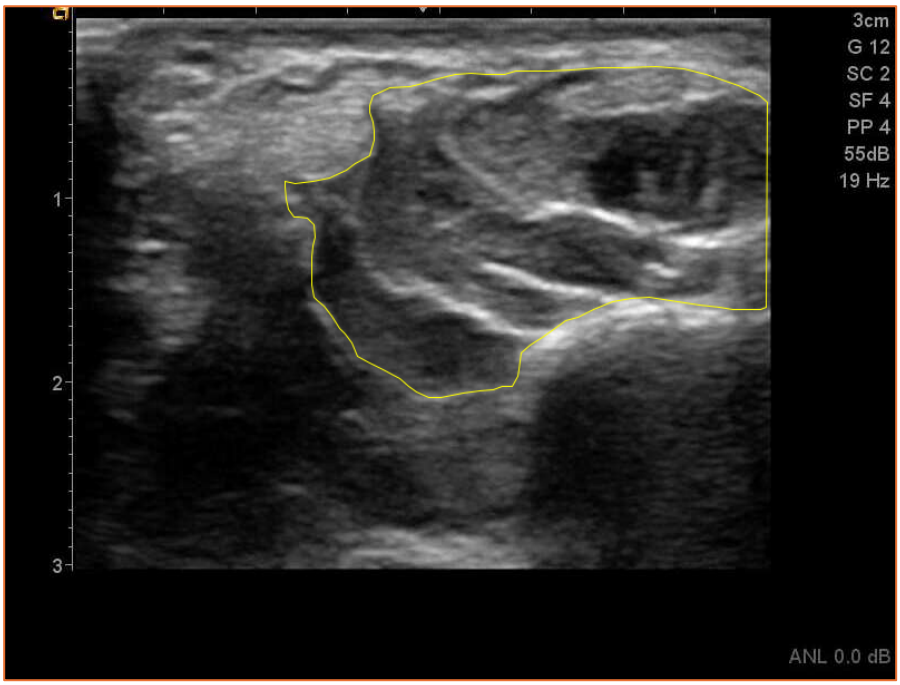
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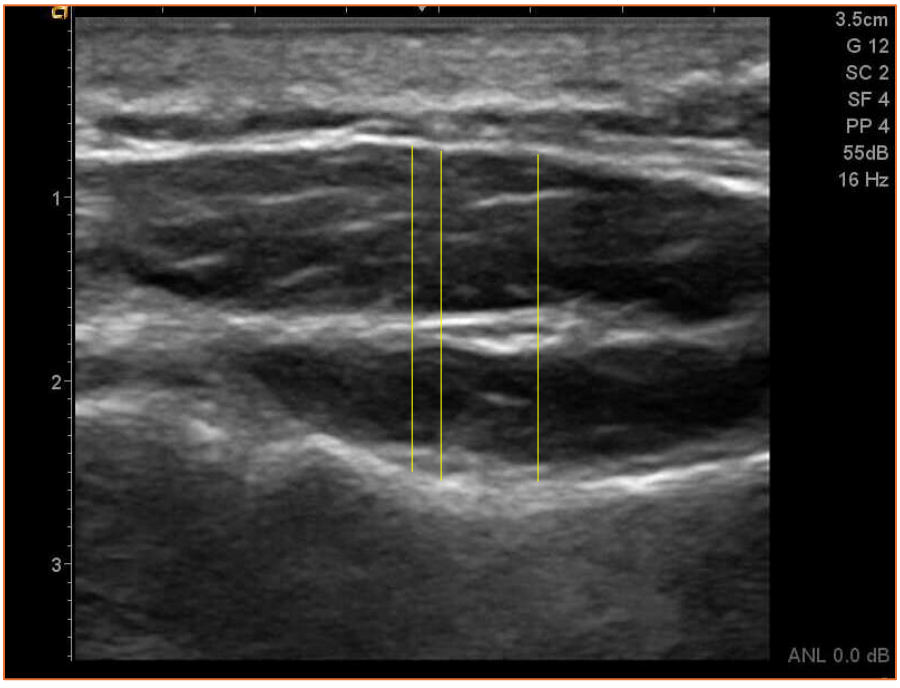
SC 2
SF 4
PP 4
55dB
19 Hz
1
2
3
ANL 0.0 dB

(d)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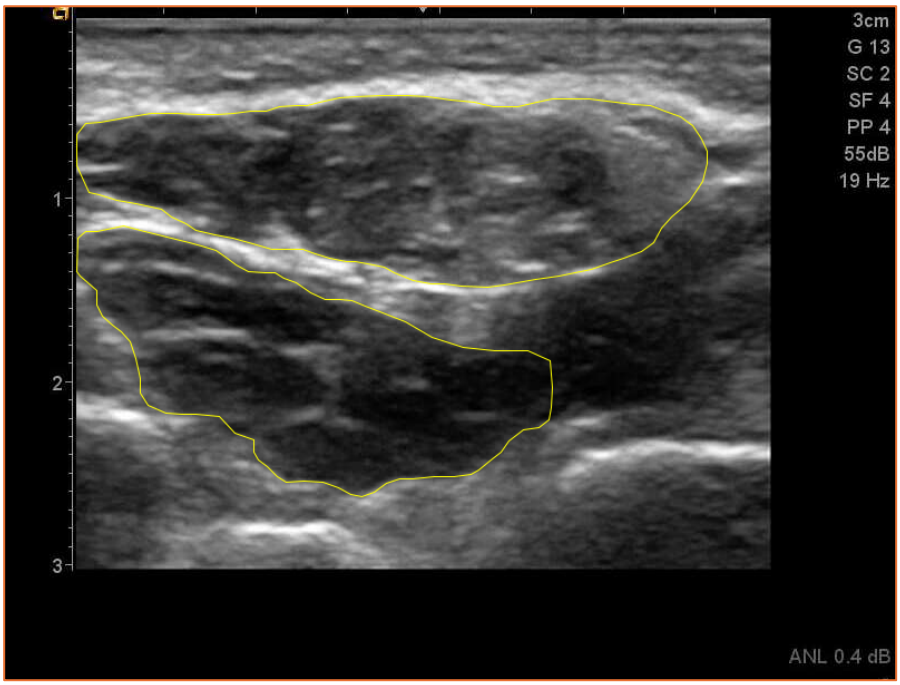
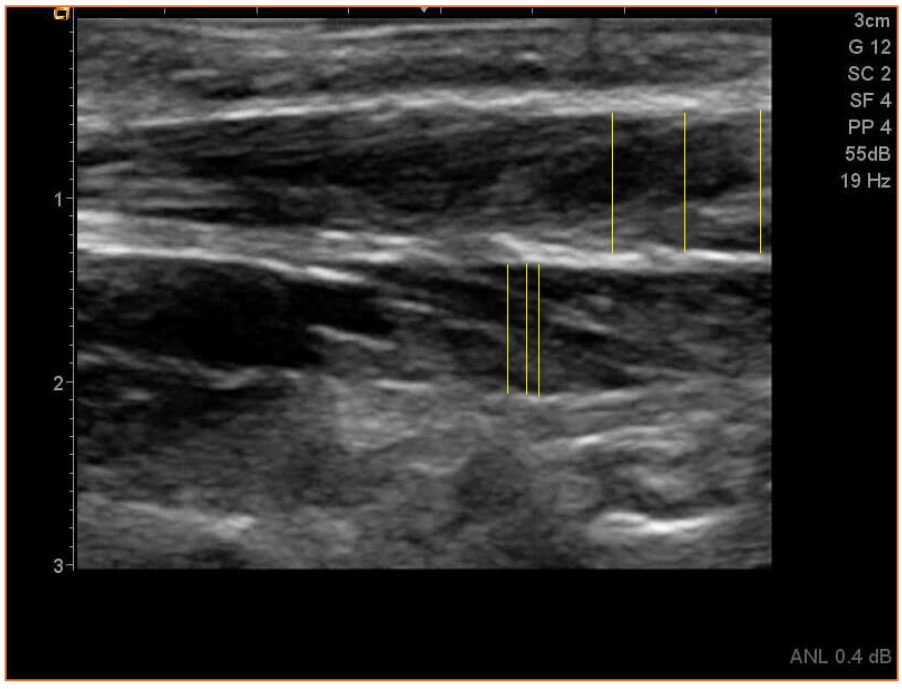
SF 4
PP 4
55dB
16 Hz
1
2
3
ANL 0.0 dB

(e)



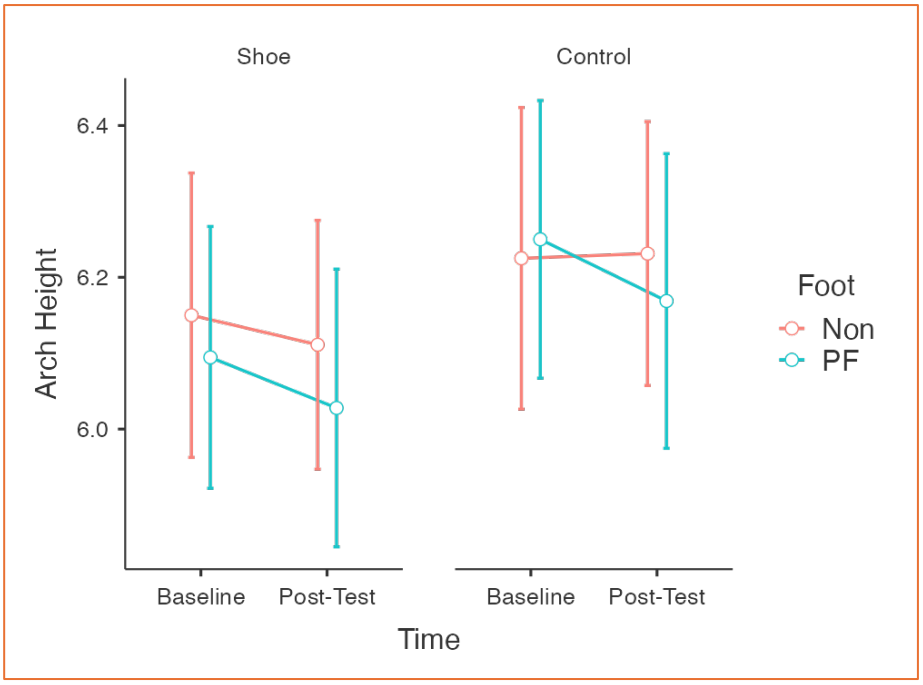
(f)



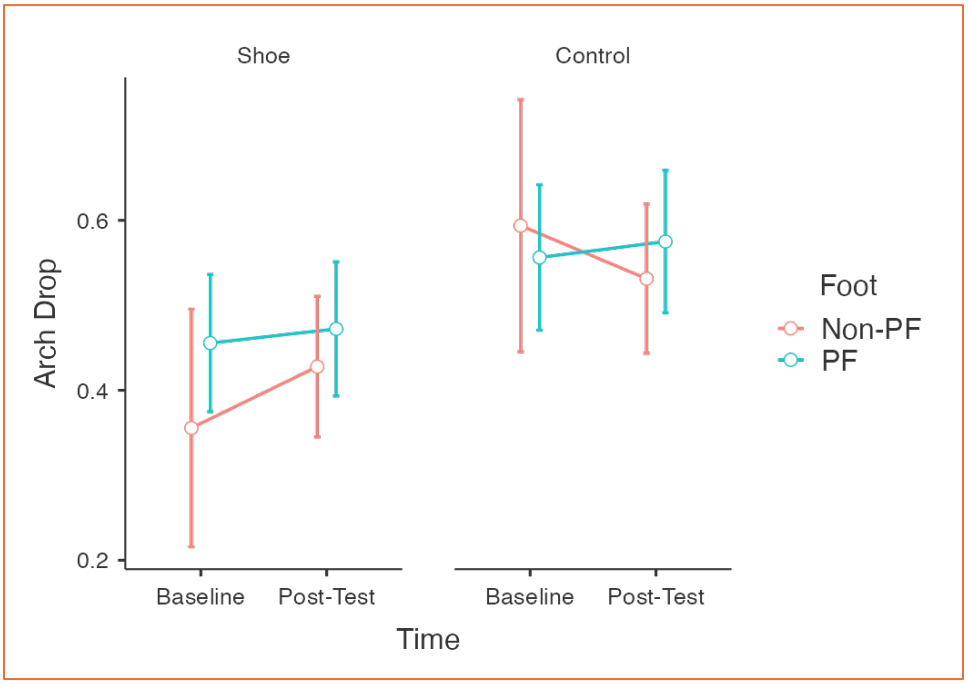
Abbreviations: ABH, abductor hallucis; CSA, cross-sectional area; FDB, flexor digitorum brevis; FHB, flexor hallucis brevis; QP, quadratus plantae

Figure 2.7. Changes over time, by group and by foot in (a) Arch height while standing, (b) Arch drop, (c) Arch height index

(a)



(b)



(c)

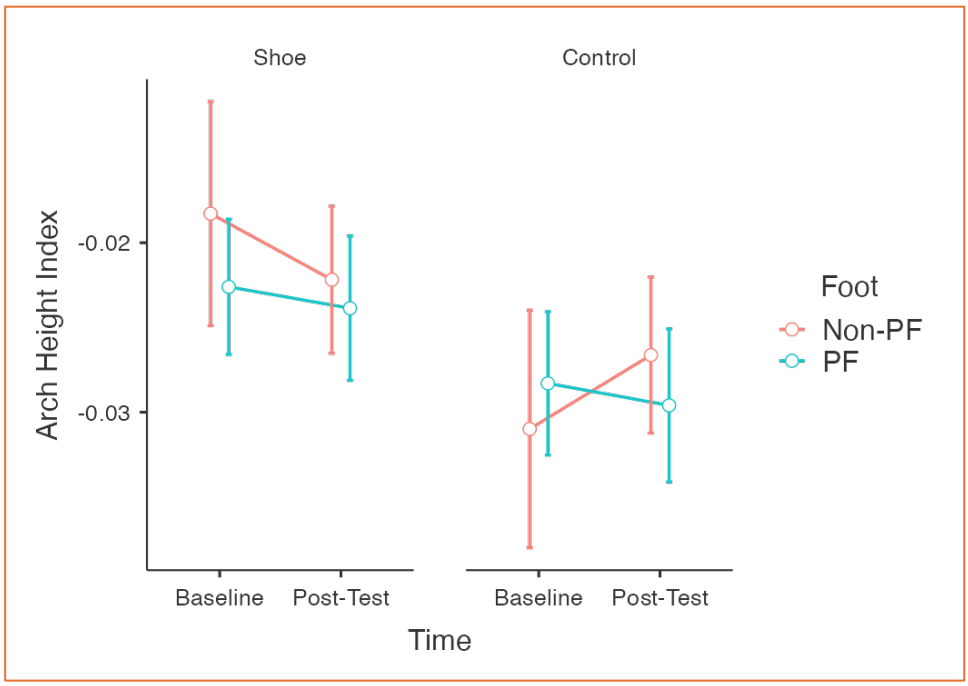
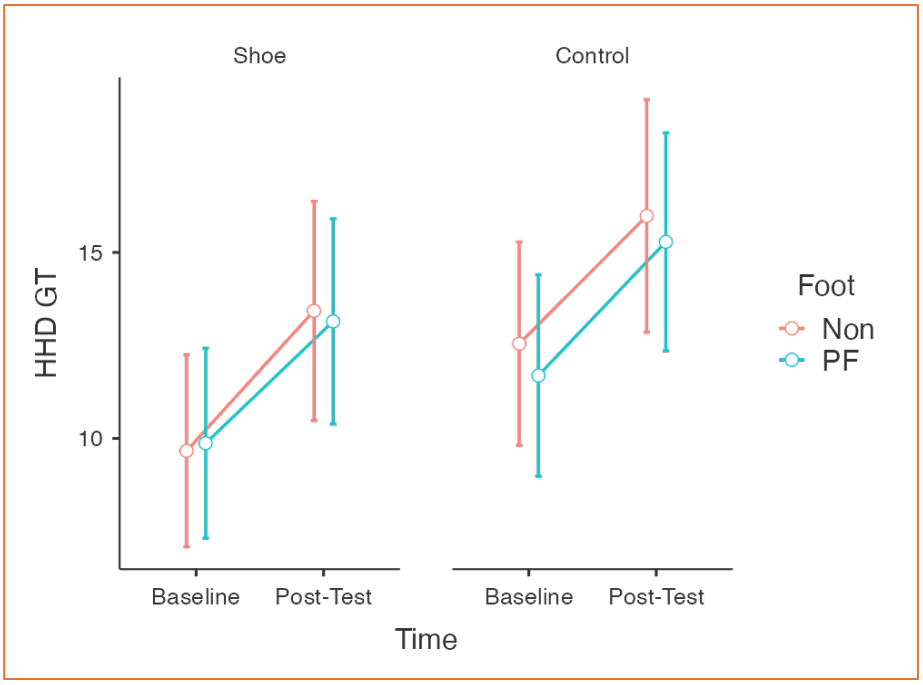
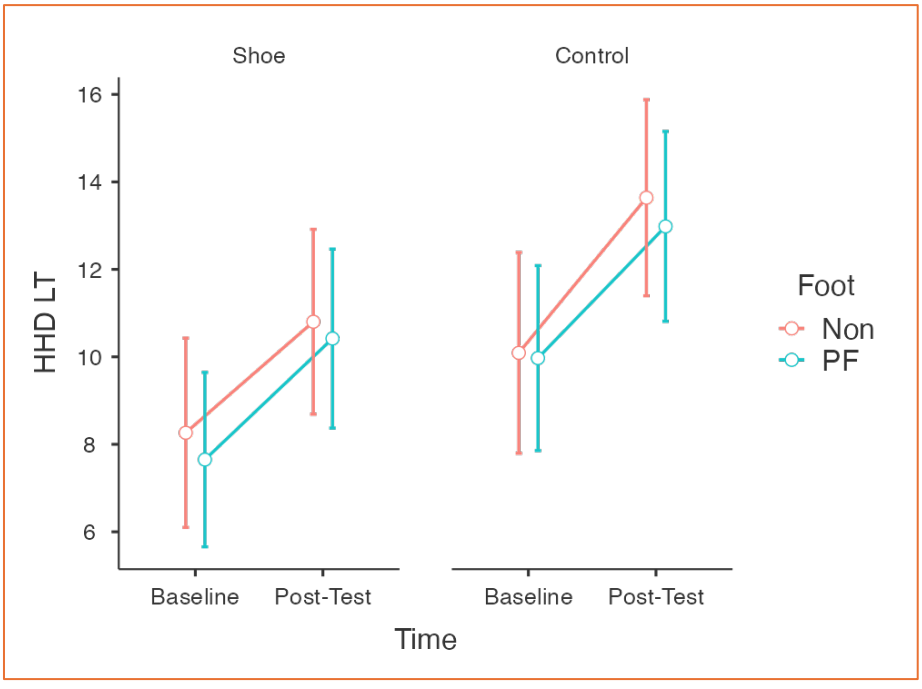

Shoe
Control
Arch Height Index
-0.02
-0.03
Baseline
Post-Test
Baseline
Post-Test
Time
Foot
Non-PF
PF

Figure 2.8. Changes over time, by group and foot for (a) HHD GT strength, (b) HHD LT strength, (c) ND GT strength, and (d) NT LT strength

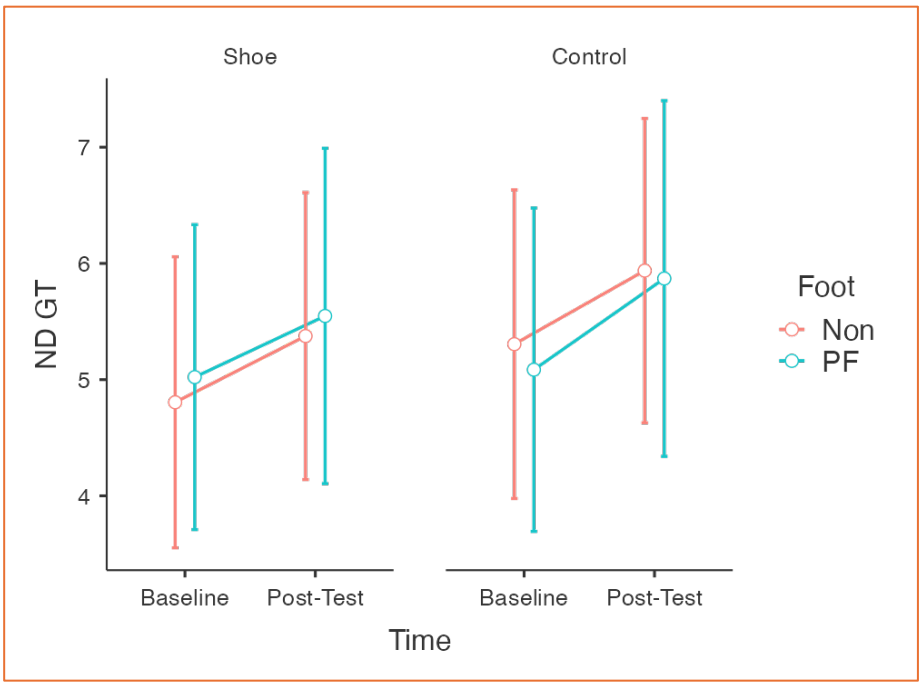
(a)



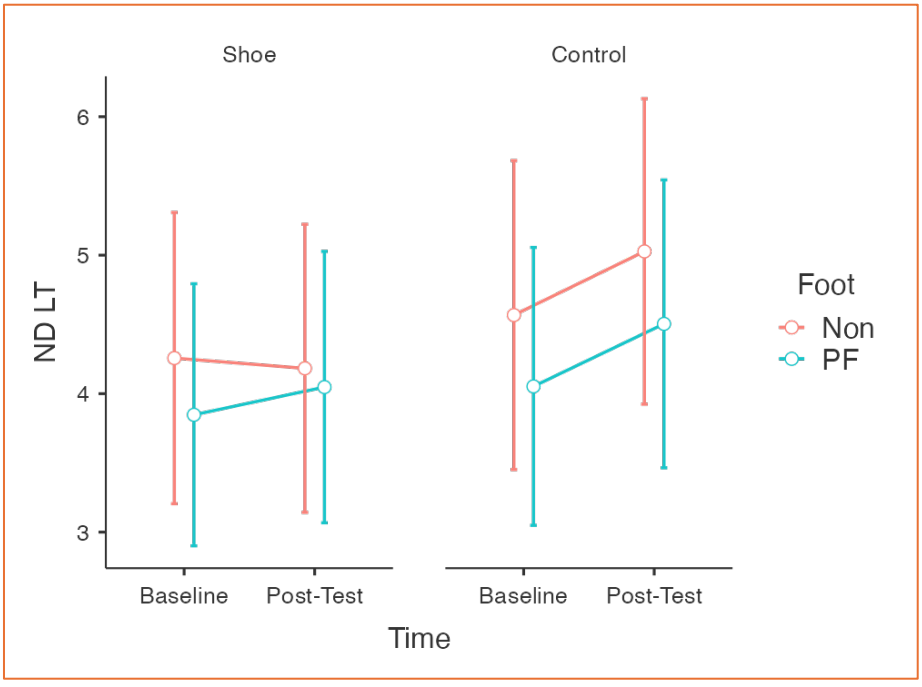
(b)



(c)



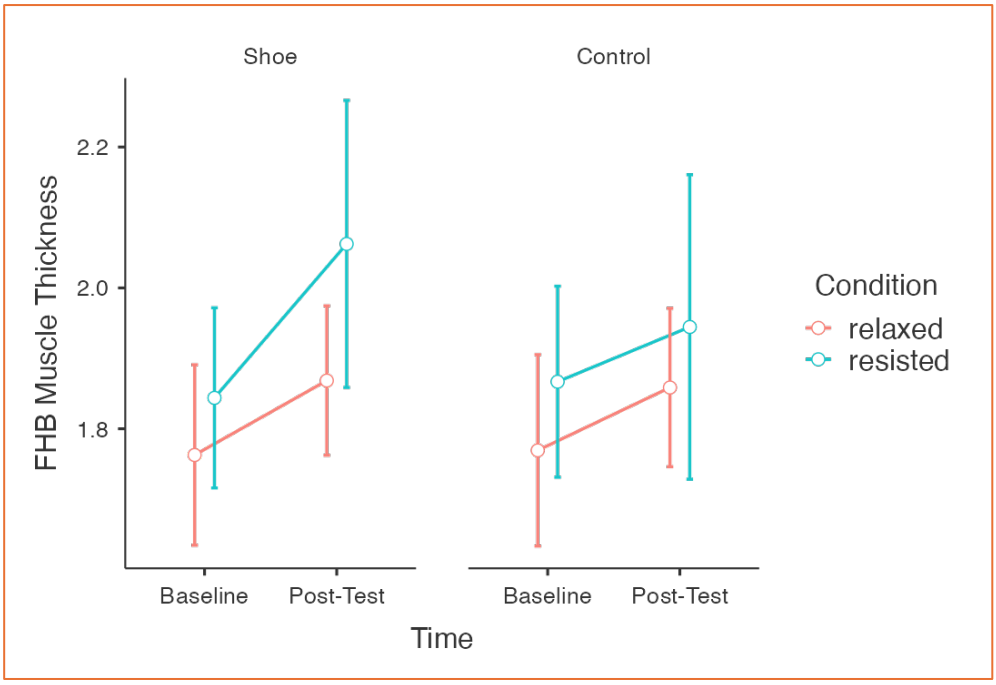
(d)



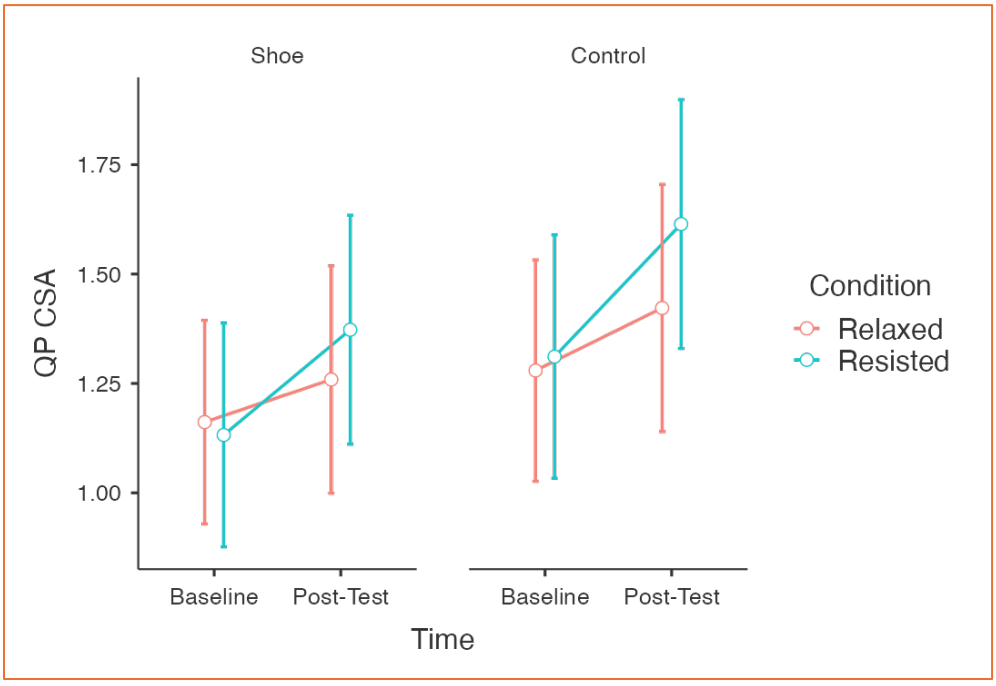
Abbreviations: HHD, handheld dynamometer; ND, novel dynamometer; GT, great toes; LT, lesser toes

Figure 2.9. Change across time by group and condition for (a) FHB Muscle thickness, (b) QP CSA, (c) FDB CSA, (d) FDB CSA Ratio, (e) ABH CSA

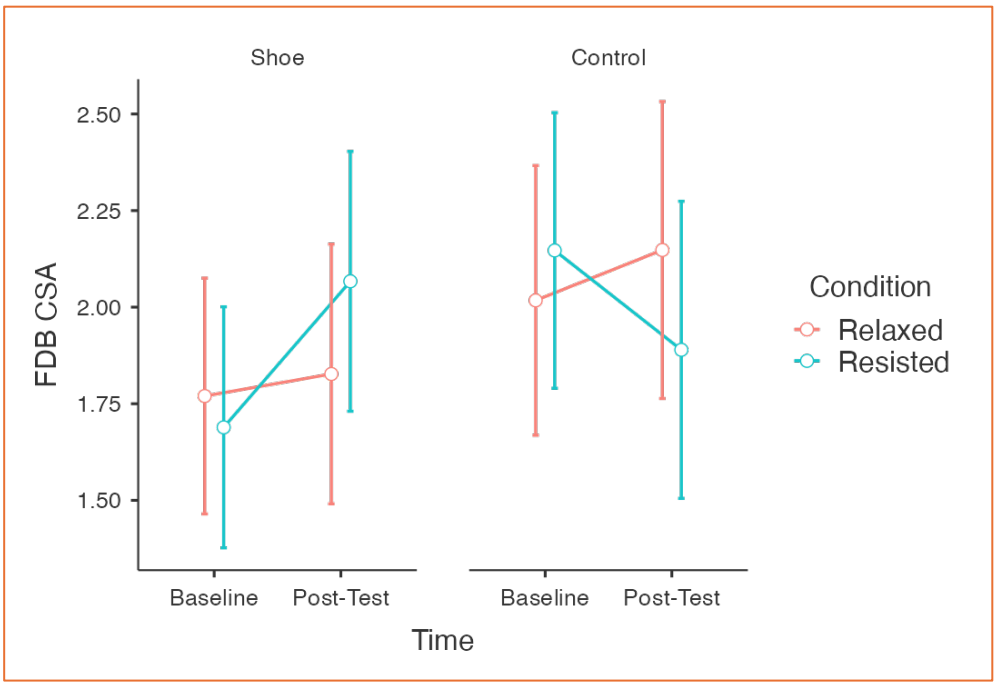
(a)



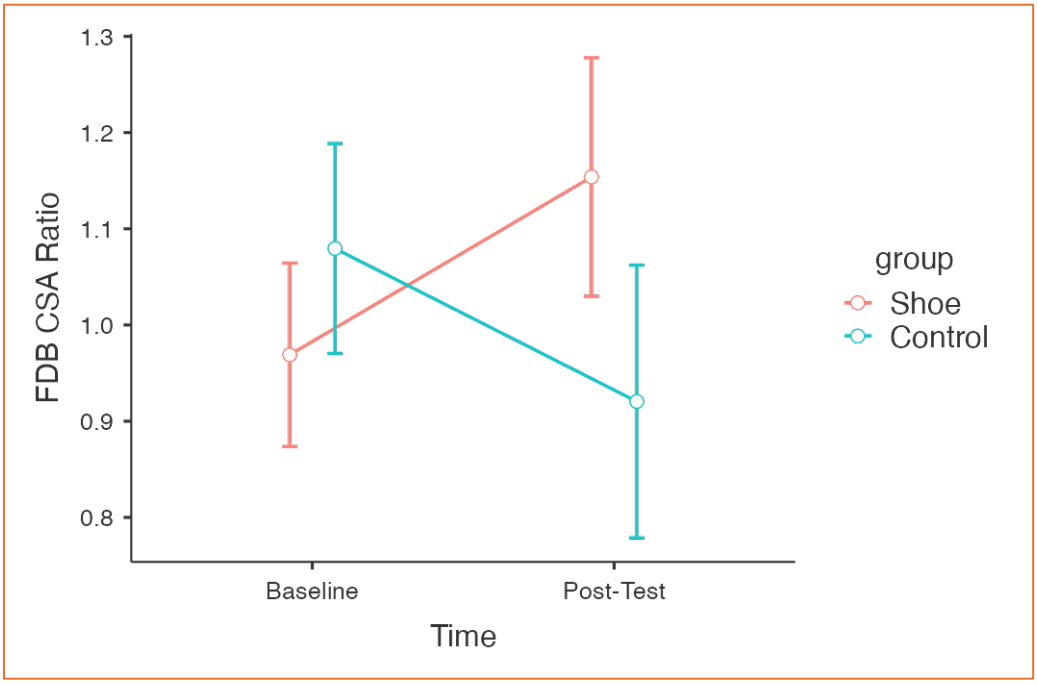
(b)



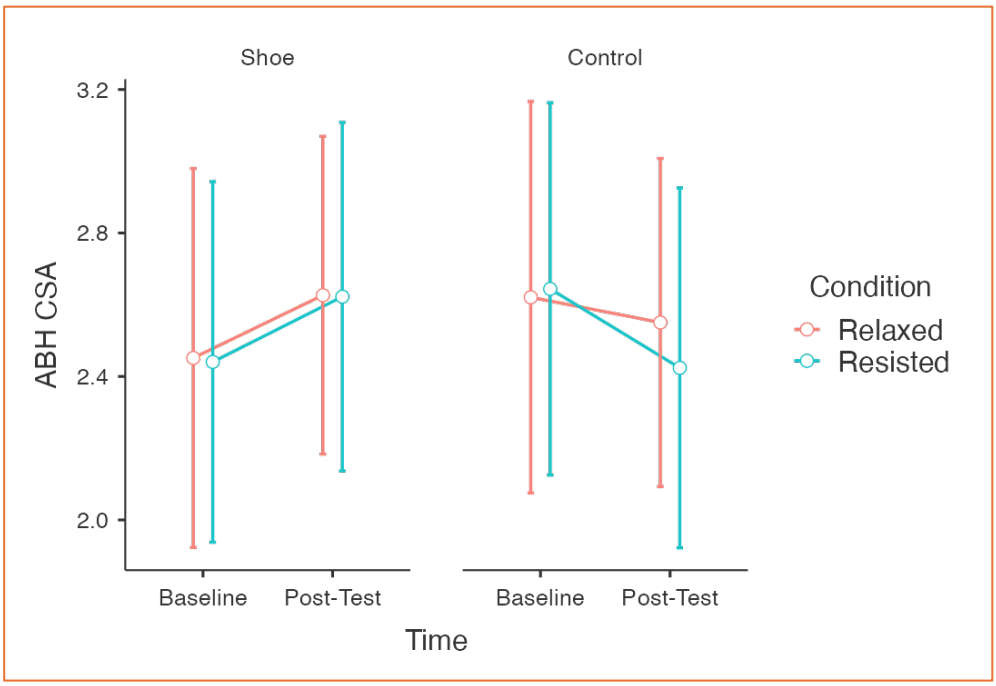
(c)


Shoe
Control
2.50
2.25
2.00
1.75
1.50
FDB CSA
Baseline
Post-Test
Baseline
Post-Test
Time
Condition
Relaxed
Resisted

(d)


1.3
1.2
1.1
1.0
0.9
0.8
FDB CSA Ratio
Baseline
Post-Test
Time
group
Shoe
Control

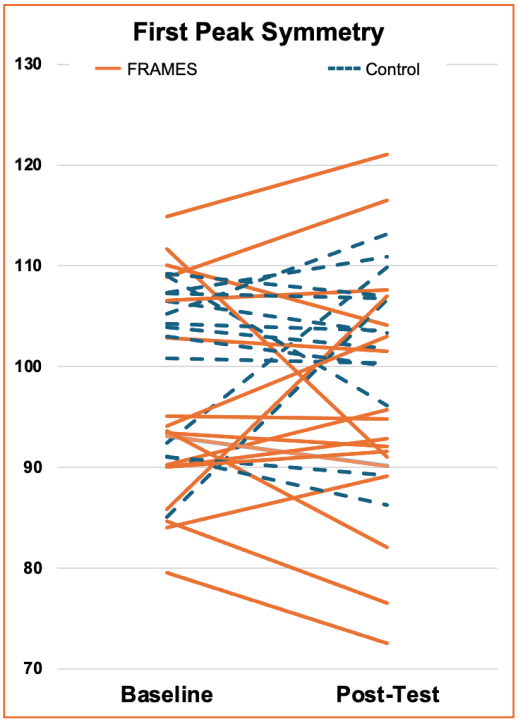
(e)



Abbreviations: ABH, abductor hallucis; CSA, cross-sectional area; FDB, flexor digitorum brevis; FHB, flexor hallucis brevis; QP, quadratus plantae

Figure 2.10. Symmetry of each participant by group from baseline to post-test for (a) First Peak Symmetry and (b) Second Peak Symmetry

(a)



(b)

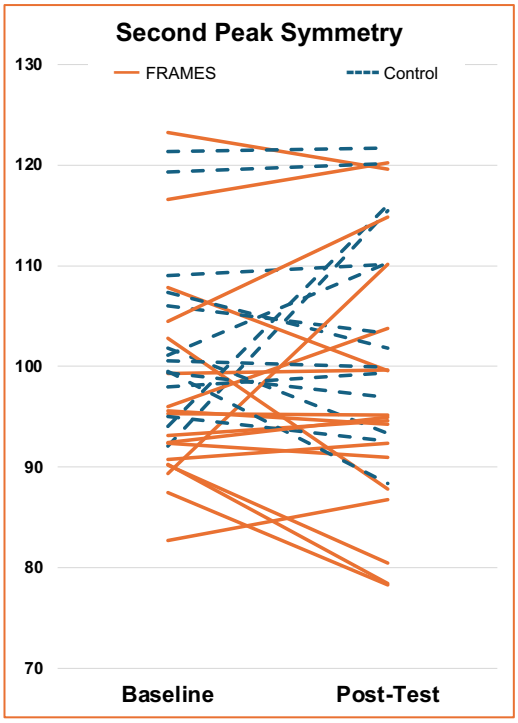
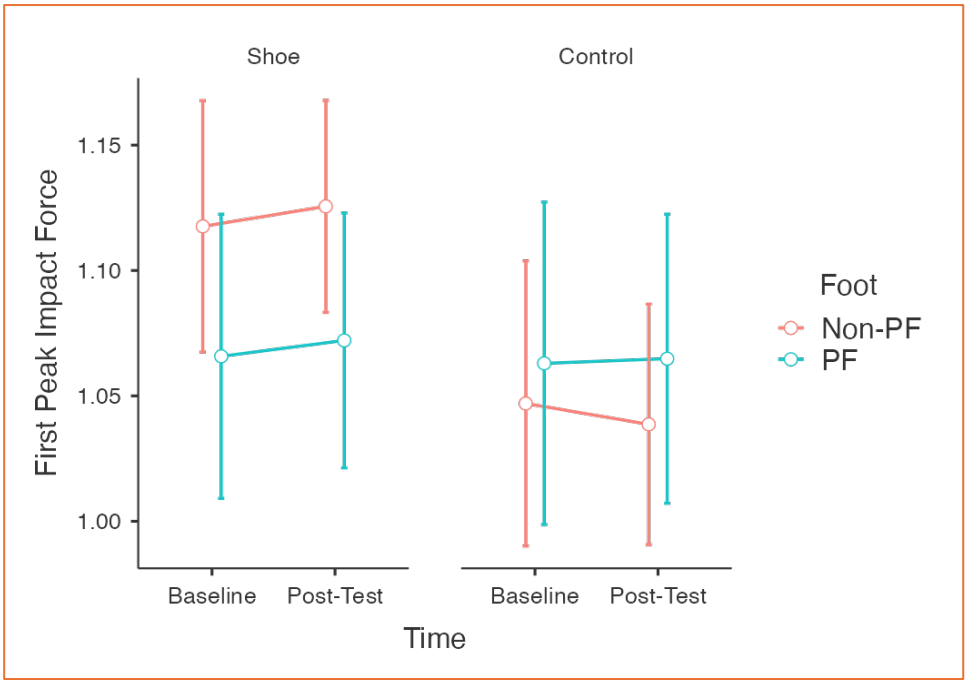
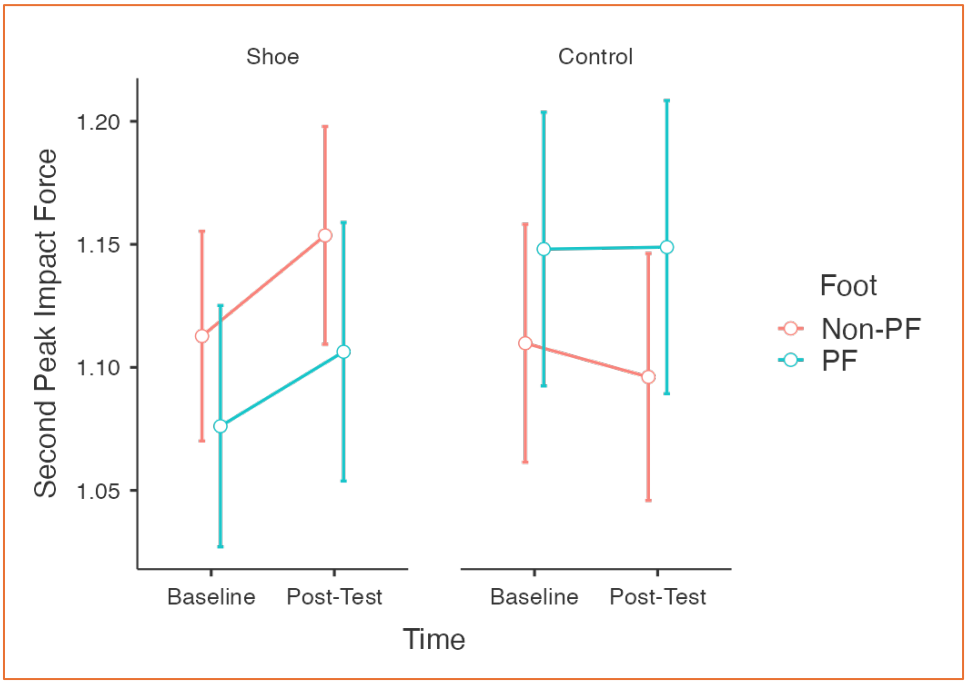


Figure 2.11. Change across time by group and condition for (a) First Peak Impact Force, (b) Second Peak Impact Force, (c) Mean Impact Force, (d) Loading Rate, (e) Impulse

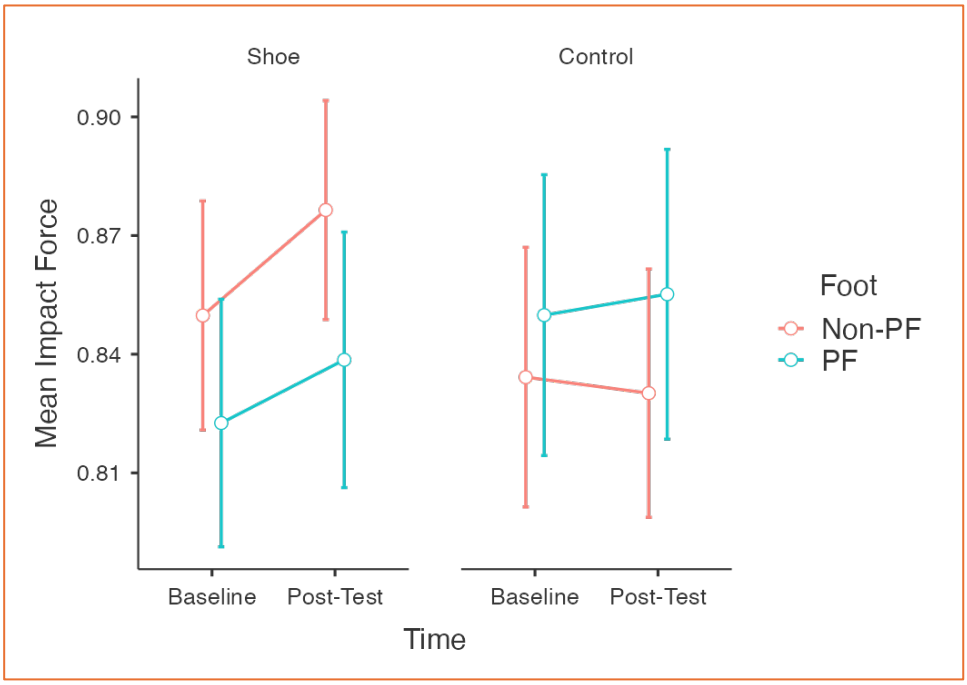
(a)



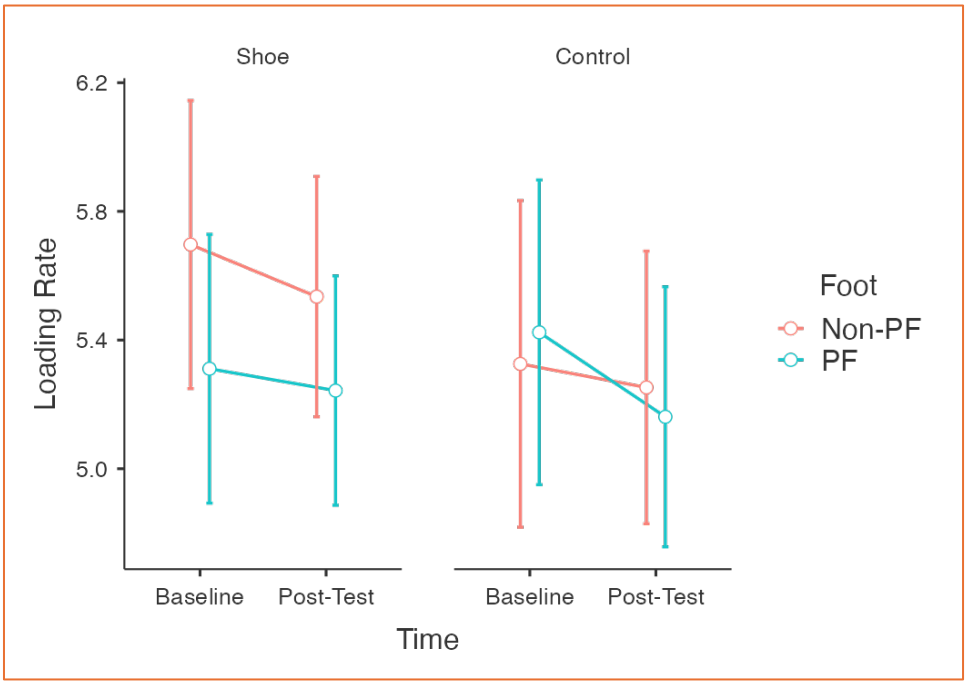
(b)



(c)


Shoe
Control
0.90
0.87
0.84
0.81
Mean Impact Force
Baseline
Post-Test
Baseline
Post-Test
Time
Foot
Non-PF
PF

(d)


Shoe
Control
6.2
5.8
5.4
5.0
Loading Rate
Baseline
Post-Test
Baseline
Post-Test
Time
Foot
Non-PF
PF

(e)

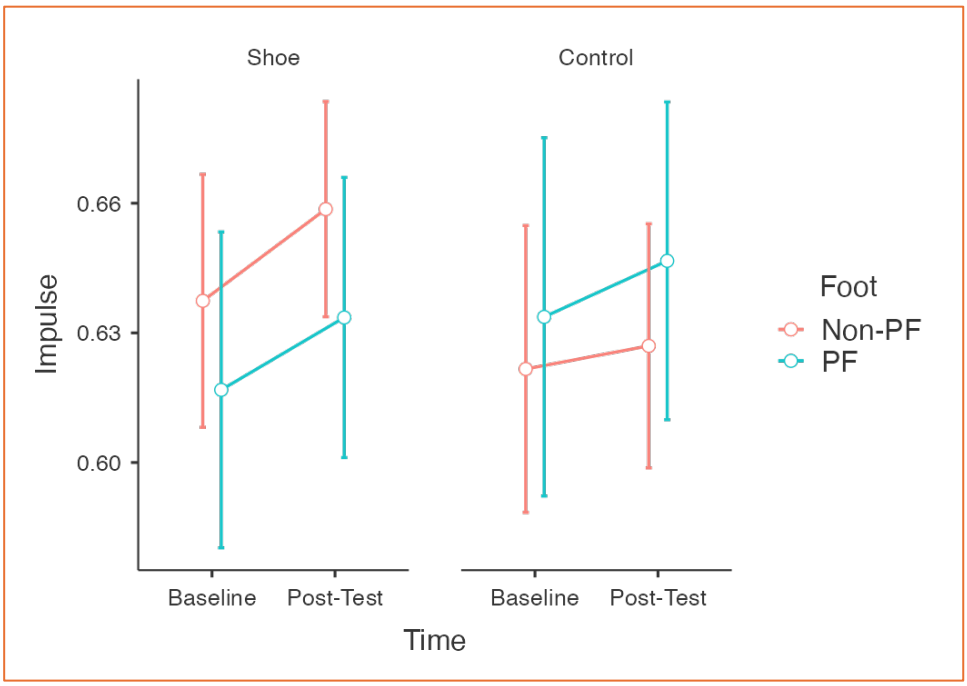
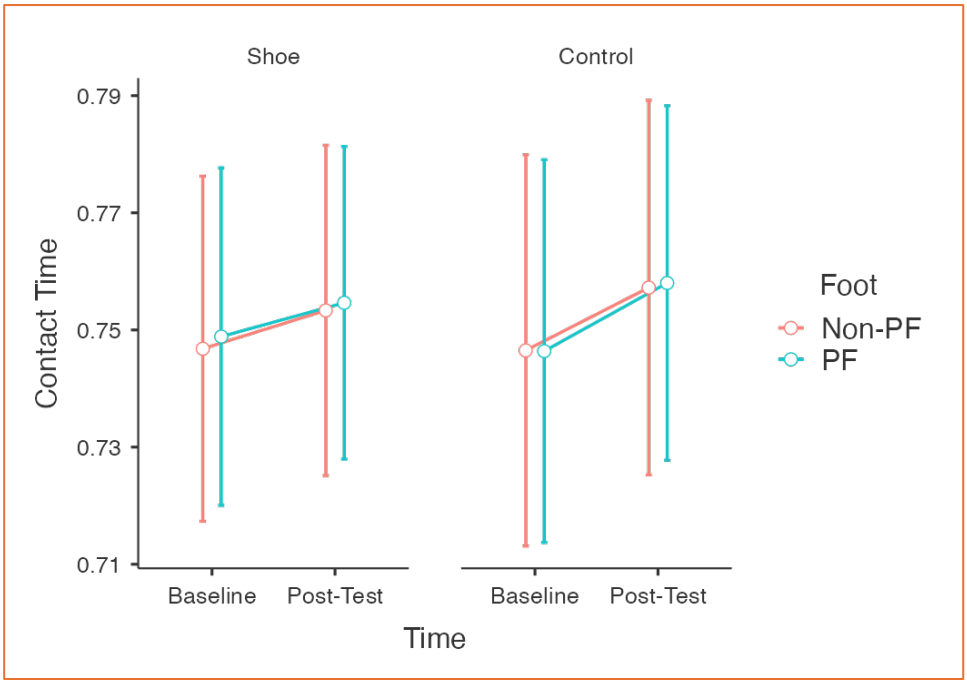
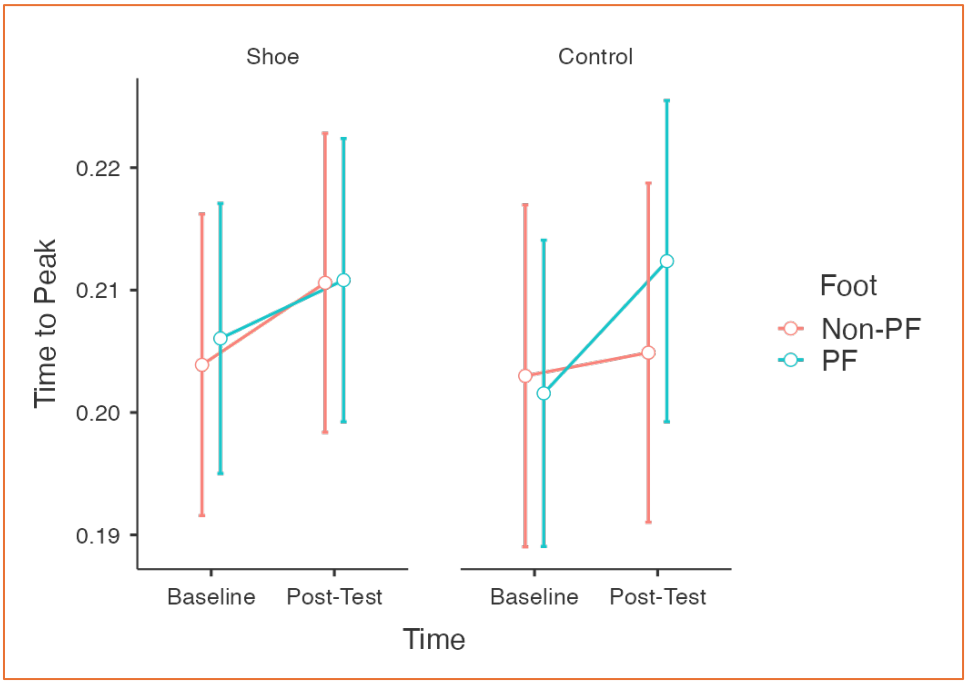

Shoe
Control
Impulse
0.66
0.63
0.60
Baseline
Post-Test
Baseline
Post-Test
Time
Foot
Non-PF
PF

Figure 2.12. Change across time by group and condition for (a) Contact Time, (b) Time to Peak, (c) Time Between Peak

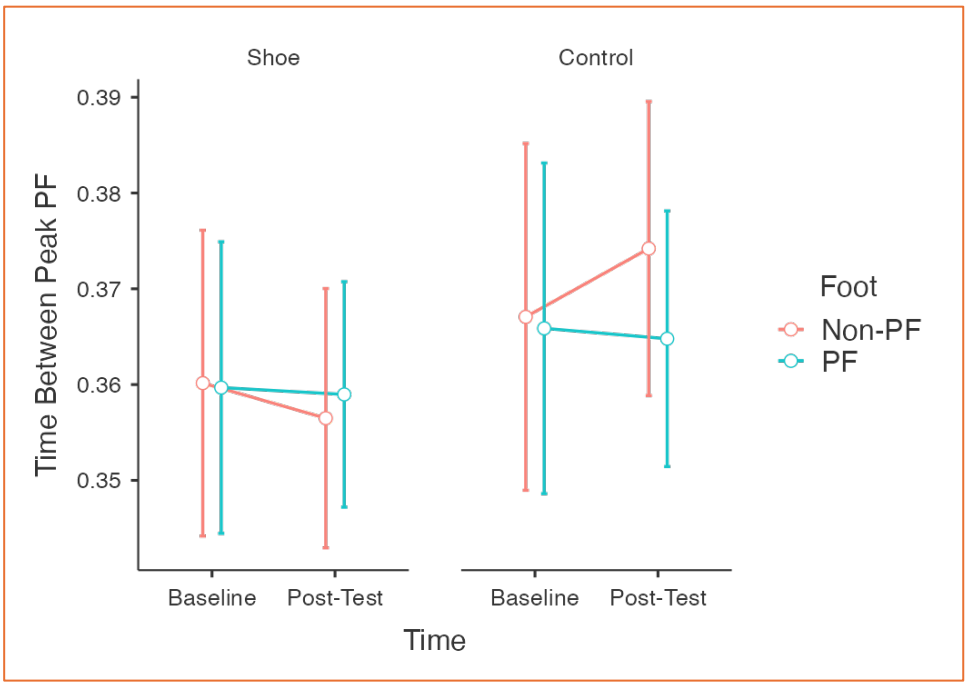
(a)



(b)



(c)


Shoe
Control
0.39
0.38
0.37
0.36
0.35
Time Between Peak PF
Baseline
Post-Test
Baseline
Post-Test
Time
Foot
Non-PF
PF

SECTION II: MANUSCRIPT III

THE EFFECTS OF BASELINE SELF-REPORTED PAIN, FUNCTION, PSYCHOLOGICAL MINDSET, AND PHYSICAL ASSESSMENTS ON CHANGES IN PAIN AND FUNCTION AFTER AN ACTIVE INTERVENTION OF MINIMALIST SHOES IN ADULTS WITH PLANTAR FASCIOPATHY: AN EXPLORATORY ANALYSIS

ABSTRACT

Background: Plantar fasciopathy (PF) is a musculoskeletal disorder that leads to foot pain, especially during movement and physical activities, but one potentially overlooked but important component is the psychological mindset of a patient with PF. Many individuals with PF attempt to self-treat by simply reducing their activity, or are prescribed passive interventions such as rest that can delay recovery or lead to recurrent episodes. This can lead to increased fear of movement, fear-avoidant behaviors due to pain, and emotional distress, which can continue a negative cycle. Individuals with PF are also known to have weakened intrinsic foot muscles (IFM), and performing strengthening interventions can improve pain and function. However, the effects of a movement-based on intervention on psychological beliefs has not been investigated.

Purpose: The purpose of this study was to determine how baseline levels of self-reported pain and function, psychological variables, and objective physical measures relate to changes in pain and self-reported function after an 8-week strengthening intervention. A secondary aim was to determine the effect of wearing minimalist shoes on psychological variables of kinesiophobia, fear-avoidance belief, and pain self-efficacy, compared to exercise only.

Methods: 34 individuals with PF were randomly allocated into the Foot Rehabilitation And Minimalist ShoES (FRAMES) group or control group (FRAMES: n=18 (13 female), 43.60 ± 11.5 years, 77.4 ± 10.8kg, 168 ± 9.56cm; Control: n=16 (11 female), 35.8 ± 11.4 years, 77.4 ± 15.5 kg, 165 ± 7.78cm). Both groups completed a strengthening protocol for 8 weeks, which included myofascial release with a massage ball, calf-raises with toes elevated on a rolled towel, and stretches for the calf and foot muscles. The FRAMES

group also wore a pair of minimalist shoes with a graded progression over 8 weeks. Outcome measures were collected at baseline and the post-test (8 weeks). Self-reported pain and function measures include 3 separate Visual Analog Scales for pain (VAS1: average pain over the past week, VAS2: average first-step pain over the past week, VAS3: heel pain of the day), and the Foot and Ankle Ability Measure (FAAM) which had 2 subscales (Activities of Daily Living (ADL) and Sport). Psychological variables were also assessed at baseline, 4-weeks, and 8-weeks, which included the Tampa Scale of Kinesiophobia (TSK-11), Fear-Avoidance Belief Questionnaire (FABQ), and the Pain Self-Efficacy Questionnaire (PSEQ). Using jamovi, Repeated Measures analysis of variance (RMANOVA) tests assessed changes in psychological outcomes by time and group, with Tukey HSD adjustments for post-hoc testing. For the exploratory analysis, linear regressions for the total cohort were completed where each of the changes over time for pain and function were the dependent variables. The predictors were the baseline levels of pain and function, kinesiophobia (TSK-11), and physical measurements of IFM strength of the PF limb with a handheld dynamometer (HHD), abductor hallucis cross-sectional area with diagnostic ultrasound in a weight-bearing position, center-of-pressure path length during single-limb balance with eyes opened, and first peak impact force during treadmill walking gait.. First, individual linear regressions of one predictor at a time were conducted. Second, combined linear regressions that included all 6 predictors in one model were completed.

Results: All individuals in this study were able to decrease their kinesiophobia and increase their self-efficacy, or confidence, despite pain, but there were no changes on fear-avoidance. Having higher pain at baseline was associated with greater decreases in

pain after the intervention, and having higher function at baseline was associated with poorer recovery for function. Higher levels of kinesiophobia at baseline were associated with greater improvements in pain and function, and kinesiophobia was a stronger predictor when alone compared to being in a combined model. Some better physical measures at baseline, including higher IFM strength and larger ABH CSA, were associated with greater decreases in pain and increases in function. However, neither first peak impact force nor path length during eyes opened balance at baseline were significant predictors for changes in pain and function

Conclusion: Individuals with PF who undergo an 8-week strengthening routine are able to decrease their fear of movement and increase their self-efficacy, showing that individuals at a variety of levels of psychological beliefs can both willingly and effectively implement a movement-based routine. Having poorer function and psychological beliefs at baseline, as well as higher pain, can lead to greater recovery regarding pain and function, but this is likely due to their larger margin for improvement. Individuals with better IFM function were able to achieve greater recovery, showing a potentially protective effect and highlighting the importance of IFM function for these individuals. The effects of movement-based intervention on individuals who are known to have fears of movement are important and should be assessed in future studies and by clinicians.

Word count: 772

Key words: plantar fasciopathy, plantar fascia, foot injury, intrinsic foot muscles, minimalist shoes, kinesiophobia, self-efficacy, fear-avoidance, rehabilitation

INTRODUCTION

Plantar fasciopathy (PF) is a common injury to the foot resulting in heel pain and decreased function.[1] It occurs when the plantar fascia, a tissue on the dorsal side of the foot, is mechanically overloaded often by body weight or a sudden increase in activity.[2] However, the effects of this injury are not only physiological. Individuals with PF report reduced physical activity and a feeling of social isolation,[3] accompanied by depression, anxiety, stress, pain catastrophization, kinesiophobia,[3–6] and pain-related fear regarding movement.[7] Patients have also experienced frustration, blaming themselves for their pain, and even avoiding social or other activities to manage their pain well.[7] These effects on an individual's psychosocial health may then continue to exacerbate their pain, creating a negative feedback cycle.

Treatments for PF often involve more conservative measures of rest, ice, heel cups or orthoses, as well as more invasive procedures such as corticosteroid injections. However, these interventions have mixed results for their effectiveness, due to heterogeneity of samples and intervention dosages.[2] One such intervention that has not been explored as much is strengthening the lower leg and intrinsic foot muscles (IFM), which is an oversight as individuals with PF are known to have weaker and smaller IFM compared to healthy individuals.[8–10] Several studies have shown that strengthening the IFM via foot and ankle exercises[11,12] and even wearing minimalist shoes[13,14] are effective in reducing pain and improving function in individuals with PF, although they are vastly outnumbered by studies evaluating more passive treatments.[2] Performing therapeutic exercises or wearing minimalist shoes may be difficult to implement in injured individuals, however, as they could potentially cause discomfort and some pain initially.

The Fear-Avoidance Model of pain could be important, which posits that pain-related fear leads one to avoid any movement or activity in order to avoid pain. Long-term, this could lead to muscle atrophy, social isolation, further disability, and eventually increase the level of fear over time.[15] This fear-avoidance model could be relevant to individuals with PF who experience increased kinesiophobia (fear of movement) and pain catastrophization (exaggeration of pain as a threat and rumination),[6] which can affect their abilities and willingness to do things. Patients with PF often avoid both social and physical activities because of pain,[3,7] allow fear of worsening pain to dominate their lifestyle choices, and even hide their pain out of shame.

However, it is curious if challenging fears by implementing movement-based interventions could improve pain and function in adults with PF. There are several factor aside from pain levels and self-perceived physical function that could potentially be contributing to the functional deficits, such as decreased IFM strength and size,[8–10] decreased vertical ground reaction forces at impact and propulsion[16] and poorer static and dynamic balance ability.[17–19] The goal of implementing strengthening exercises and minimalist shoes in daily activity was certainly to improve these objective physical measures, but also to observe how this intervention would affect self-reported measures of psychosocial behaviors, pain, and function. The purpose of this study was to determine if and how self-reported pain and function, psychological variables, and objective physical measures at baseline may predict changes in pain and self-reported function after the active intervention. We hypothesized that individuals with PF who improve the most will have baseline levels of lower kinesiophobia, stronger and larger IFM, better postural control, and higher impact forces on their PF limb. A secondary aim was to determine the

effect of wearing minimalist shoes on psychological variables of kinesiophobia, fear-avoidance belief, and pain self-efficacy, via patient-reported outcomes (PROs) assessed at baseline, at 4 weeks, and 8 weeks. We hypothesized that individuals in the FRAMES group, compared to the control group, would achieve greater improvements in kinesiophobia, fear-avoidance belief, and pain-self efficacy by the 8-week point.

METHODS

The same number of participants (n=37) were recruited according to the same inclusion and exclusion criteria as Manuscript I. All participants provided informed consent prior to beginning any study procedures, and the study was approved by the University's Institutional Review Board for Health Sciences Research (HSR-230045).

The initial procedures of screening, assessment for PF, and randomization in the baseline session were the same as Manuscript I.

Outcome measures:

Fear Avoidance Belief Questionnaire (FABQ): Participants indicated how their fear-avoidance beliefs about physical activity and work affected their pain, with 16 items rated 0 – 6 ("completely disagree" to "completely agree"). Separate scores are provided for the physical activity (FABQ-PA) and work (FABQ-W) subscales. The FABQ was initially created for low back pain, and is shown to have high internal consistency and reliability,[20] where test-retest reliability was shown to be ICC=0.97.[21] Fear-avoidance beliefs have been shown to similarly influence change scores for pain intensity across different body parts, and are often used in outpatient rehabilitation to identify subjects with elevated fear.[22] Although there are not many uses of the FABQ in studies with PF, we wanted to assess specifically how an individual's work and physical activity could

affect their pain with a shoe-based intervention, as occupation could potentially affect plantar fasciopathy rates.[23–25]

Tampa Scale of Kinesiophobia (TSK-11): Participants indicated their levels of kinesiophobia, or fear of movement. The TSK-11 has 11 items scored on a 4-point Likert scale from 1-4 ("strongly disagree" to "strongly agree"), where a higher score indicates greater kinesiophobia. The TSK-11 is a shorter version of the TSK-17, and has been shown to have excellent reliability (ICC = 0.91); face, content, and construct validity.[26] The TSK-17 has previously been used in individuals with PF, and showed that kinesiophobia contributed to 21% of the variability of foot function.[5] Kinesiophobia was assessed in these participants because of the active protocol that could have required individuals to push through some pain and potentially challenged the beliefs on their limitations.

Pain Self-Efficacy Questionnaire (PSEQ): Participants indicated their levels of self-efficacy, or belief and confidence in one's ability to complete something despite their pain. The PSEQ has 10 questions with a Likert scale from 0 to 6 ("not at all confident" to "completely confident"), where a higher score = greater self-efficacy. The PSEQ has high internal consistency and high test-retest correlation, and is significantly correlated to the impact of pain on daily life.[27] Individuals with PF who underwent a calf-raise protocol were able to achieve significant improvements in the PSEQ.[28] The PSEQ was chosen in this study because many patient-reported outcome measures in the world of PF involve questions about stress, anxiety, kinesiophobia, catastrophization, depression, and an individual's limitations. However, the PSEQ asks individuals to consider their confidence level despite their pain, which has a more positive outlook.

Other outcome measures were taken from Manuscript I and Manuscript II, which included: 3 pain constructs (average pain of the past week (VAS1), average first-step pain of the past week (VAS2), and heel pain of the day (VAS3)), self-reported function with the Foot and Ankle Ability Measure (FAAM) for ADL and Sport subscales, IFM strength, IFM size, single-leg balance, and treadmill walking gait kinetics.

Statistical Analyses

For the primary aim, participants were not split by groups during analysis due to the small sample size. Additionally, most findings were similar between groups, according to Manuscripts 1 and 2, in pain, self-reported function, and functional measures, although differences in IFM size and gait measures will be considered in the discussion. This exploratory study served to observe which traits would allow individuals to be most successful after an active intervention, with or without minimalist shoes.

Using jamovi version 2.3.28.0 (Sydney, Australia),[29] a Pearson r correlation matrix was generated to determine the strength of relationships between all pain, psychological, and functional measures at baseline with the percent changes in VAS1, VAS2, VAS3, FAAM ADL, and FAAM Sport. To calculate change in pain and function, percent change was calculated with the following equation: ((Post-Test – Baseline)/Baseline)*100. For the pain variables (VAS1, VAS2, VAS3), the final percent change was multiplied by -1 in order to interpret it more easily, where a more positive number indicated greater pain relief. For FAAM ADL and FAAM Sport, a more positive number indicated greater improvements in function. A second Pearson r correlation matrix was conducted between all baseline measures of pain, psychological, and functional measures.

For the exploratory analysis, we conducted separate linear regression analyses for each change in pain (VAS1, VAS2, VAS3) and change in function (FAAM ADL and FAAM Sport). In these models, we chose specific predictors that would be beneficial to understand clinically or easily accessible in a clinical setting, narrowing our total variables to only 6. Also, we chose variables that were more correlated to the dependent variables of changes in pain and function over time if there were many to choose from, such as for intrinsic foot muscle size.

First, baseline pain and function scores for each of the change scores were chosen. Kinesiophobia levels with the TSK were also chosen, given the higher correlations of the TSK with the change scores, and the general applicability of the questions for movement-related beliefs. Additionally, pain, function, and kinesiophobia scores are all assessed with patient-reported outcomes, which can be easy to obtain for any setting. For functional outcomes, strength of the injured limb assessed with the HHD was chosen (HHD PF), where the strength of the great toe and lesser toes was added together and normalized to bodyweight. This was chosen because strength was shown to increase when tested with the HHD, but not when tested with the ND. Also, a metric that adds together strength values can be a simpler way to understand strength between the limbs. ABH CSA was chosen because of the greater number of correlations with the change scores, and specifically in the resting position in case there were some participants who could not contract their ABH at all. It is also an easier muscle to assess with diagnostic ultrasound compared to several other IFM if clinicians were interested in learning how to complete the test, and plays an important role in supporting the arch of the foot alongside the plantar fascia. First peak impact force on the PF limb during treadmill walking gait

was chosen because PF results in heel pain, and the first peak is associated with initial heel contact in walking gait; therefore we were curious if this could play a role in pain and function. Lastly, path length during single-leg balance with eyes opened was chosen as a more simple metric that allowed us to consider movement in all 4 directions, instead of isolating to one specific direction.

For each change score in pain and function, there were 2 separate levels of linear regressions that were conducted. First, each predictor was individually assessed in a linear regression model to obtain R-squared, p-value, and the standardized estimate. Second, all predictors were combined into one model for each change score, where p-values and standardized estimates of each predictor were obtained. Separate scatter plots for pain and function scores were created to show the standardized estimates of all the predictors for both the individual models and the combined models.

For the FABQ, TSK, and PSEQ, RMANOVA tests were conducted at baseline, 4-weeks, and 8-weeks to ascertain any significant changes over time and between-group. Post-hoc testing with Tukey's HSD adjustments were performed, and within-group p-values and Cohen's d effect sizes (95% CI) were also reported.

RESULTS

Table 1 shows the mean, SD, within-group p-values by time, and effect size from baseline to 8-weeks for each group, as well as the total cohort. The TSK and PSEQ had significant main effects for time, while the FABQ-W had significant main effects by group, with a difference between-group at baseline ($p=0.029$). There were no significant group by time effects for any variable, and there were no other significant differences at baseline.

Additional Results Table D3.1 shows the correlations for all pain, psychological, and physical measures at baseline with the percent change in VAS1, VAS2, VAS3, FAAM ADL, and FAAM Sport. Additional Results Table D3.2 shows correlations for all baseline variables.

Figures 1 through 4 show the scatter plots for the standardized estimates of each independent variable, for both the individual and combined linear regression models. Additional Results Table D3.3 and D3.4 show the adjusted-R^2, p-value, and standardized estimates for the individual linear regression models, as well as the p-value and standardized estimates for the combined linear regression models. For all 3 pain variables in both the individual and combined models, each 1-standard deviation increase in pain at baseline was associated with a larger decrease in pain by the end of the study (Individual: VAS1 and VAS2, $p=0.008$, $R^2=0.175$, Std. EST=0.447; VAS3, $p<0.001$, $R^2=0.318$, Std. EST=0.582. Combined: VAS1, $p=0.007$, Std. EST=0.465; VAS2, $p=0.01$, Std. EST=0.417; VAS3, $p<0.001$, Std. EST=0.658). For both function scales in both individual and combined models, each 1-standard deviation increase in function at baseline was associated with a smaller increase in function by the end of the study (Individual: FAAM ADL, $p<0.001$, $R^2=0.536$, Std. EST=-0.742; FAAM Sport, $p=0.004$, $R^2=0.204$, Std. EST=-0.477. Each increase in kinesiophobia was associated with improved FAAM ADL ($p=0.023$, $R^2=0.124$, Std. EST=0.388) and VAS1 ($p=0.046$, $R^2=0.092$, Std. EST=0.345), but only as an individual predictor and not in the combined models. Higher IFM strength of the PF limb alone was significantly associated with greater improvement for VAS2 ($p=0.007$, $R^2=0.183$, Std. EST=0.455), and larger ABH CSA was significantly associated with improved VAS1 ($p=0.015$, Std. EST=0.41) and

FAAM ADL (p=0.042, Std. EST=0.29) but only in the combined models. First peak impact force and path length EO during single-limb balance were not significant predictors in any of the models.

DISCUSSION

The results of this study indicate that baseline levels of pain, self-reported function, kinesiophobia, and physical measures could influence the magnitude of recovery in individuals with PF after an active intervention.

Baseline values of pain and function compared to their respective percent changes over time were all significant. For all 3 pain variables in both the individual and combined models, each 1-standard deviation increase in pain at baseline was associated with a larger decrease in pain by the end of the study. For both function scales in both individual and combined models, each 1-standard deviation increase in function at baseline was associated with a smaller increase in function by the end of the study. This essentially shows that having poorer results at baseline (higher pain, lower function) is actually associated with a larger improvement in pain or function. There may be a ceiling effect present, where individuals who feel better at baseline won't have as much room to recover, therefore the magnitude of the change won't be as large. However, those who are feeling worse at baseline are capable of having a larger magnitude of recovery, simply because they have more room to change. Although having greater pain or kinesiophobia is not protective and individuals should not strive for this, this type of active intervention seems to be helpful for individuals with high levels of pain and poor function. The important finding is that all individuals can improve regardless of pain levels.

Interestingly, baseline FAAM ADL scores alone explained 53.6% of the variance in change in FAAM ADL over time, which is the highest value for all individual models. Meanwhile, baseline VAS3 only explains 31.8% of the variance in change in VAS3. This indicates that pain resolution may depend more on a variety of other factors, while any improvements in function for ADLs appear to be highly dependent on baseline function. Clinicians should consider using the FAAM questionnaire for patients with PF alongside pain questionnaires, because the FAAM does not ask specifically about pain. Rather, it inquires about the level of difficulty someone experiences during activities such as going up stairs, walking or standing for periods of time, and other usual activities of daily living. This differs from questionnaires that specifically target how pain influences function, such as the Oswestry Disability Index for back pain. Therefore, the FAAM can be a more objective measure as it can reveal functional limitations and disability that a patient is experiencing without the influence of pain, which can certainly vary heavily depending on an individual's recent activity, sleep, mood, diet, and more. Clinicians can then consider some more interventions that directly impact a patient's self-reported function, to improve upon their limitations. The FAAM is also useful because sport subscale may be important for individuals who are more athletic, which is not a component of every foot pain-related questionnaire. Importantly, individuals can mark a "Not Applicable" if they do not perform the activity at all, which is not included in the total possible score. This allows the percentage of functional ability to be more individualized. Also, if individuals do not see much of a change in their score, they may be completing more tasks than they did before, which can be seen by observing individual answers.

While the adjusted-R^2 values of the combined models for pain scores are all quite similar (VAS1: 0.379, VAS2: 0.388, VAS3: 0.407), the values for the combined models for function are quite different (FAAM ADL: 0.549, FAAM Sport: 24.4). This may be because the questions for pain are likely quite related, given they are only one question with the exact same scoring scale. Even though there are small differences between the combined models for pain in how each predictor plays a role, the overall prediction ability is similar. However, it is interesting that the combined model for FAAM ADL has over twice the predictive power of the combined FAAM Sport model. This may be because the FAAM ADL has questions about lower intensity activities that many individuals would likely complete on a daily basis. Meanwhile the FAAM Sport has questions about higher intensity activities that several individuals are not even completing at baseline and may not do during the 8 weeks, which could affect the way participants answered the survey.

Kinesiophobia was most related to FAAM ADL, then pain, and then FAAM Sport the least. This is likely because most individuals perform the tasks in the FAAM ADL subscale, but not everyone performed the tasks in the FAAM Sport subscale. Kinesiophobia alone can significantly explain 9.2% of the variance for change in VAS1, and 12.4% of the variance for change in FAAM ADL. For both FAAM subscales, as well as VAS1 and VAS3, kinesiophobia had a reduced effect on the dependent variable when there are other physical outcomes as predictors in the model, as seen in the standardized estimates, likely because these variables have shared variance. Perhaps this indicates that being able to assess kinesiophobia on its own is beneficial when wanting to understand potential rates of recovery, if not many other components are able to be assessed. This is

important because kinesiophobia is a patient-reported outcome that can be more easily assessed when compared to some of the physical measures obtained in this study. These results also show that this active protocol can be beneficial for individuals with any level of kinesiophobia at baseline by potentially challenging their fears.

Strength of the PF limb was shown to be more related to change in pain than function, especially average first-step pain of the past week (VAS2). This could be because the FAAM asks mostly about full body movements that involve the larger, more proximal lower extremity muscles, which could potentially overpower some IFM weakness. Even though baseline IFM strength and pain are not significantly correlated, those who have stronger IFM will likely have an easier time progressing the rehabilitation exercises. They may be able to become stronger at a faster rate, which could assist in foot control and likely offload the plantar fascia.[30]

The HHD PF alone explains 18.3% of the variance for change in VAS2, which is the fourth-highest in all the individual models. This can be beneficial as the devices that can assess strength (HHD) could be lower cost and easier to access than some other physical outcome measures that require diagnostic ultrasound or insole-based gait assessments. Even if HHD strength is the only physical measure that can be obtained, that may still be beneficial regarding change in pain. A second consideration for HHD strength is that previous research has shown that individuals with chronic PF (>12 months) have weaker IFM muscles than those with acute PF (<6 months),[31] so it would also be interesting to understand how length of pain can play a role, which could be easily added as a patient-reported outcome. One other interesting finding is that for FAAM ADL, the standardized estimate with HHD PF as the predictor is negative, in both

individual and combined models. This indicates that having stronger IFM at baseline is associated with a worse recovery in function ADLs. However, this could simply indicate that individuals with stronger IFM at baseline may also be more functional at baseline, leading to a ceiling effect in achievable recovery. The fact that HHD PF is a significant predictor for average first-step pain over the past week with a positive standardized estimate shows how the changes in pain and function are not entirely in agreement with one another, interestingly enough. However, the most important finding here is that having stronger IFM sets an individual with PF up for success with an 8-week active intervention in terms of pain resolution.

ABH CSA was most associated with VAS1 and FAAM ADL, but was only a significant predictor in those combined models. When considered individually, ABH CSA does not appear to significantly predict any changes in pain and function, but it plays more of a role when considering other predictors. This may mean that if clinicians are not able to assess any of the physical outcome measures that were obtained in this analysis, obtaining IFM size via ultrasound may not be the biggest priority, compared to something like HHD strength. Interestingly, ABH CSA resting did not change significantly over the protocol. ABH CSA is not significantly smaller in individuals with PF compared to healthy individuals,[9] which means that it likely is not going to see any significant increases after a protocol. Instead, its baseline size could contribute to total IFM strength, whole-body function, and subsequent pain levels, as the ABH is known to support the medial longitudinal arch in both static weight-bearing positions and gait.[32,33] As there are no deficits in ABH CSA for individuals with PF,[9] any extra increase in size at baseline could serve to only improve recovery rates. However, the muscle activity of

ABH in individuals with PF has not been explored, especially in weight-bearing conditions, so this is only a supposition that must be evaluated in future research.

Path length during EO balance and first peak impact force were not shown to be significant predictors for recovery in pain and function. Potentially, a different single-limb balance metric could be better, which could be investigated with future research. For example, number of errors committed during the testing could be beneficial, and it would not require any special equipment from a clinician. It was initially thought that heel pain might impact first peak impact force during walking gait where the heel is the first contact with the ground. However, it was not a significant predictor and heel pain did not show any correlations with impact forces at baseline either. This may be because the intervention did not include gait retraining or postural control. This intervention was directly aimed at improving IFM strength and size could explain why having stronger and larger IFM were beneficial in leading to improvements in pain. Thus, it could be interesting to assess the contribution of baseline gait and balance to recovery after a gait retraining or postural control intervention.

These findings show that there are a variety of characteristics in individuals with PF which may allow them to achieve greater levels of recovery in terms of pain and self-reported function. Both of these types of outcomes are important, but the predictors associated with poorer outcomes can indicate certain deficits that patients may need to focus on, while the predictors associated with better outcomes can serve as encouragement for patients. Overall, the function of the IFM appear to be important in individuals with PF before even starting an IFM strength-based intervention, and an intervention specifically targeting the strength of the IFM can effectively improve pain

and function. However, these findings are not intended to rule individuals out of completing a rehabilitation program, as all individuals in this study reported improvement with the intervention. Rather, this exploratory study may point towards some clinical tests that are best and easier to access when attempting to predict a patient's success with a rehabilitation intervention, to understand what they may need to focus on the most.

Even though this study did not implement a direct psychological intervention, individuals with PF were able to improve their psychological beliefs regarding fear of movement and self-efficacy. It certainly can be difficult and potentially out of scope for rehabilitation professionals to directly implement psychological interventions without the oversight of trained professionals. However, it is interesting to note that individuals at all levels of these psychological beliefs were also all able and willing to complete this type of intervention and were able to decrease some of their negative beliefs about movement.

Both groups in this study were able to reduce kinesiophobia and improve self-efficacy, although there were no changes in fear-avoidance belief. This is likely because the individuals had relatively high levels of adherence to the protocol as observed in Manuscript I, even if they may have had some kinesiophobia. The protocol likely challenged that fear of movement and improved their confidence, as individuals saw that they were capable of performing the tasks. However, fear-avoidance belief may include longer-standing beliefs about why they started having pain (caused by work or physical activity), and that they still shouldn't do activities or work that makes their pain worse. The protocol may have allowed them to gain confidence and decrease their fear, but they may also have associated the specific exercises and the minimalist shoes with activities that do ***not*** make their pain worse, thus not really changing their mindset on fear-

avoidance. Altering this type of belief could require a longer protocol or a progression, in order to challenge their beliefs as they continue to progress and improve.

Kinesiophobia and self-efficacy had a stronger relationship with self-perceived function compared to pain, while fear-avoidance belief had a stronger relationship with pain. This could be because the questions regarding fear-avoidance were quite specific, with each question specifically featuring the word “pain”. Each question was also somewhat simple, where individuals indicated their level of agreement or disagreement with statements that focused on how pain and movement (either activity or work) can worsen each other. The focus was on how pain leads someone to avoid movement, while the TSK was focused on how their pain affects the movement they are already doing, even if it is something relatively simple like walking to the mailbox. Further, the questions on the TSK did not mention the word “pain” in every question, and also features some less negative lines of questioning, such as “just because something aggravates my pain does not mean it is dangerous”. The PSEQ was also completely different from either of these, where individuals were asked to rate how confident they were in their abilities to do a task, despite their pain. Essentially, it asked for context in terms of their ability to do things. For example, could they confidently perform a task despite their pain?

The focus on this type of positive questioning from the PSEQ could actually be extremely important in individuals with PF, as they are known to constantly think about what they are limited by because of their pain and are frustrated by their lack of control over it.[7] However, individuals with PF have reported feeling positive when finding other modalities of exercise other than walking or running that would exacerbate pain, such as

biking, rowing, or swimming, and that even socializing at work with colleagues was beneficial.[7] Focusing on capabilities instead of limitations can provide some positive outlooks. Individuals with PF should still certainly be free to express their frustration, as they may tend to hide their pain and avoid asking for help initially,[7] which is not beneficial. However, clinicians may be able to strike a balance by asking patients about both their negative and positive feelings initially, especially about their abilities to do things both despite and because of their pain.[27] This can help clinicians understand a patient's unique concerns and experiences and how that affects their perceptions of pain or function.[7] Interestingly, individuals in this study reported relatively high scores even at baseline (maximum score is 60), but this was accompanied by moderate levels of pain and function at baseline, as seen in Manuscript I. While they were already quite confident, this type of active intervention could have potentially confirmed that their level of confidence was appropriate and allowed them to continue improving.

Limitations

Several participants reported pain on both limbs, but the purpose of this study was to choose the limb that was more painful. However, this could have affected results that were collected bilaterally, such as foot morphology, IFM strength, and gait. This could have, in turn, affected any findings involving bilateral outcomes at baseline and subsequent changes in pain or self-perceived function. However, even for patients with unilateral PF, the selection of the "more painful limb" is still relevant and provides us with some important information. Additionally, several variables did show differences by time and group at baseline and over time, which could have affected how these results looked for the entire cohort. However, the intention of this study is merely to understand

how some baseline measurements can affect the magnitude of recovery after an active 8-week intervention.

CONCLUSION

In individuals with PF, pain, function, kinesiophobia, and IFM function at baseline contributed in a variety of ways to the changes in pain and function after a strengthening intervention, and are important to assess clinically and in future studies. However, the important outcome is that this active, movement-based intervention was able to reduce pain and improve function in individuals with PF, regardless of their performance and self-reported measures at the start of the intervention. Additionally, participants were able to reduce kinesiophobia and improve self-efficacy in both groups. Even though there were no changes in fear-avoidance belief, all of these psychological beliefs can be important to assess in individuals with PF, because they do each ask about a different construct for individuals with PF and exert a variety of positive and negative effects on achievable recovery. Finally, an important question - could movement-based interventions serve to decrease fear of movement and increase self-efficacy despite pain, even without any direct psychological intervention? This does not mean that psychological interventions should not be used. However, there are currently no studies intervening specifically on the psychological aspects of PF and it may not always be appropriate to administer these interventions without the proper oversight. Therefore, instead of recommending implementing psychological interventions, clinicians should simply consider how important some of these beliefs and fears are in recovery from a chronic and sometimes debilitating condition such as PF. Clinicians should use that

information to guide their approach when explaining the causes, risk factors, and effective interventions in individuals with PF to their patients.

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TABLES

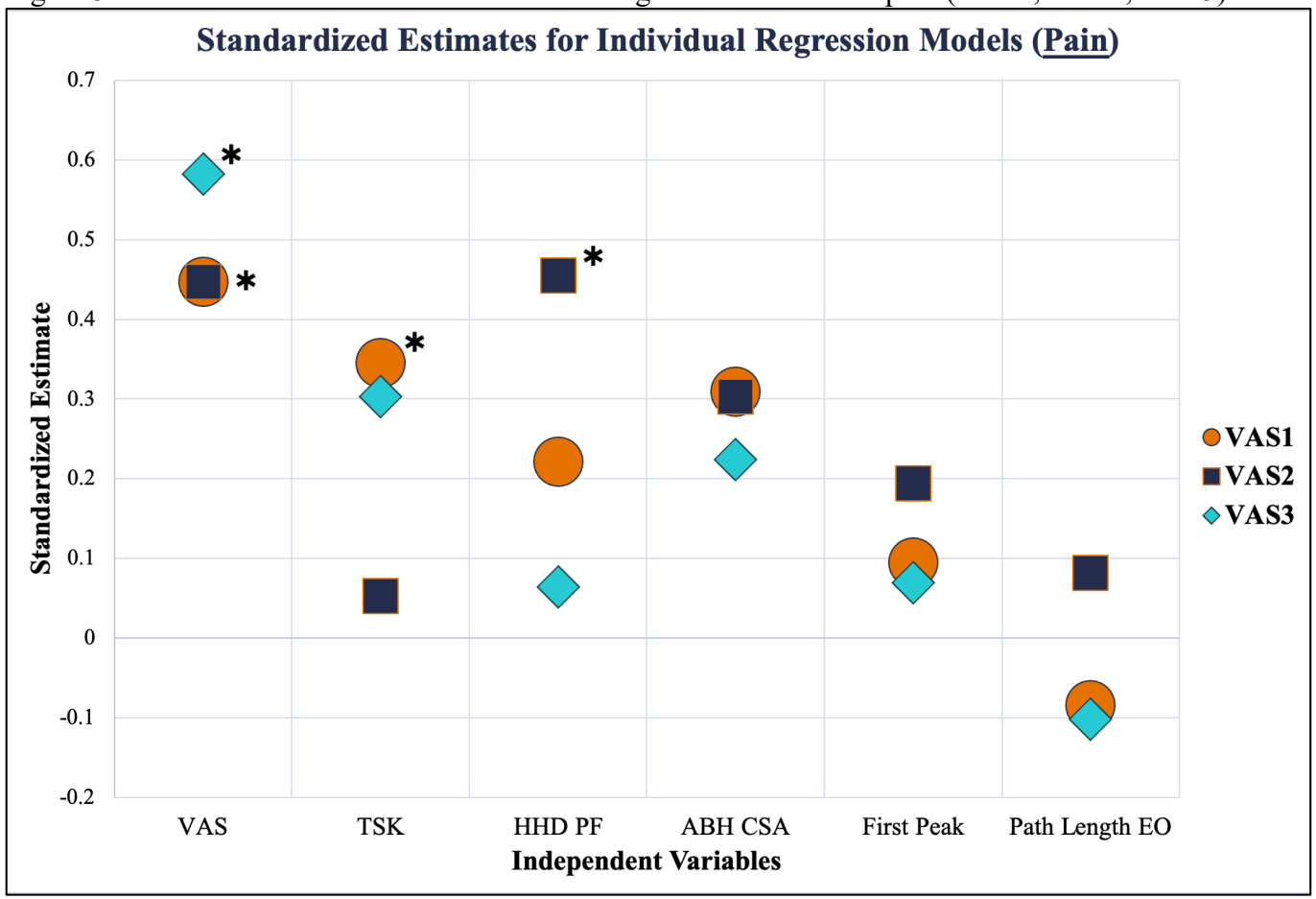
Table 3.1. FABQ-PA, FABQ-W, TSK, and PSEQ scores between control and FRAMES groups, and total cohort, across baseline, 4-week, and post-test sessions.

	Group	Baseline (T1)		4-week (T2)		8-week (T3)		Within group p-value			Effect Size: T1–T3	95% CI	
		Mean	SD	Mean	SD	Mean	SD	T1–T2	T1 –T3	T2–T3		LL	UL
FABQ-PA	Control	13.50	5.20	11.88	4.92	11.81	4.82	0.503	0.813	1.000	-0.34	-1.03	0.36
	FRAMES	12.39	4.89	12.28	3.83	11.22	5.09	1.000	0.941	0.876	-0.23	-0.89	0.42
	All	12.91	4.99	12.09	4.32	11.50	4.90	0.368	0.292	0.704	-0.29	-0.76	0.19
FABQ-W‡	Control	13.13*	8.07	12.25	8.53	9.06	8.35	0.993	0.206	0.431	-0.50	-1.20	0.21
	FRAMES	4.50*	7.39	6.72	8.53	4.78	7.06	0.669	1.000	0.825	0.04	-0.61	0.69
	All	8.56	8.76	9.32	8.97	6.79	7.88				-0.21	-0.69	0.26
TSK†	Control	25.56	4.99	22.00	5.24	20.81	5.28	**0.016**	**0.006**	0.670	-0.92	-1.65	-0.20
	FRAMES	24.56	5.27	22.94	3.21	20.89	5.31	0.555	**0.037**	0.094	-0.69	-1.37	-0.02
	All	25.03	5.09	22.50	4.24	20.85	5.22	**0.002**	**<0.001**	**0.015**	-0.81	-1.31	-0.32
PSEQ†	Control	46.50	14.33	51.69	8.51	53.88	6.86	0.155	0.176	0.862	0.66	-0.05	1.37
	FRAMES	50.72	9.75	51.61	7.61	55.17	6.86	0.997	0.634	0.386	0.53	-0.14	1.19
	All	48.74	12.12	51.65	7.92	54.56	8.07	0.100	**0.021**	0.092	0.57	0.08	1.05

† significant for main effect time
‡ significant for between group
* significant difference at baseline
Bolded values indicate significance $p<0.05$
FABQ-PA, Fear Avoidance Belief Questionnaire-Physical Activity; FABQ-W, Fear Avoidance Belief Questionnaire-Work; TSK, Tampa Scale of Kinesiophobia; PSEQ, Pain Self-Efficacy Questionnaire.

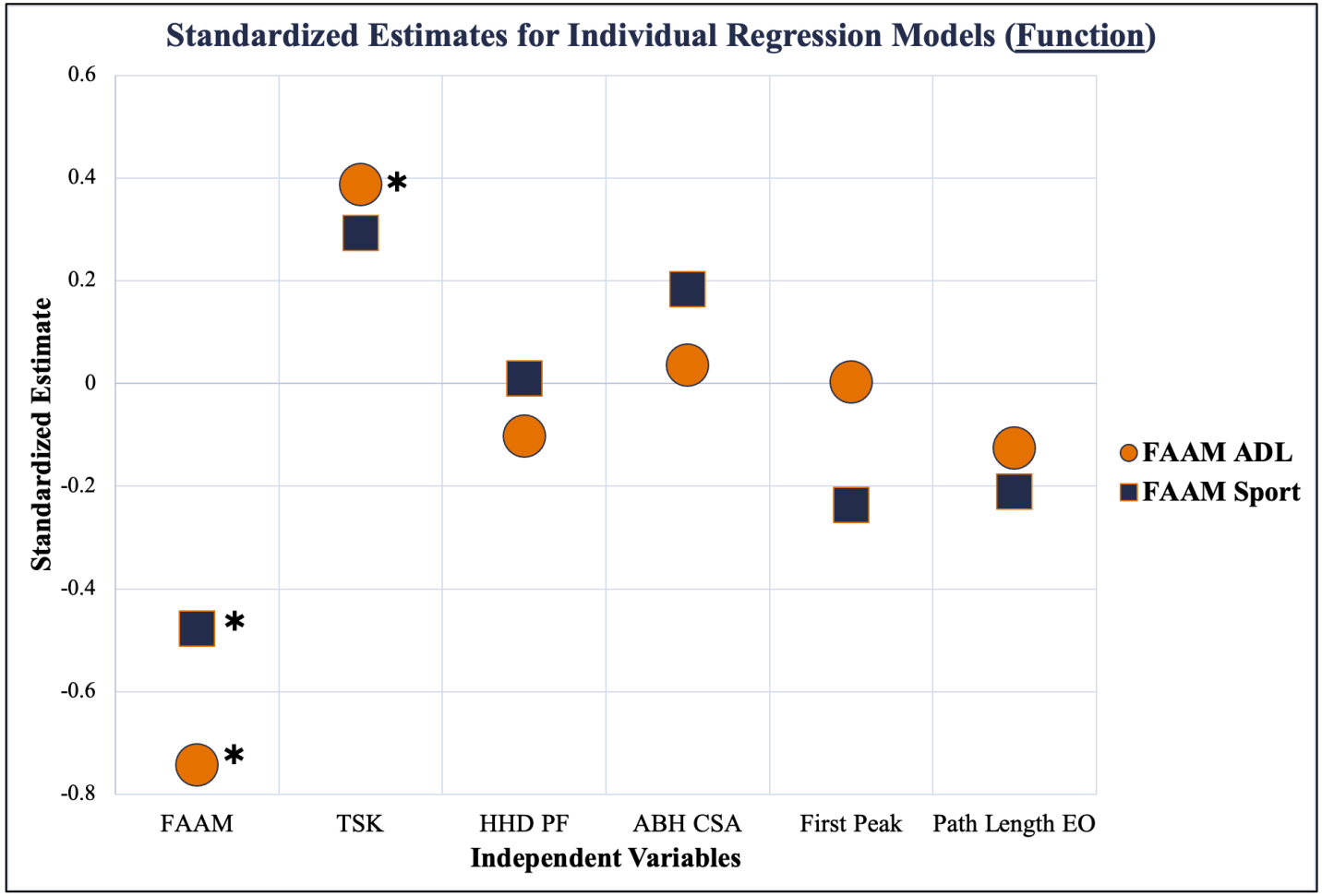
FIGURES

Figure 3.1. Standardized estimates for individual regression models for pain (VAS1, VAS2, VAS3)



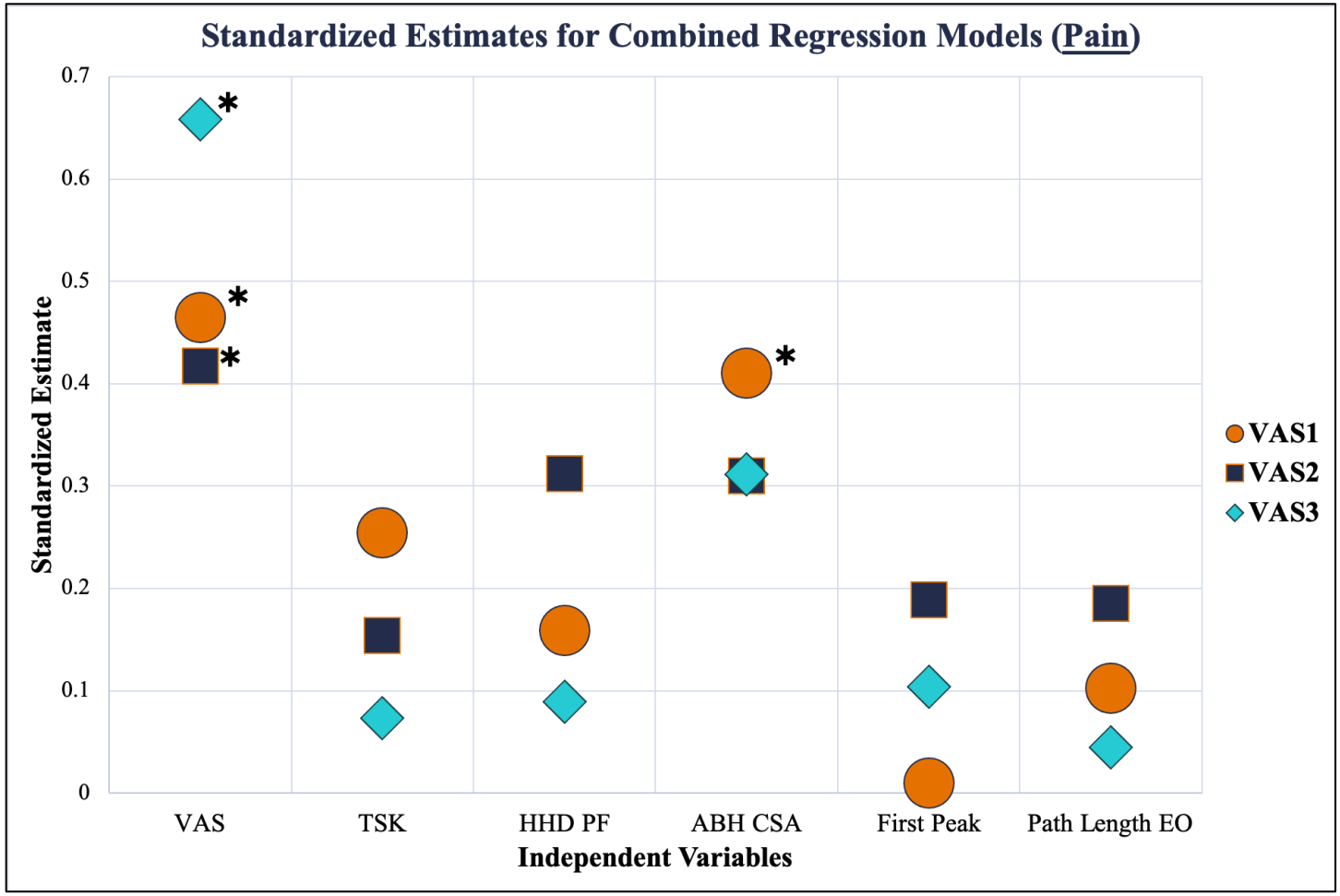
Caption: VAS, Visual Analog Scale; TSK, Tampa Scale of Kinesiophobia; HHD PF, strength of the PF limb assessed with handheld dynamometer; ABH CSA, abductor hallucis cross-sectional area; first peak, first peak impact force; Path Length EO, path length during eyes opened balance. VAS for each model was each change score's respective VAS score at baseline.

Figure 3.2. Standardized estimates for individual regression models for function (FAAM ADL, FAAM Sport)



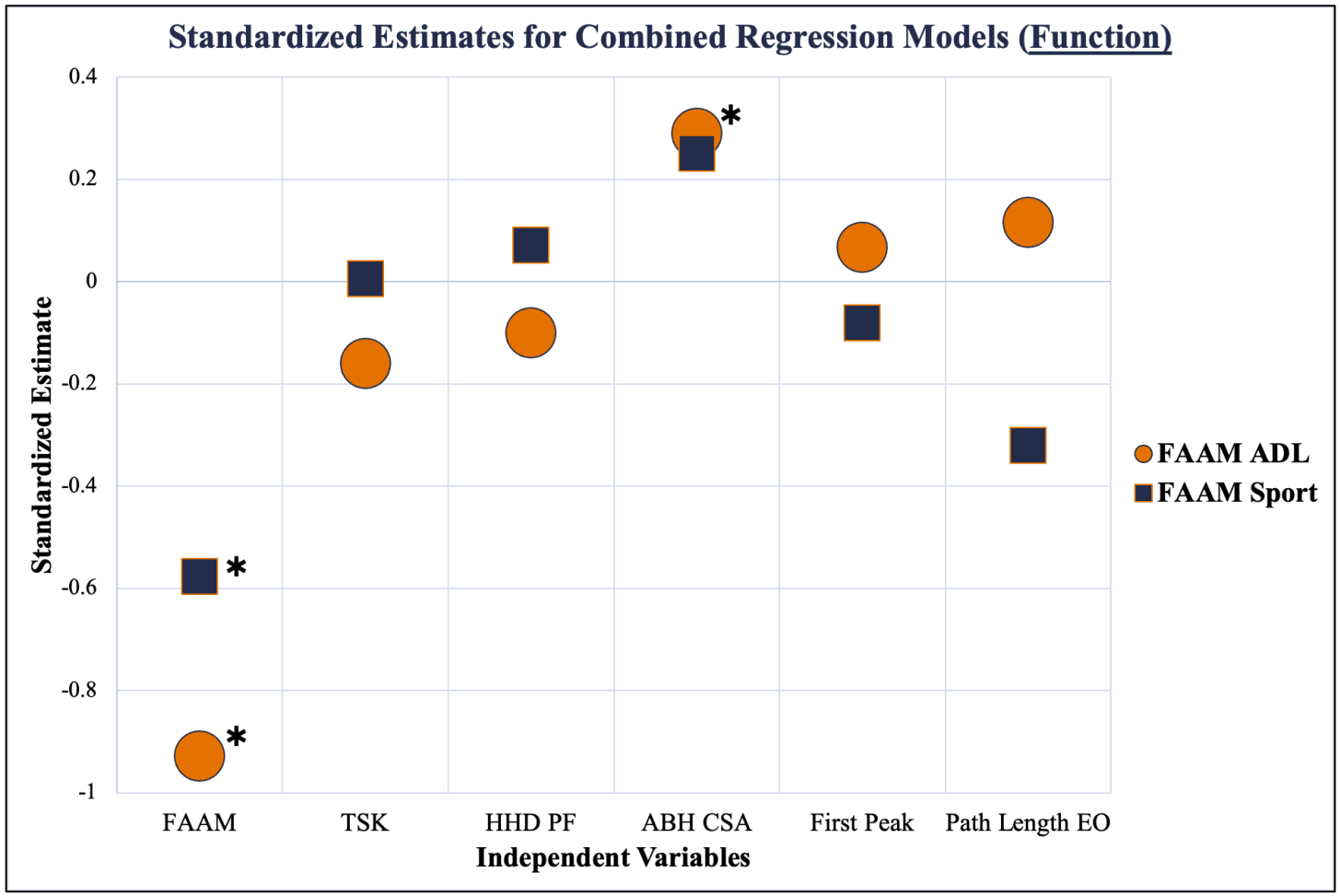
Caption: FAAM, Foot and Ankle Ability Measure; TSK, Tampa Scale of Kinesiophobia; HHD PF, strength of the PF limb assessed with handheld dynamometer; ABH CSA, abductor hallucis cross-sectional area; first peak, first peak impact force; Path Length EO, path length during eyes opened balance. FAAM for each model was each change score's respective FAAM score at baseline.

Figure 3.3. Standardized estimates for combined regression models for pain (VAS1, VAS2, VAS3)



Caption: VAS, Visual Analog Scale; TSK, Tampa Scale of Kinesiophobia; HHD PF, strength of the PF limb assessed with handheld dynamometer; ABH CSA, abductor hallucis cross-sectional area; first peak, first peak impact force; Path Length EO, path length during eyes opened balance. VAS for each model was each change score's respective VAS score at baseline.

Figure 3.4. Standardized estimates for combined regression models for function (FAAM ADL, FAAM Sport)



Caption: FAAM, Foot and Ankle Ability Measure; TSK, Tampa Scale of Kinesiophobia; HHD PF, strength of the PF limb assessed with handheld dynamometer; ABH CSA, abductor hallucis cross-sectional area; first peak, first peak impact force; Path Length EO, path length during eyes opened balance. FAAM for each model was each change score's respective FAAM score at baseline.

SECTION III: APPENDICES

APPENDIX A

The Problem

Problem Statement

Plantar fasciopathy (PF) is a common injury that can lead to foot pain,[1] decreased quality of life (QoL),[2] and high medical costs.[3] The plantar fascia is a broad band of tissue on the bottom of the foot that passively stiffens the arch in weightbearing and provides support to the medial longitudinal arch.[4] Plantar fasciopathy then occurs due to mechanical overload of the plantar fascia[1] from increased weight or activity,[5] and is often characterized by pain at the medial calcaneal tubercle, especially after periods of rest or after waking up in the morning.[1,3] Each year in the United States, roughly 2 million adults seek care from physicians for plantar fasciopathy (PF), which costs more than $300 million.[3] It is further complicated as it affects both sedentary and active individuals alike,[3] and can lead to long-term health problems such as cardiovascular disease due to reduced mobility.[3] There are also a variety of functional deficits in individuals with PF, such as reduced toe flexion strength[6] and intrinsic foot muscle (IFM) volume[7] and size,[8] and altered gait biomechanics such as decreased vertical ground reaction force (vGRF), likely due to pain.[9] These deficits may continue to make it difficult for individuals to tolerate the load they are placing on the body with their activity or weight levels, thus creating a persisting cycle of pain, decreased activity, and dysfunction.

The current treatments for PF are extensive, spanning from passive to more invasive techniques, such as orthotics, NSAIDs, or corticosteroid injections. However, most interventions have low levels of evidence and are quite heterogenous in their methods and populations,[5] and there are a significant number of patients who experience recurring or persistent symptoms for years.[2] Despite demonstrated IFM weakness in this population,[6] there is a surprising dearth of literature that focuses on IFM-specific strengthening as a treatment for individuals with PF.[10] This is especially heinous as it is known that plantar fasciopathy is an injury stemming from an individual's inability to tolerate an overload to the body. Therefore, the lack of research in this area is significant, as the IFM can offload the plantar fascia,[4] as both support the medial longitudinal arch in different ways.

Healthy individuals can improve their IFM strength and size via IFM exercises,[11] and the use of these exercises in individuals with PF has been effective thus far in reducing pain.[12–15] However, the problem is that IFM exercises are difficult to learn[16] and time-intensive. Another method of improving IFM strength is wearing minimalist shoes,[17] which may be useful given the high burden in both learning and performing IFM exercises.[16] These shoes, which have gained traction in recent years, promote barefoot-like movement with "minimal interference with the natural movement of the foot",[18] given their reduced support and cushioning that is purported to lead to muscular adaptations.[19] Walking in MS has even shown comparable IFM strength increases to performing IFM exercises in healthy individuals.[20]

However, there is a gap in clinical evidence supporting the use of minimalist shoes as a therapeutic intervention for individuals with PF, with only two studies to date

in this area.[21,22] Both of these studies reported improvements in pain and function in the minimalist shoe group and the control group, however, they did not evaluate any changes in IFM strength and size, or global physical function. This lack of investigation on IFM function is quite a limitation given that wearing minimalist shoes is known to directly increase IFM strength and size.[17]

This study addresses the critical need for interventions focused on IFM strengthening in individuals with PF, by observing if performing a rehabilitation program in conjunction with wearing minimalist shoes could amplify the positive effects of both interventions, especially in IFM strength and size. The purpose is to compare the efficacy of performing a home rehabilitation program as a control group (CON) to combining foot rehabilitation and minimalist shoes (FRAMES) in individuals with PF, in an 8-week randomized controlled trial. As the home rehabilitation program does not include rehabilitation exercises that target the IFM directly, the intention is to use MS to increase IFM strength and size, and ultimately improve patient outcomes.

The **main research question** for this dissertation was: how does implementing a strengthening routine and wearing minimalist shoes affect individuals with plantar fasciopathy in self-reported measures of pain, function, and psychological beliefs, as well as physical outcome measures of IFM function, balance and gait, compared to individuals who only undergo a strengthening routine?

Experimental Hypotheses

Specific Aim 1: To determine the effect of the FRAMES intervention on pain and function, via patient-reported outcomes (PROs), relative to the home rehabilitation program, assessed at baseline and after 4 and 8 weeks.

Primary Hypothesis 1: Individuals with PF in the FRAMES intervention will reduce their pain and improve self-reported function to a greater degree than those receiving only the home rehabilitation program.

Specific Aim 2: To determine the effect of the FRAMES intervention on IFM strength and IFM size, single-leg balance performance, and vGRF while walking on a treadmill, relative to the home rehabilitation program, assessed at baseline and after 8 weeks.

Primary Hypothesis 2: Individuals with PF in the FRAMES intervention will improve their IFM strength, IFM size, and single-leg balance performance to a greater degree than those receiving only the home rehabilitation program. Individuals with PF in the FRAMES intervention will also increase vGRF in the painful foot while walking, indicating more willingness to weight bear, to a greater degree than those receiving only the home rehabilitation program.

Specific Aim 3: To determine which baseline factors are the most important in achieving positive outcomes in individuals with PF using minimalist shoes as an intervention.

Primary Hypothesis 3: Individuals with higher levels of self-efficacy, lower levels of kinesiophobia and fear-avoidance, and more active behaviors will have the greatest reductions in pain and improvements in function.

Assumptions

- Participants will be honest when answering questions about inclusion and exclusion criteria
- Participants will adhere to the rehabilitation and/or minimalist shoes protocol and give their best effort, and answer honestly if they have or have not done the exercises
- Participants will remember to wear the Fitbits every day during waking hours
- Participants will perform with their best effort on all patient-reported outcome surveys, balance, and functional tasks.
- All measurement tools will accurately collect the data
- The ultrasound device will accurately provide images of the muscular anatomy, including its cross-sectional area and thickness.

Delimitations

- All participants were limited by our inclusion and exclusion criteria
- All participants were limited to the ages between 18 and 55
- Participants were limited to first-step morning pain on a Visual Analog scale (from 0 to 100) between 30 – 70.
- Participants were encouraged to maintain their usual habits during the study intervention and not to add any extra new interventions to their routine.
- Participants will be recruited from the university and surrounding community, and will more than likely have a variety of activity and fitness levels.
- For Manuscript 2, it was not possible to have all participants walk in minimalist shoes at the baseline session as a full selection of sizes was not always available.

Limitations

- For data collection, instructions for participants prior to the baseline session were to wear closed-toed shoes they could feel comfortable exercising in. Most participants wore running or walking shoes, though several wore business-casual-style shoes, potentially due to convenience or forgetfulness.
- At the data collection, the self-selection of speed may not have been accurate.
- For the protocol, some individuals continued to exercise and operate in their daily activities with pain, while others may have limited themselves much more.
- The study began in February of 2024 and ended in November 2024, and the different weather patterns through the year could have affected activity levels and pain due to foot stiffness.
- For the protocol, all exercises were performed at home without direct supervision, which limited our understanding of patient form during their exercises, and required patients to be forthright in their actual exercise performance.
- Some of the participants had bilateral symptoms. Everyone was instructed to select their more painful foot as the testing foot if that were the case, however, this may have led to some conflicting results for outcome measures that were collected bilaterally.
- For Manuscript 1, we did not ask those with bilateral symptoms to fill out pain levels for their less painful foot, which could have affected some of the findings on the non-injured foot in Manuscripts 2 and 3.
- For Manuscript 2, the ability to hold a muscle contraction during IFM size testing may not reflect their true muscle size.

- For Manuscript 2, there is anatomical variance between participants for the intrinsic foot muscles, especially with the variety of foot structure types

Significance of the Study

The results of this study could significantly alter how clinicians treat PF, as clinicians can use an evidence-based intervention of minimalist shoes as an adjunct to their exercise prescriptions. Currently, many clinicians recommend rest as a treatment, but those limitations can reduce on an individual's QoL and do not tackle the problem, which is commonly an overload of their musculoskeletal system. This innovative protocol relied on increasing strength with an active intervention that led to pain reductions. Although this was not specifically assessed in this dissertation, the intervention could potentially also reduce the time and energy burden for patients who can achieve positive results by simply wearing different shoes in their daily activities, subsequently improving their function and IFM size. Additionally, using minimalist shoes as a factor in rehabilitation could reduce the burden of learning and performing IFM exercises in individuals with PF,[16] given their time cost.

These results may guide researchers to further investigate the effects of minimalist shoes on recovery and IFM strength and size in a variety of clinical populations involving the lower extremities. They may also consider using some innovative but potentially more appropriate assessments, such as a novel dynamometer that likely isolates the IFM more, and performing weight-bearing ultrasound in the measurement of IFM size. Clinicians should consider allowing for more freedom in shoe choices for individuals with PF, by focusing on their comfort levels. Additionally, assessing a wide variety of outcomes in individuals with PF can be helpful when determining what treatments and recommendations to provide to patients. These can include self-reported measures of pain and function, along with psychological beliefs

such as kinesiophobia, fear-avoidance, or self-efficacy. Physical traits are also important, including IFM strength and size, balance, and gait. Certain characteristics, such as having greater IFM strength, or lower gait symmetry combined with fear of movement, can either improve or worsen recovery, respectively. Being able to assess these at baseline can importantly help clinicians improve and individualize their treatments for each patient.

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APPENDIX B: LITERATURE REVIEW

PLANTAR FASCIOPATHY

Description of Plantar Fascia + Role

The plantar fascia, or plantar aponeurosis (PA), is a broad band of tissue that originates at the medial calcaneal tubercle[1] and inserts into the distal plantar forefoot via tendinous slips.[2] It lays superficially to the intrinsic foot muscles (IFM) and has been shown to passively stiffen the arch upon weightbearing,[1] which then provides support to the medial longitudinal arch (MLA). In most of recent history, researchers have promoted multiple theories of how the PA contributes to locomotion. First, the windlass mechanism was explored in 1954 by Hicks,[3] who showed that the arch rising mechanism completely disappeared when the PA was cut from cadavers, and believed that no other tissues contributed to arch rising.[3] Therefore, the PA has always been theorized to stiffen during gait and create a rigid lever for efficient push-off. The windlass mechanism comes from the idea that the PA winds around the metatarsal heads, so upon toe extension, the PA exerts pull upon the calcaneus and then raises the MLA to stiffen the foot upon push-off.[4]

However, more recently, authors have discovered opposition to this theory, in that the MLA is more compliant and less like a rigid lever when the windlass mechanism is engaged[5] and the MLA is elongated. Even further, the stiffness does not increase when greater push-off forces are applied,[4] and the PA does not further elongate as the heel begins to elevate during gait,[6] thus inviting the concept that the IFM play a large role in modulating the force absorption and production in the foot, and may even assist in offloading PA strain.[4] The abductor hallucis, flexor digitorum brevis, and quadratus

plantae lengthen in early stance and shorten in late stance while walking, demonstrating that certain IFM operate in tandem with the PA to control the arch-spring mechanism.[7] It appears that the foot adapts to the condition it is under, and modulates foot stiffness as necessary, and is theorized to be controlled by the CNS.[8] The foot can absorb and dampen forces in acceleration but can also produce force upon acceleration, likely due to this adaptability in movement.[9,10] While the windlass mechanism may apply to a static foot, it is clear that more mechanisms are at play in dynamic movements.[8]

Plantar fasciopathy

Plantar fasciopathy (PF) is a common injury that leads to pain,[11] limited functional ability, and decreased quality of life.[12] It is estimated to affect 25% of athletes and 10% of sedentary individuals[13] and recurring symptoms can be quite common.[14] A recent NHANES database study showed that 11.1% of individuals were diagnosed with PF.[15] PF occurs when there is a mechanical overload to the tissue,[1] which may occur from an increase in body mass or a sudden spike in weight-bearing physical activity, or both simultaneously.[16] PF was initially considered to occur from microtears in fascia that creates an inflammatory response.[11] However, studies have shown little evidence of inflammatory metabolites[1] which may indicate that inflammation does not play a role in chronic PF. It should be described more as a degenerative process that stems from increasing tensile load on the plantar fascia,[1,17] or decreased medial longitudinal arch height, or possibly both.[1] This may also be shown by the thickening of the plantar fascia at the calcaneal tubercle,[18] along with damage to the collagen fibers (degeneration and disorientation).[1] Thus, the injury may best be termed a “fasciosis” or a “fasciopathy” instead of a “fasciitis” due to the degeneration,[1,19] similar to how researchers have

encouraged renaming patellar tendinitis as a "tendinopathy".[20] PF may also be known as plantar heel pain[14] or heel spur syndrome,[1] among other names.

Diagnosis

The main method of diagnosis is heel pain upon palpation at the medial calcaneal tubercle,[1,11,21] along with patient history and symptoms,[22] as patients may report a recent increase in weight-bearing activity.[23] Common signs are sharp or stabbing pain[11] is worse upon weightbearing in the morning after a long period of laying down, but pain may also worsen following prolonged weight-bearing.[23] Additionally, it may present differently in athletes compared to sedentary individuals. Though the pain may lessen after beginning movement, it may re-emerge at the end of long bouts of movement such as intense training sessions.[21]

Diagnostic imaging is not common[22] or always necessary,[21] though it is usually recommended with persistent signs of PF after treatments do not offer relief[21] to rule out other pathologies.[11] However, in order to appropriately treat PF, it must be properly diagnosed, which requires proper diagnostic tools for evaluation and to rule out other findings.[24] For example, radiographs may rule out other conditions such as arthritis or calcaneal spurs.[11] Individuals with PF are 8 times as likely to have calcaneal spurs than those without PF, though causation cannot fully be established.[25] Ultrasound is often highly useful in the diagnosis of PF, as most individuals with PF display thickened plantar fascia tissue compared to healthy controls,[21] which is shown to be correlated with increased pain symptoms.[26] The previously established clinical cutoff of impaired plantar fascia is being greater than 4.0 mm thick,[16] but has been shown to be as low as 3.15mm thick in the impaired group.[27] Ultrasound scans of individuals with PF also demonstrate

decreased echogenicity, showing a decline in tissue quality and increased fluid buildup around the tissue.[28] Shear wave elastography, via ultrasound, can determine Young's modulus of stiffness of the PF and could potentially be assessed[27] as "softer" plantar fascia is often associated with having PF.[16,27] It has been suggested that using ultrasound to establish both plantar fascia thickness and Young's modulus can improve diagnostic accuracy.[27] Lastly, MRI may be the last line of defense in persistent or atypical displays of PF, as it may elucidate findings of a stress fracture or vascular necrosis, for example.[21]

When looking at the reliability and validity of using ultrasound to diagnose plantar fascia thickness, intra-observer reliability has been shown to be as high as 0.97[29] or 0.98,[27] or as low as 0.67 and 0.77.[30] However, the study with the highest intra-observer reliability featured two assessors both with over 5 years of experience in ultrasound,[27] compared to the lowest with experience levels of 2-5 years[30] which could explain the disparity. Additionally, the group with the lower intra-observer reliability performed the analysis on measurements scanned 60 minutes apart, where the higher reliability group used the 3 measurements at one time point, which may have explained the difference. There may also be differences in quality of the ultrasound device used in each study, along with the depth, frequencies, and types of probes, which was not always mentioned. Regardless, it is still a reliable method to measure PF thickness, as inter-rater reliability has been shown to be as high as 0.82.[30]

In order to validate ultrasound as a diagnostic tool for PF, researchers have compared it to MRI the most,[31] but have also used pain levels and foot function patient-reported outcomes to assess its validity.[32] Compared with pain levels via VAS, using ultrasound to diagnose PF led to an area under the curve of 0.925, with 100% sensitivity

and 81.3% specificity.[27] However, when compared to the ability of MRI to detect a thickened plantar fascia, ultrasound showed 80% sensitivity and 88.5% specificity.[33] These differences are likely because MRI is more accurate in assessing thickness, as performing the test is not as clinician-dependent. Additionally, as specificity is lower in the study comparing to pain levels,[27] this may be because the thickness of the plantar fascia can increase due to some other factors, such as increased age, or BMI.[34] Although MRI would be the top choice for diagnosing PF,[31] ultrasound can still be cost-effective, less invasive, and more readily available in clinics.[32] It can be used to assess differences before and after interventions, and can detect relatively small differences in the thickness of PF, especially compared to those without PF.

Risk factors

Regardless of the true mechanism, PF presents a problem to many populations, including active and sedentary populations.[35,36] Many researchers have proposed risk factors by conducting systematic reviews, but only a small number of risk factors have been consistently demonstrated over and over in different populations, while many others have low evidence or heterogeneity in their study methodology.[16,37]

Body weight and body mass index (BMI), overall loading

One extremely prevalent risk factor is BMI and/or body mass,[16,17,19] but recent evidence points to this phenomenon more so in non-athletic individuals.[16,23] This is likely because in the athletic population, BMI does not account for body fat versus lean mass.[37] Fat mass may be the bigger concern with this injury then,[28] as risk factors for individuals associated with sport appear to be more related to training errors, poor technique, and high intensity and fatiguing training that results in repetitive loading.[38] Increased BMI is

a consistent risk factor for PF. A small study of 50 individuals found that compared to individuals with a BMI of 25, those with a BMI from 25 – 30 kg/m^2 had an increased odds ratio of 2.0 of developing PF, while a BMI above 30 comparatively led to an odds ratio of 5.6.[39] Separately, a study with the NHANEs database with 4957 participants found that compared to individuals with a BMI below 25, having a BMI between 25 and 30 resulted in a 1.5-fold increased risk of PF, BMI>30 was a 2.2-fold risk, and BMI> 35 had 2.7-fold increase in risk.[15] BMI has even been shown to predict function for those with PF, in that those with lower BMI indicated better function using the Foot and Ankle Ability Measure (FAAM) and lower pain intensity using Numerical Pain Rating Scale (NPRS) after 3 months, and higher BMI predicted lower function in their model.[40]

Researchers have proposed two models of PF, one of which occurs when healthy tissue undergoes abnormally high load for a sustained period of time. The other model implies that a plantar fascia with pre-existing damage or weakness is exposed to a potentially normal, but prolonged load and will then develop PF.[36] Overall loading, regardless of the mechanism, appears to play a role, as jobs that involve heavy weightlifting such as construction laborers puts individuals at more risk for developing PF.[24] Those in weight-bearing occupations also incur a greater risk of developing PF with increased time spent standing on hard surfaces, increased walking, and even increased number of times getting in and out of a forklift.[41] One problem with identifying risk factors for PF is that it is an incredibly multifactorial problem, given the 2 proposed models of the injury, as well as risk factors that involve age, sex, foot structure, body mass, occupation, activity level, and more.[38]

Pes planus and foot structure:

Foot structure has been thought to be an important risk factor in developing PF, especially in those with pes planus or pronation.[1] This is due to the consistently cited assumption that a flat foot would reduce one's ability to make the foot a rigid lever for propulsion, yet this phenomenon has not been substantiated in the literature.[1] While a lower arch may induce greater tensile strain on the plantar fascia,[1,42] a high arch may also increase the load on the plantar fascia because of reduced mobility and elasticity,[43] which reduces the ability to attenuate shock[1] and prevent microtears to the plantar fascia.[19] Regardless, much of the literature is cross-sectional in nature,[44] and therefore causality cannot be established between having a flat foot and having PF. However, individuals with flat feet do have various characteristics that could put them at enhanced risk for PF. For example, flat feet are shown to have a greater Young's modulus[45] and plantar fascia thickness[45,46] at the calcaneal insertion of the fascia compared to normal feet, indicating that the tissue is under greater stress. This thickening of the plantar fascia is a common characteristic associated with PF. Additionally, obesity and a thicker plantar fascia are both associated with one another,[34] and with the presence of flat feet.[46,47] The presence of flat foot in itself may not necessarily be a risk factor unless combined with other factors.

The problem with automatically assuming pronation is a risk factor for PF is that it is a naturally occurring motion at the foot, as it importantly contributes to stabilizing the foot in gait,[48] especially in those with flatter feet.[49] Furthermore, the definition of a "flat foot", or "overpronation" is heavily varied in the literature and data collection methods are extremely heterogenous. Kibler et al. (1991)[42] referred to it as functional versus anatomical pronation, but others have used the terms "flexible flat foot" and "rigid

flat foot".[50] The former refers to a foot that is only flat upon weight-bearing, or "functional pronation", while the latter defines a foot that is flat regardless of weight-bearing status, or anatomical pronation. This is important because control of pronation at the foot[51] may be the risk factor for developing foot conditions, as the lack of control of foot pronation could relate to inefficient force absorption in the foot. Therefore, dynamic arch motion may be the pertinent risk factor, as opposed to a static arch measurement that does not accurately reflect dynamic arch motion.[52,53] For example, navicular height may not provide as much information about dynamic arch motion as navicular drop, which is the difference in navicular height between weight-bearing and NWB.[54] Static navicular height may also not indicate the time for the navicular to reach its minimum height,[55] which could also be important in control of foot pronation. The heterogeneity of data collection and even the definition of overpronation[48] has made it difficult to elucidate the true effect of overpronation on the risk of developing PF.

Flatfoot can be reversible[54] by completing IFM exercises such as the short foot exercise (SFE) or simply performing physical activity.[56] Given that individuals with flatter feet have decreased IFM sizes,[57] muscle weakness could potentially be a factor behind a flat foot and could be absolved in some individuals by completing strengthening exercises.[54] This could be considered more of a modifiable risk factor, except in the case of anatomical pronation or rigid flat foot that cannot be helped with increased muscular strength. Therefore, it appears that the influence of a flat foot on the risk of developing PF is hazy at best, and is certainly dependent on data collection method, the cause behind the flat foot, and will require more prospective research.

Sex differences

Though anecdotally it appears that females have a higher prevalence of PF, it is still currently unclear,[38] as various studies have shown both men and women with higher incidences of PF.[15] However, there are some anatomical and biomechanical differences between men and women that could explain the conflicting results. It is interesting to note that males have been reported to have thicker plantar fascia than females,[58,59] a common finding in individuals with PF.[28] However, the thicker tissue may simply be related to the higher body mass and height of males,[58] as having a higher body mass is also known to increase plantar fascia thickness.[34]

There is also conflicting evidence on whether gender affects arch structure. Some studies have discovered no difference between the arch height index (AHI) of men and women (a formula which divides the dorsum height at 50% of foot length by the foot length), but significantly less stiff arches in women,[60,61] while another reported lower arches in women with no difference in stiffness.[62] However, this may be because of the method of collecting arch characteristics. Using the AHI Measurement System with sliding rulers to measure foot characteristics of showed no difference in AHI, and stiffness defined as the change in arch height between sitting versus standing appeared to be different between genders.[60] Meanwhile, the use of 3-D scanning software that has high precision and accuracy compared to conventional methods showed lower arch heights in women and no difference in stiffness.[62] Yet again, these differences could be explained by the heterogeneity of data collection for arch characteristics. Additionally, these findings are within asymptomatic and/or healthy individuals, so this may not apply specifically to those with PF, as the cause of PF can be multifactorial.[19]

Females may also undergo changes in decreased MLA height[63] and stiffness[64] during pregnancy, and even into the post-partum period and beyond. A flatter arch may indicate reduced control of the medial longitudinal arch,[51] which is related to PF. Pregnancy also leads to an increase in plantar foot pressure, increase in ligament laxity due to the hormone relaxin, and an aberrant gait pattern due to decreases in hip mobility that may affect foot and ankle function.[63] These components can lead to PF-specific risk factors such as increased swelling in the foot, overpronation of the foot without the strength to control the movement,[51] and changes in gait. Pregnancy may contribute to PF risk for both changes in foot structure and weight gain and retention during pregnancy and post-partum, which may place more pressure on the foot and influence PF risk.[63,65] Therefore, pregnancy could play a role in female patients regarding their increased risk of PF in some of the literature. In regards to other hormonal changes, foot length has been shown to increase and the plantar fascia has been shown to thin during ovulation compared to menstruation, ultimately leading to a reduction in balance during ovulation.[66] During ovulation, estradiol peaks, which can cause relaxation of connective tissue such as the ACL,[66] which may also affect the plantar fascia. However, it does not appear that the menstrual cycle has any effects on foot AHI or flexibility.[67] The change in plantar fascia elasticity and thickness, and ultimately, balance ability, could potentially affect rates of PF in females, but the true effects of the menstrual cycle directly on developing PF has yet to be explored.

The conflicting literature on rates of PF in male versus female patients may also be due to injury reporting rates that differ by sex. In the military, female recruits were more likely to have a reported injury than male recruits, and less likely to have an

unreported injury, ascertained via questionnaire separate from a medical exam.[68] Females tend to seek more medical care for injuries in general,[69] and specifically for PF.[70] Male and female patients with PF also demonstrate differences in their quality of life on foot pain and function, and even general health and vigor.[70] Potentially, the higher rates of PF in some females could be attributed to greater injury reporting, because of the greater effect on their quality of life.

In the US military, females are much more likely to develop PF,[71,72] but this may be due to the increased physical demands, as females are expected to do the same work as males and carry the same loads. However, they undergo more intensity and strain than males,[73] and they are carrying a heavier load relative to their lower body weight, muscle mass, and strength.[74] As an overload of any kind is associated with the development of PF,[16] this is likely a significant factor that civilian females may not necessarily experience. There are certainly physically demanding jobs in the civilian sector such as those in heavy manufacturing[75] or electrical work,[76] where women are again expected to do the same jobs but are using a higher percentage of their work capacity, leading to a potential increase in injury risk in general. This certainly applies to PF as those with heavier loaded jobs are more at risk for developing PF in general,[24] but it may explain the reason that females experience PF more in specific populations or occupations.

Age:

Increasing age has also been shown to be a risk factor,[38] as PF is most prevalent in those aged 50 to 65,[15] potentially for many reasons. First, older individuals undergo natural degenerative changes to their plantar fascia tissue as they age,[38] which leads to a loss of elasticity in the tissue[41] and an inability to resist loads that were previously

tolerable, which could lead to PF. One study showed that older individuals (> 65) are more likely to have stiffer arches compared to middle aged (45 – 64 years old) and younger individuals (25 – 44 years old) via a 3-D foot scanner comparing arch height sitting and standing.[62] However, another study showed no differences in AHI (comparing arch height from sitting to standing) or stiffness across all age groups.[60] It certainly may depend on the method of foot posture assessment, as increased contact of the medial midfoot, indicating arch lowering, is present in older individuals,[77] yet the difference in arch height between sitting and standing do not seem to be different across age groups.[60,62] Lastly, a recent database review showed that osteoporosis was considered a risk factor for PF, which was proposed to occur because it may cause microstress to the calcaneus and any muscles or tissues attached to it, which can certainly affect development of PF.[15] However, osteoporosis has been rarely connected to PF otherwise. More studies are certainly needed in this area but this may be an interesting consideration when it comes to treating older adults with PF.

Age as a risk factor may instead be more related to the quality of the tissue. For example, older individuals have significantly thickened plantar fascia,[34,78] and more uneven high signal intensity changes in the soft tissue around the plantar fascia via MRI, indicating increased damage, both of which are considered abnormal.[78] Older adults also have softer plantar fascia tissue.[79] Individuals with PF have been shown to have similar characteristics of older individuals, including thicker plantar fascia, hypoechogenicity (indicating pathological tissue), increased edema, and softer and less elastic plantar fascia tissue.[28,79] Although it cannot be confirmed if these findings in individuals with PF are causes or symptoms, the similarities in tissue quality decline between older adults and

individuals with PF should be considered. Decreased tissue quality may play a role in the development of PF for older adults, but this may also be accompanied by a host of other decrements that come with increased age, such as decreased foot and ankle muscle strength,[80] decreased range of motion in the ankle,[81] and less propulsive gait and foot mobility.[82] Being an older adult may not necessarily be a risk in itself, but it may become significant when compounded with other issues. For example, obese older adults have weaker toe muscles, but they are shown to generate higher propulsive forces than leaner individuals, which is associated with a higher incidence of foot problems.[83]

Differences between athlete versus non-athlete

Limited ankle dorsiflexion (DF) has also been reported in several studies as a risk factor,[19,23] as it is suggested that the Achilles tendon is involved with PF[37] because it extends from the same tissue. However, multiple studies have indicated no difference in ankle DF range of motion (ROM) when considering PF rates, especially in athletes.[28] A combination of factors likely influences the presence of PF, including activity level and the demands placed on the body. It may also depend on the method of assessing ankle DF and the population at hand. When evaluating recreational and collegiate runners with PF and without PF, decreased active DF ROM was shown to be a risk factor for developing PF, when measured via goniometer in a prone position with the knee bent to 90 degrees.[84] However, another study found no difference in passive ankle DF ROM between individuals with and without PF. Importantly, there was no mention of runners among these participants, so their presence in the study is unknown, and DF ROM was assessed passively with a weight of 2kg applied to the foot, which could have contributed to these conflicting findings.[85] In another separate study, Sullivan et al. (2014)[86] evaluated ankle

DF ROM with a weight-bearing lunge test, which allows the foot to be fully weight-bearing on the floor, and found that individuals with PF had greater ankle DF ROM than those without. This type of test is not fully active, but it is also not fully passive, given the weightbearing stance. Lastly, yet another study found greater ankle DF ROM during running gait, assessed via motion capture, in runners with a history of PF compared to uninjured runners.[87] These results are quite varied, but are likely due to heterogeneity in ankle DF ROM measurement methods (passive, active, kinematic) and population characteristics. PF is a very common injury among runners,[88,89] thus they may be often recruited at varying rates across studies, which could affect these findings regarding ROM. More research may need to be conducted in this area to evaluate which type of range of motion test is best to differentiate between those with and without PF, or it may just be extremely dependent on a multitude of other factors.

Risk factors for PF are multifactorial and often dependent on each other. For example, in a previous study that performed chart review for a local hospital system, it was found that men and women had different risks depending on age and BMI.[90] Other studies also had restrictions on their patient population, as, for example, one study determined that all their male participants with PF were significantly younger than female participants,[91] which makes it difficult to draw sound conclusions. Additionally, a thickened plantar fascia, a hallmark of the disease,[21] is also associated with increased BMI[34,92] and the presence of flat foot,[93] though there is still some evidence that flat foot is not associated with plantar fascia thickness.[58,92] While age and sex are not modifiable, BMI and flat-foot could be modifiable and help practitioners determine the best course of treatment for individuals with these characteristics. There are also risks associated with

medical care-seeking, as those who experience symptoms for a prolonged period of time before seeking medical care are at higher risk for worse or continuing pain,[94] and if patients have bilateral pain.[94,95]

Associated Characteristics:

Characteristics of individuals with PF have been studied extensively via mostly descriptive and cross-sectional studies, including components that are morphological, functional, biomechanical, and psychological. However, it has yet to be established whether these are symptoms or risk factors of PF, or if they are components that simply worsen PF symptoms for individuals.

Functionally, individuals with PF have displayed weakened ankle[12] and IFM strength,[12,96,97] with enhanced IFM weakness in patients with chronic compared to acute PF.[12] Muscles even further up the leg, including the quadriceps and hamstrings, have also been shown to be affected.[98] These decreases in muscle weakness are accompanied by a decrease in IFM volume[99–101] and decreased IFM cross-sectional area assessed via ultrasound.[102] There may be several potential reasons for these findings. Individuals with PF may reduce their activity based on their pain toleration or they may be prescribed rest by clinicians,[19] but the decreased activity and use of the foot could potentially lead to weakened IFM over time. It is also possible, however, that the IFM are already weakened in an individual due to other circumstances (e.g., another lower extremity injury that leads to an antalgic gait), which could then lead to PF. Potentially, those with a separate type of unilateral lower limb injury may end up taking on a greater load on the uninjured limb, which could overload the IFM and plantar fascia tissue as well.

However, regardless of how IFM function is assessed, there is still no gold standard.[103] A standardized IFM strength assessment needs to be developed and used to assess individuals with PF to truly understand the deficits, as these studies used a variety of IFM strength assessments.[103] Further, some of these studies were conducted comparing an injured to an uninjured foot in the same individual,[96] comparing injured to healthy controls,[96,97] or comparing acute to chronic PF sufferers,[12] so care should be taken when trying to summarize these findings. Although all findings show a decrease in IFM strength and size compared to any type of uninjured limb, both types of findings are important. Assessing IFM strength of those with PF against healthy individuals can help to elucidate the raw strength values that may be a risk factor, but symmetry of IFM strength between limbs may also be an important component, when comparing individuals with PF to fully healthy controls. Lastly, it may be important to perform these assessment in those without a previous history of PF at all,[87] as having had PF at one point in time could potentially have long-lasting effects due to compensations or adjustments. Long-term prospective studies would need to be conducted to provide knowledge of whether weakened IFM is a risk factor or a symptom of PF.

There are other biomechanical factors that are altered in individuals with PF. Some notable findings were decreased vertical ground reaction forces (vGRF) upon impact and propulsion while walking,[2,104,105] along with decreased impulse, and no difference in contact time, all while compared to healthy individuals.[105] There are also findings of increased foot and ankle flexibility while walking in Thai military recruits,[106] and a more flexible and lower arch,[107] and greater ankle DF while running.[87] Though static methods of ankle DF assessment either show decreased ROM or no difference

when comparing individuals with PF to healthy controls,[84–86] dynamic, fully weight-bearing assessments appear to show increased flexibility and ROM. The increased flexibility during walking and running may point to inefficient gait and a poorer quality of movement and symmetry,[108] including reduced control of pronation[51] which could potentially indicate poor force absorption and contribute to PF. It may be that the increase in vGRF contribute to an individual's PF, but there is also the possibility that individuals compensate due to pain and have decreased vGRF,[2] which is another confounding factor in determining if altered biomechanics are a result or a cause of PF. Further, individuals with PF do display a slower walking speed compared to age-matched healthy controls,[108] so it may be important to note if speeds were self-selected or prescribed for these tests, or what surface they were conducted on when evaluating differences between study findings. Walking on a treadmill with force sensors in-shoe showed no alterations in plantar pressure distribution in those with PF compared to healthy recreational runners,[13] while the above findings showing decreased vGRF were conducted with overground trials on a force plate.[2,104] This could potentially explain some differences, as there are limitations with in-shoe force sensors including incomplete data and potential alterations to individuals' gait patterns.[109]

Individuals with PF also display decreased dynamic balance via the star excursion balance test (SEBT),[110] but no differences in static balance performance on the BESS[110] or the modified Romberg test.[108] However, a static balance test on the force plate did show greater center of mass (COM) displacement in individuals with PF,[111] potentially indicating that more sensitive and less subjective balance tests (e.g., using force plate), should likely be used to detect differences in individuals with PF, as the BESS can be

highly subjective, has poor internal consistency[112] and does not adequately capture postural control.[113] Additionally, as PF could be considered more "self-limiting",[114] meaning they may choose to push through some movements or tests because there is usually no inherent structural danger, compared to a more acute injury like an ACL tear. Individuals may need to perform more functional, dynamic tests for differences to be noticeable between those with and without PF.[110]

Lastly, individuals with PF also display significantly altered psychosocial tendencies and behaviors. Notably, these patients report worse quality of life (QoL) via the Foot Health Status Questionnaire,[70,115,116] in both foot-specific (foot pain, foot function, footwear, general foot health) and general health domains (lower physical activity, social capacity, and vigor). Individuals with PF report reduced physical activity, and more importantly, a feeling of social isolation,[117] accompanied by depression, anxiety, stress, pain catastrophization, and kinesiophobia.[14,117–119] Though these findings are mostly cross-sectional in nature, one long-term study investigating changes in pain, function, and QoL over 12 months in individuals with PF found that those with pain at 12 months was predicted by higher pain scores, pain castatrophization, and night pain; function and QoL were predicted by greater pain catastrophization and baseline depression, as well as increased BMI.[120] Individuals with PF clearly have deficits in their psychosocial health which may develop due to the pain and continue to exacerbate it.

Treatment

Treatment for PF can be quite extensive, but given that the presence of general plantar heel pain could indicate a myriad of other injuries,[17,121] arriving upon differential diagnoses may be costly and time-consuming, and lead to extended periods of pain.

Conservative measures are usually first taken, such as rest, arch supports and orthotics, supportive shoe recommendations,[19,122] heel cup/padding,[123] massage, stretching, strengthening,[19] and night splints.[21] Out of these interventions, the most recent "Clinical Practice Guideline" for PF recommends the use of manual therapy, which includes dry cupping, trigger point release, joint mobilization, soft tissue mobilization (aka massage), IASTM, muscle energy.[23] Stretching is still recommended, but taping should only be used in conjunction with other physical therapy treatments for short-term improvements only. Though extensively provided as a treatment for PF clinically, orthoses are not recommended as an isolated treatment for short-term pain relief, and there is a lack of high-quality studies in this specific area.[23] Ultrasound, acupuncture, or dry needling cannot be conclusively recommended as a treatment, but night splints,[21,23] low level laser therapy and phonophoresis are recommended.[16,23]

Beyond that, treatments may include corticosteroid, prolotherapy, or PRP shots; which all can be expensive and relatively more invasive than most conservative treatments.[11] Corticosteroid injections are shown to be helpful in the short-term, but a recent systematic review indicates that the literature is low-quality and has a high risk of bias.[16] Further, as chronic PF is not considered an inflammatory process,[1] the use of corticosteroid injections may be inappropriate and may explain the lack of conclusive evidence. Platelet-rich plasma injections show similar results to corticosteroid, but the treatment protocols in each study are highly heterogenous. Extracorporeal shockwave therapy (ESWT) is a slightly newer intervention that includes very small but high-pressure pulses to improve vascularization and collagen synthesis to tissues. A variety of studies do indicate that it is better than placebo, ultrasound, or a plantar fasciotomy, and

is seen as safer and less invasive than any type of injection, with superior long-term outcomes.[16] Lastly, surgery (plantar fasciotomy) can be performed, though most consider it as a final option for those without success in conservative treatments for at least 12 months[19] given its invasive nature.[124]

The literature surrounding PF treatments is quite extensive, yet findings and clinical implications are exceedingly limited, due to heterogeneity of treatment administration, and the lack of consistent and appropriate outcome measures to assess changes in individuals with PF.[16] The inclusion of multiple treatments together can also make it difficult to isolate the efficacy of one treatment by itself. Further, not all studies isolate to true mechanical PF and may end up including individuals with calcaneal spurs and nerve entrapment issues that complicate the applicability of study findings.[16] Additionally, the information available online for consumers about PF is highly variable and of moderate quality,[125] which could mean that individuals with PF attempt to treat the condition on their own, or simply ignore the pain and delay seeking treatment, which is known to prolong the presence of PF symptoms.[94] The lack of consensus on the best treatment options among clinicians along with the variable information available to patients online may worsen or prolong PF pain.

However, there is one treatment option that has shown to be effective in nearly every randomized controlled trial is performing strengthening exercises. These can include extrinsic foot muscle exercises such as calf-raises,[126–130] or ankle inversion and eversion strengthening;[130] (Thong-On), as well as IFM exercises such as the SFE.[131–134] These protocols span anywhere from 2 weeks[128] to 4 months, but all interventions with some kind of strengthening component demonstrated reductions in pain (via VAS or

NPRS), and increases in function (via questionnaires like LEFS, FAAM, FFI, FAOS). Some studies did show superior effects of exercise to other treatments such as stretching only[126,131] or manual therapy,[127] but others showed similar effects to stretching.[130] However, most of these studies found that strengthening exercises and any other intervention both had positive results, which is still highly beneficial. Interestingly, a review of the PearlDiver database from 2007 to 2011 was conducted to assess the use of physical therapists and their most commonly used treatments. Yet, it was found that only 2.7% of the patients in the database pursued physical therapy for their PF, and only 7.1% got a physical therapist evaluation. During these sessions, 87% received manual therapy and 89% received rehabilitation interventions.[135] Despite the commonly occurring nature of PF shown in several studies across a variety of populations,[13,71,72,88,89,122] a small number were actually seen by physical therapists. It would be interesting to re-assess this rate of undergoing physical therapy in more recent years, given the recent uptick in studies involving strengthening exercises for PF.[136,137]

One other method of improving IFM strength in general is by wearing minimalist shoes,[138] as the increased flexibility, thin sole of the shoe, and lack of arch support increases the natural movement of the foot.[139] This leads to increased strength of the foot muscles as they must adapt to support the foot where the shoe will not.[104] These shoes have recently been used in a variety of clinical populations, such as older adult women with knee osteoarthritis,[140] and have been used thus far in 2 published studies about PF. Although both found positive results in decreased pain and increased self-reported function,[141,142] the shoes used do not appear to be the most true minimalist shoe. Ryan et al. (2009)[141] used Nike Free shoes, and Ribeiro et al. (2022)[142] used Moleca shoes, which

are both very flexible and zero drop, but both have a tapered toe box which is known to restrict natural movement.[143] Further research must be conducted in this area to understand the true effects of minimalist shoes on PF.

Interestingly, there were 2 studies that used barefoot running on grass in recreational runners for 6 weeks[144] and barefoot walking on a treadmill for 4 weeks,[145] both of which led to decreased pain for the participants. Reinstein et al. (2024)[145] particularly found that individuals who performed barefoot walking as opposed to traditionally shod walking, had greater decreases in pain and increases in function. These individuals were even able to increase their walking speed, as well as their time spent walking on the treadmill and outdoors.[145]

Injury prevention

Though there are not many specific recommendations for injury prevention for PF, it is an overuse injury with a major contribution being inappropriate overload, via bodyweight or increased physical activity.[16] Potentially, PF may occur because individuals are attempting to lose weight and they increase their activity too quickly; therefore, care should be taken for physicians to provide appropriate weight loss guidelines for these types of individuals.[23] Additionally, runners should take care to implement sensible training routines for their running regimen, and not increase their load too quickly.[146] Some authors do suggest that runners should consider performing foot core exercises in order to prevent injury,[147] given the IFM act in parallel to the plantar fascia tissue.[148] However, limited effectiveness appears to exist for the use of foot orthoses.[149]

INTRINSIC FOOT MUSCLES (IFM)

The IFM are an important but often overlooked group of muscles in the body regarding functional movement and gait given their small size and location in the bottom of the foot. Composed of muscles that originate and insert all within the foot, they have an important function in promoting foot stability,[150] contributing to the height and function of the medial longitudinal arch (MLA),[148] and absorbing and releasing energy for weight acceptance and subsequent propulsion in any weight-bearing movement.[7,151] The plantar IFM are primarily responsible for these actions, and have been broken down into 4 layers on the plantar aspect of the foot. The layers are as follows: (1): abductor hallucis (ABH), flexor digitorum brevis (FDB), abductor digiti minimi (AbDM); (2): quadratus plantae (QP) and lumbricals; (3) flexor digiti minimi (FDM), adductor hallucis oblique and transverse heads (AHOT), flexor hallucis brevis (FHB); and (4) plantar interossei. The dorsal IFM are on the dorsal aspect of the foot, which are the dorsal interossei and extensor digitorum brevis. However, literature mostly refers to the plantar IFM when using the general term "IFM", as these muscles are commonly linked to contributing to the foot arches.[148,150]

These muscles contribute to a phenomenon known as the "foot-core", termed by McKeon et al. (2015),[150] where the IFM act as local stabilizers in order for the extrinsic foot muscles (EFM) to contribute to global movement of the whole body. Although the IFM contribute highly to work performed at the ankle, more so than total work performed in the body,[9] they are still important for function. Importantly, the IFM assist in shock attenuation and force absorption in gait, along with subsequent propulsion, alongside the plantar aponeurosis due to the previously described windlass mechanism.[4] During weight

acceptance, the IFM slowly stretch and lengthen,[7] storing the energy in their tendons via arch compression,[10] then quickly release the energy just prior to propulsion to assist with push-off.[7,151] Removing the contribution of the IFM via a tibial nerve block was shown to decrease the ability of the foot to dissipate energy and subsequently generate power,[9] demonstrating the importance of the IFM to total body movement.

The IFM are also known to contribute to the height of the MLA during load-bearing.[148] Invoking AbH fatigue via foot muscle contractions, which was confirmed with EMG, led to an increase in navicular drop from sitting to standing.[152] It is likely that fatigue of the AbH (along with other IFM) reduced the ability to counter the falling arch,[152] and that the AbH assists in countering any MLA stretching or deformation individuals undergo.[148] Further, using electrical stimulation to increase IFM activity helped to counter deformation of the MLA during gait by reducing the amount of lengthening in the MLA.[148] Electrical stimulation also led to increasing arch height,[148,153] and decreased vGRF at the 2nd peak while walking,[153] potentially demonstrating better control of the foot. IFM activity is also shown to increase with higher gait velocity,[7] higher physical demand, such as with step-ups or cutting movements,[10] and increasing postural demand, such as going from a double-leg to a single-leg stance.[154,155] The IFM are more stabilizers than an intrinsic component of postural control,[156] as they respond to receptors on the dorsum of the foot and the stretch response, which is an automatic coordination in response to any changes in foot posture and IFM length.[150,157]

The IFM clearly are important for gait and function, but are often impaired in a variety of clinical populations with injury or disease, including those with musculoskeletal injuries, metabolic diseases, or simply older age. For example,

individuals with PF and chronic ankle instability (CAI) both have demonstrated weakened toe flexion and decreased IFM muscle size assessed via ultrasound.[96,97,102,158,159] Decreased IFM size is also present in those with patellofemoral pain (PFP),[160] specifically in the AbH, which could be related to decreased control of the MLA[51] and contribute to their PFP. Lastly, individuals with exercise-related lower leg pain (ERLLP) showed smaller FHB CSA and thickness during contraction.[161] While ERLLP is a rather all-encompassing diagnostic term that includes shin pain, stress fractures of the leg and ankle, stress reaction of the leg, general foot pain, and PF, decreased IFM size appears to be present in a variety of lower extremity pathologies. Though it is unknown whether the weakened IFM are a cause of the initial injury, or if the IFM are a result of the injury, the impairment of IFM in individuals with lower limb injuries can be detrimental. IFM weakness may predispose them to other injuries or prolong the effects of the existing lower limb injury. IFM weakness may also be present in older adults at risk for falls[162–164] and diabetics with neuropathy in the foot.[165,166] Given the importance of IFM in gait and balance, the decreased weakness in these populations can be potentially dangerous and lead to falls for older adults that can be near-fatal or fatal,[167] or amputations that can range from a toe to below the knee for those with diabetic neuropathy[168] if improperly managed.

Recent research has demonstrated that performing specific IFM strengthening exercise can lead to improved IFM strength and balance,[169] along with decreased navicular drop and foot posture index (FPI) in healthy individuals, indicating an effect on the characteristics of the MLA.[170] After implementing foot-core training exercises for 8 weeks, healthy runners demonstrated biomechanical alterations that could indicate

improved foot function, including increased rearfoot inversion especially upon heel-strike and decreased MLA excursion, indicating improved arch mechanics.[171] A similar study found that 8-weeks of foot and ankle exercises led to a decrease in running-related injuries (RRI), compared to a control group that only stretched and was 2.42 times more likely to experience an RRI than the intervention group. Time to injury was also correlated with the change in foot strength after the intervention, showing that having a stronger foot meant it took longer to get injured.[172]

Athletic populations also have benefits with IFM training beyond improved arch mechanics and reduced injury rates. IFM-based interventions led to improvements in IFM strength and foot arches,[173] propulsive vertical forces[174] and vertical jump performance,[173] horizontal jump performance,[175] direction changes during agility tests,[176] 50-meter dash time,[173] and force attenuation with jump landings.[177] Additionally, faster walking speed is associated with increased muscle CSA in some cases,[178] and the ABH is more active in ipsilateral than contralateral turns,[179] meaning that it assists with turning away from the foot in question. Admittedly, it is unknown if these specific components could be improved with actual training unlike the previous studies, and may need to be explored with future studies. Regardless, evidence has shown that performing foot and ankle strengthening exercises in healthy individuals could be beneficial in improving general function, or athlete-specific strength, function, and injury rates.

There are a variety of exercises that have been previously used in studies to target the IFM. The most well-known exercise is the SFE, which involves contracting the arch muscles of the foot to both raise and shorten the MLA by pulling the metatarsal heads towards the heel, but without any toe flexion contraction or extrinsic muscle activation.[180]

There are then a variety of exercises that may be termed by some individuals as "toe-posture" exercises or "toe yoga".[180,181] These include a toe spread out exercise (extend all 5 toes, then abduct and spread all the toes, and bring toes 1 and 5 to the ground while toes 2-4 stay extended, all toes come back down), first-toe extension (great toe extends while toes 2 – 5 remain on the floor), and 2nd-5th toe extension (2nd – 5th toes extend while the great toe remains on the floor). All 4 of these exercises have been associated with increased activation in the IFM (specifically, ABH, FHB, FDB, AbDM, QP, abductor hallucis oblique, interossei and lumbricals),[180] which explains their use in several intervention-based studies involving IFM strengthening.[182–184] Another exercise that is often used is a towel curl exercise. However, the concentric curl of the toes during the movement may involve the extrinsic toe flexor muscles[185] and not fully reflect the IFM only, thus it may not be appropriate as an "IFM exercise". Other authors have suggested using neuromuscular electrical stimulation (NMES) to strengthen the foot muscles, though it is recommended to be used in conjunction with performing IFM exercises or while weight-bearing to enhance IFM contractions[186,187] as opposed to NMES alone.[188] However, NMES can help in learning the IFM exercises, as they are reportedly difficult to learn initially,[189] and can be time-consuming to both learn and perform.

Overall, however, these aforementioned exercises are isolated to the foot, and some of the "toe-yoga" exercises are isometric in nature, which does not reflect how the IFM actually work in conjunction with the rest of the foot,[181] as the IFM operate more in weight-bearing and functional movements.[154,155] One recommendation by authors is to wear minimalist shoes, as extended time spent in the shoes either walking or running (greater than 3 weeks at least) is known to improve the strength and size of IFM in

healthy individuals,[138] though their specific effect on IFM morphology and strength has yet to be investigated in pathological populations. Another recommendation by authors, given this consideration and the time-consuming nature of IFM-specific exercises, is to perform more functional or full-body exercises. These could be any exercises that shift the COP anteriorly to load the midfoot,[181] are dynamic and more plyometric in nature,[181] such as hopping,[190] which shows increased activation of the AbH and FHB compared to isometric and IFM-isolating exercises. It may also include exercises that involve more extrinsic foot muscles like standing or walking on the toes.[190] Though they may not fully isolate the IFM, they are still important exercises that allow the IFM to stabilize the foot while the EFM act as "global movers" to produce gross functional movement.[150] However, IFM-isolated exercises may be important in individuals who have extreme limitations in their IFM function such as being unable to isolate the great toe from the lesser toes,[186] or who may not be able to perform any toe flexion movements at all.[191,192] Exercise prescription should likely depend on the needs and abilities of the individual, and their daily activity demands (ex. Activities of daily living versus sports performance). The effects of IFM strengthening on IFM strength, size, and function are mostly assessed in healthy individuals, with findings of improved sport performance and general function, and increased MLA height in those with flat feet.[55,184] However, limited research exists on the use of IFM exercises in any of the clinical populations mentioned earlier that have decreased IFM strength. There are preliminary studies on their use in individuals with PF,[131] CAI,[182,193] and PFP.[194] Strengthening IFM in a variety of individuals with lower limb injuries including PF has been shown to improve the height of the medial longitudinal arch.[195] Performing IFM exercises were found to be beneficial for

individuals with PF in areas of pain, patient-reported outcomes, and dynamic balance.[131] Additionally, individuals with CAI showed increased proprioceptive ability,[196] dynamic balance, and IFM activation rate;[193] and individuals with PFP showed decreased pain, navicular drop, and FPI.[194] Older adults performing IFM exercises were able to improve their IFM strength,[197,198] as well as general foot health and single-leg balance ability.[197] Individuals with diabetic neuropathy were even able to improve their toe strength, which could stave off the muscle atrophy and dysfunction that these individuals often face.[199]

However, more research must be conducted on the types of exercises per each clinical pathology, as well as the sets and reps involved, as there is extreme heterogeneity in these parameters. For example, Lee et al. (2019)[193] had individuals with CAI perform the SFE with a variety of progressions involving sitting, standing, and single-leg balancing positions. On the other hand, Hoch et al. (2023)[182] used the SFE along with other previously established IFM exercises of great toe extension, lesser toes extension, and toe spread out, along with balancing exercises, calf raises, and other ankle exercises. Although there are several studies for individuals with PF that used the SFE as the only IFM-focused exercise and implemented other lower body exercises and stretches, there were drastic differences in length of intervention, frequency, sets, repetitions, and the other types of exercises chosen,[131–134] which could also affect outcomes. There are also a host of other PF-related studies that involve the use of calf-raises with the toes elevated on a rolled towel, which has led to decreased pain.[126,129] The extension of the metatarsophalangeal joint is known to increase IFM activation and strength output.[200] This intervention would not be qualified as “toe-yoga” or the SFE but even all of those individuals got better. However, it could be interesting to compare results between

strictly “toe-yoga”-type exercises and this special calf-raise exercise, as they are different modalities of IFM strengthening. The lengths of interventions for other pathologies were also quite short, at 6 weeks[182] to 8 weeks[196] for CAI, and 6 weeks for PFP.[194] It is unknown if recovery could be further improved with longer interventions, if more than the SFE should be used to train the IFM, or what the prognosis for full recovery or recurrent pain is for these individuals.

An additional problem with the already small number of studies using IFM strengthening interventions in clinical populations is that IFM strength is often not investigated as an outcome measure. For example, Kamonseki et al. (2016)[131] did find that groups that performed stretching, stretching and foot exercises, and stretching and foot and hip exercises all had similar outcomes in pain, patient-reported outcomes, and balance. However, given that the actual strength of the IFM was not assessed,[131] there could be differences in IFM strength that may have been beneficial in the long-term. The lack of research on the effects of IFM strengthening exercises on IFM strength in clinical populations is certainly complicated by the fact that there is still no gold standard or widely used method of measuring IFM strength, size, or function.[103] Measurements that may be viewed as higher quality or more accurate include using MRI to assess muscle volume,[99,158] ultrasound to assess muscle thickness and cross-sectional area,[201] or EMG to assess muscle activity.[154,190] However, the problem is that many of these assessments are not easily accessible as they can be laboratory-based in nature, and can be expensive to perform. Muscle volume is shown to be related to force producing capacity[99,202] and ultrasound is a valid and reliable alternative to MRI for CSA assessment[203] that is capable of detecting change in muscle size after exercise.[204] However, neither of these measures

are able to provide a true force output, which is also important.[103] Performing individual IFM volume measurements is extremely time-costly, thus some studies have only performed IFM total volume measurements in the foot with MRI which may not be as helpful.[205] Lastly, EMG is only an assessment of muscle activity, not actual force, and there is high potential for cross-talk in the IFM given their close proximity to each other and their small size, especially with surface-level EMG.[103] Although there are several studies that have used fine-wire EMG for the plantar IFM,[206] this method is not as commonly used as surface-level EMG.

Measurements that can provide a true force output include using pressure platforms or mats to assess toe-pushing force,[207] custom-built dynamometers,[208] and a variety of handheld dynamometers.[209–211] There are also dynamometers that include performing toe flexion exercises with toe curl, which elicits more of the extrinsic foot muscles compared to tests that assess isometric toe flexion without any toe curl.[212,213] The lack of delineation in the literature between dynamometers with and without toe flexion may be problematic, as these are entirely 2 different types of actions and it may be inappropriate to compare studies across the dynamometer types. Though these devices that provide a force output and tend to be more easily accessible given their smaller size and lower cost, there is difficulty in isolating the different toe flexors that may be done more easily with ultrasound or EMG.[103] However, they can be altered during a test by altering joint positions. For example, ABH, FHB, FDB are more active and stiffer during toe flexion without interphalangeal flexion,[212] but the flexor hallucis longus has significantly higher activity during a toe grip or toe push with interphalangeal flexion, similar to a towel curl.[213] Therefore, the type of test conducted would be determined by

the purpose of the assessment. There are certainly limitations and benefits to each type of IFM assessment, but the general lack of IFM assessment before and after interventions that involve IFM strengthening, especially for clinical populations, is largely problematic. Though it can be helpful to know that injured individuals demonstrate improved pain and self-reported function levels after interventions that strengthen the IFM,[131,142] it would be extremely relevant to ascertain how the muscles themselves respond to understand if these changes can drive recovery. If the muscles do respond to these training exercises in pathological populations, then further development of IFM strengthening exercise progressions could be pursued.

MINIMALIST SHOES

History of Development

Minimalist shoes promote natural movement of the foot and whole body, with their zero-drop thin soles and lightweight and highly flexible nature. Within the running community there was a surge of interest in minimalist shoes after the book Born to Run was published,[214] detailing how the native Mexican tribe, the Tarahumara, were able to run hundreds of miles at top speeds without injuries, in their minimalist running sandals. However, minimalist running shoes have been around for thousands of years, with the first sandal found in the Upper Paleolithic Era around 45,000 years ago,[215] likely just for protection from the elements.[216] In the early 1800s, athletic shoes were created, and rubber was added in 1832.[216] In the 1960s and 70s, a modern running shoe with a cushioned heel, arch support, and a stiffened sole was developed, [215,216] in an attempt to prevent injury by matching foot type to shoe type. For example, motion control shoes were intended to help control pronation for flat-arched individuals.[216]

However, various studies have shown that matching footwear to foot type has no effect on injury rates. Minimalist shoes were introduced again in the early 2000s, with the Nike Free shoe. Born to Run continued to push forward this wave of minimalist shoes in 2009.[216] Research also showed that heel strike could contribute to MSK injuries, and it was discovered that a forefoot strike could reduce impact forces, which was promoted with the use of minimalist shoes or barefoot running.[215,216] Minimalist shoes were then designed to have no drop, no arch support, no midsole, and no heel counter (or a flexible one). However, there are large disparities in research findings about minimalist shoes in regards to biomechanics, which could be due to the variety of footwear design and the lack of standardization when defining a "minimalist shoe".[139,217] A Delphi study with 42 experts was conducted to develop a minimalist shoe definition, and a minimalist index which could rate a shoe from 0% (least minimalist) to 100% (most minimalist shoe). 95% of the participants agreed upon the following definition: "Footwear providing minimal interference with the natural movement of the foot due to its high flexibility, low heel to toe drop, weight and stack height, and the absence of motion control and stability devices". The Minimalist Index includes 5 components, each weighted 20% on the final score, which are weight, flexibility, heel to toe drop, stack height, and presence of any motion control/stability devices. This standardized definition was developed with experts from around the world, and is recommended to be used in the shoe industry and in research.[139]

In recent years, individuals have touted the use of minimalist shoes in injury prevention and performance improvements while running or playing a sport, but the literature is mostly composed of studies observing acute changes of individuals in

different footwear, as opposed to comparing habitual minimalist shoe wearers to traditionally shod wearers. Though there are some prospective studies of long-term use of minimalist shoes, they are not as extensive.[138,218–220] It has been difficult to conduct prospective studies over a longer period of time, but some data does exist of individuals who have worn minimalist shoes for a longer period of time. However, the time period is short, usually only spanning between 4 to 26 weeks,[218,219] with very few studies 6 months to a year of experience.[220,221] The longer-term effects of minimalist shoes on performance and injury rates are important, as there are notable differences in research findings when comparing acute to habitual findings. Table 1 demonstrates the differences in walking and running biomechanics both acutely and habitually, where acute changes are in comparison to traditional shoes, and habitual changes are often in comparison to the individual running in minimalist shoes prior to the intervention.

Biomechanical changes

The effects of minimalist shoes on healthy individuals, then, appears to be heavily influenced by the length of time the individual becomes accustomed to a minimalist shoe, from 10 minutes on a treadmill to years of being habitually barefoot or wearing minimalist shoes. It appears that in acute instances of wearing the shoe (usually for the first time ever that day), there are certain biomechanical characteristics that could potentially demonstrate an increased risk of injury, especially while running. These could include increased vertical peak impact forces and increased loading rates,[222–225] which are associated with common running injuries.[222] Meanwhile, individuals who have habituated to minimalist shoes for at least 8 weeks demonstrate decreased impact peak forces and loading rates,[226,227] and a transition to forefoot strike while running.[225,227–230] This also

appears as an increase in plantarflexion angle, so individuals are less dorsiflexed when they land, indicating less of a heel strike.[223,230–233] Even though these increased angles are found in acute minimalist shoe wear while running, the overall shift to a more anterior foot strike can be beneficial, as higher forces are usually seen when individuals rearfoot strike.[222] Further, adopting a forefoot or midfoot strike pattern eliminates a vertical impact peak and eliminates loading rate.[228] There are also increases in cadence and decreases in stride length,[226,230,233] which are often perceived as beneficial to decrease impact to the body. Contact time also decreases both acutely[234] and habitually,[226,231,235] although this could potentially be due to the increased presence of forefoot strike, leading to less time spent in contact with the ground. Regardless, it does appear that minimalist shoes may increase injury upon initial implementation,[222] but after a habituation period, there may be other beneficial alterations.

However, some authors report no differences in stride length or cadence, or other spatiotemporal parameters.[219,236] This could likely be due to the fact that they collected data in different methods and had entirely different protocols. For example, Fuller et al. (2017)[236] showed that there were no changes on stride rate or length, yet Khowailed et al. (2015)[226] reported decreased stride length and increased stride frequency like several others.[230,231,234] While both of these protocols used a 6-week transition to training in the shoes 25-35% of the time, the former used Asics Piranha and in-shoe force sensors, while the latter used Vibram Bikila shoes and an instrumented treadmill for their data collection. The Vibram Bikila (zero drop, anatomical toe box/ability to splay toes, stack height 7mm) are much more minimalist compared to the Asics Piranha (4mm drop, 119g, tapered toe box, stack height 22mm in heel), which could certainly influence the results.

Further, although using force sensors like loadsol has been validated to instrumented treadmills,[237] there are still some differences. For example, the insole may move in the shoe that may create some data discrepancies, and may affect an individual's gait.[109] Additionally, the in-sole sensors do not directly measure the contact forces between the ground and the foot sole, as there are first contact forces between the foot and the shoe, which may offer different results compared to in-ground force plates[109] or instrumented treadmills. Esculier et al. (2015)[139] cited that the disparities in research about minimalist shoe may be due to the variety on footwear design within the minimalist shoe community, which was why the authors conducted a Delphi study to determine the best definition for a minimalist shoe.

Even while walking, individuals demonstrate differences in their biomechanics. The decreased walking speed[238] and stride length[239] while wearing minimalist shoes for the first time walking could indicate that the thinner soles in the shoe leads individuals to walk more carefully. They are likely not used to the feeling of the heel impacting the ground that could normally be dampened by shoe foam,[240] which is demonstrated by the increase in rearfoot and forefoot vGRF in acute minimalist shoe walkers.[239] This is relevant as walking gait always involves a heel strike, as opposed to some runners who may mid- or forefoot-strike, so the heel impact may be something individuals try to avoid by walking more carefully. However, it appears that at least 8 weeks of adjusting to wearing minimalist shoes could lead to increased walking speed and stride length,[241] which could demonstrate increased comfort and confidence with a more minimalist shoe. An adjustment period does appear necessary for wearing minimalist shoes.[146]

Performance

Performance in running or sport can also be affected by the length of time an individual has worn minimalist shoes. Runners were surveyed in 2012 about using minimalist shoes, and 20% of the runners who did add barefoot or minimalist shoe running to their routines said they were initially interested in trying the shoes for performance enhancement, and 31% of them expected an increase in performance.[242] These beliefs may likely be due to some literature stating that running barefoot produces a lower VO2 max, and maximum oxygen uptake levels are lower when running barefoot.[242,243] However, these effects were mostly found in habituated minimalist shoe runners as opposed to novice runners,[244] as after 6 weeks of transitioning into minimalist shoes (worn 35% of time in training), individuals improved their 5-km trial time in minimalist shoes and had better running economy.[245] Other authors also found improved running economy after using minimalist shoes for 4 weeks,[218] 5 weeks,[246] and 10 weeks[247] via submaximal VO2 testing, and especially when experienced minimalist shoe runners wore their minimalist shoes compared to traditional shoes.[227] Hypotheses include that runners who land with more of a forefoot strike may use more elastic energy that can be stored in the muscles and tendons,[236] and shorter stride length and higher cadence can improve speed.[244] Finally, shoe mass may be important, as for every 100g of mass that is added to a shoe, the demand for VO2 increases by 1%.[244] However, the higher cadence in minimalist shoes could lead to greater energy costs, as a >10% increase in cadence leads to increased RPE.[242] This could explain why a 6-week trial of part-time minimalist shoe wear led to improved running economy,[236] but after this same study was extended to 26 weeks, where individuals transitioned into minimalist shoes for 100% of their training

time, actually had no effect on performance (running 5 kilometer time trial), running economy, or stride rate and length.[219] This is likely because the increased number of steps to travel the same distance could increase energy cost at a fixed distance. Regardless, changes in running performance in minimalist shoes are still not well established, as it can be highly dependent on the exact type of minimalist shoe chosen, the length of protocol, and the expertise and foot strike of the runner.

Minimalist shoes have also shown beneficial effects on stability in jump landings,[248] static postural control,[249–251] gait stability,[250] foot morphology,[252,253] and foot muscle strength and size in healthy adults.[138] For example, adults who wore minimalist shoes walking while obstacle crossing showed greater postural stability compared to wearing conventional shoes.[254] Individuals performing single-leg jump landings in minimalist shoes show greater dynamic stability,[248] decreased vertical forces,[248,255] and decreased loading rates.[248,255] As thicker-soled shoes are shown to increase peroneus longus activation, which is normally activated to protect against eversion, this could indicates that the thicker soles of traditional shoes are leading to greater instability at the ankle.[256] Additionally, thinner soles allow for maximal sensory input from the ground, which can create stability in the limb and modify leg stiffness in reaction to impact forces. As excessively high stiffness can lead to increased loading rates and shock, which could increase risk of injury to bone, low stiffness could then lead to soft tissue injuries;[257] the ability to moderate stiffness appropriately can be beneficial. Minimalist shoes may improve stability at the ankle, which can benefit sport performance and potentially decrease injury risk.

Foot Function

Habitual wearing of minimalist shoes is known to affect foot morphology and strength. For example, individuals from the Tarahumara tribe known for running in minimalist sandals, showed higher longitudinal arches via the AHI compared to members of the tribe who were shod,[252] which could indicate a stronger arch. After 4-weeks of minimalist shoe habituation, individuals were found to have lower Foot Posture Index values, indicating a more neutral foot.[251] Other authors have found that adults who spend more time barefoot are less likely to have flat foot,[258] and children who spend more time barefoot have significantly higher arches.[259] Although being barefoot is known to be slightly different from wearing minimalist shoes,[225,227] minimalist shoes are intended to replicate being barefoot as much as possible while providing protection for the dorsum of the foot, and data about barefoot individuals could still be relevant. However, one study did find that native barefoot walkers compared to shod walkers had lower medial arches.[260] The likely reason for this disparity is that this study used pressure to evaluate arch height, by measuring the area of the midfoot region using dynamic data from motion capture. They found that the Western, or conventionally shod individuals, had a significantly lower midfoot surface, which authors took to mean a higher arch. However, the increased area of the foot in habitually barefoot individuals also indicated that pressure was distributed more evenly across the foot, which was also supported by the finding of a wider foot in habitually barefoot individuals.[260] This may lead to lower pressures being applied over a longer period of time,[260] which could be beneficial in individuals who are suffering from injuries related to increased peak pressure. Other studies that found increased arch heights have used a static AHI, which divides the

dorsum height at 50% of foot length by the foot length,[259] or were conducted in children,[259] which could play a role as children are still growing and may have more flexible feet and different biomechanical loading patterns.[261] Barker et al. (2021)[253] also demonstrated that habitual minimalist shoe wearers had a larger arch drop (arch height change between sitting and standing), which was interpreted as an ability to increase the height of the arch while standing, a positive change.

Importantly, individuals who wear minimalist shoes for an extended period of time demonstrated stiffer longitudinal arches in most studies.[229,252,262] Holowka et al. (2018)[252] found that an increase in foot stiffness in habitual minimalist shoe wearers was correlated to increased abductor hallucis cross-sectional area, both of which could contribute to stabilizing the medial longitudinal arch to a greater degree.[152,263] Increased arch stiffness was established in both static[252] and dynamic conditions,[229,262] and the stiffness could assist individuals in absorbing force more easily.

Minimalist shoes are also shown to increase IFM strength and size if worn for at least 3 weeks, in a previous systematic review, in a variety of activities like walking, running, or performing plyometric-type training sessions.[138] Runners who wore minimalist shoes for 26 weeks (working up to minimalist shoe training at 100% of their total training) even demonstrated an increase in plantarflexion strength with greater mean weekly training distances,[219] likely due to the increase in ankle muscle activity necessary to stabilize in a minimalist shoe.[264] However, only wearing the shoes for 6 weeks in the same trial (working up to minimalist shoe training at 35% of their total training) did not have effects on plantarflexion strength,[236] showing that adaptation may need to occur over a longer period of time.

Table 1. Changes in minimalist shoe wearers, compared to traditional shoes at acute session

	Walking / non-Running		**Running**	
	Acutely	**Habitually**	**Acutely**	**Habitually**
Impact forces	↑ rearfoot (Huber 2022,[239] Broscheid 2016[265]), ↑ forefoot (Huber 2022[239])		↑ vertical peak impact (Willy 2014[222])	↓ Khowailed 2015,[226] Squadrone 2009[227]4/23/25 4:21:00 PM
Loading rates			↑ Gruber 2021,[224] Paquette 2013,[225] Sinclair 2013,[223] Willy 2014[222]	↓ Khowailed 2015[226]
Vertical stiffness			↑ Gruber 2021[224]	↓ Vercruyssen 2016[266]
Stride length	↓ Huber 2022[239]	↑ Gravestock 2014[241]4/23/25 4:21:00 PM	⊘ (Willy 2014[222]), ↓ (Squadrone 2015,[231] Stoneham 2021[264])	↓ (Khowailed 2015,[226] Fuller 2015[233]), ⊘ (Fuller 2017,[236] 2019[219])
Contact time			↓ McCallion 2014[234]	↓ Khowailed 2015,[226] Izquierdo-Renau, Squadrone 2015[231]
Contact area				↓ Izquierdo-Renau 2022[235]
Flight time				↑ Khowailed 2015[226]
Walking speed	↓ Franklin 2018[238]	↑ Gravestock 2014[241]		
Cadence	↓ (Huber 2022[239]), ↑ (Broscheid 2016[265])		⊘ (Willy 2014[222]), ↑ Squadrone 2015,[231] Greenhalgh 2014,[232] McCallion 2014[234])	↑ (Khowailed 2015,[226] Hollander 2017,[259] Fuller 2015[233]), ⊘ (Fuller 2017,[236] 2019[219])
Footstrike			↑ Forefoot (Paquette 2013,[225] Hollander 2017[259])	↑ Forefoot (Squadrone 2009;[227] Lieberman 2010,[228] 2014[229])
Plantarflexion angle	↑ Franklin 2018[238]		↑ (Sinclair 2013,[223] Squadrone 2015,[231] Greenhalgh 2014,[232]	

			Fuller 2015[233]), ⊘ (Willy 2014[222])	
Gait Stability	↑ (Cudejko 2020[250]), ⊘ (Azhar 2023[267])			
Tib. Ant. activation	↓ Franklin 2018[238]			↓ Khowailed 2015[226]
Foot Posture Index		↓ Gabriel 2024[251]		
Arch Drop		↓ Barker 2021[253]		
Arch Stiffness		↑ Holowka 2018[252]		↑ Miller 2014[262]
Ankle ROM		⊘ Gabriel 2024[251]		↑ Squadrone 2009[227]
Balance	⊘ Azhar 2023,[267] Broscheid 2016[265]	↑ Gabriel 2024,[251] Griffiths 2014[268]		
Time trial performance				↑ Fuller 2017[236]
Running economy			⊘ Warne 2014,[218] ↓ (Bellar 2014[246])	↑ (Fuller 2017,[236] Ridge 2015,[247] Squadrone 2009,[227] Warne 2014[218]) ⊘ (Fuller 2019,[219] Bellar 2014[246])

Injury risk when transitioning to minimalist shoes

The changes in wearing minimalist shoes over a long period of time may prove more beneficial than an acute bout of wearing the shoes in biomechanics, performance, and foot structure, but the length of time needed to adjust is still not clear. Transitioning to minimalist shoes is not without risk, especially for runners. To date, there are a multitude of studies that have investigated runners wearing minimalist shoes and their effects on injury rates, but the studies vary heavily in their transition progression.[146] However, the majority of the data shows that there is likely no difference in injury rates between conventional shoes and running barefoot,[269] especially when controlling for mileage.[146] Some studies even show that minimalist shoe wearers have decreased injury rates compared to conventional shoe wearers.[270,271] Most studies demonstrate that running in minimalist shoes have about the same injury rates as conventional shoes, although the location of the injuries tends to shift more towards the calf and shin.[269,272] A forefoot strike pattern is commonly observed in minimalist shoe wearers[228,229] and is associated with greater demands in the foot and ankle.[257] However, many studies do point to forefoot strike being associated with lower rates of running-related injuries,[240] which may be why minimalist shoes were so instantaneously popular at first.

There are some exceptions to the idea that minimalist shoes are not more injurious than conventional shoes. Cauthon et al. (2013)[273] conducted 3 case studies on individuals who got injured from wearing minimalist shoes, but the common theme among the 3 individuals was that they did not have a gradual transition period into the shoes, which is highly suggested by experts.[146,216] The immediate use of minimalist shoes without consideration about their lack of support compared to conventional shoes was likely the

cause of these injuries.[273] In another instance, even with a 10-week transition period, 10 out of 19 individuals transitioning to minimalist shoes showed presence of bone marrow edema in the foot.[274] However, most of the cases were asymptomatic and not enough to be classified a stress reaction, likely because the forces applied through the foot in minimalist shoes could lead to a normal process of osseous remodeling due to stress - with phases of breakdown and repair – and can even strengthen bone. Thus, the increase in the edema may not necessarily be a negative reaction to the shoes,[274] but rest periods must be adequate so the body can adapt to the higher forces over time.[273]

Lastly, Ryan et al. (2014)[272] discovered that when runners performed their training program in neutral, partial minimalist, and minimalist shoes, individuals in the partial minimalist shoes had the greatest injury rates, while those in the neutral shoe had the least. However, in this case, the runners were training for a specific 10K race, and were provided with a 12-week program,[272] while most other studies do not have a specific race in mind to train for. This could have been too much of a change for some individuals. Additionally, the runners were not reported to perform any foot or ankle strengthening in the study, which may have explained the greater injury rates.[272] Regardless, most of the data demonstrates that minimalist shoes may not necessarily increase injury rates, but they are known to change the location of the injury to more distal in the lower limb. Because of this, it is vital that runners transition into wearing minimalist shoes very gradually. Warne et al. (2017)[146] provides a specific set of recommendations, which are detailed below:

(1) Total running volume should maintain the same during the transition – and potentially even decrease overall running volume in first 2 weeks by a suggested 10 – 20%

(2) A hybrid approach of progression using time and volume: start with minimalist shoes as 10% of daily running volume, up to a maximum of 10 minutes, and increase by 5-10% each week.

(3) It may not be necessary to run in minimalist shoes 100% of the time, and it may be beneficial to use different surfaces over time.

(4) Strengthening exercises should be included during the progression. Strengthening exercises are essential in a transition to minimalist shoe.[146,216]

Although wearing minimalist shoes alone can increase IFM strength and size,[138] it may take at least 8 weeks for that to occur,[275] and performing rehabilitation exercises may serve as a protective factor against injury.[146] Minimalist shoes are known to shift individuals to more of a forefoot strike, but that tends to require more IFM activation to maintain that arch.[240] In conventional shoes, runners may feel comfortable using a rearfoot strike with a cushioned shoe as it is less demanding, but it leads to high loading rates. Conversely, it is commonly reported that wearing minimalist shoes leads to lower loading rates and vertical ground reaction forces, but minimalist shoe wearers have a greater demand placed on the foot and ankle given their lack of support and cushioning.[240] Therefore, it is vital that the foot and ankle is strengthened as they are required to do more while running in minimalist shoes to avoid injury and make the transition easier. Finally, maintaining overall running volume is proposed upon initial transition,[146] as running in minimalist shoes leads to decreased stride length, so more

steps must be taken to cover the same distance. Although there are decreased impact forces, the frequency will increase compared to conventional shoes, which may offset each other.[276] Therefore, maintaining regular running volume, but just increasing the percentage of time spent in minimalist shoes and decreasing time spent in conventional shoes over time can be beneficial.[146]

As previously discussed, there is a phenomenon in this research area about partial minimalist shoes, which many have touted as a compromise between traditional and minimalist running shoes,[216] or as a way to transition to full minimalist shoe use. These shoes tend to have less support and slightly decreased cushioning, but there is enough cushioning that a runner would still heel strike, leading to excessive loads. Ryan et al. (2014)[272] also demonstrated that the group of runners who wore partial minimalist shoes, compared to minimalist or neutral (but conventional) shoes, had the highest injury rates. It is suggested, then, to use fully minimalist shoes with a very slow transition period, rather than using partial minimalist shoes.[216]

Minimalist shoe usage in clinical populations

Wearing minimalist shoes usually leads to functional and biomechanical changes that could potentially be beneficial for a variety of clinical populations. For example, in older adults with a history of falls, wearing minimalist shoes can improve walking stability and postural control in bilateral standing with eyes open and closed compared to wearing conventional shoes. These individuals also demonstrated a decreased time to complete the Timed Up and Go test and a further reach on the Star Excursion Balance test in all directions.[277] It is likely that the conventional shoe with an elevated heel forces the center of pressure forward, which can lead to instability. On the other hand,

minimalist shoes are thinner, which can allow for the mechanoreceptors on the foot sole to adapt to the stimulus from the ground, potentially improving balance and leading to greater control of movement.[277,278] However, this study was merely cross-sectional, only capable of observing acute changes. Though healthy, young individuals who wore minimalist shoes for 4 weeks found improvements in balance via decreased center of pressure distance and smaller center of pressure area,[251] further research must assess if these changes will persist with longer-term use of minimalist shoes in a clinical population like older adults at risk for falls. It has been shown that older adults who have toe weakness and deformity increase the risk of falls in older adults.[163] However, adults who perform IFM strengthening exercises under a supervised program are able to improve their toe flexion strength and improve their general foot health[197] and balance ability.[197,279] Future research is needed to assess if the improvement in all these outcomes can actually reduce falls, such as the protocol described by Willemse et al. (2024).[280] Given that wearing minimalist shoes can improve foot strength and stability as well, clinicians and researchers could consider how these shoes can be used in more clinical populations that require improved foot strength and function.

In a cross-sectional study, older female adults with medial knee osteoarthritis performed a walking task in conventional shoes, minimalist shoes, and barefoot. The minimalist shoes had reduced knee adduction moments compared to the barefoot condition, while the conventional heeled shoe increased knee adduction moment.[281] Essentially, these shoes are able to decrease loading in the knee joint and mimic a barefoot condition while providing external foot protection to wearers. These results are persistent even after 6-months of wearing the minimalist shoes. These individuals

improved their pain, function, and stiffness as reported by the WOMAC questionnaire, and reduced their knee adduction moment and their medication intake.[282] This de-loading of the knee joint when wearing minimalist shoes has also been established in other populations, such as those with patellofemoral joint pain.[283] Bonacci et al. (2018)[284] found that using minimalist shoes decreased patellofemoral joint loading in runners with patellofemoral pain, and this was further enhanced with a prescribed increased cadence of 10%. In adolescents with patellofemoral pain, there were immediate decreases in knee flexion, knee extension moment, and patellofemoral joint reaction forces while walking and running.[283] Again, while long-term usage must be investigated, it is encouraging that minimalist shoes have some positive effects on knee joint loading.

As stated previously, injury locations in minimalist shoes seem to shift more proximally towards the foot and ankle,[269] likely due to the demand of the thinner and less supportive shoes. Running in minimalist shoes tends to lead to a forefoot strike, which can stress the foot and ankle more[216] but offload the knee, which can be beneficial to some populations who suffer from knee pain. Wearing shoes with larger drops, which is more of a conventional shoe, significantly increases peak knee extension moment,[285] which is why it may be advantageous for individuals with knee pain to wear shoes with lower or zero drops, which is closer to a minimalist shoe. Additionally, minimalist shoes allow greater sensory awareness of the foot's sole, which could help individuals minimize or moderate their loading more appropriately.[281]

Minimalist shoes can offload the knee in both walking and running conditions, but this certainly means that the demand shifts to the foot and ankle. Some may perceive that minimalist shoes would then be a poor choice for individuals with foot and ankle

pain, but there is potential that wearing minimalist shoes could actually increase foot and ankle strength in these injured individuals, as this has already been established in healthy populations.[138,219,268] This increased strength would be especially important in conditions that are known to have decreased toe strength, such as PF,[96] CAI,[159] or hallux valgus.[286] Patients with PF who wore minimalist shoes for 6 months led to improvements in the Foot-Posture Index, the Foot Health Status Questionnaire, and a 6-minute walk test, and demonstrated reduced maximum forces in the midfoot and rearfoot, and decreased peak pressures in the forefoot and midfoot, compared to the control group.[142] This is supported by the fact that healthy habitual minimalist shoe wearers are known to have higher arches than conventionally shod individuals.[252] They are also known to have wider feet[252] and increased contact area of the foot,[260] which could explain the decreased forces and pressures in the PF study as they may be able to apply the forces over a greater area on the foot. Additionally, patients with hallux valgus who wore minimalist shoes for 12 weeks showed improvements in their hallux angle, decreased forefoot width, and increased girth around the metatarsal area. They also displayed decreased peak pressures and maximum forces in the first metatarsal.[287] These changes are likely due to the increased toe box room in minimalist shoes, showing that minimalist shoes are able to morphologically alter the foot in both healthy and some clinical populations.[252,260,287]

There are a variety of benefits to using minimalist shoes as a clinical intervention tool. First, improved strength of the IFM can be seen with a variety of interventions, including running, walking, or spending daily time in the shoes in any activity.[138] However, these improvements in foot strength specifically have been seen only in healthy individuals; interestingly, none of the clinical intervention studies that have used

minimalist shoes have assessed any improvements in IFM strength or size.[141,142] Although improving pain and function is important, it is also important to assess changes in foot strength when using an intervention that is known to change foot strength. Regardless, another main benefit to using a minimalist shoe to improve IFM strength is that it may be easier than asking individuals to learn IFM exercises. They are difficult to learn and unfamiliar to most individuals, which can be frustrating for the clinician teaching the exercises and the patient learning them.[189] There is a modest workload associated with learning the exercises, especially in mental demand and effort,[189] but the workload does decrease over time.[183,189]

While the exercises then become easier for the individual to perform, the problem is that in order to progress the exercises, the volume of foot exercises must increase to become effective, which is extremely time-consuming. For example, a protocol for a current study with IFM exercises has indicated anywhere from 3 to 20 second holds for certain exercises.[182] Ridge et al. (2019)[275] also completed a protocol with toe spread, toe squeeze, and doming exercises for up to 3 sets of 30. These exercises, in addition to some ankle and hopping exercises, led to similar changes in individuals who walked in minimalist shoes for 12 weeks.[275] Therefore, although the exercises may become easier to learn, the time-cost of the exercises can be high. In that case, asking individuals to wear minimalist shoes as part of their daily lifestyle[142,220] may be a beneficial way to reduce the time-cost of performing IFM exercises daily. Though IFM and ankle exercises should considerably be performed when transitioning to minimalist shoes,[146] it may be simpler to reduce some of the exercise burden by wearing minimalist shoes. Additionally, it may be cost-effective for individuals who may not be able to afford multiple physical therapy

sessions a week to reduce their pain. Regardless, minimalist shoes could be seen as a supplement to any rehabilitation routine that includes IFM and ankle strengthening.

Comparison of minimalist shoes to being barefoot

In the past, many have tried to conflate barefoot running with minimalist shoe running and claim that minimalist shoe running replicates barefoot running. The literature does appear split on this issue, but it may come down to exact shoe types for both minimalist and conventional footwear (especially when comparing personal to lab-worn shoes), and exact population of participants (running experience, gender, etc). For example, Bonacci et al. (2013)[288] showed that highly trained runners (running 105km per week on average) had significant differences between barefoot and minimalist shoe running in stride length, ankle and knee joint moments, power, and work. Sinclair et al. (2014)[223] demonstrated that minimalist shoes do not appear to simulate barefoot movement patterns in experienced male runners (at least 30km per week). However, both of these studies used Nike Free 3.0 shoes, which are not as minimalist as other shoes on the market. In fact, Bonacci et al. (2013)[288] even discussed that the Nike Free 3.0 used has cushioning and an elevated heel, which is not present in many other minimalist shoes, especially not in the Vibram Five Fingers or VivoBarefoot which have been used in other studies.[225,227,264]

Running barefoot and while wearing minimalist shoes both lead to more anterior foot strike, and in rearfoot strikers specifically, there was an increase in loading rate of impact peak GRF compared to conventional shoes. On the other hand, the loading rate was reduced in forefoot strikers when running barefoot and in minimalist shoes.[225] While foot strike while running barefoot or in minimalist shoes shifts anteriorly regardless of

foot strike in conventional shoes, the increase in loading rate in minimalist shoes and barefoot must still be considered when transitioning to minimalist shoes. Importantly, however, this study shows that running in minimalist shoes and barefoot have similar alterations in movement patterns compared to conventional footwear.

It may be more beneficial, then to consider minimalist shoes as a compromise between barefoot and traditionally shod running. For example, when going from barefoot to minimalist to maximalist shoes, stride length and peak knee flexion moment increases, which are both associated with increased injury risk, at least to the knee.[220,221,264] Meanwhile, using minimalist shoes and running barefoot increases peak plantarflexion moment, again showing least some more similarities between the 2 conditions.[264] Further, in older adults, walking in minimalist shoes was associated with better gait performance than barefoot, which could play a role in fall prevention.[289] The minimalist shoes certainly provide protection from the ground, but also likely support the foot slightly more than barefoot and potentially increase confidence in walking. There may be barriers to walking barefoot, such as being ashamed of one's feet, a fear of falling, or even having cold feet.[289] Thus, the ability of minimalist shoes to mimic a barefoot condition truly does depend on the population, as minimalist shoes may mimic walking barefoot more so than running barefoot given that heel strike is a necessary part of walking gait, or they may be beneficial for more vulnerable populations that require some more protection. One study used experienced barefoot runners to assess if Vibram FiveFingers shoes imitate actual barefoot running compared to a standard neutral shoe,[227] and found that VO2 and peak impact forces were significantly lower with FiveFingers, and were much closer to barefoot running compared to conventional running. Meanwhile, another study used

Vibram FiveFinger shoes compared to participants' own conventional running shoes, and found that minimalist shoe running tends to more closely resemble shod than barefoot running. Therefore, the comparisons to conventional shoes may also depend on the type of shoe an individual is tested in, or their depth of experience with barefoot or minimalist shoe running.

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APPENDIX C: ADDITIONAL METHODS

1. Table C1 – Summary of Protocol Procedures
2. Table C2 – Institutional Review Board Information
    a. Institutional Review Board Documents
    b. Study flyer
3. Table C3 – Forms and Questionnaires
    a. Pre-Screening Questionnaire
    b. Pre-Screening Checklist for phone call
    c. Health History Questionnaire
    d. Pain Levels
    e. Global Rating of Change (GROC)
    f. Foot and Ankle Ability Measure (FAAM)
    g. Fear Avoidance Belief Questionnaire (FABQ)
    h. Tampa Scale of Kinesiophobia (TSK-11)
    i. Pain Self-Efficacy Questionnaire (PSEQ)
    j. NASA Activity Survey Scale
    k. Final Questions at Post-Test
    l. Final Questions 2-months Post-Test
4. Table C4 – Laboratory Measures: Instrumentation & Procedures
    a. Foot Posture Index References
    b. Ultrasound Image Measurement
    c. Data Collection Sheet
5. Table C5 – Study Protocol Adherence Assessments
    a. Study Protocol Adherence Assessments Setup
    b. Protocol Adherence Survey Questions
6. Table C6 – Home Exercise Program
    a. Rehabilitation Instruction Sheets for Patients
    b. Links to Video Demonstrations
    c. Minimalist Shoe Information Sheet

Table C2 – Institutional Review Board Documents

RESEARCH APPLICATION

Investigators Experience

The investigator is a physical therapist and athletic trainer who has experience working injured individuals both as a clinician and a researcher, by implementing rehabilitation interventions. The investigator has worked on several projects that involved intrinsic foot muscle strengthening. The investigator also has collaborated within several departments for clinical research, and has expertise with the chosen intervention of balance, range of motion, and strengthening exercises. She also leads a diverse team of graduate students and other research scientists to investigate orthopedic injury risk, interventions and rehabilitation.

Investigator Agreement

BY SIGNING THIS DOCUMENT, THE INVESTIGATOR CONFIRMS:

1. I am not currently debarred by the US FDA from involvement in clinical research studies.
2. I am not involved in any regulatory or misconduct litigation or investigation by the FDA.
3. That if this study involves any funding or resources from an outside source or if you will be sharing data outside of UVA prior to publication that you will contact the Dean's office regarding the need for a contract and letter of indemnification. If it is determined that either a contract or letter of indemnification is needed, subjects cannot be enrolled until these documents are complete.
4. The protocol will abide by the ethical standards of The Belmont Report
5. The proposed research project will be conducted by me or under my close supervision. It will be conducted in accordance with the protocol submitted to and approved by the IRB including any modifications, amendments or addendums submitted and approved by the IRB throughout the life of the protocol.
6. That no personnel will have access to subjects in this protocol or their information until they have completed the human subject research protection on-line training through CITI and the IRB-HSR has been notified.
7. That all personnel working on this protocol will follow all Policies and Procedures of:
   - the UVA Human Research Protection Program (HRPP SOPS)
   - the IRB-HSR https://research.virginia.edu/irb-hsr
   - the School of Medicine Clinical Trials Office: http://www.medicalcenter.virginia.edu/intranet/cto/index.html
   - and any additional UVA requirements for conducting research.
8. I will ensure that all those personnel delegated tasks relating to this study, whether explicitly or implicitly, are capable through expertise, training, experience or credentialing to undertake those tasks.

9. I confirm that the implications of the study have been discussed with all Departments that might be affected by it and have obtained their agreement for the study to take place.
10. That no subjects will be recruited or entered under the protocol until the Investigator has received the signed IRB-HSR Approval form stating the protocol is open to enrollment
11. That any materials used to recruit subjects will be approved by the IRB-HSR prior to use.
12. That all subjects will give informed consent unless the requirement has been specifically waived by the IRB.
13. That unless written consent has been waived by the IRB all subjects will sign a copy of the most current consent form that has a non-expired IRB-HSR approval stamp.
14. They will establish and maintain an open line of communication with research subjects within their responsibility.
15. That any modifications of the protocol or consent form will not be initiated without prior written approval from the IRB-HSR, except when necessary to eliminate immediate hazards to the subjects.
16. Any significant findings that become known in the course of the research that might affect the willingness of subjects to enroll or to continue to take part, will be promptly reported to the IRB.
17. I will report immediately to the IRB any unanticipated problems involving risk to subjects or to others including adverse reactions to biologics, drugs or medical devices.
18. That any serious deviation from the protocol will be reported promptly to the Board in writing.
19. That any data breach will be reported to the IRB, the UVA Corporate Compliance and Privacy Office , UVA Police as applicable.
20. That the continuation status report for this protocol will be completed and returned within the time limit stated on the form.
21. That the IRB-HSR office will be notified within 30 days of a change in the Principal Investigator or of the closure of this study.
22. That a new PI will be assigned if the current PI will not be at UVA for an extended period of time. If the current PI leaves UVA permanently, a new PI will be assigned PRIOR to the departure of the current PI.
23. All study team members will have access to the current protocol and other applicable documents such as the IRB-HSR Application, consent forms and Investigator Brochures.
24. Signed consent forms and other research records will be retained in a confidential manner. Records will be kept according to UVA Records Management policies.
25. No data/specimens may be taken from UVA without a signed Agreement between OSP/SOM Grants and Contracts Office and the new institution. Original study files are considered institutional records and may not be transferred to another institution. I will notify my department administration regarding where the originals will be kept at UVA. The agreement will delineate what copies of data, health

information and/or specimens may be taken outside of UVA. It will also approve which HIPAA identifiers may be taken outside of UVA with the health information or specimens.

26. If any member of study team leaves UVA, they are STRONGLY ENCOURAGED to use Exit Checklist found on IRB-HSR website at https://provost.virginia.edu/system/files/documents/Faculty-Departure-Checklist-2015_508.pdf

IF THE IRB-HSR WILL BE THE IRB OF RECORD FOR MULTIPLE SITES IN A MULTISITE TRIAL, THE UVA PI AGREES TO CARRY OUT THE FOLLOWING RESPONSIBILITIES:

1. Ensure all UVA personnel designated as Conflict of Interest Investigators complete Reviewing IRB's financial interest disclosure requirements unless the UVA personnel will adhere to the UVA conflict of interest policies that are compliant with DHHS requirements.
2. Promptly provide the Principal Investigator at each site with:
    a. Current approved protocol and consent documents;
    b. Approved modifications, amendments or changes to research protocols; and
    c. Approval of continuing reviews and reviews of unanticipated problems;
3. Notify the Principal Investigator at each site of standards and guidelines for reporting any post approval events such as adverse events, subject injuries, unanticipated problems, and protocol violations. Collect reports from Principal Investigator at each site of any unanticipated problems, deviations, suspensions and terminations, non-compliance, subject complaints, and submit such reports to Reviewing IRB per reporting requirements.
4. Notify the Principal Investigator at each site promptly of any unanticipated problems involving risks to subjects or others as determined by the Reviewing IRB.
5. Collect required information from the Principal Investigator at each site necessary for completing continuing review submissions.
6. Notify the Principal Investigator at each site promptly about any lapses of approval. Forward to the IRB of Record any request from the Principal Investigator of a site for continuation of a specific research subject on a protocol during a lapsed period of approval.

The IRB reserves the right to terminate this study at any time if, in its opinion, (1) the risks of further experimentation are prohibitive, or (2) the above agreement is breached.

Signatures

Principal Investigator

_____	_____	_____
Principal Investigator Signature	Principal Investigator Name Printed	Date

INSTRUCTIONS:
DO NOT SIGN HERE IF THIS IS A NEW STUDY SUBMISSION TO THE IRB-HSR.
SIGNATURES WILL BE OBTAINED VIA CRCONNECT.
The Principal Investigator signature is ONLY required in this word document if this submission is a modification changing the Principal Investigator.

Department Chair or Designee

BY SIGNING THIS DOCUMENT THE DEPARTMENT CHAIR AGREES:

1. To work with the investigator and with the board as needed, to maintain compliance with this agreement.
2. That the Principal Investigator is qualified to perform this study.
3. That the protocol is scientifically relevant and sound.
4. He/she is not the Principal Investigator or a sub investigator on this protocol.

_____	_____	_____
Department Chair or Designee Signature	Department Chair or Designee Name Printed	Date

INSTRUCTIONS:
The person signing as the Department Chair cannot be the Principal Investigator or a sub-investigator on this protocol.
If the Department Chair fills one of these rolls on this protocol, the Department Chair's supervisor must sign here.
The Department Chair or Designee signature is ONLY required on this word document if this submission involves a modification changing the Principal Investigator.

Brief Summary/Abstract

Plantar fasciopathy (PF) is a common condition that causes pain on the plantar aspect of the rearfoot and decreases an individual's quality of life. PF affects up to 25% of active individuals, 10% of sedentary adults, and military servicemembers. Individuals with PF have limited physical function involving walking, running, and standing, and report lower energy levels, which affects activities of daily living. These individuals exhibit smaller and weaker intrinsic foot muscles (IFM) compared to healthy individuals. Those with PF also have decreased vertical ground reaction forces (vGRF) while walking, which is likely an attempt to reduce pain. Although a variety of interventions for PF have been explored, including corticosteroid injections, insoles, rest, and stretching, there is poor consensus for any of these treatments. Despite demonstrated IFM weakness in this population, there is a surprising gap in the literature that focuses on IFM-specific strengthening as a treatment for individuals with PF.

Minimalist shoes (MS) have increased flexibility and decreased arch support that may increase IFM activation to support the arch of the foot. There is evidence that healthy individuals who wear MS in an 8-week walking intervention can improve their IFM strength and size. In individuals with PF specifically, only one study to date

incorporated wearing MS daily, while another study implemented IFM-specific exercises. Both interventions led to improvements in pain and patient-reported outcomes (PROs), but wearing MS in addition to performing a rehabilitation program could potentially amplify the positive effects. This study will be an 8-week randomized trial involving two groups of individuals with PF. Both groups will receive a standard rehabilitation program, while the intervention group (Rehabilitation and Minimalist Shoes, [RAMS]) will add wearing MS into their daily routine. Following the intervention, we will measure pain (self-reported measures), function (balance), IFM strength and size (dynamometer and ultrasound imaging), and kinetics during walking gait.

We hypothesize that the RAMS group will improve pain and function levels, increase IFM strength and size, and normalize gait mechanics to a greater degree in individuals with PF, compared to those who only perform a rehabilitation program. The data will first be analyzed with a one-way ANOVA in order to compare the 2 groups at baseline and post-intervention data collection. Then, a two-way repeated measures ANOVA will be conducted to compare the magnitude of improvement of the 2 treatment groups. A correlation matrix will be conducted to understand how IFM strength and size and gait kinetics are related to self-reported measures. Then, regression models will be explored to understand what contributes the most to self-reported pain and function improvements.

This novel approach may improve treatment options for individuals with PF. Further, if individuals with PF have increased IFM strength and size following the incorporation of MS, it may become a standard part of the treatment for PF. Lastly, our results may lead us to further investigate the effects of wearing minimalist shoes on recovery in a variety of clinical populations involving the lower extremities and spine.

Sponsor

1. **Explain the sponsorship for this study.**
2. University of Virginia Department of Kinesiology will be providing internal funding.

Support Source

1 .Describe what will be provided and by whom.

1. This study is funded by a $1,000 doctoral student grant from the Virginia Athletic Trainers' Association. The award letter is included in the documents.
2. This study is funded via a $1,000 doctoral student grant from the University of Virginia's School of Education and Human Development, for the Innovation, Development and Exploration Awards (IDEAs grant). The award letter is included in the documents.
3. The study will be funded via a $10,000 doctoral and early researcher grant from the American College of Sports Medicine via Xero Shoes, for the Xero Shoes' Minimal Footwear Research Grant. The award letter is included in the documents and will be awarded starting on July 1.

4. The study has a contract with the company Xero shoes to send the investigator 20 pairs of minimalist shoes free of charge. The award letter is included in the documents.

Human Participants

1. **How many subjects will be enrolled in this study by the UVA site?** 38

2. **Will subjects be recruited or receive study interventions in a UVA patient care setting?** Yes

If YES, all study team members must review the Guideline for Research in Patient Care Settings prior to the start of the study.

Research Involving Students and Employees as Subjects

1. **Explain which study procedure the employees or students will participate in.** (i.e. all procedures, lab controls, MRI dry run)?
   Students will participate in all of the study procedures

2. **Provide justification for recruitment of the employee/student in this research proposal**: *You are required to provide a rationale other than convenience for selecting this group.*
   The rationale is that the students at the University of Virginia are very diverse in their activity level, and there are many students who participate in recreational exercise and sport, as well as those who do not exercise at all. They are also often required to do plenty of walking around campus. All of these things could lead to plantar fasciopathy, and this will be an opportunity for these students to receive treatment free of charge.

3. **Does the Principal Investigator of this study directly supervise/evaluate the Employee/Student within the work or educational setting?** E*mployees and students assigned to a particular investigator or laboratory should not be directly recruited for participation in any study conducted by that investigator or laboratory, although such employees and students may, on their own, volunteer to participate.*
   The PI may directly evaluate the student within the work or educational setting, and in this case, a separate individual who is on study team will recruit those students who are supervised by the PI.

4. **Explain what provisions are implemented to mitigate the risks involved in including employees/students as subjects in the study.** *(e.g., ensuring that participation is voluntary, course grades will not be based on research participation, informed consent will be obtained from the subject by an individual other than the person in a position of power; the researcher will not have access to the data collected until after the class grades have been posted)*

Participation will fully be voluntary. This will be fully be explained when contacting individuals about the study, whether in person, electronically, or over the phone. Course grades will not be based on research participation.

5. **Describe how students and employees are recruited for this study. (e.g.- verbal scripts, flyers, listservs, and/or web-based systems for student subject pools)**
Recruitment and consent of student/employee subjects are not held to a different standard in the IRB review process, and the researchers must ensure that the recruitment and informed consent processes minimize the possibility of coercion or undue influence and maintain subject confidentiality.

Students and employees will be recruited for this study with flyers, emails that get sent out to an entire class, social media advertisements (by posting the flyer created), and in-person by members of the study team when possible.

6. **Is there financial or other types of compensation offered for participation in this study for students and employees who are participating?**

No.

Recruitment

Recruitment includes identifying, review of records to determine eligibility or any contact to determine a potential subject's interest in the study.

***IMPORTANT:**
If PHI is collected, contact with potential subjects may only be performed by individuals who work under the UVA HIPAA covered entity, which means they meet one of the following criteria:

- a UVA student working in the UVA HIPAA Covered Entity*
- a faculty or staff member in an appointment in the UVA HIPAA Covered Entity*
- a volunteer approved by the School of Medicine

INFORMATION: * The UVA HIPAA Covered Entity includes the following areas: UVA Health including the School of Medicine & the School of Nursing, the Sheila C. Johnson Center, the Exercise and Sports Injury Laboratory and the Exercise Physiology Core Laboratory and University Physicians Group (UPG). Identifiable health info may also be shared with the following areas without tracking the disclosure as agreements are in place to protect the information:

- VP Office of Research
- Nutrition Services (Morrison's)
- UVA Center for Survey Research

1. How do you plan to IDENTIFY potential subjects?

To "identify" a potential subject refers to steps you plan to take to determine which individuals would qualify to participate in your study. This does NOT include steps to contact those individuals.

If your study involves more than one group of subjects (e.g., controls and cases or subjects and caregivers) note below which groups are being identified by the given method.

Check the method(s) you plan to utilize:

a. ☒ Electronic Medical Record Review or Report (can include EPIC Slicer Dicer, Clarity, Caboodle, and other EMR reporting tools) / EMR data copy from an enterprise research database (CDR-IRB-HSR# 10797, OR OMOP, TriNetX, i2b2, ACT IRB-HSR #20840:) / Database established for health care operations (departmental clinical database or UVA Enterprise Data Warehouse) / Quality Improvement Data (*e.g. Performance Improvement, Practice Improvement, Quality Improvement*).

DHHS: *Pre 2018 Common Rule:* Study team requests Waiver of Consent to identify prospective subjects. *2018 Common Rule:* Allowed under Preparatory to Research if the investigator will identify subjects through oral or written communication with prospective subject or LAR OR the investigator will obtain identifiable private information or bio-specimens by accessing records or stored identifiable bio-specimens. HIPAA: Allowed under Preparatory to Research if PHI to be accessed.

b. ☐ Review of a research data repository that was established to keep data to be used for future research such as a departmental research database or use of data from a separate current active research protocol. The research repository or study from which you are finding potential subjects must also have an IRB protocol approval. If this item is checked, enter the IRB # below.
IRB#

DHHS: *Pre 2018 Common Rule:* Study team requests Waiver of Consent to identify prospective subjects. *2018 Common Rule:* Allowed under Preparatory to Research if the investigator will identify subjects through oral or written communication with prospective subject or LAR OR the investigator will obtain identifiable private information or bio-specimens by accessing records or stored identifiable bio-specimens. HIPAA: Allowed under Preparatory to Research if PHI to be accessed.

c. ☐ Patients UVA health care provider supplies the UVA study team with the patient's contact information without the patients' knowledge.

DHHS:

Pre 2018 Common Rule: Study team requests Waiver of Consent to identify prospective subjects. *2018 Common Rule:* Allowed under Preparatory to Research if the investigator will identify subjects through oral or written communication with prospective subject or LAR OR the investigator will obtain identifiable private information or bio-specimens by accessing records or stored identifiable bio-specimens. HIPAA: Allowed under Preparatory to Research if PHI will be shared by the health care provider.

d. ☐X Patient obtains information about the study from their health care provider. The patient contacts the study team if interested in participating. (Health care provider may or may not also be a member of the study team)

DHHS: NA HIPAA: Allowed under Health Care Operations

e. ☐X Potential subjects will not be directly identified. They will respond to an indirect advertisement such as a flyer, brochure, poster, listserv email, etc. If this choice is checked, check 3d- INDIRECT CONTACT.

f. ☐ Potential subjects have previously signed a consent to have their name in a registry/database to be contacted for future studies of this type.
IRB-HSR# of registry/ database:

g. ☐ Other*:*

IMPORTATANT: If item # a, b or c is checked above and if this study involves the use of protected health information, the PI and study team understand that: x☐YES

- The use or disclosure is sought solely to review protected health information as necessary to prepare the research protocol or other similar preparatory purposes.
- No PHI will be removed from the UVA covered entity.
- The PHI that the researcher seeks to use, or access is necessary for the research purposes.

2. How will potential subjects be CONTACTED?

To "contact" a potential subject, refer to the initial contact you plan to take to reach a potential subject to determine if they would be interested in participating in your study. This may include direct contact by such methods as by letter, phone, email or in-person or indirect contact such as the use of flyers, radio ads etc. If your study involves more

than one group of subjects (e.g., controls and cases or subjects and caregivers) note below which groups are being contacted by the given method.

Check the methods below you plan to utilize:

a. ☒ Direct contact of potential subjects by the study team by **approaching IN PERSON while at UVA Hospital or UVA Health Clinic OR via letter, phone, direct e-mail by members of the study team who *ARE NOT* the health care providers of the patient**. Information will not be collected from psychotherapy notes.

Indicate what method(s) will be used below and include a copy with your application:

☒ IN PERSON++
☐ Letter
☒ Telephone
☒ Email
☐ Study Information Sheets
☐ Other:

Note: Letter, telephone, and email scripts must be submitted for review by the IRB-HSR when checked. See Recruitment Tools for templates.

++ IN PERSON: You should share the following information with the potential subject:

- Your name
- Who you are: physician, nurse etc. at the University of Virginia.
- Why you want to speak with them
- Ask if you have their permission to explain the study to them
- If asked about how you obtained their information, use one of the following as an option for response.
  - DO NOT USE THIS RESPONSE UNLESS YOU HAVE OBTAINED PERMISSION FROM THE SUBJECT'S UVA PHYSICIAN: Your doctor, Dr. insert name wanted you to be aware of this research study and gave us permission to contact you.
  - We obtained your information from your medical records at UVA.
  - Federal regulations allow UVA Health to release your information to researchers at UVA, so that we may contact you regarding studies you may be interested in participating. We want to assure you that we will keep your information confidential.

Pre 2018 Common Rule:

DHHS/HIPAA: Study team requests a Waiver of Consent and Waiver of HIPAA Authorization to contact potential subjects.
2018 Common Rule:
DHHS: Allowed under Preparatory to Research if the investigator will identify subjects through oral or written communication with prospective subject or LAR OR the investigator will obtain identifiable private information or bio-specimens by accessing records or stored identifiable bio-specimens.
HIPAA: Study team requests a Waiver of HIPAA Authorization to contact potential subjects.

b. ☐X Direct contact of potential subjects by the study team by **approaching in PERSON at UVA OR via letter, phone, direct e-mail by members of study team who *ARE* health care providers of the patient**. Information will not be collected from psychotherapy notes.

Indicate what method will be used and include a copy with your application:

☐X IN PERSON++
☐Letter
☐Telephone
☐Email
☐X Information sheets (Small flyers)
☐Other:

Note: Letter, telephone, and email scripts must be submitted for review by the IRB-HSR.
See Recruitment Tools **for templates.**

++ IN PERSON: You should share the following information with the potential subject:

- Your name
- Who you are: physician, nurse etc. at the University of Virginia.
- Why you want to speak with them
- Ask if you have their permission to explain the study to them
- If asked about how you obtained their information, use one of the following as an option for response.
  - DO NOT USE THIS RESPONSE UNLESS YOU HAVE OBTAINED PERMISSION FROM THE SUBJECT'S UVA PHYSICIAN: Your doctor, Dr. insert name wanted you to be aware of this research study and gave us permission to contact you.
  - We obtained your information from your medical records at UVA.
  - Federal regulations allow UVA Health to release your information to researchers at UVA, so that we may contact

you regarding studies you may be interested in participating. We want to assure you that we will keep your information confidential.

Pre 2018 Common Rule: *DHHS:* Study team requests a Waiver of Consent to contact potential subjects. *HIPAA:* Allowed under Health Care Operations. 2018 Common Rule: *DHHS:* Allowed under Preparatory to Research if the investigator will identify subjects through oral or written communication with prospective subject or LAR OR the investigator will obtain identifiable private information or bio-specimens by accessing records or stored identifiable bio-specimens. *HIPAA:* Allowed under Health Care Operations.

c. ☐ **Potential subjects are not patients.** The study does not include obtaining subjects health information. Subjects will be contacted directly via email, phone, letter, or presentation in group setting with consent then obtained individually in a private setting.

Indicate what method will be used below and include a copy with your application:

☐IN PERSON++
☐Letter
☐Telephone
☐Email
☐Information Sheets
☐Other:

Note: Letter, telephone, and email scripts must be submitted for review by the IRB-HSR when checked. See Recruitment Tools for templates.

++ IN PERSON: You should share the following information with the potential subject:

- Your name
- Who you are: physician, nurse etc. at the University of Virginia.
- Why you want to speak with them
- Ask if you have their permission to explain the study to them
- If asked about how you obtained their information, use one of the following as an option for response.
  - DO NOT USE THIS RESPONSE UNLESS YOU HAVE OBTAINED PERMISSION FROM THE SUBJECT'S UVA PHYSICIAN: Your doctor, Dr. insert name wanted you to be aware of this research study and gave us permission to contact you.

- We obtained your information from your medical records at UVA.
- Federal regulations allow UVA Health to release your information to researchers at UVA, so that we may contact you regarding studies you may be interested in participating. We want to assure you that we will keep your information confidential.

Pre 2018 Common Rule: *DHHS:* Study team requests a Waiver of Consent to contact potential subjects. *HIPAA:* NA 2018 Common Rule: *DHHS:* Allowed under Preparatory to Research if the investigator will identify subjects through oral or written communication with prospective subject or LAR OR the investigator will obtain identifiable private information or bio-specimens by accessing records or stored identifiable bio-specimens. *HIPAA:* NA

d. ☒ **Indirect contact** (flyer, poster, brochure, TV, radio, listserv emails) where patient provided info about the study from their health care provider and **EITHER the patient contacts study team or gives their healthcare provider permission for the study team to contact them**).

Indicate what method will be used below and include a copy with your application:

☒ Flyer
☐ Poster
☐ Brochure
☒ Listserv Email
☐ Television
☐ Radio
☐ Video
☒ Other: Social Media (Twitter/X, Instagram, Facebook, etc. – script included), UVA Health Clinical Trials Website (advertisement included in documents)

Note: Letter, telephone, and email scripts must be submitted for review by the IRB-HSR when checked. See Recruitment Tools for templates.

3. Will any information be obtained from a potential subject during "prescreening"?

IF YES, submit any documents that will be used to collect pre-screening information so that the IRB may confirm what questions will be asked and include which HIPAA identifiers will be collected on the document.

☐**NO** ☐**X YES, Explain:**

Yes, if participants are interested they will fill out a secure survey on UVA REDCap to indicate that they do or do not meet the inclusion criteria. They will be asked to provide some contact information to be contacted, and a series of yes or no questions. IF they qualify, they will then be contacted by a member of the study team. They will then be contacted by phone call, and the an investigator will go over the answers to the questions from the survey to double check that they fit the criteria. Then, an initial baseline appointment will be set-up. The pre-screening survey, the telephone script, screening data collection sheet are included in the application.

Pre-screening for IRB purposes is the term used to describe activities PRIOR to obtaining Informed Consent and may not include any research procedures. The activities may involve pre-screening of potential subjects over the telephone or in person to determine their initial eligibility for, and interest in a study and is a common strategy in the recruitment process. Questions appropriate for pre-screening address the specific inclusion/exclusion criteria for the study and other issues of suitability, for example, an individual's ability to come to the research site multiple times. It is NOT appropriate at this point in the process (i.e., prior to obtaining informed consent/enrollment) to gather information that is not directly related to assessing eligibility and suitability (e.g., obtaining complete medical histories, obtaining blood specimens for lab tests).

NOTE: To comply with HIPAA regulations only the minimum necessary information may be collected at this time. This means that only questions pertaining to the Inclusion and Exclusion Criteria may be asked.

Pre 2018 Common Rule:
DHHS: Study team requests a Waiver of Documentation of Consent for Pre-screening questions.

2018 Common Rule: No waiver of documentation of consent required per 45CFR46.116 (g).
45CFR46.116(g) an IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subjects legally authorized representative if either of the following conditions are met: the investigator will obtain information through oral or written communication with the prospective subject or LAR or the investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.
HIPPA:
HIPAA does not apply if:
--no PHI is collected or

--if PHI is collected from a potential subject by an individual from a department that is not part of the HIPAA covered entity.
HIPAA does apply if the collection occurs by individuals* who work in a department that is part of the HIPAA covered entity.

IF YES, Will any of the questions involve health information?
Yes

IF YES, will you collect HIPAA identifiers with the health information?
Yes

IF YES, which HIPAA identifiers will be recorded?
Name, email, and phone number

Do you confirm that health information with HIPAA identifiers will not be shared outside of UVA until a consent form is signed or only shared in a de-identified manner? ☐X YES

4. **Do you plan to ask the subjects to do anything for the study, other than answering questions, prior to signing a consent? ►IF YES, explain in detail what you will ask them to do**.
[example: come to the first visit fasting, stop taking medications, that may be an exclusion criterion, change diet, etc. Note: As this is still part of pre-screening, the study team is not permitted to gather information that is not directly related to inclusion/exclusion criteria or other issues of suitability (e.g., is person able to come to UVA for multiple visits]

☐NO **☐X YES, Explain:**
Yes, we will ask them to wear a pair of conventional running or exercising shoes that they own to the first visit – they can either be shoes that they wear to exercise, or they can be shoes that would be comfortable to exercise in. We will also ask that they refrain from having caffeine or other similar energy-altering substances.

NOTE: Only those members of the study team with a DEA# (license to prescribe medication) are allowed to determine if a potential subject may be asked/informed to stop taking a medication which is an exclusion criterion. It is recommended that the potential subject notify their health care provider if they plan to stop a prescription drug. If a subject is asked to stop taking a drug, document the date and name of the person on the study team giving the verbal order to stop medications (again- must be a person with a DEA#).

DHHS: Study team requests the use of Verbal Consent (Waiver of Documentation of Consent) for minimal risk screening procedures.
HIPPA:

If the individual, obtaining consent, works under the HIPAA Covered Entity this is covered under Health Care Operations. If the individual obtaining consent does not work under the HIPAA covered entity, HIPAA does not apply.

5. CONSENTING PROCESS:

HIPPA: If the individual, obtaining consent, works under the HIPAA Covered Entity, consenting is covered under Health Care Operations. If the individual obtaining consent does not work under the HIPAA covered entity, HIPAA does not apply.

a. From whom will consent/assent be obtained-choose all that apply?

☒ Adults
☐ Parents of Minors
☐ Minors
☐ Adults who Lack Capacity to Provide Informed Consent
☐ Pregnant Women
☐ Non-English Speakers (MUST include either fully translated consent or short forms with submission)

b. Who will be introducing the consent, conduct the discussion and obtain consent/assent from the potential subject(s)?

The principal investigator is ultimately responsible for the conduct of the study and must ensure that informed consent from each potential research subject is:

1. Obtained by an IRB approved consent designee, and
2. Documented using the **method approved by the IRB.** Informed consent must be obtained before the subject takes part in any aspect of the research study unless the IRB has approved a waiver of the requirement to obtain consent.

Check all applicable options:

☒ Principal Investigator
☒ Qualified member(s) of the study team

c. **When will potential subjects be asked to provide consent/assent?**

Consent should not be solicited immediately before beginning an elective procedure or scheduled therapy because the subject will not have time to consider whether to participate or not. When using DocuSign for electronic consent the subject must has access to their own computer, tablet, or smart phone. For security reasons, subjects should not use public or shared devices for signing e-informed consents.

Potential subjects will be asked to provide consent on the same day that procedures commence.

►IF consent will be obtained the same day that study procedures commence, explain why the subject cannot be given more time to decide to consent and what will be done to ensure the potential subject has enough time to make an informed decision. ☐N/A

This will reduce the need to come into the lab multiple times, to make it easier for the patient. The potential subject will be able to ask as many questions as they would like, and they can take as long as they want to decide if they want to be in the study. They may choose to return another time and that will be allowed as well.

d. Where will informed consent/assent be obtained?

Check all applicable options:

☐X
IN PERSON WRITTEN Informed Consent (**on-site** wet ink signature)

☐ **IN PERSON ELECTRONIC** Informed Consent using an electronic device such as a tablet or a computer when subjects are **on-site** with study personnel present.

☐**REMOTE ELECTRONIC** Informed Consent where **subject is not in the same location as the investigator**. **If checked, completed i-vi below:**

i. Provide justification for requesting remote electronic consenting:
Answer/Response:

ii. What ELECTRONIC platform will be used by the study team and how will the signature be proven legitimate?
Answer/Response:

iii. How will the subject be provided with a copy of the signed consent document to satisfy HIPAA regulatory requirements?
*For example, can participants download a PDF of the signed consent? Will the study team download the PDF, print it, and send a paper copy to each participant? Will the study team send an emailed version to each subject? **
**In this scenario, the Data Security Plan needs to 1) include the collection of email addresses and 2) show how participants will be*

informed of such in the privacy/confidentiality section of the consent form.

Answer/Response:

iv. **How will assent and parental permissions be obtained for minors when using e-Consent? What if two-parent signatures are needed. How will this be managed by the UVA study team?** ☐N/A-no minors are enrolled
Answer/Response:

v. **How will the translation be addressed for non-English speaking subjects when using e-Consent? How will e-Consent be witnessed in this scenario?**
☐N/A-English speaking subjects only
Answer/Response:

vi. **What if a subject does not have the right technology or ability to use e-Consent. How will the UVA study team manage this scenario?**
Answer/Response: N/A

IMPORTANT INFORMATION FOR IN PERSON e-CONSENTING or REMOTE e-CONSENTING:

The study team must AGREE to comply with the following requirements: ☐ N/A

- Provide subjects with a way to access a copy of the consent document.
- Confirm the subject or LAR identity using 2 forms of identification.
- Include instructions on how to print the consent form or provide a mechanism to email a copy of the signed consent form to the subject.
- Document e-Consent using a verifiable electronic signature AND use an application that meets the required UVA Data Security standards. (Docusign, UVA RedCap) & (Qualtrics) for completion of surveys).
- Document the subject's agreement to provide electronic consent AND consent to participation in the study: (TWO separate consent fields).

e. **If recruiting minors or adults with impaired decision-making capacity, specify how parental guardian/LAR consent will be obtained prior to approaching the minor or the decisionally impaired adult subject.**
☐X N/A
Answer/Response:

f. **What protections are in place to protect the rights and welfare of subjects so that any possible coercion or undue influence is eliminated?**

Check all applicable options:

☐Consent will be obtained by the CRC rather than the Investigator
☐X Employees will be reassured that their decision will not affect their job or benefits.
☐X Students will be reassured that their decision will not affect their status as a student or their grades.
☐If minors are enrolled, parental permission will be obtained prior to explaining the study to a minor and the minor's assent will be obtained prior to initiation of study procedures.
☐X All subjects, especially those who are educationally disadvantaged will be asked open ended questions to confirm that they understand the study.
☐Other Explain:

AND CONFIRM the following:

I. Subjects will be assured that their relationship with their UVA health care provider(s) will not be affected if they decide not to participate
☐X YES
II. Subjects will be given all the time needed to make their decision and will not be pressured for a quick decision. ☐X YES
III. Subjects will be encouraged to seek advice from friends and family before signing consent.
☐X YES

g. How will the person obtaining consent/assent assess subject understanding and how will questions be answered?
Once the consent form has been read, the person obtaining consent will summarize the consent form verbally and ask the potential subject open-ended questions to make sure the subject understands what's happening in the study. For example, they may be asked to summarize what they believe will happen to them if they complete in the study. They may also be asked if they feel like there are any risks of being in the study.

h. Are there any cultural considerations (e.g., tribal or group permission requirements) or technological limitations that must be considered?
No.

Study Procedures- Biomedical Research

1. Where will the study procedures be done?
Check One:

____ UVA Health facilities (In patient or outpatient)
If checked, verify all study team members have reviewed the "Research in Patient Care Settings Guidance"
____ UVA Community Health Culpeper Hospital
____ UVA Community Health Haymarket Hospital
____ UVA Community Health Prince William Hospital
__x__ UVA but not UVA Health/: Exercise and Sport Injury Laboratory, 550 Brandon Ave., Charlottesville, VA 22903
____ Non UVA Location: List specific location Answer/Response:

2. If the study involves medical risk and study procedures will be done outside of the UVA Medical Center what is your plan to protect the subjects in case of a medical emergency?

____ *NA*

Check all applicable options:

_____ MD, RN, onsite during procedures
___x__ Individual trained in CPR on site during procedures
___x__ AED and Individual trained to use it onsite
___x__ Call 911
_____ Other: Describe Answer/Response:

3. List the procedures, in bullet form, that will be done for RESEARCH PURPOSES as stipulated in this protocol. ALL

4. Do you confirm that, except for blood draws through a peripheral site, that all invasive procedures will be performed by a licensed health care provider under the supervision of an MD? N/A

5. Will you be using data/specimens in this study that were collected previously, with the use of a research consent form, from another research study? No

6. Will any of the procedures listed in item # 3 have the potential to identify an incidental finding? No

7. Do any of the procedures listed above, under question # 3, utilize any imaging procedures for RESEARCH PURPOSES? Yes

►IF YES, check one of the following two options:

_____This imaging research examination utilizes the same imaging techniques, equipment, scanning sequences that would be used, if the subject were to

have the imaging performed for clinical care. There exists the potential for the discovery of clinically significant incidental findings.

►If checked, answer the following:

L**ist procedures:**

Ultrasound imaging will be conducted to assess the sizes of the intrinsic foot muscles (abductor hallucis, flexor hallucis brevis, and quadratus plantae & flexor digitorum brevis) and thickness of the plantar fascia (previously approved via the Protocol document but did not update in Application).

Will the images be read by a licensed radiologist and the reading placed in the subject's medical record?

No

►IF NO: The PI takes full responsibility for the identification of incidental findings:

- The PI will have all incidental findings reviewed by a radiologist who will advise the PI regarding clinical significance.
- The PI will inform the subjects verbally of all incidental findings that are of clinical significance or are of questionable significance**.**
- A follow-up letter describing the finding should be provided t**o t**he subject with instructions to either show the letter to their PC or if the subject has **no** PCP, the subject should be instructed to make an appointment at UVA or at the Free Clinic.

__x__ This imaging research examination utilizes non-standard/investigational imaging modality, techniques, equipment, scanning sequences, etc. It is impossible to determine the significance of such images, therefore abnormalities will not be shared with the subject because the meaning of the exam is not yet proven and is of unknown clinical benefit.

L**ist procedures:**

Ultrasound imaging to evaluate muscle size and plantar fascia thickness changes

8. Will your study involve measures used to screen or assess for depression and/or suicidality <u>for research purposes? No</u>

9. Will any data from this study be <u>submitted to or held for inspection by the FDA</u>?

No

Risk/ Benefit Analysis

1. What are the potential benefits for the participant as well as benefits which may accrue to society in general, as a result of this study?

The potential benefits are that the participant may have decreased foot pain, and increased intrinsic foot muscle strength and/or size, which may also improve their self-perceived and actual function. For society in general, then we may be able to potentially implement the use of minimalist footwear into rehabilitation for injured individuals with plantar fasciopathy to improve their recoveries.

2. Do the anticipated benefits justify asking subjects to undertake the risks?

The interventions will both offer a potential health benefit in terms of decreased foot pain and increased function, and answer research questions regarding which interventions are best for those with plantar fasciopathy. The primary benefit is to the individual participant, as they will immediately and directly find pain relief. They may be able to inform interventions and further research for the good of general society in the future, however. The risk to benefit ratio is justified given the various choices in the intervention process that is meant to reduce risks as much as possible.

Payment: Compensation, Reimbursement, Retention

1. Are subjects being reimbursed for travel expenses ?

INSTRUCTIONS:

- If subject will NOT submit receipts for actual expenses (e.g. hotel, food, you MUST answer this NO.
- If subjects will have mileage/distance traveled, calculated and confirmed *via Mapquest for example, this question should be answered YES
- Reimbursements must be paid with Oracle Expenditure types found under the Travel Heading.
- For instructions on how to process a reimbursement please see "Goods and Services Procurement Guide". You may also call the Procurement Help Desk at 924-4212.
- The money will not be reportable to the IRS as income.

Answer/Response: Yes

►IF YES, explain rate/ amount/ upper limits of reimbursements.

Answer/Response: Individuals will have their parking paid for in the Student Health and Wellness Building where the tests are being conducted. Parking is $1 per hour and will be fully covered.

►IF YES, Do you confirm you are aware of the following procedures to follow for reimbursements?

INSTRUCTIONS

- Subject will submit receipts for actual expenses (e.g. hotel, food)
- Reimbursements must be paid with Oracle Expenditure types found under the Travel Heading.
- For instructions on how to process a reimbursement see "Goods and Services Procurement Guide.. You may also call the Procurement Help Desk at 924-4212. The money will not be reportable to the IRS as income, but will be withheld if the subject owes money to the state.
- Reimbursements may not be done with gift cards

Answer/Response: Yes. Subjects will submit their license plate state and number to the administrative team for the Department of Kinesiology ahead of time or prior to the lab session.

2. Are subjects compensated for being in this study?

Answer/Response: Yes

▶ IF YES, answer the following questions (2a-2d).

2a. What is the maximum TOTAL compensation to be given over the duration of the protocol?

Answer/Response: $125

2b. Explain compensation to be given.

Answer/Response: The compensation to be given is for completing the protocol.

2c. Is payment pro-rated?

e.g. some compensation is given even if subjects do not complete the entire study

Answer/Response: No

If No, explain why payment cannot be pro-rated.

Answer/Response: Participants must complete the entire study, as they need to return the Fitbit in order to receive their payment. Additionally, the payment is coming from a grant, which means that there is a limited amount.

2d. Is money paid from UVA or State funds (including grant funds) or will items such as gift cards be distributed through UVA?

INSTRUCTIONS

Examples of when to say no:

- Researcher is using their own personal funds to compensate participants.
- Compensation is coming from a UVA Foundation and therefore not subject to UVA financial policies and procedures.

Examples of when to say yes:

- Sponsor, via a grant or contract, sends money to OSP/ SOM Grants and Contracts office to cover cost of compensation to be given to subjects. Subjects are then paid via Oracle system
- UVA researcher purchases gift cards for distribution to subjects and there is NO outside sponsor.
- Sponsor purchases gift cards/ debit cards and sends to UVA for study team to distribute to the subjects.

Answer/Response: Yes

►IF YES, answer the following questions [2d(i)-2d(ii)].

2d(i). How will the researcher compensate the subjects?

__x_ Check issued to participant via UVA Oracle or State system

_____ Petty cash account*

*Per UVA Policy petty cash payments are limited to a maximum of $100 per payment and $599 per calendar year per individual.

_____ Gift card/Debit Card

_____ Other type of compensation:
Specify Answer/Response:

2d(ii). Which category/ categories best describes the process of compensation?

Choose one of the following 3 options

___x__ All compensation will be made via check issued to participant via UVA Oracle or State system
The preferred method

_____ Compensation will include an alternative method (petty cash, gift card, other) and tax information will be collected, securely stored, and submitted electronically to Procurement Services as required.

►If this box is checked and an alternate method will be used, justify why you are unable to issue checks through the UVA Oracle or state system.

Guidance to answer this question.

See question: When is it justifiable to provide compensation using an alternative method of payment while still collecting tax information?

Answer/Response:

IMPORTANT: If you check this box you will be required to submit the subjects' name, Social Security number, full address and amount of payment to Procurement at the end of each calendar year. The Office of the VP for Research will send you instructions on this procedure at a later date.

If the sponsor is providing the gift card/debit card and sending to UVA study team for distribution, please include the statement "SPONSOR REQUEST" under the request for justification.

_____ Compensation will include an alternative method (petty cash, gift card, other) and tax information cannot be collected. Total possible compensation per participant for participating in the research study over one year is limited to <=$100.

_____ What is the maximum total amount an individual may receive in a calendar year for participating in this study?

_____

INSTRUCTIONS: If the subject will receive <$100/year in this study check this option and insert the following answer to both questions below. Subjects will be compensated $100 or less per year for this protocol and subjects may hesitate to enroll in the study if it requires they share their Social Security number for such a small amount of money.

►If an alternate method will be used justify why you are unable to issue checks through the UVA Oracle or state system:

Guidance to answer this question.

See question: When is it justifiable to provide compensation using an alternative method of payment while still collecting tax information?

Answer/Response:

►If you are unable to collect the tax information justify why it cannot be collected.

Answer/Response:

Guidance to answer this question.
See question: When is it justifiable to provide compensation if the tax information cannot be collected?

3. **Will subjects be provided with incentives, and/or tokens of appreciation or non-monetary gifts, such as totes, books, toys, or other such materials?**
Answer/Response: Yes

If yes, submit a description and/or picture and approximate retail value of each item:
Answer/Response: The individuals in the intervention group will be able to keep their shoes after the protocol has ended. If they do not complete the protocol, they must return the shoes. Individuals will also be able to keep massage balls given for the rehabilitation protocol if they complete the protocol.

The IRB-HSR will review the items to verify if the use of these items appears to be exert undue influence. The convened board may be asked to review the retention incentives to make this determination. Full Board review will always be requested for any item valued over $25.00 for items given to children and over $50.00 for items given to adults. If the board deems any item is inappropriate for use at UVA, the study team will be notified in writing of the board's determination.

Device Information: (Device being evaluated)

1. **List name of device being evaluated**.
Xero Shoes HFS – Lightweight Road Running Shoe

2. **Describe pertinent animal data that is available regarding the safety of this device**.
N/A

3. **Describe pertinent human data that is available regarding the safety of this device**. There are a few studies that have utilized this brand of shoes. Neither of them reported any adverse events. These are the articles: **https://doi.org/10.1111/sms.13089**, https://doi.org/10.1152/japplphysiol.00128.2015. Neither of the two previous studies utilizing this device for individuals with plantar fasciopathy reported any adverse events. One study indicated that wearing minimalist shoes can lead to increased bone marrow edema, but that may also be considered an adaptation to increased impact on the bone, so it could also be a positive adaptation. These events are mitigated by a slow, gradual transition into minimalist shoes, as well as implementing a foot strength rehabilitation routine, both of which are occurring in this present study.

4. **Have there been any human deaths associated with this device?**
   No

5. **In how many humans has this device been used previously?**
   Unknown. This is a very widely-used brand of minimalist shoes.

6. **If this protocol will be used in children describe any previous use of this device with children of a similar age range**.
   N/A

7. **Is this device implanted?**
   No

8. **Is this a post-marketing study?**
   No

9. **Does this device have an IDE# from the FDA?**
   No

   ►IF NO, check the applicable items in the table below:

IDE Exemption Criteria

x	A legally marketed device when used in accordance with its labeling
	A diagnostic device if it complies with the labeling requirements in §809.10(c) and if the testing: • is noninvasive; • does not require an invasive sampling procedure that presents significant risk; • does not by design or intention introduce energy into a subject; and

	• is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure; *Additional guidance for an in vitro diagnostic device studies may be found on the FDA website.*
	Consumer preference testing, testing of a modification, or testing of a combination of devices if the device(s) are legally marketed device(s) [that is, the devices have an approved PMA, cleared Premarket Notification 510(k), or are exempt from 510(k)] AND if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk;
	A device intended solely for veterinary use;
	A device shipped solely for research with laboratory animals and contains the labeling "CAUTION – Device for investigational use in laboratory animals or other tests that do not involve human subjects."
	A custom device : According to 21CFR812.2(c) (7) a custom device as defined in 812.3(b) is exempt unless the device is being used to determine safety or effectiveness for commercial distribution. A custom device means a device that: (1) Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist; (2) Is not generally available to, or generally used by, other physicians or dentists; (3) Is not generally available in finished form for purchase or for dispensing upon prescription; (4) Is not offered for commercial distribution through labeling or advertising; and (5) Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.
	NA- None of the items above apply- device determined to NOT be exempt from IDE regulations. *If applicable will submit any documentation from the sponsor regarding device risk determination (e.g. significant risk vs. non-significant risk)*

Data and Safety Monitoring Plan

This study has been deemed minimal risk. Because this study poses minimal risk to the subject, **adverse events will only be collected or recorded if a causal relationship to the study intervention is suspected.** If any adverse event is considered serious and unexpected, the event must be reported to the IRB-HSR within 7 days from the time the study team receives knowledge of the event.

1. Definitions

1.1 How will you define adverse events (AE)?

Do not change this answer

An adverse event will be considered any undesirable sign, symptom or medical condition considered **related to the intervention**. Medical condition/diseases present before starting the intervention will be considered adverse events only if they worsen after starting the study and that worsening is considered to be related to the study intervention. An adverse event is also any undesirable and unintended effect of research occurring in human subjects as a result of the collection of identifiable private information under the research.

1.2 How will you define an unanticipated problem?

Do not change this answer

An unanticipated problem is any issue that involves increased risk(s) to participants or others. This means issues or problems that cause the subject or others to be placed at greater risk than previously identified, even if the subject or others do not incur actual harm. For example if a subject's confidentiality is compromised resulting in serious negative social, legal or economic ramifications, an unanticipated problem would need to be reported. (e.g. serious loss of social status, loss of job, interpersonal conflict.)

1.3 What are the definitions of a protocol deviation and/or noncompliance?

Do not change this answer

A protocol deviation is defined as any change, deviation, or departure from the study design or procedures of research project that is NOT approved by the IRB-HSR prior to its initiation or implementation**.** Protocol deviations may be major or minor.

Noncompliance can be a protocol deviation OR deviation from standard operating procedures, Good Clinical Practices (GCPs), federal, state or local regulations**.** Noncompliance may be minor or sporadic, or it may be serious or continuing.

Additional Information: see the IRB-HSR website at
Protocol Deviations, Non-compliance and Protocol Exceptions

2. What risks are expected due to the intervention in this protocol?

Expected Risks related to study participation	Pick One
There is a small risk that breaches of privacy and/or confidentiality might occur. The risk of violation of subject privacy and confidentiality is minimal due to the requirements of the privacy plan in this protocol.	Occurs rarely
There is a risk of foot cramping during exercises	Occurs infrequently
There is a risk of foot or calf soreness from wearing minimalist shoes	Occurs infrequently
There is a risk of bone stress fracture from wearing minimalist shoes	Occurs rarely
There is a risk of feeling upset or discomfort from answering questions.	Occurs infrequently

3. When will recording and reporting of unanticipated problems/adverse events begin?

__X___After subject signs consent

_____After subject begins study intervention

_____Other Specify Answer/Response:

4. When will the recording/reporting of unanticipated problems/adverse events end?

_____Subject completes participation in the protocol

_____End of intervention

_____30 days post intervention

__X___Subject completes intervention and follow up period of protocol

_____Other: Specify Answer/Response:

5. What is your plan for safety monitoring?

Do not change this answer

Safety monitoring and aggregate review of adverse events, unanticipated problems, protocol violations and any data breach will be performed by the PI and IRB-HSR through continuation review at least annually.

6. What is your plan for reporting a Unanticipated Problem, Protocol Deviations or Data Breach?

Type of Event	**To whom will it be reported:**	*Time Frame for Reporting*	*How reported?*
Unanticipated Problems that are not adverse events or protocol deviations This might include a Data Breach.	IRB-HSR	Within 7 calendar days from the time the study team received knowledge of the event.	Unanticipated Problem report form. Unanticipated Problem Report Form
Protocol Deviations/Noncompliance (*The IRB-HSR only requires that MAJOR deviations be reported, unless otherwise required by your sponsor, if applicable.)* **OR** **Protocol Exceptions**	IRB-HSR	Within 7 calendar days from the time the study team received knowledge of the event.	Protocol Deviation, Noncompliance and Protocol Exception Reporting Form Protocol Deviation Protocol Exception Reporting Form
Data Breach* of Protected Health Information	The UVA Corporate Compliance and Privacy Office ITC: if breach involves electronic data Police if breach includes items that are stolen: Stolen on UVA Grounds	As soon as possible and no later than 24 hours from the time the incident is identified. As soon as possible and no later than 24 hours from the time the incident is identified. IMMEDIATELY.	UVA Corporate Compliance and Privacy Office- Phone 924-2938 **ITC:** Information Security Incident Reporting procedure, https://security.virginia.edu/report-information-security-incident

	OR Stolen off UVA Grounds- contact police department of jurisdiction of last known location of PHI		Police: phone- (434) 924-7166

*A data breach is defined in the HITECH Act (43 USC 17932) as an unauthorized acquisition, access, or use of protected health information (PHI) that compromises the security or privacy of such information.

Additional Information may be found on the IRB-HSR Website: Data Breach

Privacy Plan

The following procedures must be followed.

- The data will be secured per the Data Security Plan of this protocol.
- Only investigators for this study and clinicians caring for the patient will have access to data.
- UVA University Data Protection Standards will be followed.
- If identifiable data is transferred to any other location such as a desktop, laptop, memory stick, CD etc. the researcher must follow the University's Highly Sensitive Data Protection Standard for Individual-Use Electronic Devices or Media Additional requirements may be found in the University's Security of Network-Connected Devices Standard. If identifiable data is taken away from the UVA Health , Medical Center Policy # 0218 will be followed.
- Data will be securely removed from the server/drive, additional computer(s), and electronic media according to the University's Electronic Data Removal Standard.
- Data will be encrypted or removed if the electronic device is sent outside of UVA for repair according to the University's Electronic Data Removal Standard .
- If PHI will be faxed, researchers will follow the UVA Health Policy # 0194.
- If PHI will be emailed, researchers will follow the UVA Health Policy # 0193 and University Data Protection Standards (UDPS 3.0).
- Data may not be analyzed for any other study without additional IRB approval.
- If you are using patient information you must follow UVA Health Policy # 0021.
- Both data on paper and stored electronically will follow the University's Record Management policy and the Commonwealth statute regarding the Destruction of Public Records.

If you have a question or concerns about the required security standards contact InfoSec at it-security@virginia.edu

Summary of Requirements to Comply with UVA Health, Medical Center and University Policies and Guidance as noted above:

Highly Sensitive Data is:
-personal information that can lead to identity theft if exposed or
-data that reveals an individual's health condition and/or history of health services use.
Protected Health Information (PHI) a type of Highly Sensitive Data, is health information combined with certain HIPAA identifiers making the health information identifiable per HIPAA regulations
Sensitive Data is -any additional research data that is not publicly available
Identifiable Data under HIPAA regulations is considered to be *Highly Sensitive Data at UVA.*
A **Limited Data Set** (LDS) under HIPAA regulations is considered to be *Sensitive Data* at UVA. The only HIPAA identifiers associated with data: dates and or postal address information limited to town or city, state, and zip code.

Highly Sensitive Data (Identifiable Health Info per HIPAA)	**Sensitive Data (Limited Data Set and De-identified data per HIPAA)**
General Issues	*General Issues*
Discussions in private Do not share with those not on the study team or those who do not have a need to know.	Do not share with those not on the study team or those who do not have a need to know.
Password protect	Password protect
Physically secure (lock) hard copies at all times if not directly supervised. If not supervised hard copies must have double protection (e.g. lock on room OR cabinet AND in building requiring swipe card for entrance).	Physically secure (lock) hard copies at all times if not directly supervised.
For electronic documents turn off File Sharing; turn on firewalls; use up to date antivirus and antispyware; delete data securely.	For electronic documents turn off File Sharing; turn on firewalls; use up to date antivirus and antispyware; delete data securely.
Encrypt See Encryption Solutions Guidance *Files on UVA Health Network drives are automatically encrypted. If not stored there it is study teams responsibility to make sure data are encrypted.*	
If device sent out for service or repair, encrypt or remove data AND contract for repair using a UVA Purchase order.	If device sent out for service or repair, encrypt or remove data AND contract for repair using a UVA Purchase order.
Store files on a network drive specifically designated for storing this type of data, e.g. high-level security server/drives managed by Information Technology Services or the "F" and "O" managed by UVA Heath Computing Services. You may access it via a shortcut icon on your desktop, but you are not allowed to take it off line to a local drive such as the desktop of your computer (e.g. C drive) or to an individual Use Device*. May access via VPN	
Do not share with sponsor or other outside group before consent is obtained	Do not share with sponsor or other outside group before consent is obtained or the IRB has granted

or the IRB has granted appropriate approvals and contract is in place.	appropriate approvals and contract is in place.
If collected without consent/ HIPAA authorization will NOT be allowed to leave UVA HIPAA covered entity** unless disclosure is approved by the IRB and the disclosure is tracked in EPIC	If collected without consent/ HIPAA authorization will NOT be allowed to leave UVA HIPAA covered entity** unless disclosure is approved by the IRB and a contract is in place prior to sharing of data.

Highly Sensitive Data (Identifiable Health Info per HIPAA)	**Sensitive Data (Limited Data Set and De-identified data per HIPAA)**
Electronic Data Collection & Sharing	*Electronic Data Collection & Sharing*
(e.g. smart phone app, electronic consent using tablet) MUST consult with InfoSec or UVA Health Web Development Office: 434-243-6702 ▪ University Side: IT-Security@virginia.edu ▪ UVA Health: Web Development Center.	
May use: • Globus • Drop Box- UVA Health IT • Qualtrics Portal for HSD • Any additional programs identified by Information Security at ITS Web in the Software Gateway. UVA Health employees can also review Online Account Request to find additional options. May NOT use: • UVA Box • UVA Collab • Question Pro • non-UVA licensed cloud providers, such as Dropbox, Google Drive, SkyDrive, Survey Monkey, etc.	May use: • Globus • Drop Box- UVA Health IT • Qualtrics portal for MSD • UVA Box • UVA Collab • Any additional programs identified by Information Security at ITS Web in the Software Gateway. UVA Health employees can also review Online Account Request to find additional options. May NOT use • non-UVA licensed cloud providers, such as Dropbox, Google Drive, SkyDrive, Survey Monkey, etc.
The following vendors for handling communication with subjects are NOT allowed: • Google Voice • Facebook (including Messenger) • Linked In • Snapchat	The following vendors for handling communication with subjects are NOT allowed: • Google Voice • Facebook (including Messenger) • Linked In • Snapchat
Individual-Use Device	*Individual-Use Device*

Do not save to individual-use device* without annual written approval of your Department AND VP or Dean. If approval obtained, data must be password protected and encrypted.	
Do not save an email attachment containing HSD to an individual use device*. (e.g. smart phone)	

E Mail	*E Mail*
Do not share via email with Outlook Web/ or forward email using other email vendors like Gmail/ Yahoo	
Do not send via email on smart phone unless phone is set up by UVA Health	
Email may include name, medical record number or Social Security number only if sending email to or from a person with * HS in their email address. *NOTE: VPR & IRB staff do not meet this criteria!*	In addition to sharing LDS, may include initials if persons sending and receiving email works within the UVA HIPAA covered entity.**
FAX	*FAX*
Verify FAX number before faxing	Verify FAX number before faxing
Use Fax Cover Sheet with Confidentiality Statement	Use Fax Cover Sheet with Confidentiality Statement
Verify receiving fax machine is in a restricted access area	Verify receiving fax machine is in a restricted access area
Verify intended recipient is clearly indicated	Verify intended recipient is clearly indicated
Recipient is alerted to the pending transmission and is available to pick it up immediately	Recipient is alerted to the pending transmission and is available to pick it up immediately
TEXT	*TEXT*
Not acceptable.	Only acceptable if using a University contracted phone or with approval from Information Security.
LOST OR STOLEN RESEARCH DATA	LOST OR STOLEN RESEARCH DATA
Must report in accordance with the protocol and in accordance with the Reporting an Information Security Incident Procedure Any data breach must also be reported to the IRB of Record if the report meets the criteria of an Unanticipated Problem.	Must report in accordance with the protocol and in accordance with the Reporting an Information Security Incident Procedure Any data breach must also be reported to the IRB of Record if the report meets the criteria of an Unanticipated Problem.

** Individual Use Device – examples include smart phone, CD, flash (thumb) drive, laptop, C drive of your computer,*

*** At UVA this includes the following areas:, the UVA Health including the School of Medicine & the School of Nursing, the Sheila C. Johnson Center, the Exercise and Sports Injury Laboratory and the Exercise Physiology Laboratory.*

Identifiable health info may also be shared with the following areas without tracking the disclosure as agreements are in place to protect the information:

- *VP Office of Research*
- *Nutrition Services (Morrison's)*
- *UVA Center for Survey Research*

Legal/Regulatory/Ethical Considerations

Recruitment

The following procedures will be followed:

- Finders fees will not be paid to an individual as they are not allowed by UVA Policy.
- All recruitment materials will be approved by the IRB-HSR prior to use. They will be submitted to the IRB after the IRB-HSR has assigned an IRB-HSR # to the protocol.
- Only those individuals listed as personnel on this protocol will recruit and or conduct the consenting process with potential subjects.

Retention Incentives

Any item used by the sponsor/ study team to provide incentive to a subject to remain in the study, other than compensation identified in the Payment section, will be submitted to the IRB for review prior to use. The IRB-HSR will provide the study team with a Receipt Acknowledgement for their records. Retention incentive items are such things as water bottles, small tote bags, birthday cards etc. Cash and gift cards are not allowed as retention incentives.

Clinical Privileges

The following procedures will be followed:

- Investigators who are members of the clinical staff at the University of Virginia Medical Center must have the appropriate credentials and been granted clinical privileges to perform specific clinical procedures whether those procedures are experimental or standard.
- The IRB cannot grant clinical privileges.
- Performing procedures which are outside the scope of the clinical privileges that have been granted may result in denial of insurance coverage should claims of negligence or malpractice arise.
- Personnel on this protocol will have the appropriate credentials and clinical privileges in place before performing any procedures required by this protocol.
- Contact the Clinical Staff Office- 924-9055 or 924-8778 for further information.

Sharing of Data/Specimens

Data and specimens collected under an IRB approved protocol are the property of the University of Virginia. You must have "permission" to share data/ specimens outside of

UVA other than for a grant application and or publication. This "permission" may come in the form of a contract with the sponsor or a transfer agreement with others. An agreement/ contract is needed to share the
data outside of UVA even if the data includes no HIPAA identifiers and no code that could link the data back to a HIPAA identifier.

- No data will be shared outside of UVA, beyond using data for a grant application and or publication, without a signed agreement /contract approved by the SOM Grants and Contracts office/ OSP or written confirmation that one is not needed.
- No specimens will be shared outside of UVA without a signed agreement/contract approved by the SOM Grants and Contracts office/ OSP or written confirmation that one is not needed.

Prisoners

If the original protocol/ IRB application stated that no prisoners would be enrolled in this study and subsequently a subject becomes a prisoner, the study team must notify the IRB immediately. The study team and IRB will need to determine if the subject will remain in the study. If the subject will remain in the study, the protocol will have to be re-reviewed with the input of a prisoner advocate. The prisoner advocate will also have to be involved in the review of future continuations, modifications or any other reporting such as protocol violations or adverse events.

Prisoner- Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.
For additional information see the OHRP website at
http://www.hhs.gov/ohrp/policy/populations/index.html

Compensation in Case of Injury

If a subject requests compensation for an injury, the study team should notify the IRB-HSR (924-9634/924-2620) the UVA Health Patient Relations Department (924-8315). As a proactive courtesy, the study team may also notify UVA Health Patient Safety and Risk Management (924-5595).

On request, the study team should provide the UVA Risk Management Office with the following information/documents:

- Subject Name and Medical Record Number
- Research medical records
- Research consent form
- Adverse event report to IRB
- Any letter from IRB to OHRP

Subject Complaints

During a research study, the study team may receive complaints from a subject. If the study team is uncertain how to respond to a complaint, or is unable to resolve it with the subject, the study team may contact the IRB-HSR (924-9634/924-2620), the UVA Health Patient Relations Department (924-8315).

Request for Research Records from Search Warrant or Subpoena

If the study team receives a request for research records from a search warrant or subpoena, they should notify UVA Health Information Services at 924-5136. It is important to notify them if information from the study is protected by a Certificate of Confidentiality.

Informed Consent

Unless waived by the IRB, subjects will be fully informed of the:

- purpose of the study,
- reasonably anticipated benefits,
- potential risks or discomfort participation in the study may entail,
- and any alternative treatments.

They will also be informed that their

- consent is voluntary and that they may withdraw their consent to participate at any time, and
- (if applicable) choosing not to participate will not affect the care the subject will receive for the treatment of his or her disease.

The consent documents used to obtain informed consent of the subject must be approved by the IRB prior to use. Any written materials (consent/ short form) will be provided to the potential subject in a language they can read understand. The subjects will be given sufficient time to read the consent form and have the opportunity to ask questions.. Only subjects who are fully able to understand the risks, benefits, and potential adverse events of the study, and provide their consent voluntarily will be enrolled. After this explanation and before entry into the study, consent should be appropriately recorded. Subjects will be given a copy of the signed consent/ short form.

Institutional Review Board (IRB)

No subjects will be recruited or entered under the protocol until the Investigator has received the signed IRB-HSR Approval form stating the protocol is open to enrollment. Any modifications of the protocol or consent form will not be initiated without prior written approval from the IRB-HSR, except when necessary to eliminate immediate hazards to the subjects.

Investigator Responsibilities

The investigator is responsible for ensuring that the study is performed in accordance with the protocol and applicable local, state and federal regulatory requirements including ICH guidelines on Good Clinical Practice (GCP-E-6).

Studies with a Certificate of Confidentiality

If a study has a Certificate of Confidentiality (automatic for any study funded in whole or in part by the federal government that collects *identifiable sensitive information**) researchers:

- May not disclose or provide, in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- May not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.
- May disclose information only when:
    - Required by federal, state, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to state and local health departments), excluding instances of disclosure in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding.
    - Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual.
    - Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
    - Made for the purposes of other scientific research that is in compliance with applicable federal regulations governing the protection of human subjects in research.

* The term "*identifiable, sensitive information*" means information about an individual that is gathered or used during the course of biomedical, behavioral, clinical, or other research, where the following may occur:

- An individual is identified; or
- For which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

PROTOCOL

Background

27. Provide the scientific background, rationale and relevance of this project.

Plantar fasciopathy (PF) is a common injury that can lead to foot pain [1], decreased quality of life (QoL) [2], and reduced energy and activity levels [3]. PF is usually characterized by pain upon palpation at the medial calcaneal tubercle, especially after long periods of rest or after waking up in the morning [1,3]. PF affects up to 10% of sedentary adults [3,4], 25% of active individuals [4], and military servicemembers [5]. Roughly 1 million adults per year in the United States seek care from physicians for PF, with total costs of more than $300 million [6]. Though symptoms have been known to resolve within 10 months on their own [1], pain can also persist for years [7] with individuals at a nearly 50% risk of still having PF 10 years after onset [8]. Recurrence is common and can lead to further long-term health problems such as cardiovascular disease that stems from reduced mobility due to PF [3].

The plantar fascia supports the medial longitudinal arch (MLA) [1] via the windlass mechanism, where passive dorsiflexion of the toes tenses the plantar fascia and raises the MLA, which improves MLA stiffness and foot stability [9]. PF is thought to occur due to mechanical overload of the plantar fascia [1] from increased weight [10] or activity. Individuals with PF demonstrate weaker toe flexion strength [11] compared to healthy controls, as well as decreased total IFM volume [12], and significantly decreased flexor hallucis brevis (FHB) cross-sectional area (CSA) [13]. Though insignificant, slight decreases were observed in flexor digitorum brevis (FDB) CSA, and abductor hallucis (ABH) thicknesses [13]. Individuals with PF also display altered gait biomechanics compared to healthy controls, such as decreased vertical ground reaction force (vGRF) at propulsion while walking [9,14,15], likely a compensation due to pain [14]. The impairments in physical activity also have psychosocial implications, as depression, anxiety, stress, catastrophization (negative mindset towards current or anticipated pain), and kinesiophobia (fear of movement) are associated with pain and function limitations in individuals with PF [7].

It is suggested that intrinsic foot muscles (IFM) may reduce the load placed upon the plantar fascia [16], as IFM also contribute to MLA height [9]. Healthy individuals who perform IFM training demonstrate improved IFM strength and balance [17], and those who wear minimalist shoes (MS) for an extended period of time are shown to increase IFM strength and size [18]. MS allow for barefoot-like movement [19], where the footwear "provides minimal interference with the natural movement of the foot" [20]. They are highly flexible; have low heel-toe drop, weight and stack height; and no motion control and stability devices [20]. It is likely that the reduced arch support and increased flexibility of the shoe [21] leads to muscular adaptations. Importantly, walking in MS has also shown comparable IFM strength increases to an IFM strengthening routine in healthy individuals [22]. Using MS to improve IFM function may be useful as there is a high motor learning burden in both learning and performing IFM strengthening exercises [23].

Limited research has examined the implementation of IFM strengthening or minimalist shoes in individuals with PF [10,24]. To date, only one study has implemented

IFM strengthening in individuals with PF [25], and only one study has evaluated the use of minimalist shoes in these individuals [26], both of which led to reduced pain and increased function evaluated through patient-reported outcomes (PROs).

Objectives/Hypothesis

The goal of this proposal is to compare the efficacy of only performing a current standard-of-care rehabilitation program to supplementing a rehabilitation program with the use of minimalist shoes (MS) in daily activities in individuals with plantar fasciopathy (PF). We are primarily interested in observing if wearing MS can lead to changes in pain levels and self-perceived function. We would also like to establish if individuals with PF are able to achieve IFM strength or size increases by walking in MS. Lastly, we aim to investigate if the combination of changes in pain and IFM function can lead to alterations in walking gait as indicated by changes in vGRF.

We hypothesize that individuals who undergo rehabilitation and wear minimalist shoes (**F**oot **R**ehabilitation **A**nd **M**inimalist Sho**ES**, [FRAMES]) will improve pain and function levels, increase IFM strength and size, and normalize gait mechanics to a greater degree in individuals with PF, compared to those who only perform a control rehabilitation program (CON).

Study Design: Biomedical

1. Will controls be used?

No

7. What is the study design?

Randomized control-study, single-blind (assessor is blinded to group assignments).

8. Does the study involve a placebo?

No

Human Participants

Ages: __18-55 years old__

Sex: __Males and females__

Race: __All__

Subjects- see below

1. Provide target # of subjects (at all sites) needed to complete protocol.

38

2. Describe expected rate of screen failure/ dropouts/withdrawals from all sites.

10% expected dropout

3. How many subjects will be enrolled at all sites?

38

4. How many subjects will sign a consent form under this UVA protocol?

38

Inclusion/Exclusion Criteria

1. List the criteria for inclusion

- Ages 18-55
- First-step pain in the morning over the past week at a minimum Visual Analog Scale score of 30mm
- Heel pain or pain on the bottom of the foot for at least a month with insidious onset
- Willingness and ability to comply with scheduled visits and study procedures.

2. List the criteria for exclusion

- Other current lower extremity neuromusculoskeletal injuries
- Other lower extremity neuromusculoskeletal injuries other than to the foot in the last 3 months
- Previous history of foot and ankle fractures or surgeries
- Corticosteroid injection within the last 6 months
- Current participation in a formal rehabilitation program for plantar fasciopathy
- Previous experience wearing minimalist shoes
- Subjects with known pregnancy

3. List any restrictions on use of other drugs or treatments.

None

Statistical Considerations

- **Is stratification/randomization involved?**

  Randomization will be used, stratification will be used to ensure that there is equal distribution of randomization within sex (male, female).

  Participants will be block randomized into their treatment group after the informed consent process, by sets of 10 subjects to ensure balance in the groups over time. The randomization scheme will be conducted on REDCap's Randomization feature.
  The randomization will be blinded to the assessor who is conducting data collection sessions on the participants.
  A secondary study coordinator on this study will conduct the randomization process and they will be the only person with access to the randomization scheme.

►**IF YES, who will generate the randomization scheme?**

_____ Sponsor
_____ UVA Statistician. Insert name Answer/Response:
_____ UVA Investigational Drug Service (IDS)
___x__ Other*:* A secondary study coordinator on this study

2. What are the statistical considerations for the protocol?

Study design: A randomized controlled trial will be used. 38 participants total with plantar fasciopathy will be recruited and randomized into one of 2 groups. They will either receive an intervention of just rehabilitation exercises, or they will receive the rehabilitation exercises and wear minimalist shoes in their daily lives. The purpose of the study will be to assess if wearing minimalist shoes and performing rehabilitation exercises can decrease pain and improve function of individuals with plantar fasciopathy to a greater degree than those who only perform the rehabilitation exercises.

Endpoints: For the baseline data collection session, we will obtain participant demographics, self-reported pain-level, patient-reported outcomes, intrinsic foot muscle (IFM) size, IFM strength, and walking gait kinetics (vertical ground reaction forces and loading rate). At the 4-week point, pain levels and patient-reported outcomes will be reported. The final 8-week data collection session will collect the same data as the baseline session.

Aim 1: To determine the effect of the FRAMES intervention on pain and patient-reported function compared to CON among individuals with PF.
Hypothesis: Individuals with PF in the FRAMES intervention will reduce their pain and improve self-reported function to a greater degree than individuals in CON.
Strategy: We will test this hypothesis using PROs, including a Visual Analog Scale to score pain levels, the Foot and Ankle Ability Measure to assess functional limitations, and Global Rating of Change Score to evaluate the meaningfulness of changes in pain and function.

Aim 2: To determine the effect of the FRAMES intervention on IFM strength and size compared to CON among individuals with PF.
Hypothesis: Individuals with PF in the FRAMES intervention will increase their IFM strength and size to a greater degree than individuals in CON.
Strategy: We will test this hypothesis by measuring IFM strength with a handheld dynamometer and IFM size with diagnostic ultrasound.

Aim 3: To determine the effect of the FRAMES intervention on balance and vGRF while walking compared to CON among individuals with PF.
Hypothesis: Individuals with PF in the FRAMES intervention will increase vGRF in their painful foot while walking, potentially indicating more willingness to weight bear, compared to individuals in CON.

Strategy: We will test this hypothesis using a force plate, insole pressure sensors, and an instrumented treadmill during a walking task.

Aim 4: To determine which baseline characteristics allow an individual with plantar fasciopathy to succeed after an intervention of minimalist shoes and rehabilitation
Hypothesis: Individuals with higher levels of self-efficacy, lower levels of kinesiophobia and fear-avoidance, and stronger intrinsic foot muscles will be the most successful.
Strategy: We will test this hypothesis by completing confirmatory factor analyses and path diagrams (regression models) to discover which factors are most important in obtaining recovery.

Sample size estimate/power: For all analyses we will assume a statistical power of 0.80 and an a priori alpha level of 0.05.

3. Provide a justification for the sample size used in this protocol.
The a priori sample size of 38 total participants provides 80% power, α=0.05, moderate Cohen's d effect size (ES) of 0.5, and 10% dropout according to G*Power's "ANOVA: Repeated measures, within-between interaction" test (30). Pain on the FHSQ was the primary outcome measure for this analysis, given the previous study investigating the effects of MS for 6 months on individuals with plantar fasciopathy found ES = 0.81 (11). However, our protocol is only 8 weeks and we are expecting a more conservative effect size to achieve adequate power.

4. What is your plan for primary variable analysis?
Aim 1: For the dependent variables (pain levels, function, and global rating of change), mean, SD, and change scores between the 3 sessions will be obtained (1 to 2, 2 to 3, and 1 to 3). One-way ANOVAs will be conducted to compare the 2 groups at baseline, mid-intervention, and post-intervention. Then, a two-way repeated measures ANCOVA will compare the magnitude of improvement between the 2 treatment groups. Covariates will include length of time with pain, age, and sex. Cohen's d effect sizes and 95% confidence intervals will also be calculated to estimate the magnitude and precision of group differences.
Aim 2 + 3: For the dependent variables (IFM size and strength, walking kinetics), mean, SD, and change scores between the 2 sessions will be obtained. One-way ANOVAs will be conducted to compare the 2 groups at baseline and post-intervention. Then, a two-way repeated measures ANCOVA will compare the magnitude of improvement between the 2 treatment groups. Cohen's d effect sizes and 95% confidence intervals will also be calculated to estimate the magnitude and precision of group differences.
Aim 4: For this aim, path analysis will be conducted to determine which baseline characteristics lead to the greatest chances of recovery, and models will be tested against each other to determine the most important characteristics. Additionally, a correlation matrix will be run among these variables to determine how they affect each other. Lastly, a confirmatory factor analysis will be used to evaluate the components of patient-reported outcomes that are the most important.

5. What is your plan for secondary variable analysis?
Secondary analyses include preparing a correlation matrix to understand how IFM strength, size, and gait kinetics are related to self-reported measures of recovery. Then, regression models will be explored to understand what contributes the most to self-reported pain and function improvements.

6. Have you been working with a statistician in designing this protocol?
Yes

7. Will data from multiple sites be combined during analysis?
No

Study Procedures-Biomedical Research

1. What will be done in this protocol?

Subjects will follow these procedures:

1. Initial screening survey via QR code
2. Screening double-check over the phone, and first appointment set up
3. Obtain informed consent for all participants
4. Obtain participant demographics
5. Obtain patient-reported outcomes
6. Measure foot morphology and observe foot posture index
7. Measure IFM size
8. Measure IFM strength
9. Assess balance
10. Obtain kinetics of walking

Screening:

- Potential participants will submit a survey of interest form that also indicates their eligbility/exclusion critera.
- After the investigator receives the information, the participant will be called and the screening questions will be reviewed to ensure the participant qualifies.
- If they qualify, the investigator will schedule their baseline session with the participant.
- If the participant is not eligible, they will not proceed to the next step.
- When participants are sent a confirmation email with their baseline assessment, they will also be provided instructions to:
    - Wear closed-toed shoes that they would use for walking or fitness

- Refrain from using caffeine or other mind- and energy-altering substances that day

Consent:

- Participants will report to the Exercise and Sport Injury Lab (EASIL) for their first appointment, where they will fill out the electronic consent form if they agree to testing.

Participants will then complete the following:

Confirmation of plantar fasciopathy: We will confirm that they have pain by pressing on the heel and asking how it feels. Participants will also sit on a treatment table, and the bottom of their heel will be scanned by an ultrasound probe in order to capture the thickness of their plantar fascia. This will be compared to normative data to add to the diagnosis.

Participant Demographics:
Subjects will have their height and weight assessed, and will indicate what their shoe size is for normal athletic shoes

Patient-Reported Outcomes:
Participants will be given a series of subjective questionnaires to evaluate the function of their affected foot and their current physical activity. The following will be evaluated:

- Health History Questionnaire:
  - They will be asked to provide their age, sex, their dominant foot (which foot they would kick a soccer ball with), their painful foot (or the foot that has worse pain), the length of time of pain, and occupation.
  - Participants will be asked to list any previous lower extremity surgeries or fractures, or lower leg or foot injuries.
  - Participants will be asked if they have seen a physician for their foot pain, and if they have ever received previous physical therapy for their injury, or what other treatments they have used in the past.
  - Goals:
    - Participants will be asked to write down their goals for wanting to participate in the rehabilitation program in the study.
    - At the end of the intervention, participants will be asked how much progress they think they made towards their initial goal.
- Pain levels: Participants will indicate their pain levels from 0-100 on a line, from “no pain” to “worst pain imaginable”, for the following items.
  - Average pain over the past week
  - First-step pain over the past week (the pain that you feel upon waking up in the morning and taking a first step)
  - Average heel pain of the day

- Global Rating of Change (GROC): Perception of recovery
    - Participants will indicate their perception of overall recovery from the time they began having pain until now, from “a very great deal worse” to “a very great deal better”.
- Foot and Ankle Ability Measure (FAAM): Foot function
    - Participants will indicate how difficult a list of things are to do on a scale from 0 – 4, from “no difficulty at all” to “unable to do”.
- Tampa Scale of Kinesiophobia (TSK-11):
    - Participants will indicate how much fear they have about movement, on a scale from 1 – 4, from “strongly disagree” to “strongly agree”.
- Fear Avoidance Belief Questionnaire (FABQ):
    - Participants will indicate how much certain physical activities, such as bending, lifting, or driving, affect or would affect their pain, on a scale from 0 – 7, from “completely agree” to “completely disagree”.
- Pain Self-Efficacy Questionnaire (PSEQ)
    - Participants will indicate their levels of self-efficacy or confidence even with pain, on a scale from 0 – 6, from “not at all confident” to “completely confident”
- NASA Activity Survey (NAS):
    - Participants will select a response that best describes their activity level in the last month, from not exercising regularly to heavy physical exercise such as running or vigorous aerobic exercise.

<u>Foot characteristics:</u>

- Participants will have their foot length, width, and arch height assessed using the Arch Height Index tool.
- Participants will have their foot girth measured with a soft measuring tape.
- Participants will also tell us their shoe size in most athletic shoes.
- Participants will also have their foot posture assessed via the Foot Posture Index (FPI)

<u>Intrinsic Foot Muscle Size:</u>

- Participants will stand on a stair constructed for ultrasound data collection, with their shoe and sock off. The stair has a slot cut out of the bottom in order to place the ultrasound probe on the bottom of the foot in a weight-bearing position.
- The muscles on the bottom of their foot will be examined using diagnostic ultrasound, which is an imaging technique that uses sound waves to examine structures.
- The following muscles will be assessed:
    - 1. Abductor Hallucis
    - 2. Flexor hallucis brevis
    - 3. Flexor digitorum brevis and quadratus plantae (these are done at the same time with one scan)

- Participants will have 3 measurements obtained while standing with no muscle contraction for muscle thickness, and one measurement for cross-sectional area. The same will occur while their foot muscles are activated, as the investigator will provide resistance or participants will push down against the platform with the toes where applicable.

Intrinsic Foot Muscle Strength:

- Participants will complete 2 separate intrinsic foot muscle strength assessments
- For the first test, participants will lay on their back on a treatment table with their shoe and sock off, with the foot hanging off the edge of the table and the knee placed at 90 degrees.
    - Participants will have a sensor placed under their toes, and will be asked to push against the sensor as hard as they can for 5 seconds, with resistance provided from the investigator.
    - Participants will perform 3 trials for the great toe, and then 3 separate trials for the lesser toes.
- For the second test, participants will lay on their back on a low-pile carpet with their shoe and sock off, with the knee placed at 90 degrees.
    - Participants will have a card attached to a hanging scale placed under their toes, and will be asked to push down on the card as hard as they can
    - The investigator will pull the card out from under the toes over a period of 3 seconds to obtain a peak force reading, to indicate one's toe-pushing ability.

Balance:

- Participants will be asked to balance on a single limb (injured foot) with hands on their hips for 10 seconds while standing on a force plate that measures their sway.
- They will be asked to perform this task with their eyes opened and closed, for 3 trials each. If they are unable to maintain the single-limb stance during a trial, we will repeat the test until 3 successful trials are recorded, but with a maximum of 10

Walking Gait Kinetics:

- Participants will wear an insole that can sense pressure for this test, inside their normal shoes.
- Participants will walk on a treadmill that also has force sensors under it for a 5-minute warmup, at a self-selected speed that will be recorded and used for subsequent test sessions.
- Participants will then walk for 3 minutes on the treadmill for data collection, also at a self-selected speed. 4 trials of 30 seconds will be recorded.
- Lastly, participants will walk 3 times back and forth on a runway in the laboratory, at a self-selected speed. 3 trials will be completed and recorded. They will also be participating in markerless motion capture during this process, so that 3-D kinematics can be captured.

- In the post-intervention test session, individuals in both groups will also perform trials at a new self-selected speed on the treadmill, as individuals with PF may walk slower due to pain, and we are interested in seeing if their speed can increase after the intervention.
- Individuals in minimalist shoes will use their minimalist shoes in a second round of gait analysis. These measures are quick and will take no more than 5-8 minutes for each round of data collection.
- Participants will have their footwear assessed according to the Minimalist Index, developed by a team of scientists (found here). It will involve weighing their shoe, measuring sole thickness, and observing its sole flexibility.
    - Participants will indicate if they are currently wearing orthotics in the shoes they wore to the intervention, AND their daily shoes if they did not wear orthotics in those shoes. Information will be recorded in REDCap.
    - Participants will also take a photo of their shoe without any identifying information, with the help of the investigator, and upload it to a provided survey link within their REDCap profile. At the end of the protocol, they will be reminded to wear the same shoes to the lab. The shoes will be saved to the secure server and sent from that location.

Free-living physical activity: Average daily step count will be assessed during a 1-month observation period following the study intake visit. Compliance will be monitored using a combination of step count and heart rate data and participants who are non-compliant with Fitbit wear (<10 hours) for 2 consecutive days will be contacted by a study team member.

Intervention protocol:

- Participants will be randomized into either a control rehabilitation group (COM) or a Foot Rehabilitation And Minimalist Shoes (FRAMES) group. The randomization will be performed directly on REDCap using their Randomization feature, and the assessor will be blinded to group allocation. They will perform their assigned interventions for an 8-week period.
- The rehabilitation protocol that both groups will do is as follows:
    - Myofascial release routine of ball rolling under one foot at a time using a Naboso massage ball[27]
    - Calf-raises on an elevated surface with a towel under the toes, with 3-s concentric, 3-s eccentric, and 2-s isometric phases, as done in a previous study[28]
    - Lunge calf stretch: stand in a lunge position facing the wall, with your arms against the wall (straight). Lean forward until you feel a stretch in your back leg.
    - Calf stretch with knee bent: place your heel close to the wall and your toes onto the wall. Lean forward until you feel a stretch, keeping the knee straight.

- Foot stretch: Cross the affected leg over the other, as shown in the picture. Hold the base of your toes and pull the toes towards your shin until you feel a stretch in your foot / plantar fascia. [28]

- The footwear protocol will involve participants wearing minimalist shoes for a set amount of daily hours each week, in any weight-bearing activity such as walking, or conducting household chores and errands. They may not run in the shoes.
    - Participants will also wear pedometers that are fixed to the shoe to gain an understanding of actual compliance over the 8 weeks.
- Lastly, participants will be asked to wear a light-weight wrist-worn physical activity monitor (Fitbit Charge 4) to be worn daily during waking hours until their final study visit.
    - The wrist-worn monitor will monitor the participants' movements and activity levels during free-living conditions.
    - We will be collecting and storing steps, heart rate, and physical activity data to an SQL database on a UVA managed server. Data will be obtained using the Fitbit API and stored on the server.
    - In order to sync data in real-time during the observation period, participants will download the Fitbit mobile application and the Fitbit will be registered to the Fitbit application using a study team email (the emails will be numbered like so: frames1@virginia.edu... frames10@virginia.edu). The Fitbit will then be synced to the participant's mobile device for the entirety of their study involvement.
    - Compliance will be monitored using a combination of step count and heart rate data and participants who are non-compliant with Fitbit wear (<10 hours) for 2 consecutive days will be contacted by a study team member via email or phone based on participant preference.
    - After successful completion of the free-living and organized physical therapy monitoring periods, the participant will return to the physical activity monitor to the study team.

The exercise and footwear progressions are listed below, and participants will perform their assigned protocol 7 days a week.

Week →	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
MFR (mins/day)	3	3	4	4	4	5	5	5
Calf-raises	Bilateral, 3x12	2-up-1 down, 3x12	1-leg, 3x8	1-leg, 4x8	1-leg, 3x8	1-leg, 3x8	1-leg, 3x10	1-leg, 3x10
Lunge calf stretch	2 x 30 sec	2 x 30 sec	2 x 30 sec	2 x 30 sec	2 x 30 sec	2 x 30 sec	2 x 30 sec	2 x 30 sec
Calf stretch, knee bent	2 x 30 sec	2 x 30 sec	2 x 30 sec	2 x 30 sec	2 x 30 sec	2 x 30 sec	2 x 30 sec	2 x 30 sec
Foot stretch	2 x 30 sec	2 x 30 sec	2 x 30 sec	2 x 30 sec	2 x 30 sec	2 x 30 sec	2 x 30 sec	2 x 30 sec
MS (hrs/day)	1	2	4	6	8	8	8	8

Follow-up sessions:

- To evaluate compliance to the protocol, participants will fill out a daily survey indicating their compliance by confirming if they did the rehabilitation routine that day or not, and if they have any questions or concerns for the study team. These surveys will be sent out with Qualtrics and their text message-based distribution system
- At the 4-week point in the intervention, participants will fill out the patient-reported outcomes detailed earlier via a link provided by the investigators, and check-in with the study team to ensure they are adhering to the protocol and ask any questions.
- At the 8-week point in the intervention, participants will return to the lab for a second assessment session, where all the aforementioned procedures will be repeated. They will be asked to wear the same shoes they wore for the initial session, and will be returning their Fitbit device at this time as well.
- 2 months after their follow-up session, participants will be asked to fill out the patient-reported outcomes detailed earlier via a link provided by the investigators. There will also be a few more questions asking if they continued the intervention after the study ended, as detailed in the questionnaires document.

3. If this protocol involves study treatment, explain how a subject will be transitioned from study treatment when they have completed their participation in the study.

The subject will be able to resume normal activities as they would like. There are no devices that need to be removed. The subject will return the Fitbit at the final data collection session, but may keep the minimalist shoes if they are in that group. All participants may keep the massage ball if they finish the protocol.

Subject Compliance with Study Procedures

3. **Explain how the study team will monitor the subject for compliance with the study procedures.**

(e.g. study team will administer study drug/ study interventions, study drug inventory of dispensed and returned drug, diary etc.)

To evaluate compliance to the protocol, participants will fill out a daily survey indicating their compliance by confirming if they performed the rehabilitation exercises or not, their and if they have any questions or concerns for the study team.

4. **Describe criteria for when a subject is considered to be non-compliant with study procedures.**

(e.g. subject returns more than 20% of the study drug, subject misses 20% of study visits)

A subject misses filling out 4 daily surveys during a week more than once (if they ignore a warning), or does not adhere to the prescribed footwear protocol (either do not wear them enough or wear them too much).

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Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

*Participant's Name*_____

What is the purpose of this form?

This form will provide you with information about this research study to help you decide if you want to be in it. You do not have to be in the study if you do not want to. You should only agree to take part in this study after reading this consent form and discussing it with the study team.

This consent form may contain words or information you do not understand. The Principal Investigator, Susan Saliba (Assistant Professor in Sports Medicine/Athletic Training), and the research Study Coordinators (Doctoral students, Sports Medicine) who are familiar with the study, will explain anything that you do not clearly understand. Please ask as many questions as you need to make sure that you understand this study and why you are being asked to participate.
Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a copy of this form.

Who is funding this study?

The Virginia Athletic Trainers' Association and the University of Virginia School of Education will be funding this study.

Key Information About This Research Study

Principal Investigator:	Susan Saliba, PhD, ATC, PT University of Virginia School of Education and Human Development Department of Kinesiology PO Box 400407 Charlottesville, VA 22904 Telephone: (434) 243-4033

You are being asked to take part in a research study. You do not have to take part in this study.
You should only agree to take part in this study after reading this consent form and discussing it with the study team. You may also discuss this with your family, friends, health care providers or others before you make a decision.

What is the purpose of this study?

The purpose of this study is to find out if performing foot exercises and wearing minimalist shoes in your daily life can help your foot pain feel better. We are hoping to understand if wearing the shoes will help more than just doing the exercises. We also

hope to learn if it can increase the strength and size of your foot muscle, and if there will be any changes in how you walk. You are being asked to take part in this study because you have foot pain and have been diagnosed with plantar fasciopathy.

Why would you want to take part in this study?
You might like to take part in this study to resolve symptoms of your plantar fasciopathy and increase your function.

Why would you NOT want to take part in this study?
You might not want to take part in this study because you will need to come to the Exercise and Sport Injury Laboratory in the Student Health and Wellness Center at 550 Brandon Ave. 2 times, for about 2 hours each session.

What will I have to do if I take part in this study?
Full details of all the procedures are found later in this form. If you agree to take part in this study, you will:

- Agree to take part in 2 in-person assessments
- Complete daily surveys for 8 weeks consisting of 2-3 questions.
- Have the following evaluated:
    - Demographic characteristics
    - Self-reported function and pain
    - Foot muscle size
    - Foot muscle strength
    - Measurements, including during walking
- Perform home rehabilitation exercises
- Possibly wear a pair of minimalist footwear, according to the prescribed number of hours each day.

What is the difference between being in this study and getting usual care?
If you take part in this study, the following things will be done differently than if you do not take part in this study. This is not a treatment study. You do not need to be in this study to be treated for your condition.

- You may be instructed to wear a particular pair of shoes as a treatment method that has been shown to increase intrinsic foot muscle strength and size in healthy individuals. These muscles support the foot, so wearing the shoes may be an advantage for improving your function.
- You will perform rehabilitation exercises as a home program, and will not need to come in for any rehabilitation or physician appointments.

How many people will take part in this study?
Up to 38 people will be in this study at UVA.

How long will this study take?

Your participation in this study will require 2 study visits over an 8-week period of time. The two visits will each last about 2 hours. You will also fill out surveys remotely, via an emailed link, after 4-weeks, and speak to the study team at that time to check-in. This study will also require you to perform home exercises and complete daily surveys that may take less than a minute to complete.

What will happen if you are in the study?

SCREENING (phone call will last about 5 – 10 minutes)

Before you can start in the study, a member of the study will ask you some questions to make sure you are eligible and it is safe for you to participate. The results will be recorded for research purposes.
These include the following questions about:

- Your general health relating to your foot injury
- The severity of your pain and length you have had it
- Previous or current injuries or issues that may prevent you from being in the study

If these items show you are eligible, you will be scheduled for a study visit to begin the study.

STUDY PROCEDURES:

If you agree to participate, you will sign this consent form before any study related procedures take place.

Visit 1:

For all subjects:

1) Confirmation of plantar fasciitis: We will confirm that you have heel pain, by pressing on the heel and asking how it feels. We will also scan the bottom of your foot with an ultrasound probe, as it will tell us the thickness of your plantar fascia, and add to the diagnosis of plantar fasciitis.
2) Questionnaires: You will complete 7 surveys evaluating your foot and general function.
    - Health History: You will be asked to provide some demographic information including age, sex, your dominant foot (which foot you would kick a soccer ball with), your painful foot,the length of time of pain, and occupation. You will also be asked about previous treatments you have used for your heel pain, and your goals for being in this intervention.
    - Pain: You will indicate your pain levels from 0-100 on a line, from “no pain” to “worst pain imaginable”
        - Average pain over the past week
        - First-step pain over the past week (the pain that you feel upon waking up in the morning and taking a first step)
        - Average heel pain of the day

    - Perception of recovery: You will indicate your perception of your overall recovery from the time you began having pain until now,from “a very great deal worse” to “a very great deal better”.
- Foot function: The Foot and Ankle Ability Measure (FAAM) will ask you how difficult a list of things are to do on a scale from 0 – 4, from “no difficulty at all” to “unable to do”.
    -
    - Tampa Scale of Kinesiophobia (TSK-11): You will fill out a survey asking about your level of kinesiophobia, or “fear of movement”
    - Fear Avoidance Belief Questionnaire (FABQ): You will indicate how much certain physical activities, such as bending, lifting, or driving, affect your pain
    - Pain Self-Efficacy Questionnaire (PSEQ): You will select a response that describes how confident you are about doing certain tasks.
    - NASA Activity Survey (NAS): You will select a response that best describes your activity level in the last month.

3) We will then take several measurements:
    - Measurements of: Height, Weight, and you will tell us your normal athletic shoe size.
    - Foot characteristics:
        - Your foot length, width, and arch height assessed using the Arch Height Index tool.
        - Your foot girth measured with a soft measuring tape.
        - You will also have your foot posture assessed via the Foot Posture Index (FPI)

    - Foot muscle size:
        - You will stand on a stair with your shoe and sock off. The stair has a slot cut out of the bottom so the ultrasound probe can be placed on the bottom of the foot.
        - The muscles on the bottom of your foot will be examined using diagnostic ultrasound, which is an imaging technique that uses sound waves to examine structures.
        - You will have ultrasound gel applied to the bottom of the foot, as well as a probe that will emit sound waves and allow us to look at the structure of your foot.
        - You will have measurements in a resting position and while your foot muscles are activated.
    - Intrinsic foot muscle strength
        - You will lay on your back on a table with your toes hanging off, and a sensor will be placed under the toes. You will be asked to push against the sensor as hard as you can with your toes to measure your strength. You will be doing this test with each of the big toe and the little toes.

    - You will lay on your back will lay on your back on a carpet with your shoe and sock off, with your knee placed at 90 degrees. You will have a card attached to a hanging scale placed under your toes, and will be asked to push down on the card as hard as you can. The investigator will pull the card out from under the toes over a period of 3 seconds.
- Balance:
    - You will be asked to balance on a single limb (injured foot) with hands on your hips for 10 seconds while standing on a force plate that measures your sway.
    - You will be asked to perform this task with your eyes opened and closed, for 3 trials each. If you are unable to maintain the single-limb stance during a trial, we will repeat the test until 3 successful trials are recorded.
- Walking gait kinetics:
    - You will wear an insole in your shoe that can sense pressure.
    - You will wear your normal shoes, and walk on a treadmill for a 5-minute warmup and then a 3 minute session of data collection, all at a self-selected speed.
    - You will then walk 3 times back and forth on a runway to capture data about walking on normal ground, at a self-selected speed. You will also be participating in markeless motion capture so we can understand how your knees, hips, and ankles are moving.
    - Your footwear will be evaluated for its characteristics including weight, sole thickness, and sole flexibility. You will also take a picture of your shoe and upload it to a survey. So when you come back in for your final session, you will have a reminder of which shoes to wear to the lab, as the picture will be emailed to you as a reminder.
- Physical Activity and Fitness monitoring:
    - You will be asked to wear a light-weight wrist-worn physical activity monitor (Fitbit Charge 5). This will be worn every day between study visits 1 and 2.
    - The Fitbit will monitor your movements and heart rate.
    - We will be collecting and storing the data from the Fitbit in a secure database at UVA.
    - You will temporarily need to download the Fitbit mobile application on your phone. You will have access to your data through the app throughout the study.
    - We will monitor whether you are wearing your Fitbit and whether you have charged your Fitbit. If you fail to do either, you will receive an email from the study team as a reminder to do so.
    - You will return the Fitbit at your second study visit.
    - You will not receive payment for this study if the Fitbit is not returned.

4) <u>Randomization:</u>

You will be randomly assigned (like the flip of a coin) to 1 of 2. You have an equal chance of being assigned to any one of the groups. You cannot choose which group you are assigned to.

If you are in GROUP 1: Home exercises and Minimalist Shoes

a) You will incorporate wearing minimalist shoes into your daily routine, which aims to strengthen the foot muscles. The standard-of-care home exercises aim to improve function of your foot and lower leg.
   1. You will be performing these rehabilitation exercises at home on your own 6 days a week, and the exercises will take about 15-20 minutes to complete.
   2. You will be taught the exercises at the first testing session, and then be given hard copy printouts of the rehabilitation exercises you will be asked to complete in your home. These printouts will include how many of each exercise to do, and how and for how long you will wear the shoes each day.
   3. You will be asked to fill out a daily survey, sent via text, to indicate if you have completed your exercises. These rehabilitation sessions will begin after Visit One and continue for 8 weeks.

b) The exercises you will be asked to complete are listed below, and will take about 15-20 minutes each day to complete:
   1. Bottom-of-the-foot massage: You will use a small rubber ball that will be provided to roll on the bottom of the foot, for the prescribed minutes each day.
   2. Calf-raises with towel roll: You will perform calf raises on an elevated surface such as a stair, with a towel rolled up under the toes, for the prescribed method each day.
   3. Lunge calf stretch: stand in a lunge position facing the wall, with your arms against the wall (straight). Lean forward until you feel a stretch in your back leg.
   4. Calf stretch with knee bent: place your heel close to the wall and your toes onto the wall. Lean forward until you feel a stretch, keeping the knee straight.
   5. Foot stretch: Cross the affected leg over the other. Hold the base of your toes and pull the toes towards your shin until you feel a stretch in your foot / plantar fascia.

If you are in GROUP 2: Rehabilitation Only and NO minimalist shoes

a) The standard-of-care home exercises aim to improve function of your foot and lower leg.

1. You will be performing these rehabilitation exercises at home on your own 6 days a week, and the exercises will take approximately 15 – 20 minutes.
2. You will be taught the exercises at the first testing session, and then be given hard copy printouts of the rehabilitation exercises you will be asked to complete in your home. These printouts will include how many of each exercise to do.
3. You will be asked to fill out a daily survey, sent via text, to indicate if you have completed your exercises. These rehabilitation sessions will begin after Visit One and continue for 8 weeks.

b) The exercises you will be asked to complete are listed below, and will take approximately 15-20 minutes each day to complete:
   1. Bottom-of-the-foot massage: You will use a small rubber ball that will be provided to roll on the bottom of the foot, for the prescribed minutes each day.
   2. Calf-raises with towel roll: You will perform calf raises on an elevated surface such as a stair, with a towel rolled up under the toes, for the prescribed method each day.
   3. Lunge calf stretch: stand in a lunge position facing the wall, with your arms against the wall (straight). Lean forward until you feel a stretch in your back leg.
   4. Calf stretch with knee bent: place your heel close to the wall and your toes onto the wall. Lean forward until you feel a stretch, keeping the knee straight.
   5. Foot stretch: Cross the affected leg over the other. Hold the base of your toes and pull the toes towards your shin until you feel a stretch in your foot / plantar fascia..

<u>Check-in</u> (about 4 weeks after Visit 1):

1) You will receive a link via email to fill out surveys that are similar to the surveys you will fill out at Visit 1:

- Pain:
- Foot function: The Foot and Ankle Ability Measure (FAAM)
- Tampa Scale of Kinesiophobia (TSK-11)
- Fear Avoidance Belief Questionnaire (FABQ)
- Pain Self-Efficacy Questionnaire (PSEQ)
- NASA Activity Survey (NAS)

Availability: You will then indicate some times for a study team member to call you, to check-in about the protocol and answer any questions you may have

<u>Visit 2 (about 8 weeks after Visit 1):</u>

1) Questionnaires:

- Pain:
- Foot function: The Foot and Ankle Ability Measure (FAAM) Tampa Scale of Kinesiophobia (TSK-11)
- Fear Avoidance Belief Questionnaire (FABQ)
- Pain Self-Efficacy Questionnaire (PSEQ)
- NASA Activity Survey (NAS)

2) We will take several measurements that were taken at Visit 1, including:

- Height and weight
- Foot characteristics
- Foot muscle size
- Intrinsic foot muscle strength
- Balance
- Walking gait kinetics
    - If you are in the minimalist shoe group, we will also be performing this walking task in those shoes.
- At this time you will also return your Fitbit.

2-month Follow-Up (about 2 months after your follow-up appointment):

You will receive a link via email to fill out surveys that are similar to the surveys you will fill out at the follow-up session:

- Pain:
- Foot function: The Foot and Ankle Ability Measure (FAAM)
- Tampa Scale of Kinesiophobia (TSK-11)
- Fear Avoidance Belief Questionnaire (FABQ)
- Pain Self-Efficacy Questionnaire (PSEQ)
- NASA Activity Survey (NAS)

Study Schedule

	Phone call 1 (Screening)	**Visit 1 (Baseline)**	**Study period**	**Check-in (Mid-point)**	**Visit 3 (Final session)**	**2-month follow up**
Study Week	-1	0	1 – 8	4	8	16
Review study eligibility	x	x				
Informed consent		x				
Demographics		x		x	x	

Pain levels		x		x	x	x
Foot function		x		x	x	x
Recovery		x		x	x	x
Kinesiophobia		x		x	x	x
Fear-Avoidance Belief		x		x	x	x
Self-Efficacy		x		x	x	x
Intrinsic foot muscle size		x			x	
Intrinsic foot muscle strength		x			x	
Balance		x			x	
Walking kinetics		x			x	
Home exercise instruction		x	x			
Minimalist shoe instruction (if applicable)		x	x			
Daily Check-in			x			
Wear Fitbit			x			
Mid-point check-in				x		

END OF STUDY:

After you've completed the study, you will no longer need to perform the exercises and you may keep the exercise ball and shoes, if you have been provided with them.

WHAT ARE YOUR RESPONSIBILITIES IN THE STUDY?

You have certain responsibilities to help ensure your safety. These responsibilities are listed below:

5. You must be completely truthful about your health history.
6. Follow all instructions given.
7. You should tell the study doctor or study staff about any changes in your health or the way you feel.
8. Answer all of the study-related questions completely.
9. Inform the study doctor or study staff as soon as possible if you cannot continue in the study.

If you want to know about the results before the study is done:

As the research moves forward, your study leader will keep you informed of any new findings about the research itself that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you may ask for more information about the study results.

What are the risks of being in this study?

A risk of allowing us to collect information about you is a potential loss of privacy. The University of Virginia will do its best to protect your records so that facts about you and your health will be kept private. The chance that information identifying you will be given to someone else is very small. However, we cannot *guarantee* it will be safe.

Risks and side effects related to the interventions include:

Likely

- You may experience some foot or calf cramping during the exercises, but you may take as much rest as needed between exercise sets.
- You may experience some foot or calf soreness from wearing the minimalist shoes at first while you adjust to them.

  These 2 items will very likely resolve on their own with no further problems.

Less Likely

- There is a possibility of a bone stress fracture from wearing minimalist shoes, but research has shown that performing rehabilitation exercises, slowly transitioning into wearing the shoes, and only being allowed to walk in them can help reduce this risk.
- Risks from Wearing Monitors: You may experience mild skin irritation from the wrist-worn dual heart rate and movement intensity monitor as these monitors and straps will be in direct contact with your skin. If you experience any discomfort or skin irritation, please promptly inform the researchers. Mild skin irritation and discomfort should be temporary and subside once the monitors and straps are removed. However, if the skin irritation persists beyond 24 hours or intensifies, please contact the researchers.

Risks from Completing Questionnaires

Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and to the next question

Other unexpected risks:
You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You will not benefit directly from taking part in this study. However, you may experience:

- improvement of your foot pain
- increased function

In addition, information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

3. Your current treatment with your regular doctor and nurses

If you are an employee of UVA your job will not be affected if you decide not to participate in this study.
If you are a student at UVA, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will get paid $125 at the end of the study, and your parking costs will be covered as well.

Will being in this study cost you any money?

All of the procedures in this study will be provided at no cost to you or your health insurance.
You will be responsible for the cost of travel to come to any study visit, but not for parking costs.
See the "Will you be paid for being in this study?" section of this form for more information.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include

a) Your study physician is concerned about your health
b) Your injury gets worse
c) The side effects of the exercises are too dangerous for you
d) New information shows the exercises will not work or is not safe for you
e) You do not follow instructions

If you decide to stop being in the study, we will ask you to call the study office at 434-924-0086 to let the lead researcher or research assistant know that you have decided to stop being in the study.

Any data collected about you up until the time you leave the study must be kept in order to determine the results of the study.

How will your personal information be shared?

The UVA researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

i. Personal information such as name, address and date of birth

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the Study team member listed BELOW to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Jennifer Xu – Study Coordinator
tnd9vf@virginia.edu

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22903 Telephone: 434-924-2620

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the UVA Study Tracking Number (at the bottom of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

You may also report a concern anonymously by calling the UVA Compliance Hotline phone number at 1-800-235-8700.

The study team will need to communicate with you by email and text message
However, you do not need to respond via text, and any emails sent that require a response will only be to schedule sessions. If you have questions for the study team, the daily survey you fill out will allow you to be contacted via a phone call.

If you choose to communicate with the study team by unsecure email (email that is not encrypted) or text message to your personal phone, there is some risk that your health information could be read or accessed by someone else while the information is sent or saved by your email or phone provider.

Your personal email or phone provider may also share or release your information because they do not have to follow the privacy laws that UVA follows. Sometimes email and phone providers release information to marketing companies for use in direct advertising. If you choose to communicate by email or text messaging, UVA cannot control this potential loss of privacy but we want to tell you about this possible risk.

If you agree to being texted and emailed, and responding to emails to schedule a session, the study team will collect your phone and /or email address from you that you would like them to use to contact you. Please note, if you agree to text messaging, charges may apply depending on your data/text plan with your phone provider.

You have to agree to receive emails and text messages to be in this study.

Yes_____ I agree to be contacted by email or text.
If you agree to texting or emailing, the study team will collect your phone and /or email address that you would like them to use. Please note, if you agree to text messaging, charges may apply depending on your data/text plan with your phone provider.

No_____ I DO NOT agree to be contacted by email or text.
If you do not agree, you will not be able to be in the study.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form, it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Signature of Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

Please indicate with check box the identified individual(s):

☐ Subject

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE

Notification of My Health Care Provider

Please indicate below whether you want us to notify your health care provider that you have agreed to take part in this study.

_____ Yes, I want the study doctor to notify my health care provider that I have agreed to take part in this study.

Health Care Provider Name:

Health Care Provider Address:

Study team will send a copy of the consent form to the health care provider.

_____ No, I do not want the study doctor to notify my health care provider that I have agreed to take part in this study or I do not have a health care provider.

Leaving the Study Early

If you leave the study early the study leader will keep the data collected about you up until the time you leave the study to help determine the results of the study.

Check one option below:

____ I am withdrawing my consent from the intervention or treatment part of this study but agree to continue to have follow up information about me collected by the study team.

The follow up information will be collected by:

- Sending me surveys/ questionnaires once
- In person follow up visit to repeat baseline visit 1 procedures

____ I am withdrawing my consent for this study. No additional information may be collected about me including follow up information from my medical records.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Data Security Plan

WF SUMMARY DETAILS	
Version Date:	*02-19-24*
Workflow Name:	*HSR230045-MS in PF*
Proposal Org / Dept. No.	*31200 CU-KINE Kinesiology*
Principal Investigator:	*Susan Saliba - saf8u*
DSP Submitted by:	*tnd9vf*
Protocol File Uploaded to Study Documents:	*Yes*

HIPAA Identifier Options

OPTIONS	OPTION SELECTED	HOW STORED
Note: You will refer to this list throughout the document.	If the identifier is not listed, it is not applicable.	Options include: ▪ Original source data collection (receive, collect, or record at UVA) ▪ Store long term at UVA (data will be used for future unspecified research, e.g., banking) ▪ Send or transmit outside of UVA ▪ Not Applicable
1. Name	*1. Name - Highly Sensitive Data*	*Original source data collection*
2a. Postal address includes street and/or PO Box, and town or city, state, and zip code	*2. Street address, town or city, state, and zip code – Highly sensitive data*	*Original source data collection*
2b. Postal address that includes only town or city, state, and/or zip code		
3. All date elements (except year) for dates related to an individual, e.g. service date	3. All date elements (except year) for dates related to an individual, e.g. service date	*Original source data collection*
4. Telephone numbers	*4. Telephone numbers - Highly Sensitive Data*	*Original source data collection*
5. Fax numbers		
6. Electronic mail addresses	*6. Electronic mail addresses - Highly Sensitive Data*	*Original source data collection*
7. Social Security number		
8. Medical Record number		
9. Health plan beneficiary numbers		
10. Account numbers		

OPTIONS	OPTION SELECTED	HOW STORED
11. Certificate/license numbers		
12. Vehicle identifiers and serial numbers, including license plate numbers		
13. Device identifiers and serial numbers		
14. Web Universal Resource Locators (URLs)		
15. Internet Protocol (IP) address numbers		
16. Biometric identifiers, including finger and voice prints		
17. Full face photographic images and any comparable images		
18. Other unique number, characteristic, code related to an individual, e.g. initials	*18. Other unique number, characteristic, code related to an individual, e.g. initials*	*Original source data collection*

COLLECTION & STORAGE OF HUMAN SUBJECT RESEARCH DATA

A) Paper Documents

OPTIONS	SELECTED
Storage location	*Appropriate UVa location (See list below), UVa approved storage facility*
Other: (Please describe)	*We will be storing paper documents in a file cabinet in a locked room when unattended.*

***Appropriate UVA locations include one or more of the following:**

- Kept in a locked office in a building with 24-hour swipe locks when unattended
- Kept in a locked file cabinet in a locked room when unattended
- Kept in an office where study are personnel present in room at all times located in a building with 24-hour swipe locks or a room with a lock when unattended
- Behind two locked doors when unattended

B) Emailed to other UVA Personnel

OPTIONS	SELECTED
Research data emailed to UVA personnel with a @virginia.edu email address with an encrypted email. -or/and- Research data e-mailed to and from UVA personnel with *HS or uvahealth.org e-mail address.	
Other Email Characteristics: (Please describe)	

C) Electronic Medical Record (EPIC)

OPTIONS	
Data will be collected in EPIC as part of routine care or as part of medical center encounters during the research study.	*Not Applicable*

D) UVA-approved eCRF or Clinical Trials Management system

LIST	USED / SELECTED
hstsdsmpogapp.hscs.virginia.edu	

LIST	USED / SELECTED
OnCore (uva-oncore-prod.advarra.app)	OnCore (uva-oncore-prod.advarra.app
Redcap-int.hscs.virginia.edu	*Redcap-int.hscs.virginia.edu*
https://reveal.studymanager.com/	
Advarra: https://uva-edc.forteresearchapps.com/	
I acknowledge that ANY electronic use devices used to connect to any servers/websites checked above are supported by UVA Health IT	*Yes*

E) UVA Servers & Websites

LIST	USED / SELECTED
domatlas.eservices.virginia.edu	
Elson1.studenthealth.virginia.edu	
es3.eservices.virginia.edu	*es3.eservices.virginia.edu*
gcrcserver.itc.virginia.edu	
\\HIT-SS1-User F drive	
\\HIT-SS2-User F drive	
\\HIT-SS3-User F drive	
\\HIT-SS4-User F drive	
\\hscs-share1\	
\\hscs-share2\	
\\hscs-share3\	
\\HSCS-ss8	
iTHRIV Research Data Commons	
Ivy Secure Computing Platform/ Ivy Secure Cloud/Ivy Cloud	
Payment Works	
\\radshare\	
School of Nursing SECURE NET	
Upgusers1.hscs.virginia.edu	
UVA HIT DropBox	
UVA Qualtrics HSD survey tool: https://virginiahsd.co1.qualtrics.com/ControlPanel/	
UVA Central Qualtrics Survey tool: https://virginia.az1.qualtrics.com/homepage/ui	*https://virginia.az1.qualtrics.com/homepage/ui* *The data will be deidentified, individuals will only be referred to by their participant numbers. The Central UVA Qualtrics is being used because it is the only version that allows for daily texts of the survey to be sent out. Further, there is dual-factor authentication for security purposes, I will be the only one with access to the database itself, and the data will only be exported to a secure platform. Lastly, there is not health information being transferred on this portal, as individuals will only vaguely indicate what they would like to speak to the study team about using checkboxes, no free text. If subjects would like to speak to a study team member, a study team member will be notified via email of the subject's ID number and their availability, no other identifying information. UVA IT Compliance has already confirmed Central UVA Qualtrics is the correct database.*

LIST	USED / SELECTED

F) Web-based or Cloud Format (not listed above)

LIST	USED / SELECTED
Data will be collected and/or stored in UVA Box or UVA-Collab	*No*
If you are using other web-based or cloud servers please describe:	*We will be storing information on a UVA managed server with security rules consistent with high security data storage. It is a SQL database housed on a UVA ITS managed virtual server called ACL Goals, which has been approved for use by IRB-HSR in a separate study (HSR230060)*
Check the HIPAA Identifiers stored on UVA Box or Collab	

Individual Use Devices

Current list of individual use device choices available for use:

- No Individual Use Devices will be used
- Flash (thumb) drive
- External drive
- CD or DVD
- Desktop Computer
- Laptop
- Tablet
- Smart phone
- Camera
- Video recorder
- Audio recorder
- Biometric recording device
- Fitness Trackers
- Other

G) Individual use devices	
If you selected "Other" above, please identify the device type:	Tablet
Please describe your process for collecting, storing and/or transmitting data on the Individual Use Devices you selected in earlier steps (phones, flash drives, CDs, etc.):	Biomechanics data will be Bluetooth synced to a local tablet. After data collection is complete for a given participant visit, the data will synced with a UVA managed laptop computer and uploaded to REDCap and to the es3services server. Once successful upload is confirmed, data will be deleted from the tablet and laptop computer.
Check the HIPAA Identifiers stored with the data on this device (e.g. such as full-face picture or video):	No HIPAA identifiers will be recorded as part of this research.
Mobile computing devices such as tablet or smartphone	

Who is the owner of the device?	
I confirm that Mobileiron has been installed on the device.	
USB Flash devices	
Is the USB Flash device encrypted?	
If USB flash (thumb) drive is encrypted, does it comply with UVA Health Encryption standard?	
Do you use a unique password/PIN to unlock this device?	
Is this device being encrypted?	
If yes, do you use a 256-bit or higher encryption technology?	
Do you have a secure handling procedure in place (e.g., device is stored in a locked room and in a restricted access building)?	
Describe any backups made of the data stored on the device. Please include the location & method of data transfer:	Data will be synced to the device via Bluetooth, downloaded from the device via USB to a local laptop
How long will the data remain on the individual-use device before being transferred?	< 1 hour
After the information is transferred elsewhere, will you follow UVA Electronic Data Removal Standard to securely delete all data from this device?	Yes
Will anyone other than the study team or sponsor/CRO have access to data on this device?	No
If yes, describe	
Other storage alternatives that were considered and the reasons they are unworkable	The tools used to collect biomechanics data require syncing with their proprietary application in order to be saved. There are no other options if these tools are used.
The justification for storage of these data on this individual use device is:	The individual use device is a passthrough. Data will not be stored for more than 1 hour.

G) Individual use devices	
If you selected "Other" above, please identify the device type:	Flash drive
Please describe your process for collecting, storing and/or transmitting data on the Individual Use Devices you selected in earlier steps (phones, flash drives, CDs, etc.):	Ultrasound images will be exported to a flash drive from the ultrasound device. It will be opened with a UVA managed computer and the data will be uploaded to REDCap and to the es3services server. Once successful upload is confirmed, data will be deleted from the flash drive.
Check the HIPAA Identifiers stored with the data on this device (e.g. such as full-face picture or video):	No HIPAA identifiers will be recorded as part of this research.

Mobile computing devices such as tablet or smartphone	
Who is the owner of the device?	
I confirm that Mobileiron has been installed on the device.	
USB Flash devices	
Is the USB Flash device encrypted?	
If USB flash (thumb) drive is encrypted, does it comply with UVA Health Encryption standard?	
Do you use a unique password/PIN to unlock this device?	
Is this device being encrypted?	
If yes, do you use a 256-bit or higher encryption technology?	
Do you have a secure handling procedure in place (e.g., device is stored in a locked room and in a restricted access building)?	
Describe any backups made of the data stored on the device. Please include the location & method of data transfer:	Data will be synced to a flash drive, opened on a UVA managed desktop computer, and uploaded to REDCap and the es3services server.
How long will the data remain on the individual-use device before being transferred?	< 1 hour
After the information is transferred elsewhere, will you follow UVA Electronic Data Removal Standard to securely delete all data from this device?	Yes
Will anyone other than the study team or sponsor/CRO have access to data on this device?	No
If yes, describe	
Other storage alternatives that were considered and the reasons they are unworkable	The ultrasound device has no other option to export the data. There are no other options.
The justification for storage of these data on this individual use device is:	The individual use device is a passthrough. Data will not be stored for more than 1 hour.

G) Individual use devices	
If you selected "Other" above, please identify the device type:	Desktop computer – UVA managed
Please describe your process for collecting, storing and/or transmitting data on the Individual Use Devices you selected in earlier steps (phones, flash drives, CDs, etc.):	Biomechanics data from the motion capture will be saved to a desktop computer that the assessor is logged into, then transferred to the es3services server and uploaded to REDCap. Once successful upload is confirmed, data will be deleted from the computer.
Check the HIPAA Identifiers stored with the data on this device (e.g. such as full-face picture or video):	No HIPAA identifiers will be recorded as part of this research.
Mobile computing devices such as tablet or smartphone	

Who is the owner of the device?	
I confirm that Mobileiron has been installed on the device.	
USB Flash devices	
Is the USB Flash device encrypted?	
If USB flash (thumb) drive is encrypted, does it comply with UVA Health Encryption standard?	
Do you use a unique password/PIN to unlock this device?	
Is this device being encrypted?	
If yes, do you use a 256-bit or higher encryption technology?	
Do you have a secure handling procedure in place (e.g., device is stored in a locked room and in a restricted access building)?	
Describe any backups made of the data stored on the device. Please include the location & method of data transfer:	Data will be saved to the desktop computer for a short period of time.
How long will the data remain on the individual-use device before being transferred?	< 1 hour
After the information is transferred elsewhere, will you follow UVA Electronic Data Removal Standard to securely delete all data from this device?	Yes
Will anyone other than the study team or sponsor/CRO have access to data on this device?	No
If yes, describe	
Other storage alternatives that were considered and the reasons they are unworkable	The tools used to collect biomechanics data require syncing with their proprietary application in order to be saved. There are no other options if these tools are used.
The justification for storage of these data on this individual use device is:	The individual use device is a passthrough. Data will not be stored for more than 1 hour.

G) Individual use devices	
If you selected "Other" above, please identify the device type:	Fitbit Charge 4 device
Please describe your process for collecting, storing and/or transmitting data on the Individual Use Devices you selected in earlier steps (phones, flash drives, CDs, etc.):	Data will be collected for 8 weeks and synced to the Fitbit application which will be installed on the participants personal mobile device. At the same time, the study team will be using an API call to capture all available Fitbit data to an SQL database housed on a UVA ITS managed virtual server called ACL Goals, which has been approved for use by IRB-HSR in a separate study (HSR230060). At the conclusion of the study visits for each subject, the Fitbit device will be factory reset and the study Fitbit account will be un-registered from the Fitbit application on the

	participant's personal mobile device. No identifiers will be stored on the individual use device, but Fitbit data will be comingled with identifiers once it is stored in the SQL database.
Check the HIPAA Identifiers stored with the data on this device (e.g. such as full-face picture or video):	No HIPAA identifiers will be recorded as part of this research
Mobile computing devices such as tablet or smartphone	
Who is the owner of the device?	
I confirm that Mobileiron has been installed on the device.	
USB Flash devices	
Is the USB Flash device encrypted?	
If USB flash (thumb) drive is encrypted, does it comply with UVA Health Encryption standard?	
Do you use a unique password/PIN to unlock this device?	
Is this device being encrypted?	
If yes, do you use a 256-bit or higher encryption technology?	
Do you have a secure handling procedure in place (e.g., device is stored in a locked room and in a restricted access building)?	
Describe any backups made of the data stored on the device. Please include the location & method of data transfer:	Data will be stored and backed up, via ITS scheduled backups, once it has been uploaded and stored in the study team's SQL database.
How long will the data remain on the individual-use device before being transferred?	This is dependent on how often the participant syncs their device, but the device will be factory reset at the end of their 8 week observation period.
After the information is transferred elsewhere, will you follow UVA Electronic Data Removal Standard to securely delete all data from this device?	Yes
Will anyone other than the study team or sponsor/CRO have access to data on this device?	Yes
If yes, describe	The participant will be able to access their own data throughout the study.
Other storage alternatives that were considered and the reasons they are unworkable	N/A
The justification for storage of these data on this individual use device is:	This is the only way that fitness trackers will allow for data capture.

Transmission & Storage of the Human Subject Research Data Outside of UVA

QUESTION	
Will data be transmitted to a sponsor?	*No*
Will data be transmitted to a colleague at another institution?	
Will data be transmitted to a sponsor or a colleague at another institution?	*No*
I acknowledge that ANY electronic individual use devices used to connect to any servers/websites listed below are supported by UVA Health System IT. (CRO)	*No*
Check the HIPAA Identifiers stored by the Sponsor or CRO	
If sharing data with anyone outside of UVA, do you confirm that you will obtain a contract with them via the School of Medicine Grants and Contracts Office or the Office of Sponsored Programs (OSP)?	
Data will be sent and stored in an encrypted fashion (e.g. will only be shared and via Secure FX, Secure FTP, HTTPS, PGP) and the server/drive is configured to store data regulated by HIPAA	
Name (URL) of website (e.g. http://remote.sponsor.com/project name)	
Paper documents will shipped using trackable method.	*NA, paper documents will not be shipped*
Data encrypted on an individual use device and shipped using trackable method. Password to the encrypted data transmitted separately.	*NA, data will not be shipped on an individual use device*
Data faxed to a receiving machine in a restricted-access location. The intended recipient is clearly indicated, alerted to the pending transmission and available to pick up immediately.	*NA, data will not be faxed*

DATA SENSITIVITY

When paired with health information, any of the below data elements are considered Highly Sensitive Data by UVA's Data Protection policy (https://uvapolicy.virginia.edu/policy/IRM-003). Please note that Social Security Numbers, Driver's license numbers, passport numbers, financial account numbers, and credit card numbers are considered Highly Sensitive Data regardless of whether or not they are paired with health information.

1. Name
2. Postal address, other than town or city, state, and zip code (e.g. street name or GPS information.)
3. Telephone numbers
4. Fax numbers
5. Electronic mail addresses

6. Social Security Numbers
7. Medical Record Numbers
8. Health plan beneficiary numbers
9. Account numbers (e.g. bank numbers, credit card numbers, hospital bill account number)
10. Certificate/license numbers (e.g. passport number, driver's license number, medical board license number)
11. Vehicle identifiers and serial numbers, including license plate numbers
12. Device identifiers and serial numbers
13. Web Universal Resource Locators (URLs)
14. Internet Protocol (IP) address numbers
15. Biometric identifiers, including finger and voice prints
16. Full face photographic images and any comparable images

Data Security Study Team

NOTES

UVA Health Information Security Review

The data protection measures and privacy plan as described in this data security document (named "HSR230045 Data Security Plan 11-09-23_Approval11152023.docx") are compliant with UVA data protection standards and guidelines and are approved by UVA Health Information Security (UVA Health InfoSec).

Please remember that data security and compliance with federal and state laws and University policies require continuous vigilance.

Date: 11/15/2023
SN #:
UVA Health InfoSec

Zach Nortey pbx3kt@uvahealth.org
NTS consultant

Table C2b. Study flyer

Do you have plantar fasciitis?

The UVA Department of Kinesiology is seeking to understand the effects of wearing minimalist shoes for 8 weeks on pain and function for for adults aged 18 - 55 with plantar fasciitis.

This study involves:

- 2 laboratory visits 8 weeks apart (2-3 hours each) to assess pain and function
- Each day: performing rehabilitation exercises (~15 mins), filling out a short survey
- Wearing a Fitbit daily and potentially a pair of minimalist shoes

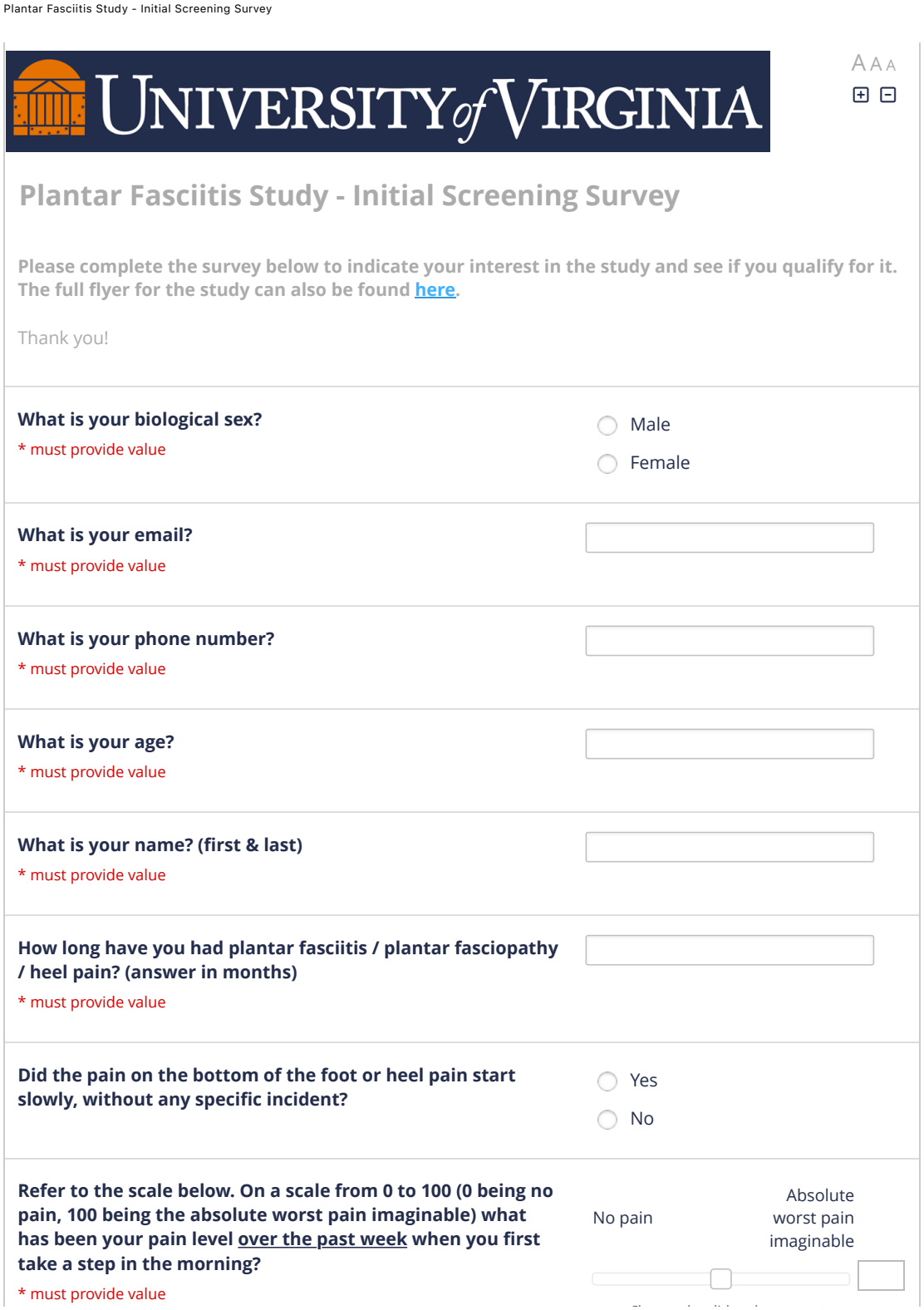
Study-related tests and rehabilitation will be provided free of charge, and you will also be compensated with $55 for completing the study.

You may be eligible if you:

- Are 18 - 55 years old, and are **not** pregnant
- Have **not** had a lower extremity fracture or surgery
- Have **not** sustained a lower extremity injury in the past 3 months
- Have **not** had a corticosteroid injection in the last 6 months

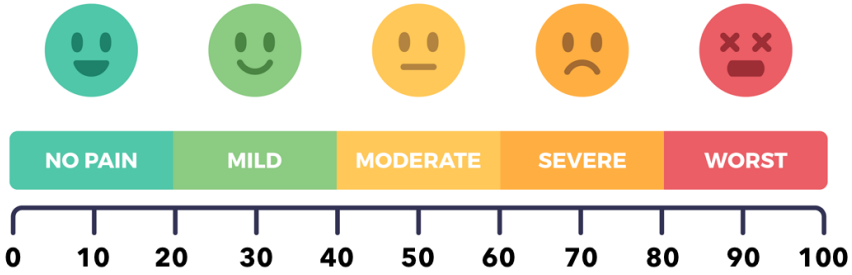
For more information, scan the QR code!
Or contact Jennifer Xu -- *tnd9vf@virginia.edu*
Principal Investigator: Susan Saliba, IRB-HSR #230045

Table C3a – Pre-Screening Questionnaire



Change the slider above to set a response

reset



Do you have any other current lower extremity neuromusculoskeletal injuries?

* must provide value

Yes No

Have you had any other lower extremity neuromusculoskeletal injuries other than the foot in the past 3 months?

* must provide value

Yes No

Do you have any previous history of foot and ankle fractures or surgeries?

* must provide value

Yes No

Have you had a corticosteroid injection within the last 6 months?

* must provide value

Yes
No

Are you currently participating in a formal rehabilitation program for plantar fasciitis?

* must provide value

Yes No

Do you have any previous experience wearing minimalist shoes?

* must provide value

Yes No

Are you currently pregnant?

* must provide value

Yes No

What days and times are the best for a phone call?

	9am - 12pm	12pm - 3pm	3pm - 7pm	Unavailable all day	Other specific times
Monday * must provide value	☐	☐	☐	☐	☐
Tuesday * must provide value	☐	☐	☐	☐	☐
Wednesday * must provide value	☐	☐	☐	☐	☐
Thursday * must provide value	☐	☐	☐	☐	☐
Friday * must provide value	☐	☐	☐	☐	☐
Saturday * must provide value	☐	☐	☐	☐	☐

Thank you! The study team will be in touch with you shortly. If you have questions in the meantime, please email Jen Xu (tnd9vf@virginia.edu).

Submit

Powered by REDCap

Table C3b – Pre-Screening Checklist for phone call

Prescreen Date: _____ Investigator initials: _____ Screening ID: _____

Study Title:	**FRAMES Study**		
Eligibility Checklist			
Inclusion Criteria (must answer YES to all)			
1	Age (must be between 18-55): _____		□ Yes □ No
2	Have you had heel pain or pain on the bottom of your foot for at least a month?		□ Yes □ No
3	Did the pain on the bottom of the foot or heel pain start slowly, without any specific incident?		□ Yes □ No
4	On a scale of 0 – 100, what is the pain you have had in the morning upon taking your first step over the past week? (Must be at least 30): _____		□ Yes □ No
Exclusion Criteria (must answer NO to all)			
1	Have you had other lower extremity neuromusculoskeletal injuries other than to the foot in the last 3 months?		□ Yes □ No
2	Do you have a history of surgery to your foot or ankle?		□ Yes □ No
3	Have you ever sustained a foot or ankle fracture?		□ Yes □ No
4	Have you had a corticosteroid injection within the last 6 months?		□ Yes □ No
5	Are you currently participating in a formal plantar fasciitis rehabilitation program?		□ Yes □ No
6	Do you have any previous experience with wearing minimalist shoes?		□ Yes □ No
7	Are you pregnant?		□ Yes □ No
Notes:			
Participant is *(circle one)*: Eligible Not Eligible Investigator's signature indicating review and approval of enrollment into the study: _____ _____ *Investigator Signature* *Date*			

IF Eligible and permission to keep contact information is granted:

Name	

Table C3c – Health History Questionnaire

1. What is your age?
    a. _____
2. What is your sex?
    a. Female
    b. Male
3. What is your ethnicity?
    a. Hispanic or Latino
    b. NOT Hispanic or Latino
    c. Unknown / Not reported
4. What is your race? Select all that apply
    a. American Indian/Alaska Native
    b. Asian
    c. Native Hawaiian or Other Pacific Islander
    d. Black or African American
    e. White
    f. More than One Race
    g. Unknown/Not Reported
5. What is your dominant foot? (which would you use to kick a soccer ball?
    a. Right
    b. Left
6. What is the highest level of education you have completed?
    a. No formal education
    b. Less than primary school
    c. Primary school completed
    d. High school (or equivalent) completed
    e. TAFE (technical college) completed
    f. College/university completed
    g. Other
7. What is your occupation?
    a. Architecture
    b. Arts, Design, Entertainment Occupations
    c. Building and Grounds Cleaning and Maintenance Occupations
    d. Business Occupations
    e. Community and Social Service Occupations
    f. Computer and Mathematical Occupations
    g. Construction and Extraction Occupations
    h. Education, Training, and Library Occupations
    i. Emergency Services
    j. Engineering Occupations
    k. Farming, Fishing, and Forestry Occupations
    l. Financial Operations Occupations
    m. Food Preparation and Serving Related Occupations
    n. Healthcare Practitioners and Technical Occupations
    o. Installation, Maintenance, and Repair Occupations

p. Legal Occupations
q. Life, Physical, and Social Science Occupations
r. Office and Administrative Support Occupations
s. Personal Care and Service Occupations
t. Production Occupations
u. Protective Service Occupations
v. Management Occupations
w. Media Occupations
x. Sales and Related Occupations
y. Sports Occupations
z. Transportation and Materials Moving Occupations
aa. Other (please specify)

8. Which of the following categories best describes your employment status?
    a. Employed, working 40 or more hours per week
    b. Employed, working 1-39 hours per week
    c. Not employed, looking for work
    d. Not employed, NOT looking for work
    e. Retired
    f. Disabled, not able to work
    g. Other
9. Have you had any previous lower extremity surgeries or fractures, or lower leg or foot injuries?
    a. Yes
    b. No

If so, please explain:

10. Have you had any previous lower leg or foot injuries?
    a. Yes
    b. No
    c. If so, please explain:
11. Do you have pain in one foot or both?
    a. Both
    b. Only one foot
12. If only one foot: which foot is your painful foot?
    a. Right
    b. Left
13. If in both feet: which foot is your more painful foot?
    a. Right
    b. Left
14. How long have you had your pain?
    a. ____ months
15. Have you ever seen a physician for your foot pain?
    a. Yes
    b. No
    c. If so, please describe your experience below:
16. Have you ever seen a physical therapist for your foot pain?
    a. Yes

b. No
c. If so, please describe your physical therapy experience below:

17. What other treatments have you used in the past? Select from “I tried it, and it was a success”, or “I tried it, it did not work”, or “Have not tried this”
    a. Taping
    b. Insoles
    c. Massage
    d. Extracorporeal Shockwave Therapy
    e. Electrical stimulation
    f. Ultrasound
    g. Laser therapy
    h. Stretching
    i. Rehabilitation exercises
    j. Dry needling
    k. Accupuncture
    l. Corticosteroid injections
    m. PRP injections
    n. Other types of injections
    o. Surgery
    p. Haven’t tried anything
    q. Other: please describe
18. What are your goals (or goal) for participating in this intervention?
    a. _____

Table C3d – Pain Levels

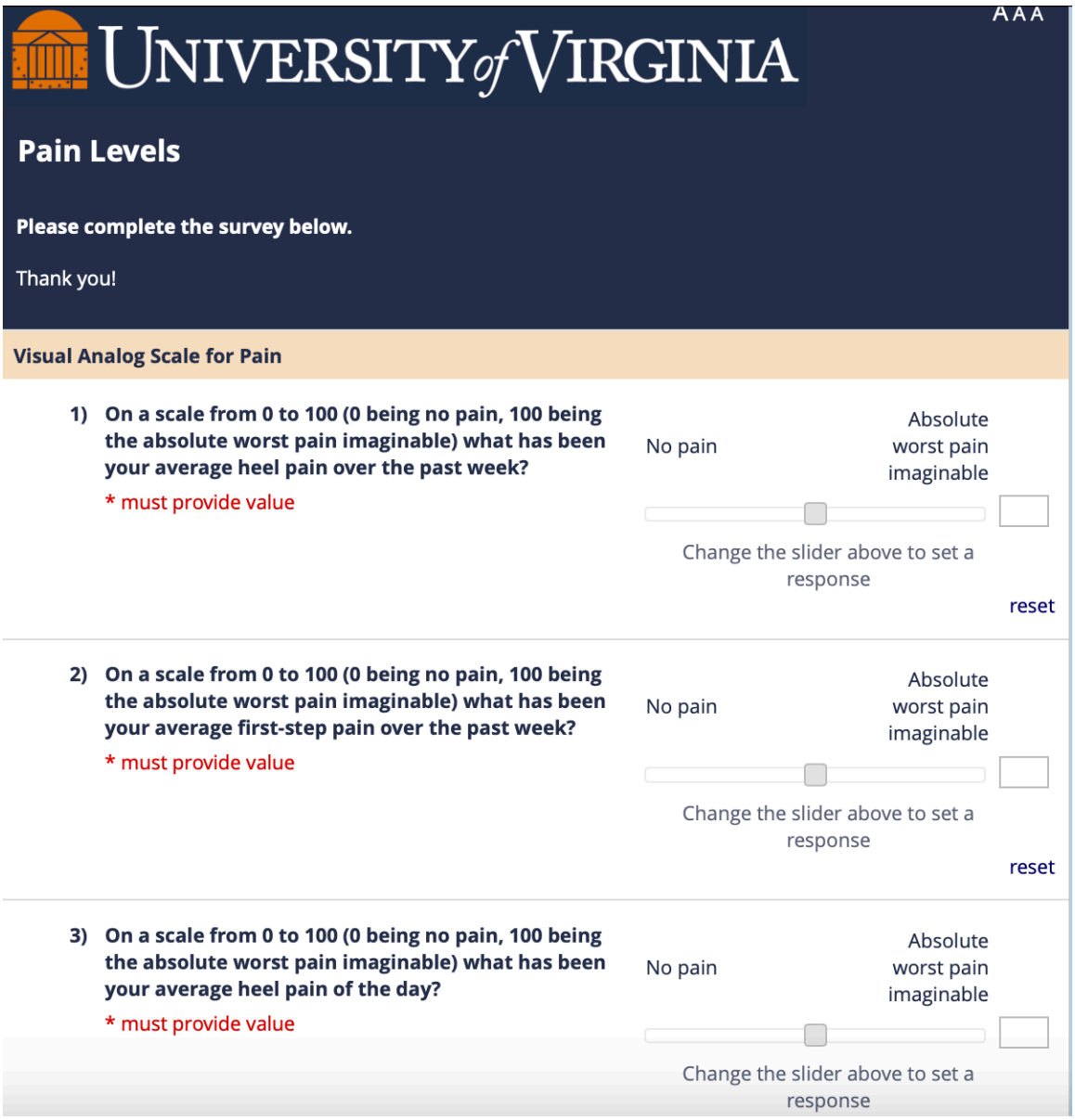


Table C3e – Global Rating of Change Questionnaire

Using the descriptions below, indicate your perception of overall recovery from the first time you began having pain until now.

◊ A very great deal worse	◊ About the same	◊ A very great deal better
◊ A great deal worse		◊ A great deal better
◊ Quite a bit worse		◊ Quite a bit better
◊ Moderately worse		◊ Moderately better
◊ Somewhat worse		◊ Somewhat better
◊ A little bit worse		◊ A little bit better
◊ A tiny bit worse		◊ A tiny bit better

Caption: For the 4-week and 8-week questionnaires, the question was “Using the descriptions below, indicate your perception of overall recovery from the first day of this study until now.”

Table C3f – Foot and Ankle Ability Measure

Please Answer every question with one response that most closely describes your condition within the past week. If the activity in question is limited by something other than your foot or ankle mark "Not Applicable" (N/A).

Because of your foot and ankle, how much difficulty do you have with:

	No difficulty	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do	N/A
Activities of Daily Living Subscale						
Standing	O	O	O	O	O	O
Walking on even ground	O	O	O	O	O	O
Walking on even ground without shoes	O	O	O	O	O	O
Walking up hills	O	O	O	O	O	O
Walking down hills	O	O	O	O	O	O
Going up stairs	O	O	O	O	O	O
Going down stairs	O	O	O	O	O	O
Stepping up and down curbs	O	O	O	O	O	O
Squatting	O	O	O	O	O	O
Coming up on your toes	O	O	O	O	O	O
Walking initially	O	O	O	O	O	O
Walking 5 minutes or less	O	O	O	O	O	O
Walking approximately 10 mins.	O	O	O	O	O	O
Walking 15 minutes or greater	O	O	O	O	O	O
Home responsibilities	O	O	O	O	O	O
Activities of daily living	O	O	O	O	O	O
Personal care	O	O	O	O	O	O
Light to moderate work (standing, walking)	O	O	O	O	O	O
Heavy work (push/pulling, climbing, carrying)	O	O	O	O	O	O
Recreational activities	O	O	O	O	O	O
Sports Subscale						
Running	O	O	O	O	O	O
Jumping	O	O	O	O	O	O

Starting & stopping quickly	O	O	O	O	O	O
Cutting/lateral movements	O	O	O	O	O	O
Ability to perform activity with normal technique	O	O	O	O	O	O
Ability to participate in your desired sport as long as you like	O	O	O	O	O	O

1. How would you rate your current level of function during your usual activities of daily living from 0 to 100? (with 100 being your level of function prior to your foot or ankle problem, and 0 being the inability to perform any of your usual daily activities).
    a. _____

2. How would you rate your current level of function during your sports-related activities, from 0 to 100? (with 100 being your level of function prior to your foot or ankle problem and 0 being the inability to perform any of your usual daily activities?
    a. _____

3. Overall, how would you rate your current level of function?
    a. Normal
    b. Nearly Normal
    c. Abnormal
    d. Severely Abnormal

Table C3g – Fear Avoidance Belief Questionnaire

Here are some things which other patients have told us about their pain. For each statement please indicate how much physical activities, such as bending, lifting, or driving, affect or would affect your pain.

	Completely disagree			Un-sure		Completely agree	
	0	1	2	3	4	5	6
My pain was caused by physical activity							
Physical activity makes my pain worse							
Physical activity might harm my foot							
I should not do physical activities which (might) make my pain worse							
I cannot do physical activities which (might) make my pain worse							
My pain is caused by work							
My work aggravated my pain							
My work is too heavy for me							
My work makes or would make my pain worse							
My work might harm my ankle							
I should not do normal work with my present pain							
I cannot do normal work with my present pain							
I cannot do normal work till my pain is treated							
I do not think that I will be back to normal work within 3 months							
I do not think that I will ever be able to go back to that work							

Table C3h – Tampa Scale of Kinesiophobia (TSK-11)

Rate the following items on a scale from 1 to 4. Options are:

1: Strongly disagree
2: Disagree
3: Agree
4: Strongly agree

1. I'm afraid that I might injure myself if I exercise	1	2	3	4
2. If I were to try to overcome it, my pain would increase	1	2	3	4
3. My body is telling me I have something dangerously wrong	1	2	3	4
4. People aren't taking my medical condition seriously enough	1	2	3	4
5. My accident has put my body at risk for the rest of my life	1	2	3	4
6. Pain always means I have injured my body	1	2	3	4
7. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening	1	2	3	4
8. I wouldn't have this much pain if there weren't something potentially dangerous going on in my body	1	2	3	4
9. Pain lets me know when to stop exercising so that I don't injure myself	1	2	3	4
10. I can't do all the things normal people do because it's too easy for me to get injured	1	2	3	4
11. No one should have to exercise when he/she is in pain	1	2	3	4

Table C3i – Pain Self-Efficacy Questionnaire

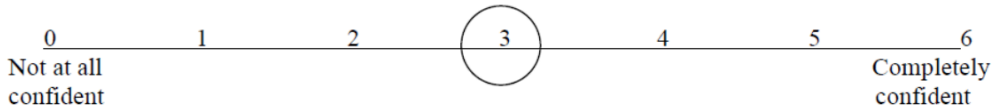
PAIN S-E QUESTIONNAIRE (PSEQ)

Nicholas (1989)

NAME: _____ DATE: _____

Please rate how **confident** you are that you can do the following things at present, **despite the pain**. To indicate your answer circle one of the numbers on the scale under each item, where 0 = not at all confident and 6 = completely confident.

For example:



Remember, this questionnaire is not asking whether or not your have been doing these things, but rather **how confident you are that you can do them at present, despite the pain.**

	Not at all confident						Completely confident
1. I can enjoy things, despite the pain	0	1	2	3	4	5	6
2. I can do most of the household chores (e.g. tidying -up, washing dishes, etc.), despite the pain	0	1	2	3	4	5	6
3. I can socialise with my friends or family members as often as I used to do, despite the pain.	0	1	2	3	4	5	6
4. I can cope with my pain in most situations	0	1	2	3	4	5	6
5. I can do some form of work, despite the pain. ("work" includes housework, paid and unpaid)	0	1	2	3	4	5	6
6. I can still do many of the things I enjoy doing, such as hobbies or leisure activities, despite the pain	0	1	2	3	4	5	6
7. I can cope with my pain without medication.	0	1	2	3	4	5	6
8. I can still accomplish most of my goals in life, despite the pain	0	1	2	3	4	5	6
9. I can live a normal lifestyle, despite the pain	0	1	2	3	4	5	6
10. I can gradually become more active, despite the pain	0	1	2	3	4	5	6

Table C3j – NASA Activity Survey Scale

Appendix NASA activity scale (NAS)

Code for physical activity status

Select the appropriate number (0–10) in the space for physical activity code according to which of the following best describes your activity level for the previous month:

Do not exercise regularly, ie

0 — Avoid walking or exertion, eg always use elevator, drive whenever possible instead of walking.

1 — Walk for pleasure, routinely use stairs, occasionally exercise sufficiently to cause heavy breathing or perspiration.

Participate regularly in recreation or work requiring modest physical activity, such as golf, horseback riding, calisthenics, table tennis, bowling, weight-lifting or yard work.

2 — 10–60 min per week.

3 — Over 1 h per week.

Participate regularly in heavy physical exercise, eg, running or a comparable activity such as brisk walking, indoor biking, swimming, cycling, rowing, skipping rope, running in place, or engaging in vigorous aerobic exercise such as tennis, basketball, or handball.

4 — Run less than 1 mile per week or walk less than 1.3 miles per week or spend less than 30 min per week in comparable physical activity.

5 — Run 1–5 miles per week or walk 1.3–6.9 miles per week or spend 30–60 min per week in comparable physical activity.

6 — Run 6–10 miles per week or walk 7–13.9 miles per week or spend 1–3 h per week in comparable physical activity.

7 — Run 11–15 miles per week or walk 14–20 miles per week or spend 4–6 h per week in comparable physical activity.

8 — Run 16–20 miles per week or walk 21–26.9 miles per week or spend 7–9 h per week in comparable physical activity.

9 — Run 21–25 miles per week or walk 27–33.9 miles per week or spend 10–12 h per week in comparable physical activity.

10 — Run over 25 miles per week or walk over 34 miles per week or spend over 12 h per week in comparable physical activity.

Table C3k – Final Questions at Post-Test

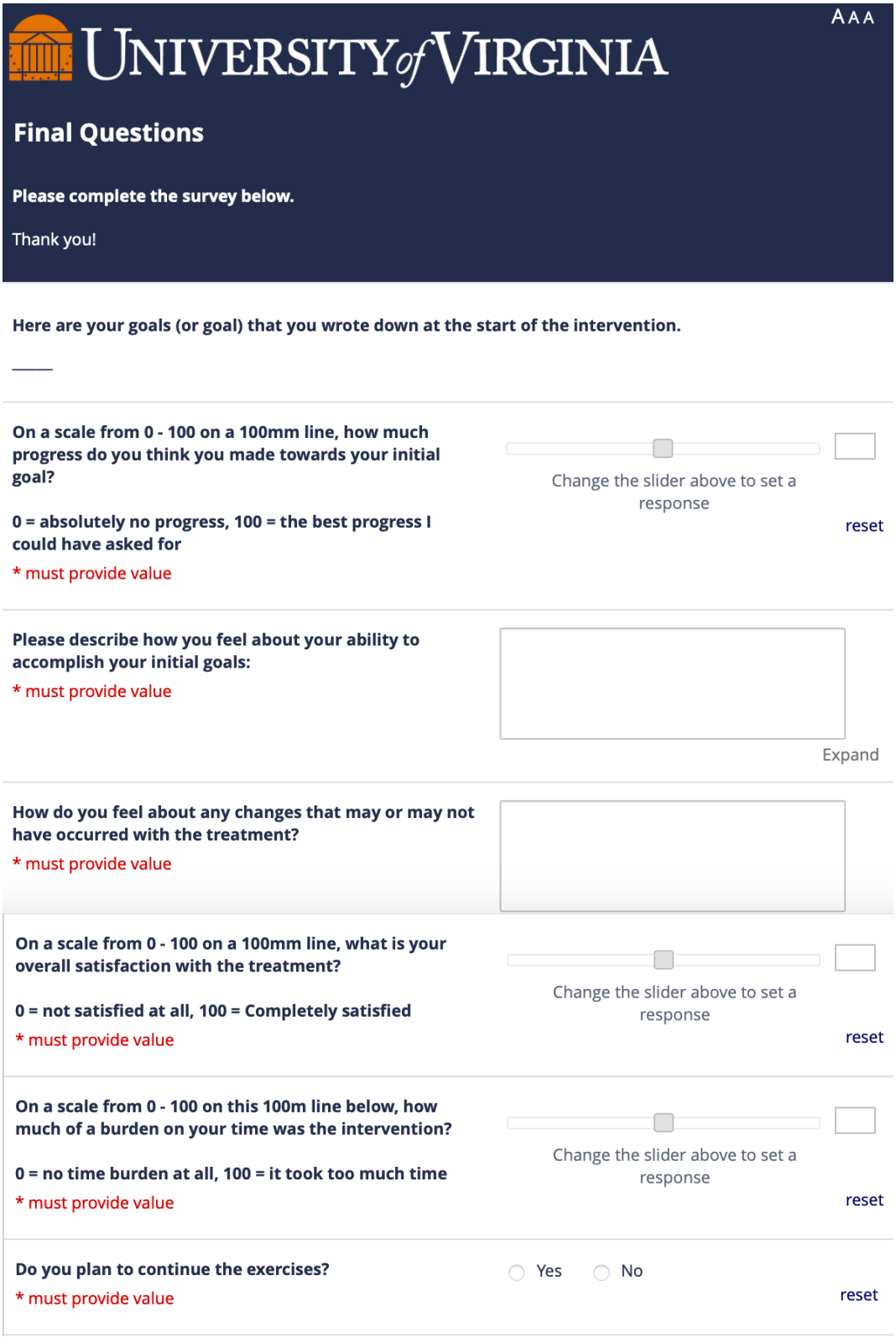


Table C31 – Final Questions 2-months Post-Test

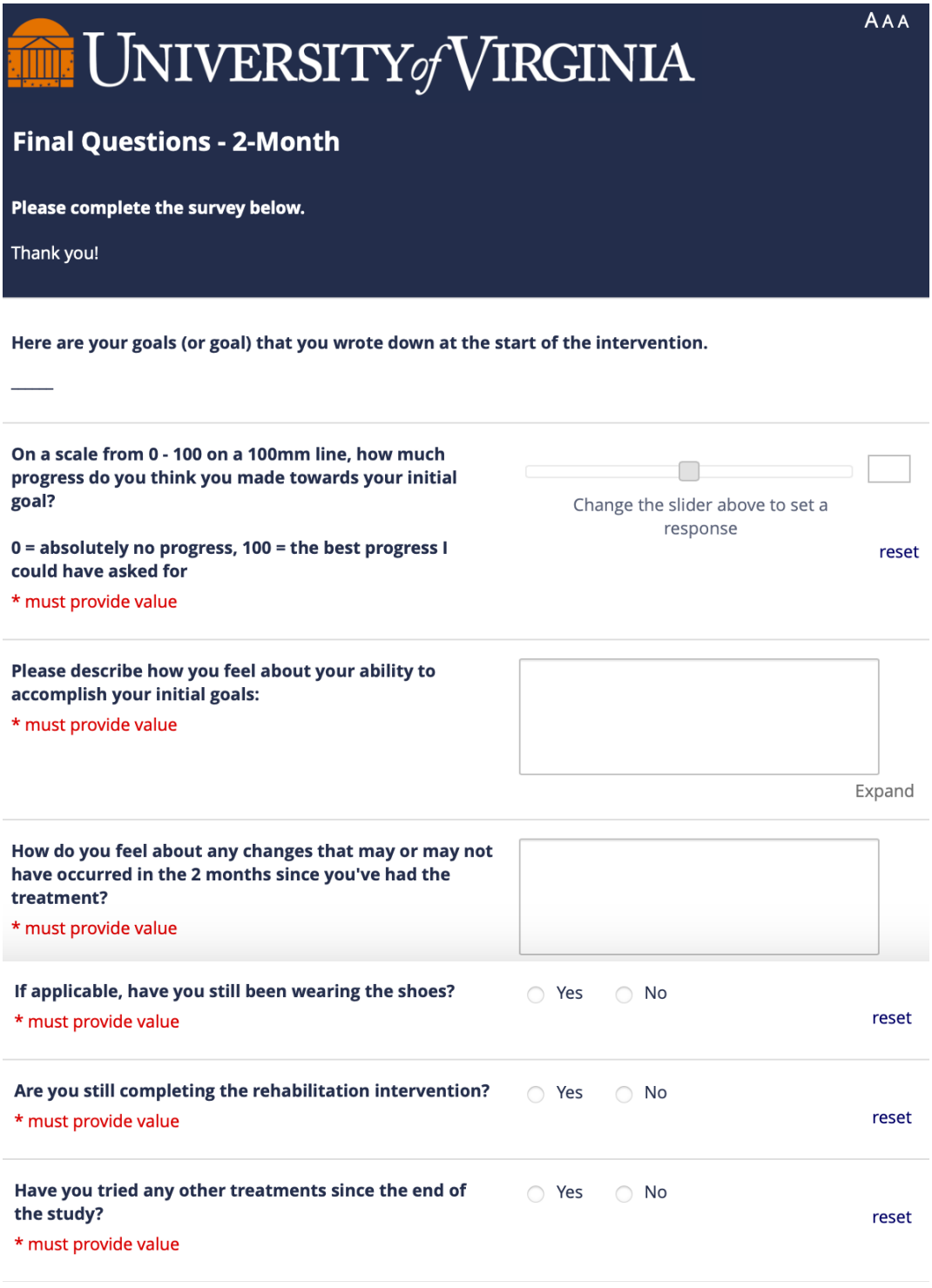


Table C4a. Instrumentation & Procedures – Foot Posture Index Information & Reference Sheets

THE FOOT POSTURE INDEX©
FPI-6

Reference Sheet

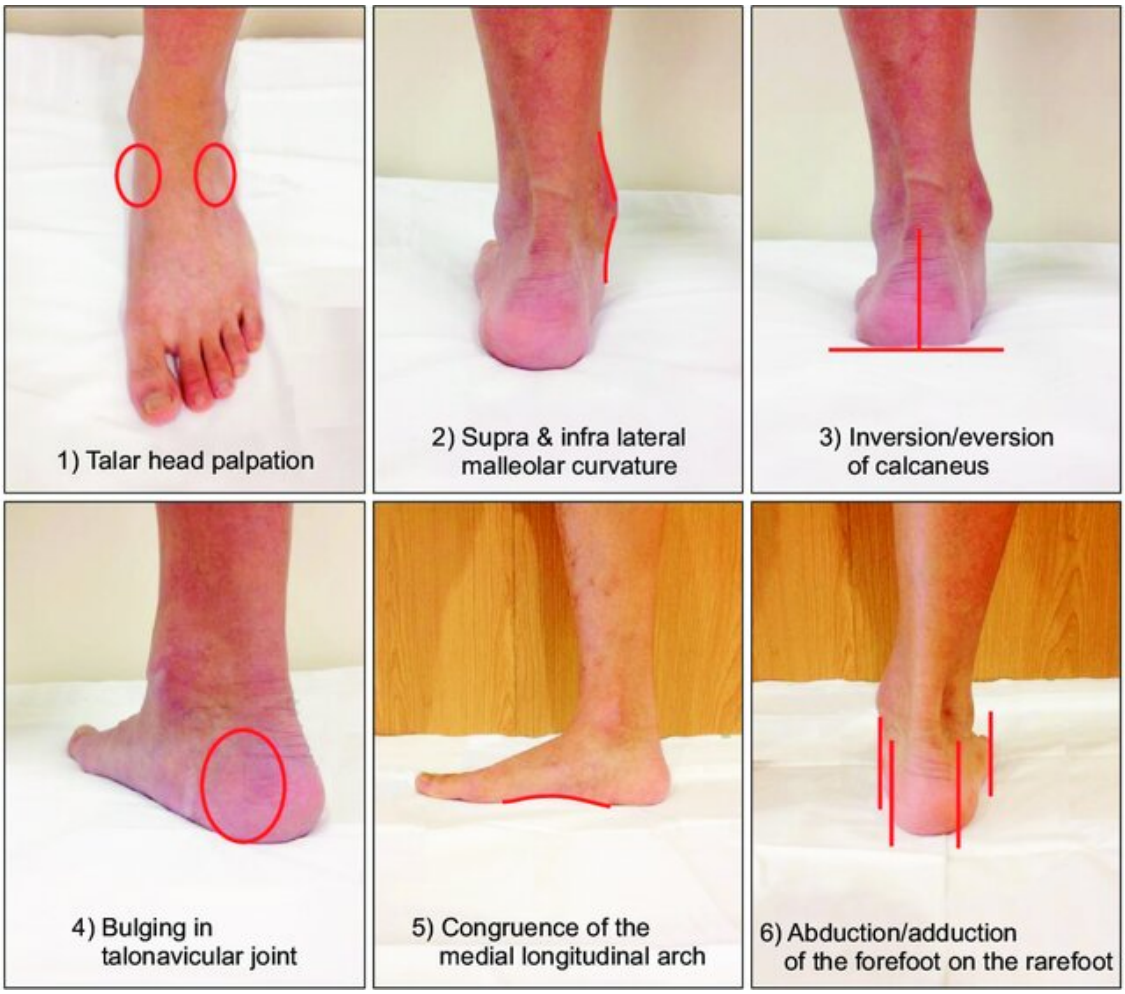
The patient should stand in their relaxed stance position with double limb support. The patient should be instructed to stand still, with their arms by the side and looking straight ahead. It may be helpful to ask the patient to take several steps, marching on the spot, prior to settling into a comfortable stance position. During the assessment, it is important to ensure that the patient does not swivel to try to see what is happening for themself, as this will significantly affect the foot posture. The patient will need to stand still for approximately two minutes in total in order for the assessment to be conducted. The assessor needs to be able to move around the patient during the assessment and to have uninterrupted access to the posterior aspect of the leg and foot.

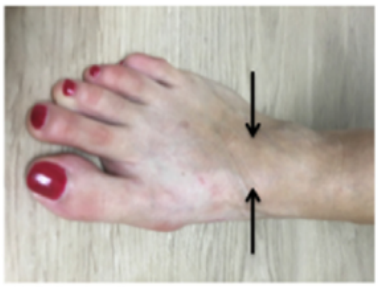
If an observation cannot be made (e.g. because of soft tissue swelling) simply miss it out and indicate on the datasheet that the item was not scored.

If there is genuine doubt about how high or low to score an item always use the more conservative score.

Rearfoot Score	**-2**	**-1**	**0**	**1**	**2**
Talar head palpation	Talar head palpable on lateral side/but not on medial side	Talar head palpable on lateral side/slightly palpable on medial side	Talar head equally palpable on lateral and medial side	Talar head slightly palpable on lateral side/ palpable on medial side	Talar head not palpable on lateral side/ but palpable on medial side
Curves above and below the malleoli	Curve below the malleolus either straight or convex	Curve below the malleolus concave, but flatter/ more shallow than the curve above the malleolus	Both infra and supra malleolar curves roughly equal	Curve below malleolus more concave than curve above malleolus	Curve below malleolus markedly more concave than curve above malleolus
Calcaneal inversion/eversion	More than an estimated 5° inverted (varus)	Between vertical and an estimated 5° inverted (varus)	Vertical	Between vertical and an estimated 5° everted (valgus)	More than an estimated 5° everted (valgus)
Forefoot Score	**-2**	**-1**	**0**	**1**	**2**
Talo-navicular congruence	Area of TNJ markedly concave	Area of TNJ slightly, but definitely concave	Area of TNJ flat	Area of TNJ bulging slightly	Area of TNJ bulging markedly
Medial arch height	Arch high and acutely angled towards the posterior end of the medial arch	Arch moderately high and slightly acute posteriorly	Arch height normal and concentrically curved	Arch lowered with some flattening in the central portion	Arch very low with severe flattening in the central portion – arch making ground contact
Forefoot abd/adduction	No lateral toes visible. Medial toes clearly visible	Medial toes clearly more visible than lateral	Medial and lateral toes equally visible	Lateral toes clearly more visible than medial	No medial toes visible. Lateral toes clearly visible

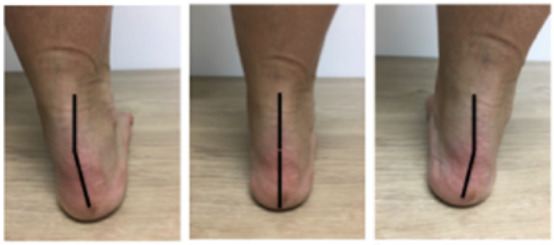
For further information, manuals and extra datasheets see: www.leeds.ac.uk/medicine/FASTER/FPI/


1) Talar head palpation
2) Supra & infra lateral malleolar curvature
3) Inversion/eversion of calcaneus
4) Bulging in talonavicular joint
5) Congruence of the medial longitudinal arch
6) Abduction/adduction of the forefoot on the rarefoot

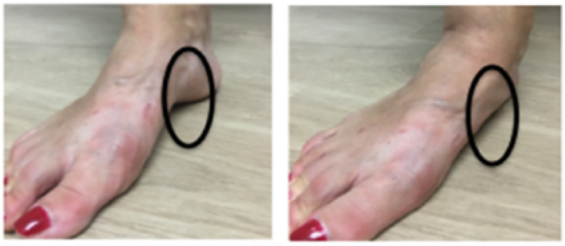


FPI 1. Talar head palpation

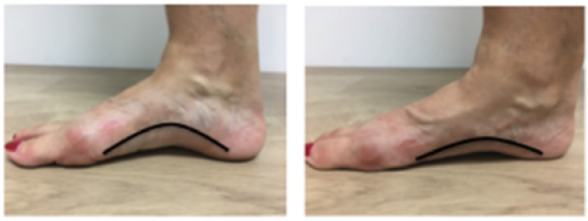
FPI 2. Supra and infra lateral malleolar curvature



FPI 3. Calcaneal inversion/eversion



FPI 4. Prominence of the Talo Navicular joint

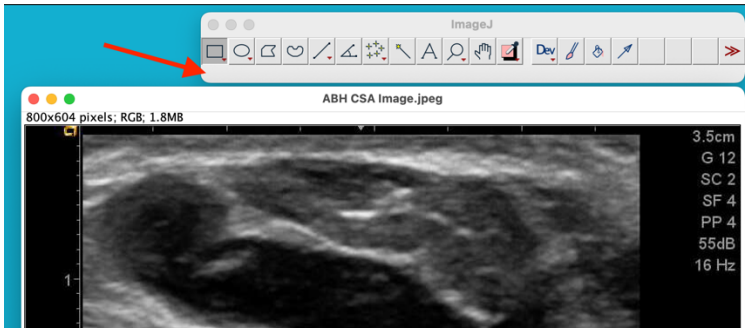


FPI 5. Congruence of the internal longitudinal arch

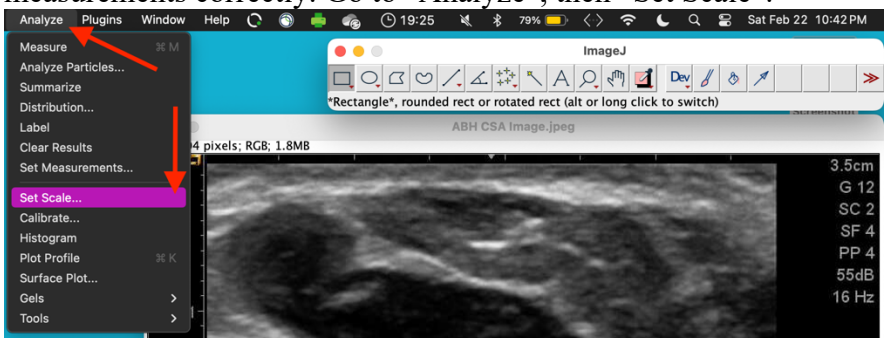
FPI 6. Abduction/aduction of thr forefoot with respect to the rear foot

Table C4b. Ultrasound Image Measurement

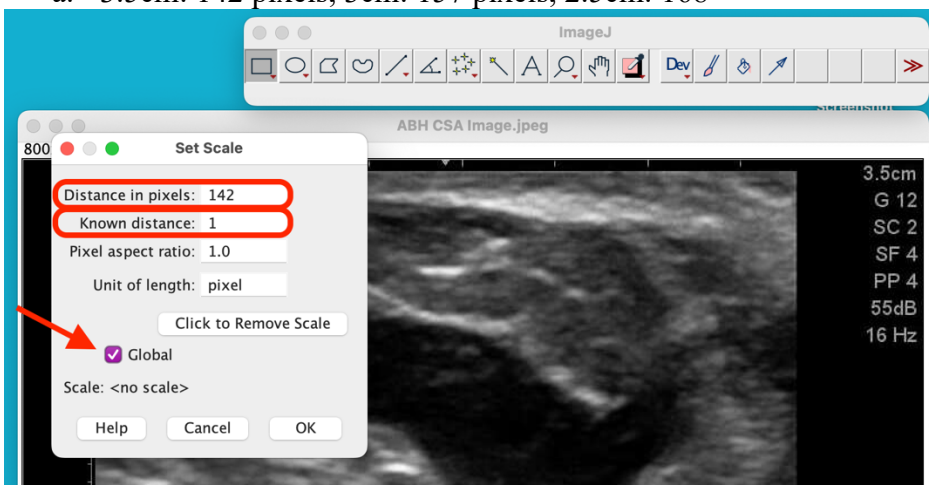
1. Open ImageJ and open the image to measure by dragging it into the top taskbar as shown here.



2. Before measuring the image, the scale needs to be set in order to provide measurements correctly. Go to "Analyze", then "Set Scale".

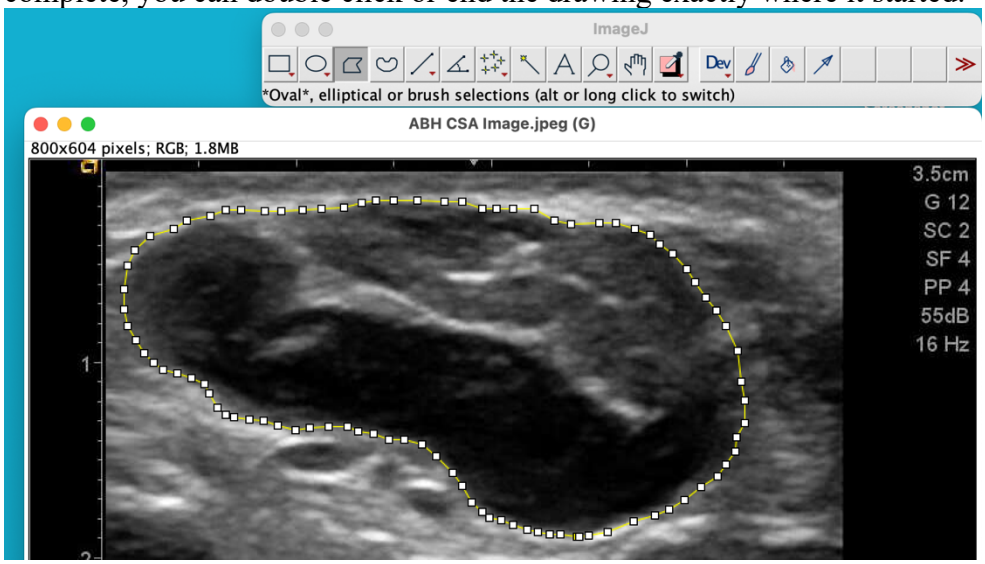


3. In this window, change the "Distance in pixels" to the appropriate number according to the list below. Change "Known distance" to 1, and select the "Global" box to apply this setting to all subsequent images in the present session.
    a. 3.5cm: 142 pixels, 3cm: 157 pixels, 2.5cm: 168

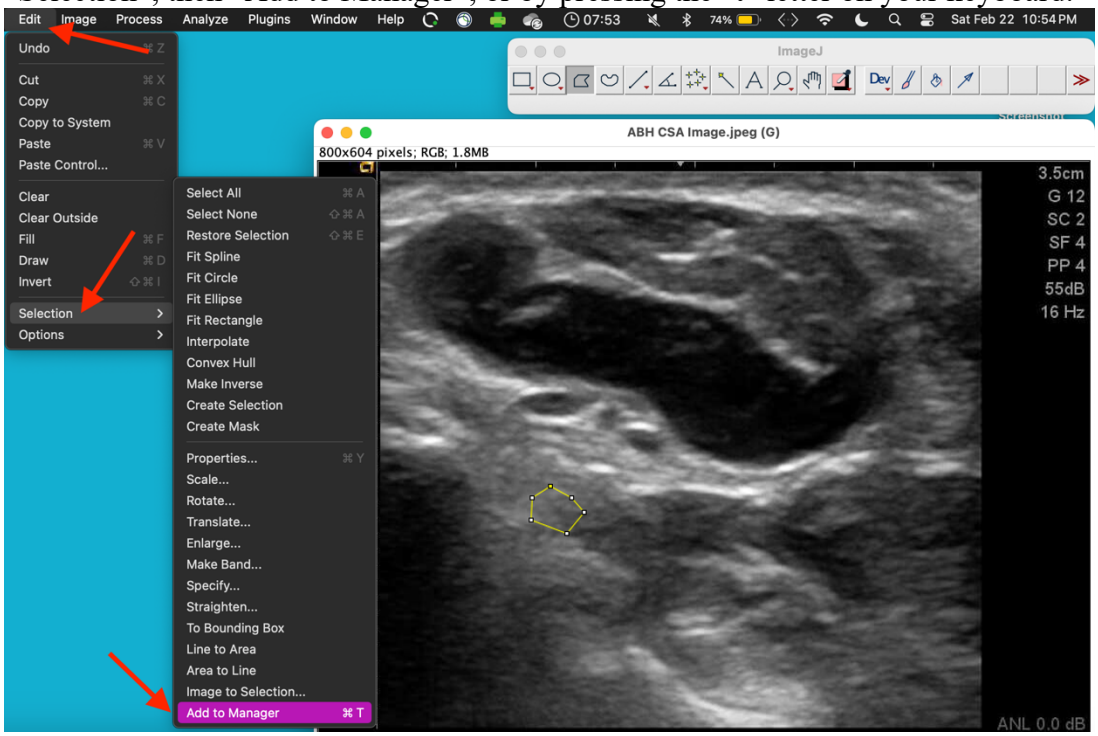


4. To measure cross-sectional area, select the polygon tool, indicated with an arrow in this picture below.

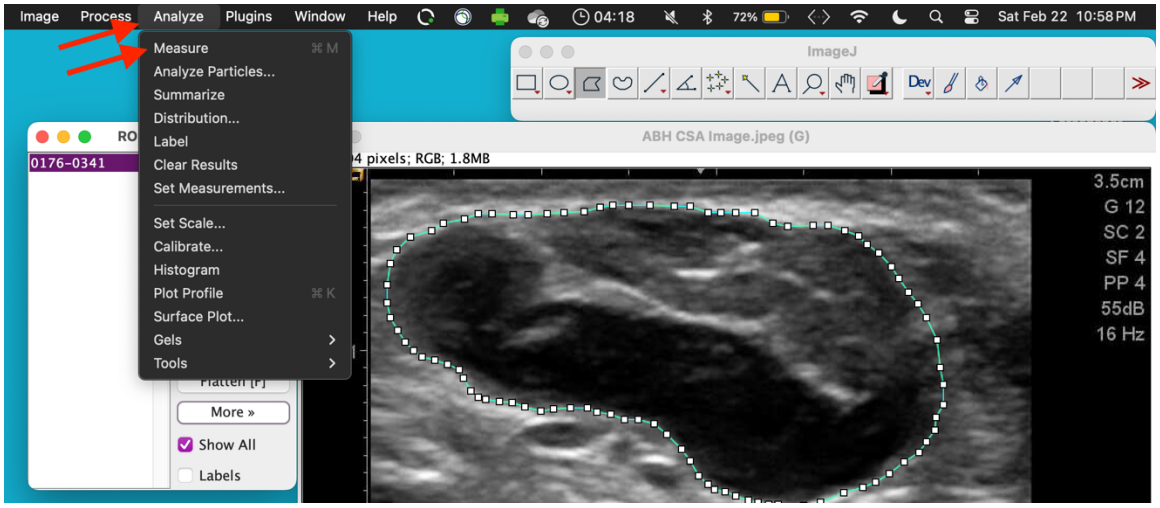
5. Identify the border of the muscle, and begin drawing along the border. Once it is complete, you can double click or end the drawing exactly where it started.



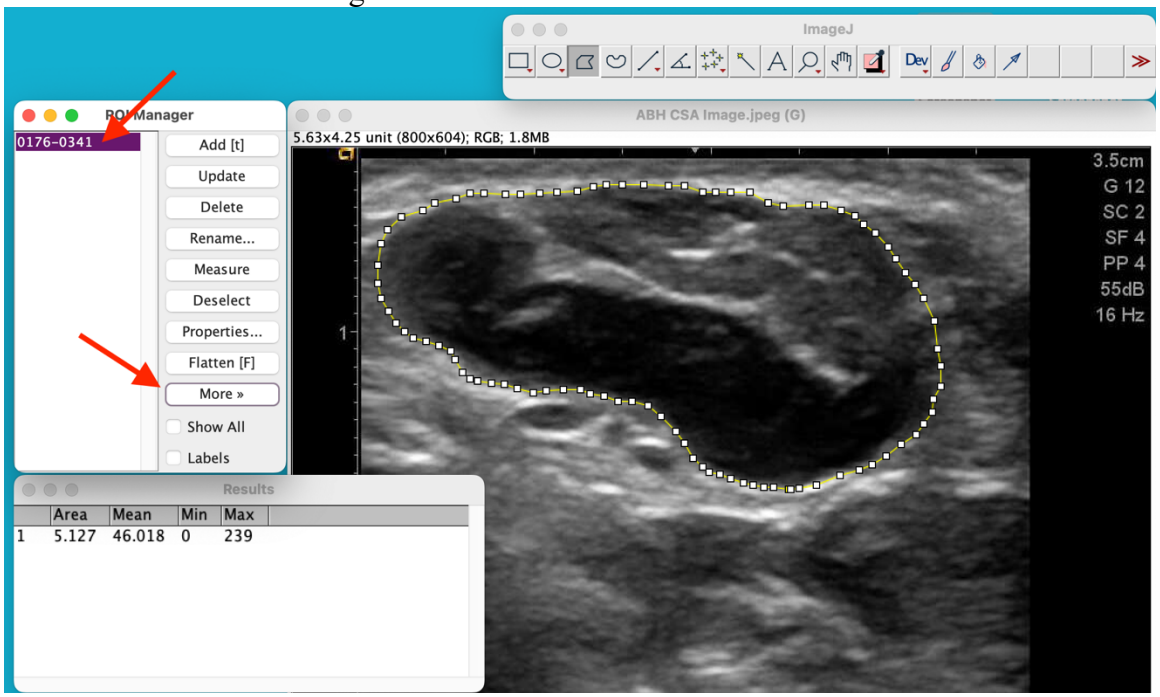
6. Once complete, add the drawn line to the "ROI manager" by going to "Edit", "Selection", then "Add to Manager", or by pressing the "t" letter on your keyboard.



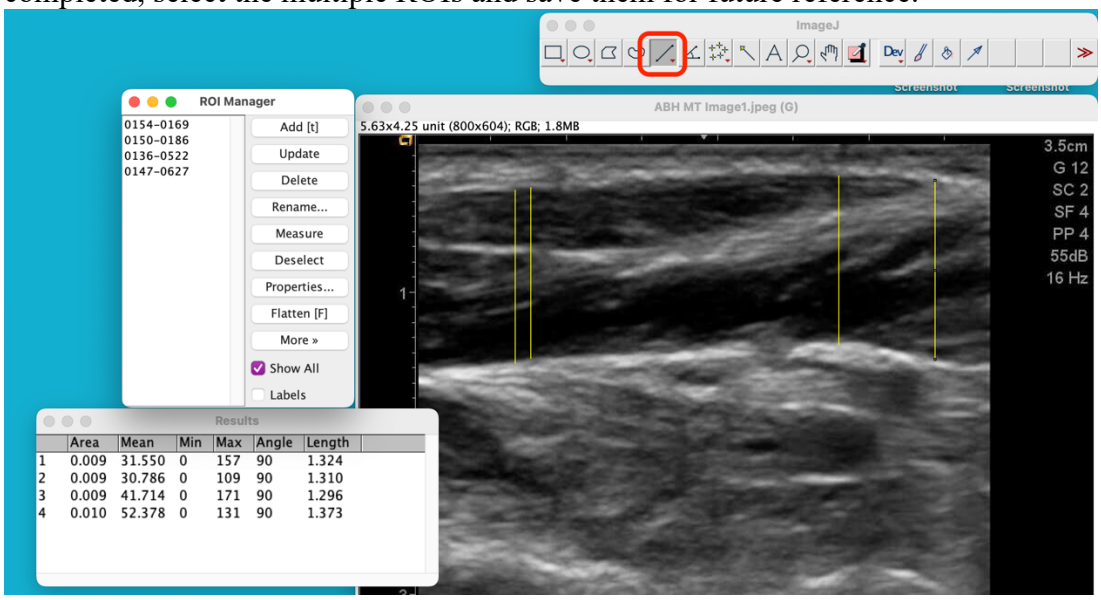
7. Measure the drawn line by going to “Analyze”, then “Measure”, or by pressing the “m” letter on your keyboard. The measurement will be under “Area” in the pop-up box.



8. Save the ROI in order to reference later. Return to the ROI manager box and select the ROI that you would like to save. Select “More”, and “Save” in the pop-up window. Save it as the image name.roi.



9. To measure muscle thickness, select the line drawing tool, circled here in red. Determine the muscle borders, and try to find the thickest point in the muscle. When found, draw a line from one border to the other. Perform the muscle thickness measurement at least 3 times to try and get the thickest point in the muscle, but add the line to the ROI manager after each measurement. Once the measurements are completed, select the multiple ROIs and save them for future reference.



Other measurement and border locations for muscles are within Manuscript II.

Table C4c. Instrumentation & Procedures – Data Collection Sheet

FRAMES Study Sheet

Demographics					
Participant #					
Date (MM/DD/YYYY):					
Time Point (circle one):		Baseline		Post-Intervention	
Involved Limb:		Right		Left	
PF Image #s:		**PF Thickness**			

Age (years):	**Height (cm):**	**Weight (kg):**	**Shoe size (athletic):**

Patient Reported Outcomes & Questionnaires:

- ☐ Health History Questionnaire
- ☐ Pain Levels
- ☐ Foot Health Status Questionnaire (FHSQ)
- ☐ Tampa Scale of Kinesiophobia (TSK)
- ☐ Fear-Avoidance Belief Questionnaire (FABQ)
- ☐ Pain Self-Efficacy Questionnaire (PSEQ)
- ☐ NASA Activity Questionnaire

Foot Morphology				
	Seated		**Standing**	
	Left	Right	Left	Right
Foot length (cm):				
Foot width (cm):				
Arch Height @ 50% length (cm):				
Foot girth @ 50% length (cm):				

Foot Posture Index (FPI)										
	Left					**Right**				
Talar head palpation	-2	-1	0	+1	+2	-2	-1	0	+1	+2
Supra/infra-lateral malleoli curve (behind)	-2	-1	0	+1	+2	-2	-1	0	+1	+2
Calcaneal frontal plane position (behind)	-2	-1	0	+1	+2	-2	-1	0	+1	+2
Prominence in **talonavicular joint** region (inside)	-2	-1	0	+1	+2	-2	-1	0	+1	+2
Congruence of **medial longitudinal arch** (inside)	-2	-1	0	+1	+2	-2	-1	0	+1	+2
Abduction/adduction of forefoot on rearfoot	-2	-1	0	+1	+2	-2	-1	0	+1	+2

Ultrasound Intrinsic Foot Muscle Activation					
Abductor Hallucis		**Thickness 1**	**Thickness 2**	**Thickness 3**	**CSA**
	Resting				
	Resisted				
Flexor Hallucis Brevis		**Thickness 1**	**Thickness 2**	**Thickness 3**	**CSA**
	Resting				
	Resisted				
FDB/QP		**Thickness 1**	**Thickness 2**	**Thickness 3**	**CSA**
	Resting				
	Resisted				

Toe Strength: Handheld Dynamometer				
Condition	**Trial 1 (kg)**	**Trial 2 (kg)**	**Trial 3 (kg)**	**Trial 4 (kg)**

Toe Strength on Novel Toe Dynamometer				
Condition	**Trial 1 (kg)**	**Trial 2 (kg)**	**Trial 3 (kg)**	**Trial 4 (kg)**

Conditions: 1 = great toe R foot, 2 = lesser toes R foot, 3 = great toe L foot, 4 = lesser toes L foot

Static Balance

Coordinate on Force Plate			
-X	**+X**	**-Y**	**+Y**

Eyes Open:

	Success	**Reason Failed**			
		Non-testing limb touch down		Testing limb off the force platform	Hands came off hips
		Front/back	Side		
Trial 1					
Trial 2					
Trial 3					
Trial 4					
Trial 5					
Trial 6					
Trial 7					
Trial 8					
Trial 9					
Trial 10					

Eyes Closed:

	Success	**Reason Failed**				
		Non-testing limb touch down		Testing limb off force platform	Eyes opened	Hands came off hips
		Front/back	Side			
Trial 1						
Trial 2						
Trial 3						
Trial 4						
Trial 5						
Trial 6						
Trial 7						
Trial 8						
Trial 9						
Trial 10						

LoadSol: Treadmill Conventional Shoes			
LoadSol size & color			
Baseline Self-Selected Speed		**(Post Intervention Self-Selected Speed)**	
Trial 1: Completed	Baseline	Post-Intervention	(Post-Intervention)
Trial 2: Completed	Baseline	Post-Intervention	(Post-Intervention)
Trial 3: Completed	Baseline	Post-Intervention	(Post-Intervention)
Trial 4: Completed	Baseline	Post-Intervention	(Post-Intervention)

LoadSol: Overground Conventional Shoes		
Trial 1: Completed?	Baseline	Post-Intervention
Trial 2: Completed?	Baseline	Post-Intervention
Trial 3: Completed?	Baseline	Post-Intervention

LoadSol: Treadmill Minimalist Shoes	
LoadSol Size and color	
Self-Selected Speed	
Trial 1: Completed	Post-Intervention
Trail 2: Completed	Post-Intervention
Trial 3: Completed	Post-Intervention
Trial 4: Completed	Post-Intervention

LoadSol: Over Ground Minimalist Shoes	
Trail 1: Completed	Post-Intervention
Trail 2: Completed	Post-Intervention
Trial 3: Completed	Post-Intervention

Minimalist Shoe Index: for their conventional shoe on involved limb						
Weight (g)		Online:	**Brand/model**			
Heel Thickness (mm)		Online:	**Heel-to-toe drop (mm)**		Online:	
Toe Thickness (mm)		Online:				
Motion Control and Stability Technologies	A	Multi-density midsole: Typically, a different color emphasizes this feature.				
	B	Thermoplastic medial post. Plastic reinforces medial portion of midsole.				
	C	Rigid heel counter				
	D	Elevated medial insole under arch (left), compared with a flat insole (right).				
	E	Supportive tensioned medial upper - limit medial foot movement				
	F	Medial flare. Medial tip of midsole extends beyond footbed.				
Longitudinal Flexibility	5	Minimal resistance to longitudinal bending				
	4	Slight resistance to longitudinal bending				
	3	Moderate resistance to longitudinal bending				
	2	High resistance to longitudinal bending				
	1	Very high resistance to longitudinal bending				
	0	Extreme resistance to longitudinal bending				
Torsional Flexibility	5	Minimal resistance to torsion				
	4	Slight resistance to torsion				
	3	Moderate resistance to torsion				
	2	High resistance to torsion				
	1	Very high resistance to torsion				
	0	Extreme resistance to torsion				

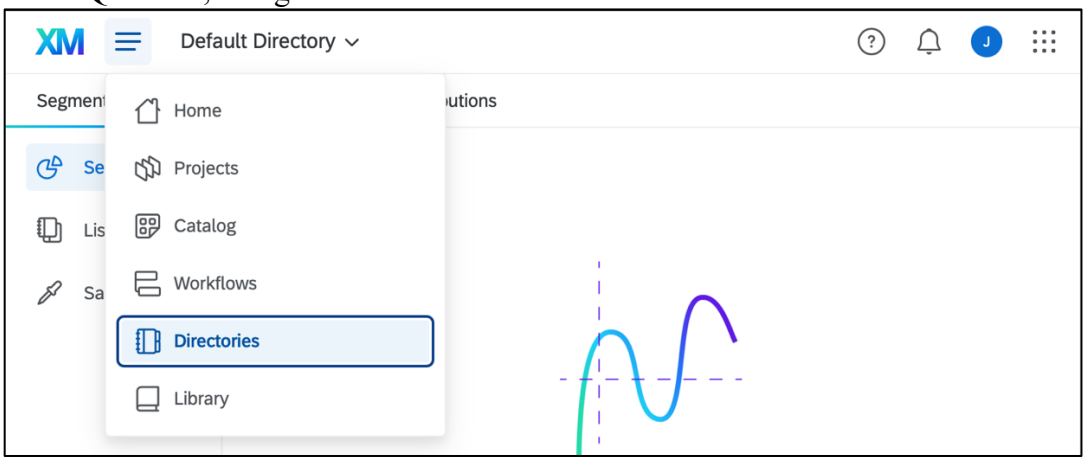
Fitbit Information	
Registration: Completed	Yes No
Email used	

Daily Survey	
Registration: Completed	Yes No

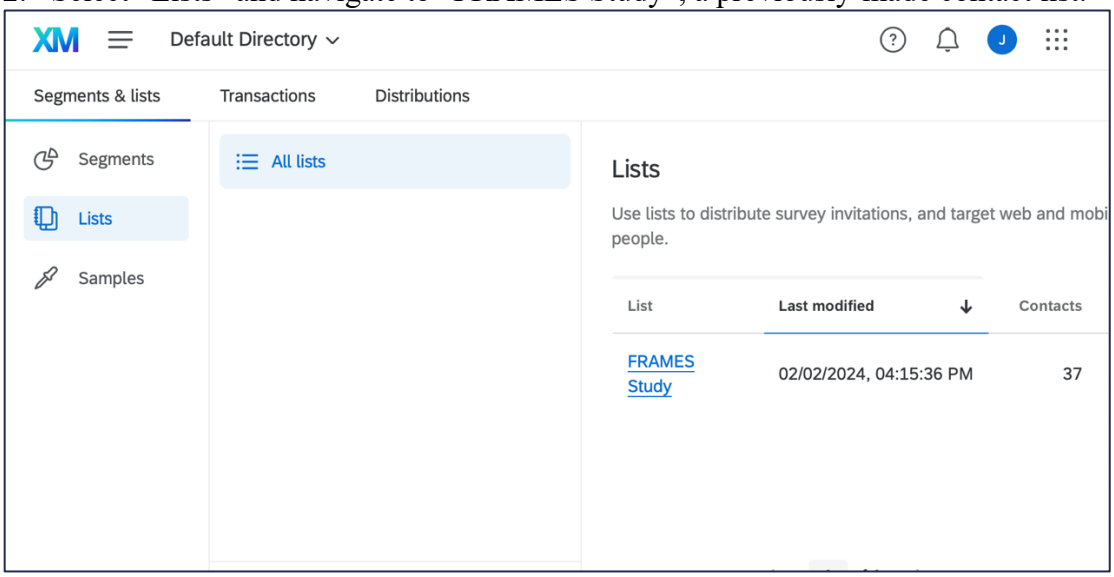
Table C5a. Study Protocol Adherence Assessments Setup

Note: Qualtrics at UVA opened permission to use the Text Message (SMS) distribution method specifically for this study. This must be enabled to work.

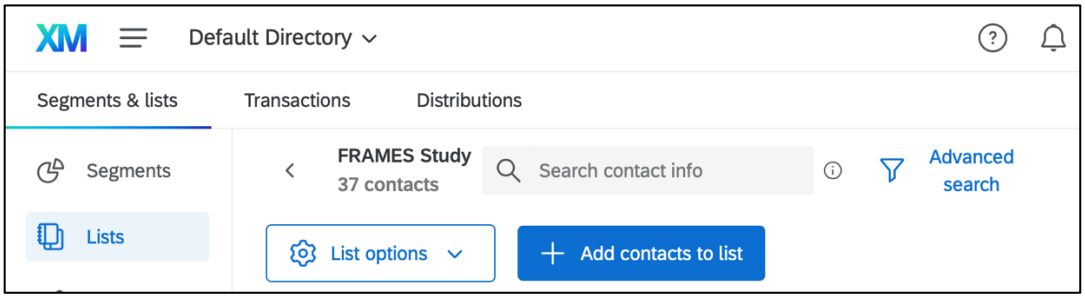
1. In Qualtrics, navigate to Directories.



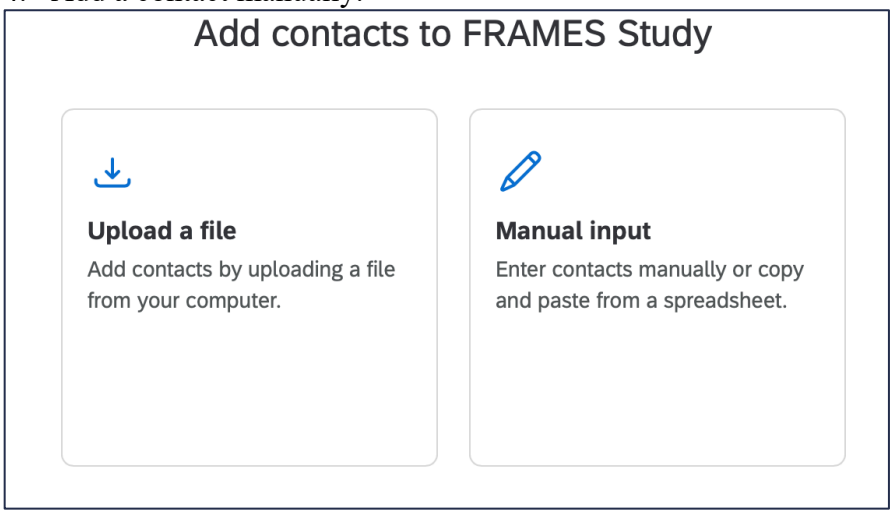
2. Select “Lists” and navigate to “FRAMES Study”, a previously-made contact list.



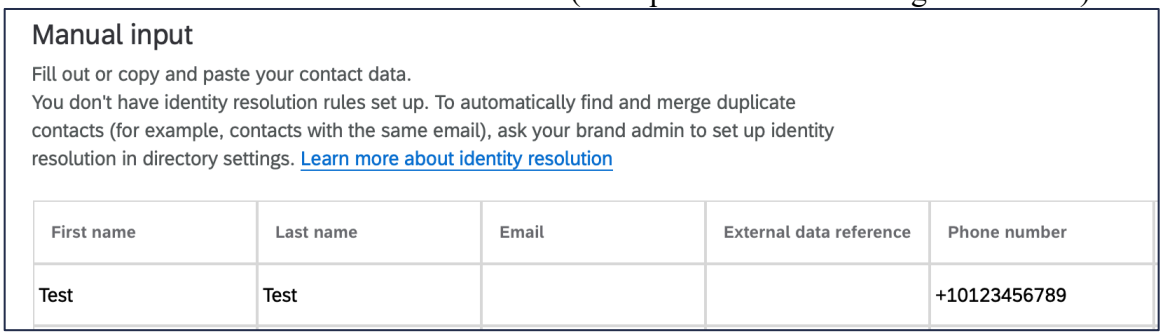
3. Click “+ Add contacts to list”



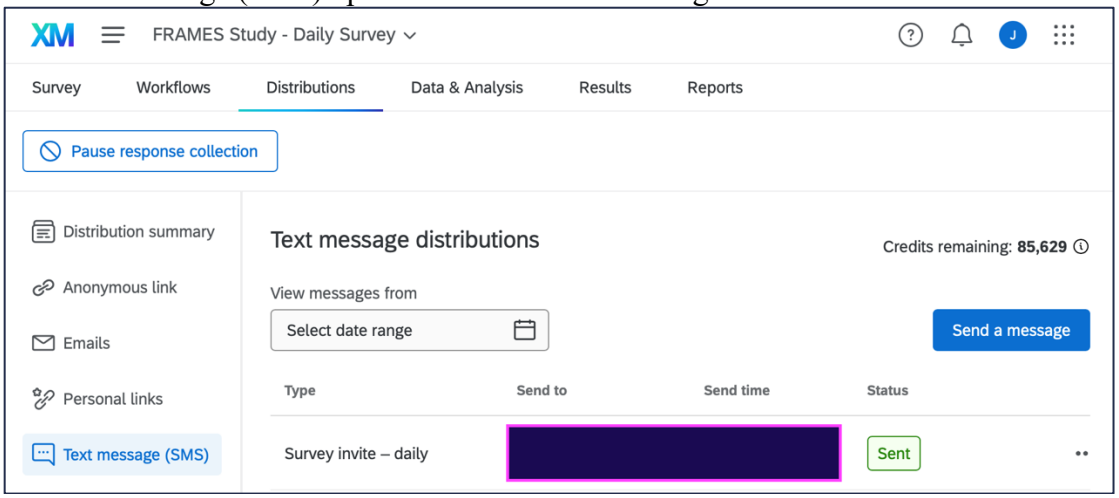
4. Add a contact manually.



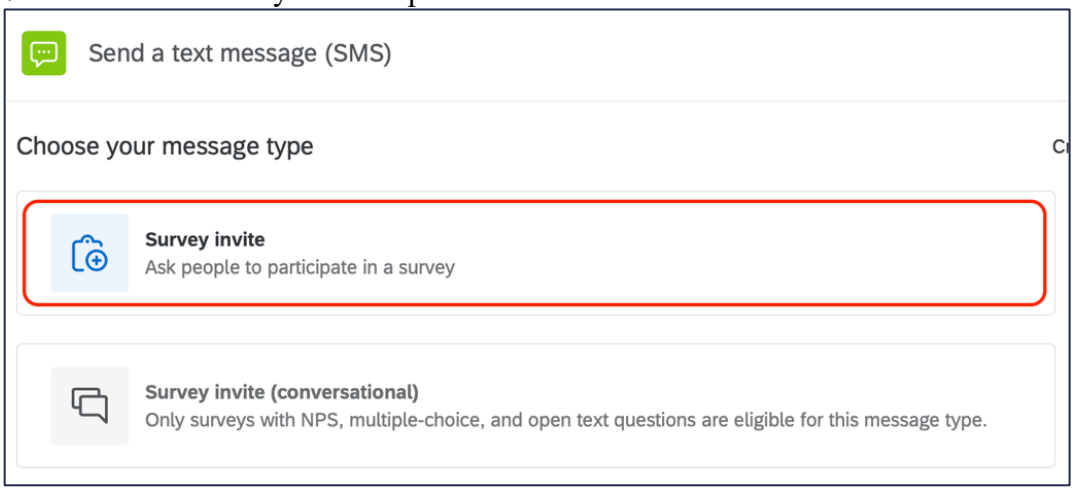
5. Add subject id to First name and Last name, and add phone number WITH country code – must be added or it will not send (example is a random string of numbers).



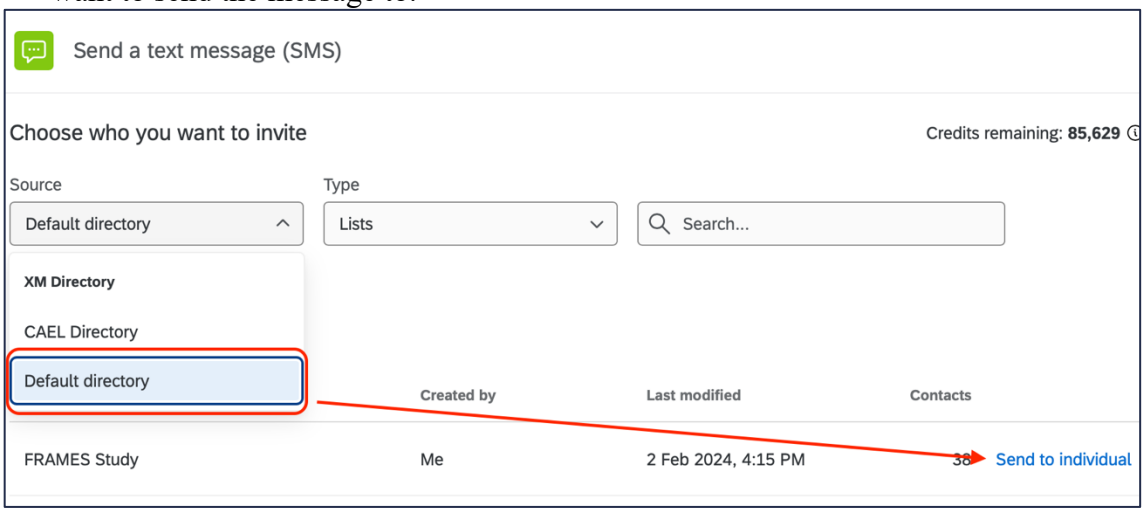
6. Navigate back to the survey page, to the "Distribution" tab at the top and select the Text Message (SMS) option. Click "Send a message".



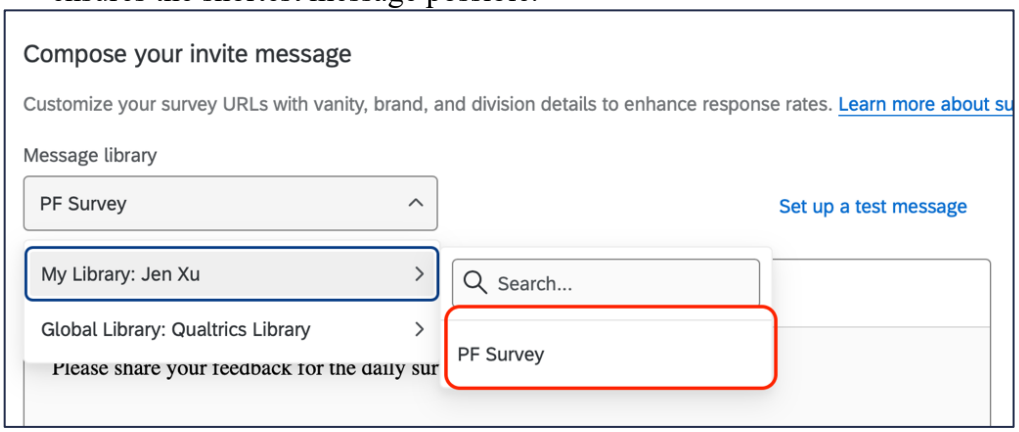
7. Select the “Survey invite” option.



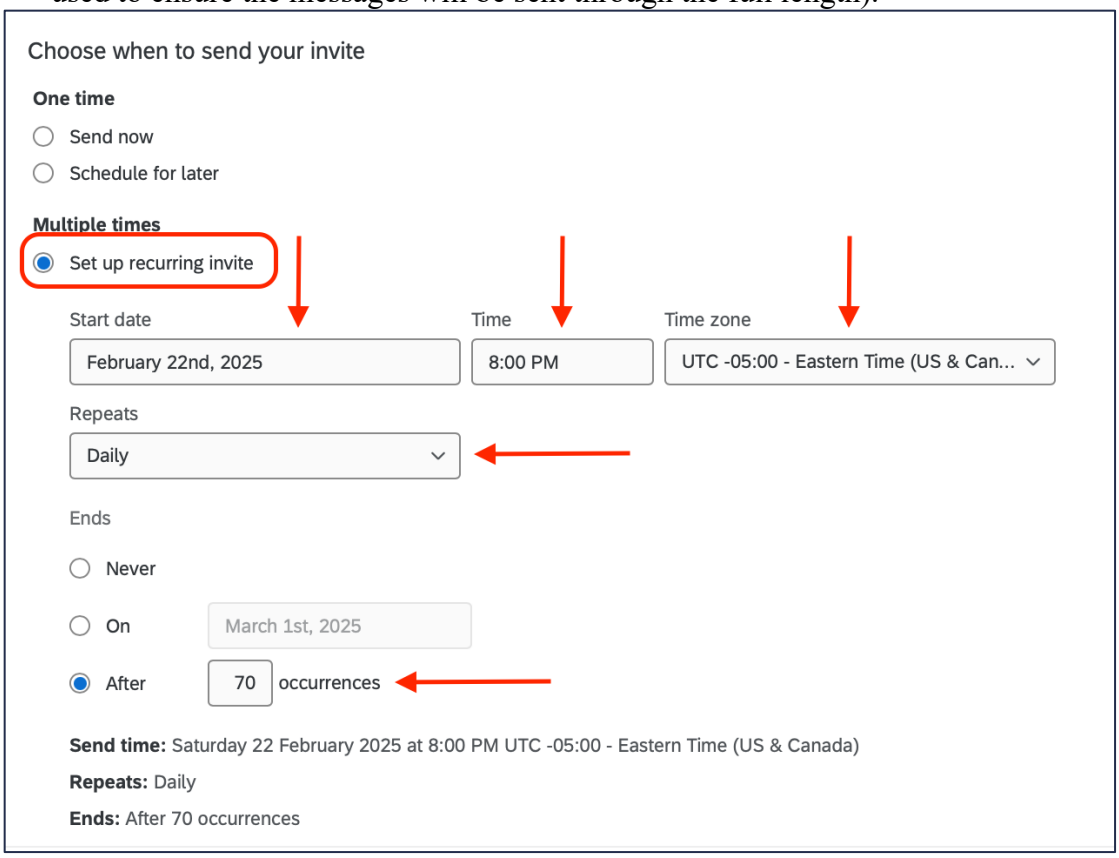
8. In the default directory, click “Send to individual”. Select the individual who you want to send the message to.



9. In the message library, select the PF Survey. Credits are used up by character so this ensures the shortest message possible.



10. Set up a recurring invite. Select the date, time, and time zone. The individual should pick a time that is convenient for them to receive and answer the text. The text should repeat daily, and end after 70 occurrences (the intervention is 56 days long, but 70 is used to ensure the messages will be sent through the full length).



11. Review the details of the invite in the next page. Click “Schedule”, and you will be brought back to the main home page.

12. To export the data as an Excel sheet, navigate to “Data & Analysis” and click “Export & Import”. Export/Download as a CSV.

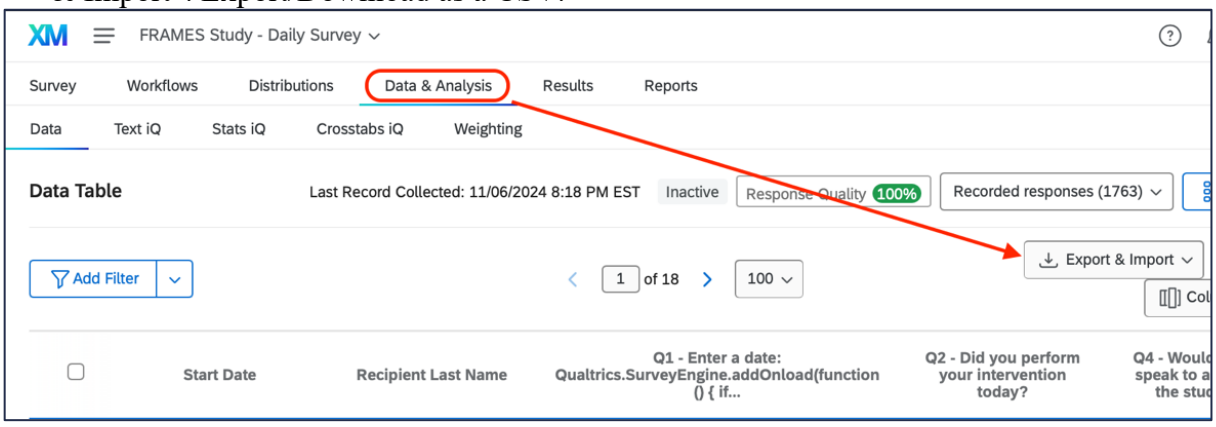


Table C5b. Protocol Adherence Survey Questions

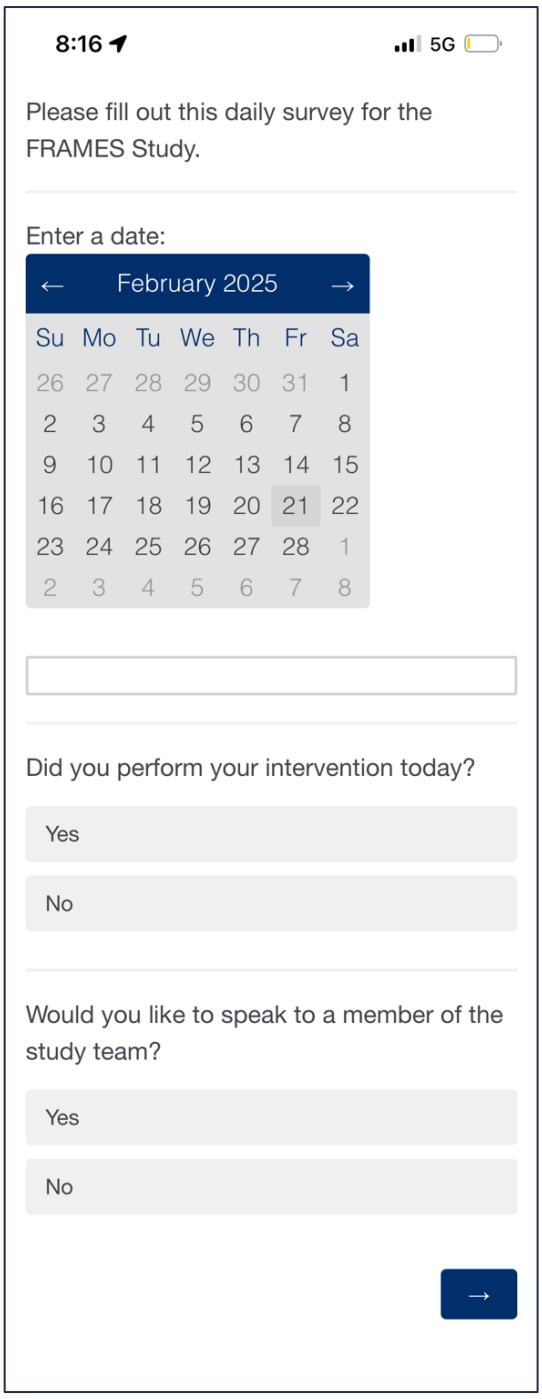


Table C6a. Home Exercise Program – Instruction Sheets Provided for Patients

Find at: https://bit.ly/foot-rehabilitation

Rehabilitation Plan

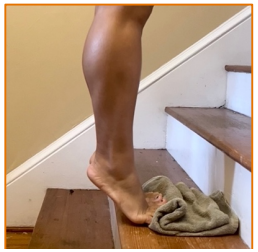
This sheet will tell how to do each exercise (sets and repetitions are detailed in a table below). Aim to complete these exercises **every day,** to the best of your ability. If you have questions, please use the daily survey you'll be sent to contact the study team. Use the link or QR code above to view videos of the exercises as well.

1) **Massage bottom of foot with ball:** Roll the bottom of your foot with the ball provided to you, up & down the bottom of the foot. Do not push so hard that it causes pain, but it should be a comfortable massage.
2) **Calf-raises (on a stair with towel under toes)**
    a. Stand on a stair with the back half of the foot off (ball of your foot should remain on the stair). Roll up a towel or anything similar and place it under your toes as shown.
    b. Perform your calf-raises by the sets/reps indicated in the table below.
    c. Rise upwards for 3-seconds, hold for 2-seconds at the top, and then lower for 3-seconds.

3) Stretches:

- Lunge calf stretch: stand in a lunge facing the wall, with arms straight against the wall. Lean forward to feel a stretch in your back leg.
- Calf stretch, knee bent: place your heel close to the wall, toes onto the wall, & bend the knee. Lean forward until you feel a stretch.
- Foot stretch: Cross the affected leg over the other. Hold the base of your toes and pull the toes towards your shin.

Week	1	2	3	4	5	6	7	8
Massage (mins. per day)	3	3	4	4	4	5	5	5
Calf-raises	Bilateral, 3x12	2-up-1 down, 3x12	1-leg, 3x8	1-leg, 4x8	1-leg, 3x8	1-leg, 3x8	1-leg, 3x10	1-leg, 3x10
Calf stretch (knee straight)	2 x 30 seconds							
Calf raise (knee bent)	2 x 30 seconds							
Foot stretch	2 x 30 seconds							

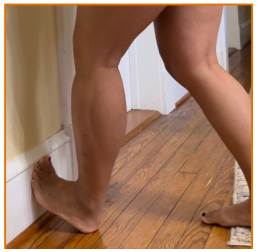
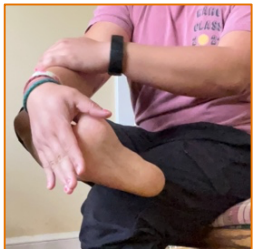



Table C6b. Links to Video Demonstrations

The video demonstrations can be found in this Google Drive folder: Find at: https://bit.ly/foot-rehabilitation

Table C6c. Minimalist Shoe Information Sheet Provided for Patients

Minimalist Shoes Plan

For this portion of the protocol, you will be asked to wear minimalist shoes, which are generally described as…thin, flexible shoes with plenty of room in the toe-box. They are meant to elicit a more "natural" way of walking. The pair you have are the **Xero HFS**.

You'll wear the shoes for a set amount of hours each day, as indicated. You will want to wear them when you are walking (no running permitted in them), but we still want you to maintain your regular daily activity.

- For example, if you have been walking as a daily exercise routine, then you may wear the shoes for that
- You can also wear it while you're completing errands, walking to work/class, etc.
- You may want to trial the shoes out for shorter walks dispersed through the day initially, and that is okay too, as long as you are wearing them for the amount of time indicated per day.
- As you progress in the protocol, if it is comfortable, you may be able to increase your walking/activity in the shoes (while still aligning with the correct number of hours). You may contact us with any and all questions you have about progressing to more hours in the shoes.

Week	1	2	3	4	5	6	7	8
Hours per day	1	2	4	6	8	8	8	8

Here are some symptoms to watch out for that may be indicative of other injuries:

- Increased night pain
- Increased pain with prolonged exercise/movement
- Increased lower leg/foot pain in both sides

If you have any of these symptoms for a few prolonged days in a row, please reach out to a member of the study team.
If you have any pain or discomfort beyond a pain level of 3 out of 10, please stop the exercises on that day and reach out.

APPENDIX D: ADDITIONAL RESULTS

Additional Results Table D2.1. Operational definitions of balance and gait kinetics measures.

Lateral Displacement (cm)	The maximum lateral displacement from the centroid of the data
Centroid	The average X and average Y of the data
Medial Displacement (cm)	The maximum medial displacement from the centroid of the data
(Lateral and medial displacement were calculated from X Max and X Min displacement, as it differed depending on the feet)	
Average X Deviation (cm)	The average X deviation from the X centroid of the data
Anterior Displacement (cm)	The maximum anterior displacement from the centroid of the data (listed as Y Max displacement initially)
Posterior Displacement (cm)	The maximum posterior displacement from the centroid of the data (listed as Y Min displacement initially)
Average Y Deviation (cm)	The average Y deviation from the Y centroid of the data
Path Length (cm)	The path length for the duration of the trial (of centroid displacement)
Path Area (cm^2)	The path length normalized to the circular area
Lateral Velocity (cm/s)	The maximum velocity in the lateral direction
Medial Velocity (cm/s)	The maximum velocity in the medial direction
Anterior Velocity (cm/s)	The maximum velocity in the anterior direction
Posterior Velocity (cm/s)	The maximum velocity in the posterior direction
Area 95% (cm^2)	The area of the 95^{th} percentile ellipse
Ellipse-95^{th} Percentile	Encompasses 95% of the data points if the data is normally distributed
Contact Time (s)	The full time the foot is on the ground, between initial contact and toe-off
Initial Contact	The instant that force goes above 50 Newtons (N)
Toe-Off	The instant that force goes below 50 N
First Peak	The first local maximum where force was greater than 70% bodyweight
Second Peak	The second local maximum where force was greater than 70% bodyweight
Time to Peak (s)	The time between initial contact and first peak
Time Between Peak (s)	The time between first peak and second peak
Loading Rate (N/s)	The force at first peak divided by the time from initial contact to first peak
First Peak Impact Force (N)	The impact force at first peak

Second Peak Impact Force (N)	The impact force at second peak
Mean Impact Force (N)	The mean impact force from initial contact to toe off
Impulse (Ns)	Area under the force-time curve during the whole stance phase multiplied by contact time

Additional Results Table D3.1. Correlations for all pain, psychological, and functional outcome measures relative to percent change of pain and self-reported function

	Percent Change				
Baseline values	**VAS1**	**VAS2**	**VAS3**	**FAAM ADL**	**FAAM Sport**
VAS1	0.133	-0.041	0.006	**0.449**	0.114
VAS2	0.137	0.127	-0.009	**0.365**	0.021
VAS3	0.094	-0.041	0.091	**0.362**	0.043
GROC	0.026	0.201	0.154	-0.233	-0.154
FAAM ADL	-0.136	-0.065	0.134	**-0.814**	-0.349
FAAM Sport	0.005	0.059	0.254	**-0.342**	**-0.778**
TSK	0.139	-0.091	-0.057	**0.475**	0.328
FABQ-Work	0.048	0.016	0.07	0.259	-0.07
FABQ-PA	0.255	0.174	**0.366**	0.313	0.308
PSEQ	-0.216	-0.126	0.041	**-0.382**	-0.113
Pain Length	-0.31	-0.261	**-0.364**	-0.133	-0.255
Arch Height Non	0.049	-0.19	0	-0.265	-0.053
Arch Height PF	0.111	-0.103	0.02	-0.168	-0.128
Arch Drop Non	-0.053	0.016	0.106	-0.135	-0.025
Arch Drop PF	0.033	-0.051	0.175	-0.064	-0.011
AHI Non	0.076	-0.003	-0.084	0.136	-0.016
AHI PF	-0.012	0.016	-0.156	0.021	0.008
HHD GT Non	0.171	**0.503**	0.146	-0.102	-0.082
HHD LT Non	0.288	**0.521**	0.119	-0.134	0.065
HHD GT PF	0.144	**0.491**	0.2	-0.132	-0.128
HHD LT PF	0.233	**0.511**	0.088	-0.129	0.068
ND GT Non	-0.001	0.223	-0.117	-0.053	0.129
ND LT Non	0.087	0.276	-0.062	-0.191	0.074
ND GT PF	0.111	0.273	0.046	-0.188	0.065
ND LT PF	0.002	0.203	-0.085	-0.24	-0.135
PF Thickness	-0.282	-0.304	-0.267	-0.298	-0.021
ABH MT	0.223	0.071	0.184	-0.014	-0.006
ABH MT Resisted	**0.367**	0.243	0.264	0.168	0.199
ABH MT Ratio	**0.374**	0.343	0.234	**0.344**	**0.397**
ABH CSA	**0.445**	**0.36**	**0.49**	-0.029	0.11
ABH CSA Resisted	0.341	0.306	**0.412**	0.025	-0.064
ABH CSA Ratio	-0.181	-0.086	-0.117	0.088	-0.246
FDB MT	0.168	0.131	0.179	0.097	-0.022
FDB MT Resisted	0.145	0.075	0.269	0.086	-0.121
FDB MT Ratio	-0.037	-0.123	0.067	-0.041	-0.115
FDB CSA	0.24	0.181	0.319	0.129	-0.196
FDB CSA Resisted	0.21	0.174	0.339	0.011	-0.277
FDB CSA Ratio	-0.068	-0.09	0.035	-0.202	-0.243
FHB MT	0.017	0.109	-0.01	-0.067	-0.107

FHB MT Resisted	0.043	0.108	0.048	-0.089	0.054
FHB MT Ratio	0.051	0.015	0.12	-0.041	0.299
FHB CSA	0.233	0.178	0.176	0.034	0.278
FHB CSA Resisted	0.324	0.324	**0.39**	-0.153	0.063
FHB CSA Ratio	-0.04	0.037	0.114	-0.198	-0.204
QP MT	-0.067	-0.252	-0.109	0.046	-0.26
QP MT Resisted	0.057	-0.064	0.001	0.196	0.107
QP MT Ratio	0.152	0.143	0.108	0.125	0.32
QP CSA	0.151	0.001	0.051	-0.205	-0.188
QP CSA Resisted	-0.092	-0.07	-0.026	-0.255	**-0.439**
QP CSA Ratio	**-0.574**	-0.241	-0.386	-0.169	-0.28
Lateral Disp. EO	0.133	0.099	0.086	-0.162	-0.142
Medial Disp. EO	-0.02	0.017	0.021	-0.306	-0.247
Avg. X Deviation EO	0.07	0.111	0.05	-0.231	-0.207
Anterior Disp. EO	0.039	0.104	0.079	-0.102	-0.154
Posterior Disp. EO	0.082	0.175	0.08	-0.012	-0.062
Avg. Y Deviation EO	-0.028	0.135	0.073	-0.063	-0.202
Path Length EO	0.042	0.058	-0.03	-0.165	-0.139
Path Area EO	0.111	-0.083	-0.057	0.147	0.19
Lateral Velocity EO	0.01	0.121	0.011	-0.098	-0.154
Medial Velocity EO	0.282	0.311	**0.372**	-0.062	0.1
Anterior Velocity EO	-0.139	-0.168	-0.118	**-0.45**	**-0.365**
Posterior Velocity EO	-0.026	-0.022	-0.158	-0.082	-0.123
95% Ellipse Area EO	0.043	0.128	0.079	-0.153	-0.217
Lateral Disp. EC	-0.08	0.018	0.078	-0.131	-0.304
Medial Disp. EC	0.125	0.042	0.275	-0.198	-0.227
Avg. X Deviation EC	0.015	0.008	0.085	-0.177	-0.222
Anterior Disp. EC	0.137	0.06	0.24	-0.07	-0.036
Posterior Disp. EC	-0.002	-0.052	0.011	-0.102	-0.156
Avg. Y Deviation EC	0.111	0.068	0.167	-0.046	-0.158
Path Length EC	0.056	0.009	0.154	-0.198	-0.184
Path Area EC	-0.132	0.031	-0.257	0.012	0.108
Lateral Velocity EC	-0.002	0.005	-0.012	-0.102	-0.293
Medial Velocity EC	0.229	0.162	0.341	-0.145	-0.047
Anterior Velocity EC	0.032	-0.011	0.196	-0.22	0.027
Posterior Velocity EC	0.094	0.033	0.215	-0.124	-0.223
95% Ellipse Area EC	0.071	0.013	0.138	-0.119	-0.196
Self-Selected Speed	-0.336	-0.147	0.057	**-0.431**	**-0.538**
Contact Time Non	0.174	-0.045	0.028	0.289	0.293
TTPeak Non	0.04	-0.152	-0.027	0.274	**0.387**
TBPeak Non	0.156	-0.044	0.024	0.074	-0.019
Loading Rate Non	-0.072	0.144	0.064	-0.231	**-0.43**
First Peak Non	-0.111	0.089	0.042	-0.06	**-0.459**
Second Peak Non	-0.118	-0.089	-0.106	-0.031	-0.35
Mean Force Non	-0.18	-0.08	-0.111	-0.119	**-0.451**

Impulse Non	-0.011	-0.122	-0.101	0.252	-0.108
Contact Time PF	0.162	-0.06	0.006	0.256	0.299
TTPeak PF	0.05	-0.062	-0.016	0.237	**0.376**
TBPeak PF	0.211	-0.003	0.141	0.003	0.047
Loading Rate PF	0.008	0.073	0.106	-0.135	-0.335
First Peak PF	0.045	0.046	0.127	0.025	-0.213
Second Peak PF	0.058	0.023	0.157	-0.073	-0.138
Mean Force PF	0.046	-0.033	0.08	-0.018	-0.171
Impulse PF	0.15	-0.052	0.069	0.156	0.058
Contact Time Symm.	-0.109	-0.088	-0.144	-0.231	-0.008
TTPeak Symm.	0.013	0.178	0.026	-0.143	-0.126
TBPeak Symm.	0.07	0.083	0.176	-0.123	0.106
Loading Rate Symm.	0.135	-0.12	0.088	0.172	0.257
First Peak Symm.	0.169	-0.041	0.118	0.099	0.265
Second Peak Symm.	0.179	0.108	0.287	-0.056	0.167
Mean Force Symm.	0.218	0.045	0.207	0.088	0.247
Impulse Symm.	0.204	0.043	0.196	-0.025	0.212

Bolded values indicate significance $p<0.05$

Abbreviations:

Additional Results Table D3.2. Correlations for all baseline pain, psychological, and functional outcome measures

	VAS1	VAS2	VAS3	FAAM ADL	FAAM Sport	TSK	FABQ-W	FABQ-PA	PSEQ
VAS2	**0.814**	—							
VAS3	**0.907**	**0.688**	—						
FAAM ADL	**-0.584**	**-0.461**	**-0.478**	—					
FAAM Sport	**-0.448**	**-0.257**	**-0.379**	**0.565**	—				
TSK	**0.456**	0.184	**0.438**	**-0.655**	**-0.449**	—			
FABQ-Work	**0.625**	**0.445**	**0.674**	**-0.374**	-0.18	**0.441**	—		
FABQ-PA	0.26	-0.01	0.277	**-0.343**	**-0.345**	**0.677**	0.161	—	
PSEQ	**-0.378**	**-0.366**	-0.26	**0.484**	0.241	**-0.638**	**-0.432**	**-0.527**	—
Age	-0.111	-0.027	-0.041	-0.096	0.132	-0.181	-0.074	-0.231	-0.22
Height	-0.159	-0.162	-0.162	0.127	**0.394**	0.295	-0.216	-0.3	-0.077
Weight	0.058	0.089	0.185	-0.272	-0.055	-0.088	0.152	0.176	-0.104
BMI	0.155	0.18	0.261	-0.332	-0.307	-0.271	0.302	**0.345**	-0.026
Length of Pain	-0.059	-0.014	-0.122	0	0.101	0.177	-0.104	-0.11	-0.237
HHD GT Non	-0.125	0.15	-0.251	0.162	0.325	-0.303	0.025	-0.178	-0.167
HHD LT Non	-0.052	0.1	-0.159	0.131	0.124	-0.147	0.074	-0.049	-0.225
HHD GT PF	-0.101	0.163	-0.202	0.141	0.32	-0.274	0.087	-0.112	-0.202
HHD LT PF	-0.147	-0.007	-0.248	0.176	0.172	-0.217	-0.01	-0.081	-0.14
ND GT Non	-0.103	0.111	-0.217	-0.001	0.127	-0.214	-0.099	-0.273	-0.074
ND LT Non	-0.136	0.099	-0.234	0.225	0.178	**-0.402**	-0.199	**-0.339**	0.062
ND GT PF	-0.078	0.093	-0.21	0.145	0.169	-0.237	-0.136	-0.215	-0.009
ND LT PF	-0.121	0.085	-0.209	0.305	0.332	**-0.4**	-0.156	-0.312	0.038
Arch Height Non	-0.081	-0.091	-0.05	0.22	0.046	-0.078	-0.208	-0.024	-0.082
Arch Height PF	-0.062	-0.086	-0.079	0.208	0.191	-0.027	-0.054	-0.136	-0.168
Arch Drop Non	0.069	0.076	0.112	0.031	0.033	0.115	**0.392**	0.059	-0.074
Arch Drop PF	0.222	0.086	0.249	-0.109	-0.13	0.323	**0.458**	**0.344**	-0.124
AHI Non	-0.09	-0.07	-0.133	0.009	0.002	-0.158	**-0.411**	-0.106	0.106
AHI PF	-0.225	-0.076	-0.264	0.183	0.134	-0.319	**-0.479**	-0.323	0.148
PF Thickness	-0.325	**-0.357**	-0.2	0.311	-0.075	-0.089	-0.312	-0.13	0.294
ABH MT	-0.003	0.043	0.013	0.072	0.214	-0.151	-0.016	-0.045	0.049

ABH MT Resisted	0.035	0.043	-0.06	-0.117	0.024	0.024	-0.057	0.111	-0.044
ABH MT Ratio	0.087	0.022	-0.126	**-0.352**	-0.302	0.296	-0.065	0.285	-0.173
ABH CSA	-0.064	0.011	-0.088	0.214	0.243	-0.156	-0.079	0.022	0.133
ABH CSA Resisted	-0.045	0.05	-0.027	0.115	0.311	-0.195	-0.159	-0.054	0.153
ABH CSA Ratio	0.051	0.117	0.12	-0.141	0.12	-0.087	-0.155	-0.147	0.07
FDB MT	-0.149	-0.096	-0.14	0.02	0.25	0.052	-0.099	0.177	-0.246
FDB MT Resisted	-0.136	-0.1	-0.088	0.008	0.315	-0.106	-0.061	0.077	-0.155
FDB MT Ratio	-0.017	-0.049	0.04	0.011	0.075	-0.219	0.022	-0.147	0.125
FDB CSA	0.175	0.161	0.283	-0.074	0.117	-0.089	0.157	0.037	-0.041
FDB CSA Resisted	0.09	0.134	0.249	0.023	0.15	-0.027	0.177	0.154	-0.276
FDB CSA Ratio	-0.128	-0.069	-0.04	0.134	0.089	0.114	0.019	0.247	**-0.382**
FHB MT	-0.289	-0.027	**-0.398**	0.089	0.319	-0.169	-0.146	-0.157	-0.158
FHB MT Resisted	-0.324	-0.114	**-0.434**	0.099	0.213	-0.141	-0.156	-0.04	-0.112
FHB MT Ratio	-0.041	-0.206	0.024	0.005	-0.24	0.064	0.041	0.229	0.14
FHB CSA	-0.02	-0.106	0.026	-0.018	-0.001	-0.062	0.197	-0.027	0
FHB CSA Resisted	-0.239	-0.107	-0.266	0.255	0.125	-0.223	-0.256	0.007	0.142
FHB CSA Ratio	-0.274	-0.108	-0.277	0.226	0.094	-0.048	**-0.416**	0.078	0.137
QP MT	-0.072	-0.178	-0.056	-0.104	0.199	0.066	0.009	0.102	-0.182
QP MT Resisted	0.059	0.095	0.082	-0.257	0.081	0.11	-0.005	-0.008	-0.095
QP MT Ratio	0.103	0.211	0.119	-0.104	-0.074	0.086	0.003	-0.053	-0.01
QP CSA	-0.005	-0.051	0.026	0.13	-0.152	-0.032	-0.054	0.043	-0.188
QP CSA Resisted	-0.043	0.047	-0.08	0.005	-0.117	-0.035	-0.046	-0.062	-0.18
QP CSA Ratio	-0.218	0.018	-0.338	-0.072	0.175	-0.061	-0.235	-0.23	0.033
Lateral Disp. EO	-0.039	0.031	-0.028	0.096	0.262	-0.144	-0.16	-0.189	-0.029
Medial Disp. EO	-0.142	-0.041	-0.078	0.085	**0.389**	-0.173	-0.205	-0.238	0.09
Avg. X Deviation EO	-0.101	0.025	-0.119	0.168	**0.349**	-0.142	-0.251	-0.252	-0.039
Anterior Disp. EO	-0.077	-0.006	-0.015	0.069	0.262	-0.251	-0.213	-0.206	0.06
Posterior Disp. EO	0.02	0.113	0.056	0.017	0.178	-0.26	-0.127	-0.186	0.136
Avg. Y Deviation EO	-0.091	0.063	-0.014	0.085	0.245	-0.129	-0.237	-0.211	0.023
Path Length EO	-0.097	0.078	-0.116	-0.016	0.255	-0.268	-0.239	-0.262	-0.079
Path Area EO	-0.013	0.033	-0.134	-0.169	-0.232	0.03	0.121	-0.065	-0.159
Lateral Velocity EO	-0.03	0.069	-0.015	-0.101	0.195	**-0.361**	-0.228	-0.232	0.051

Medial Velocity EO	**-0.373**	-0.265	-0.328	0.164	0.258	0.017	-0.143	**-0.376**	0.083
Anterior Velocity EO	-0.103	0.117	-0.082	0.012	**0.396**	-0.066	-0.2	-0.068	-0.26
Posterior Velocity EO	-0.007	0.047	-0.068	-0.069	0.134	-0.292	-0.101	-0.307	0.063
95% Ellipse Area EO	-0.07	0.041	-0.041	0.119	0.311	-0.17	-0.227	-0.25	0.049
Lateral Disp. EC	-0.123	-0.042	-0.014	0.293	0.191	0.124	-0.146	-0.108	-0.085
Medial Disp. EC	0.07	0.083	0.149	-0.041	0.296	0.251	-0.075	0.219	0.059
Avg. X Deviation EC	-0.123	-0.013	-0.05	0.196	0.334	0.259	-0.178	-0.113	-0.089
Anterior Disp. EC	0.086	0.098	0.129	-0.087	0.258	-0.144	-0.184	-0.001	0.128
Posterior Disp. EC	0.099	0.124	0.156	0.023	0.26	-0.21	-0.219	-0.152	-0.011
Avg. Y Deviation EC	0.176	0.169	0.222	-0.091	0.198	-0.223	-0.187	-0.033	0.146
Path Length EC	-0.099	-0.028	-0.016	0.064	0.346	-0.024	-0.245	-0.277	0.027
Path Area EC	-0.352	-0.193	**-0.387**	-0.108	-0.141	-0.042	0.006	-0.306	-0.069
Lateral Velocity EC	-0.069	0.009	-0.018	-0.101	0.216	-0.229	-0.195	-0.146	0.006
Medial Velocity EC	-0.107	-0.023	-0.068	0.012	0.351	0.042	-0.21	-0.188	0.119
Anterior Velocity EC	-0.206	-0.187	-0.179	0.138	0.32	0.058	-0.084	-0.176	0.006
Posterior Velocity EC	0.04	0.014	0.124	-0.053	0.267	-0.136	-0.138	-0.183	0.207
95% Ellipse Area EC	0.071	0.116	0.131	-0.012	0.299	-0.06	-0.227	-0.094	0.038
Self-Selected Gait Speed	-0.227	-0.019	-0.182	**0.459**	**0.545**	**-0.506**	-0.246	-0.321	0.228
Contact Time Non	0.268	0.121	0.181	0.131	-0.277	-0.251	0.236	0.184	-0.013
TTPeak Non	0.196	0.036	0.184	-0.133	-0.303	**-0.377**	0.324	0.13	0.176
TBPeak Non	0.256	0.289	0.149	0.185	-0.074	0.001	-0.033	0.092	-0.252
Loading Rate Non	-0.249	-0.125	-0.273	0.245	**0.353**	0.346	**-0.387**	-0.221	-0.184
First Peak Non	-0.291	-0.212	-0.331	0.293	0.262	0.324	**-0.387**	-0.23	-0.215
Second Peak Non	0.125	0.194	-0.03	-0.002	0.03	0.22	-0.314	-0.046	-0.259
Mean Force Non	-0.054	-0.01	-0.156	0.088	0.174	0.179	**-0.37**	-0.142	-0.209
Impulse Non	0.301	0.163	0.135	0.106	-0.215	-0.107	-0.01	0.122	-0.138
Contact Time PF	0.223	0.071	0.129	0.145	-0.246	-0.223	0.268	0.181	0.021
TTPeak PF	0.168	0.068	0.043	-0.099	-0.289	**-0.358**	0.316	0.087	0.197
TBPeak PF	0.103	0.001	0.113	0.234	0.061	0.122	0.029	0.031	-0.078
Loading Rate PF	-0.16	-0.098	-0.093	0.242	0.275	0.319	-0.249	-0.135	-0.12
First Peak PF	-0.172	-0.136	-0.161	0.303	0.158	0.254	-0.128	-0.127	-0.062
Second Peak PF	0.146	0.242	0.02	0.077	0.107	0.28	-0.081	-0.02	-0.052

Mean Force PF	0.035	0.07	-0.038	0.18	0.12	0.198	-0.084	-0.083	-0.045
Impulse PF	0.164	0.096	0.053	0.217	-0.07	0.01	0.115	0.057	-0.015
Contact Time Symm.	-0.276	-0.277	-0.293	0.07	0.202	0.176	0.15	-0.028	0.176
TTPeak Symm.	-0.109	0.044	-0.307	0.095	0.126	0.142	-0.097	-0.133	-0.022
TBPeak Symm.	-0.245	**-0.466**	-0.05	0.102	0.201	0.154	0.108	-0.055	0.271
Loading Rate Symm.	0.115	0.012	0.258	-0.003	-0.116	-0.091	0.229	0.075	0.114
First Peak Symm.	0.096	0.066	0.147	0.042	-0.087	-0.066	0.244	0.064	0.147
Second Peak Symm.	0.031	0.09	0.021	0.072	0.111	0.124	0.162	-0.007	0.165
Mean Force Symm.	0.068	0.075	0.082	0.101	-0.012	0.044	0.23	0.012	0.147
Impulse Symm.	-0.062	-0.024	-0.042	0.153	0.103	0.104	0.18	-0.036	0.137

Additional Results Table D3.3. Linear regression models for changes in pain

		Δ VAS1			**Δ VAS2**			**Δ VAS3**		
		Adj. R^2	p-value	Std. EST.	Adj. R^2	p-value	Std. EST.	Adj. R^2	p-value	Std. EST.
Individual linear regression models	VAS1	**0.175**	**0.008**	**0.447**						
	VAS2				**0.175**	**0.008**	**0.447**			
	VAS3							**0.318**	**<0.001**	**0.582**
	TSK	**0.092**	**0.046**	**0.345**	-0.028	0.767	0.053	0.064	0.081	0.303
	HHD PF	0.019	0.209	0.221	**0.183**	**0.007**	**0.455**	-0.027	0.717	0.065
	ABH CSA	0.067	0.080	0.309	0.063	0.087	0.303	0.020	0.210	0.224
	First peak	-0.024	0.606	0.095	0.005	0.288	0.194	-0.028	0.704	0.070
	Path length EO	-0.025	0.642	-0.084	-0.025	0.650	0.082	-0.022	0.571	-0.102
Combined linear regression models	VAS1		**0.007**	**0.465**						
	VAS2					**0.01**	**0.417**			
	VAS3								**<0.001**	**0.658**
	TSK		0.140	0.254		0.336	0.154		0.652	0.073
	HHD PF		0.310	0.159		0.058	0.312		0.556	0.089
	ABH CSA		**0.015**	**0.410**		0.057	0.310		0.052	0.312
	First peak		0.503	0.010		0.206	0.189		0.474	0.104
	Path length EO		0.516	0.102		0.246	0.185		0.771	0.045
	Total adjusted R^2 (p)	**R^2 = 0.379 (p=0.006)**			**R^2 = 0.388 (p=0.005)**			**R^2 = 0.407 (p=0.004)**		

VAS, Visual Analog Scale; TSK, Tampa Scale of Kinesiophobia; HHD PF, strength of the PF limb assessed with handheld dynamometer; ABH CSA, abductor hallucis cross-sectional area; first peak, first peak impact force; Path Length EO, path length during eyes opened balance.

VAS for each model was each change score's respective VAS score at baseline. Bolded values indicate significance (p<0.05).

Additional Results Table D3.4. Linear regression models for changes in function

		Δ FAAM ADL			**ΔFAAM Sport**		
		Adj. R^2	p-value	Std. EST.	Adj. R^2	p-value	Std. EST.
Individual linear regression models	FAAM ADL	**0.536**	**<0.001**	**-0.742**			
	FAAM Sport				**0.204**	**0.004**	**-0.477**
	TSK	**0.124**	**0.023**	**0.388**	0.057	0.093	0.293
	HHD PF	-0.020	0.561	-0.103	-0.031	0.956	0.010
	ABH CSA	-0.031	0.845	0.035	0.002	0.308	0.183
	First peak	-0.033	0.986	0.003	0.024	0.194	-0.236
	Path length EO	-0.016	0.484	-0.126	0.013	0.242	-0.210
Combined linear regression models	FAAM ADL		**<0.001**	**-0.928**			
	FAAM Sport					**0.009**	**-0.577**
	TSK		0.316	-0.161		0.978	0.006
	HHD PF		0.447	-0.100		0.672	0.072
	ABH CSA		**0.042**	**0.290**		0.159	0.252
	First peak		0.594	0.067		0.629	-0.080
	Path length EO		0.397	0.116		0.105	-0.320
	Total adjusted R^2 (p)	**R^2 = 0.549 (p<0.001)**			**R^2 = 0.244 (p=0.043)**		

FAAM, Foot and Ankle Ability Measure; TSK, Tampa Scale of Kinesiophobia; HHD PF, strength of the PF limb assessed with handheld dynamometer; ABH CSA, abductor hallucis cross-sectional area; first peak, first peak impact force; Path Length EO, path length during eyes opened balance.

FAAM for each model was each change score's respective FAAM score at baseline. Bolded values indicate significance ($p<0.05$).

APPENDIX E: BACK MATTER

Recommendations for Future Research

- When implementing a strengthening intervention in individuals with PF, both functional and psychological outcomes should be assessed.
- If possible, all individuals should walk in minimalist shoes at both baseline and post-test to understand the global effect of the minimalist shoe intervention.
- Kinematic analyses of walking gait should be used in the future, to capture joint moments and impact loading at each joint, which could provide more insight into adaptations individuals with PF face, and potentially why these changes occur.
- Weight-bearing ultrasound measurements of the intrinsic foot muscles (IFM) should be implemented whenever possible, in order to capture how these muscles behave in their most advantageous positions.
- Future studies are needed to investigate how a longer routine of wearing minimalist shoes, working up to 100% daily wear time, can affect individuals with PF.
- Future studies should evaluate the range of passive and active motion of the ankle and metatarsophalangeal joints before and after a intervention that implements minimalist shoes for individuals with PF.
- Future studies are needed to determine if implementing a transition protocol based on a baseline step count can be easier for patients to adhere to and more relevant to their own baseline activity levels, or if this obtains better results. This could be done with a 1-week assessment period of regular activity, and then a graded exposure protocol could be implemented.
- Future studies should investigate the use of IFM exercises, such as the short foot exercise to lift the arch, compared to wearing minimalist shoes. It is important to understand how these types of interventions can alter foot morphology, IFM strength and size, and subsequent physical task abilities.
- Future studies are needed to understand if implementing postural control exercises or gait re-training interventions can be effective in specifically improving those outcomes.
- Future studies should consider implementing a strengthening or minimalist shoe routine in either only sedentary individuals or runners with PF, as the etiology behind the presence of PF can be different, and should be separately explored.
- Future studies should investigate how walking on different surfaces and terrain can alter gait patterns of individuals with PF, especially when comparing minimalist shoes to conventional shoes.
- Future studies should consider developing some kind of psychological intervention to go along with a more physical intervention.
- Future studies could consider the use of minimalist shoes as a treatment for a variety of lower extremity and spine injuries that are known to have decreased intrinsic foot muscle strength or size, or injuries involving overload to the knee.
- Future studies could investigate if thinner and more flexible minimalist shoes, such as the Vibram Five Fingers, can provide similar effects, or if they would potentially cause more pain due to their increasingly minimal nature.

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