


## A randomized clinical trial comparing hip abductors strengthening and manual therapy in patients with plantar fasciitis: a study protocol

### Um teste clínico randomizado comparando o fortalecimento de abdutores do quadril e terapia manual em pacientes com fascite plantar: um protocolo de estudo

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**ABSTRACT | BACKGROUND:** Plantar fasciitis (PF) is a common cause of heel pain and deformity of the ankle joint. More than 11%-15% of the population with foot symptoms need long-term care. Various physical therapy intervention with conventional therapy, including manual therapy, has been proven to help this condition. **OBJECTIVE:** To evaluate the effect of Hip abductor strengthening and Manual therapy (MT) in a patient with Plantar Fasciitis (PF). **METHODS:** The design of the study will be A Two Group Pretest-Posttest randomized control trial. A total of 30 male and female participants aging above 18-60 years experiencing pain provoked by taking the first few steps in the morning, pain in the plantar heel region, will be allocated randomly into two groups- Group A will receive Manual therapy (MT) with conventional physiotherapy while Group B will receive hip abductors strengthening with conventional physiotherapy. Both groups will receive 16 sessions of treatment for 4 days each week for 4 weeks. "Foot function index," "Podiascan," "Navicular drop test" will be used as outcome measures and will be evaluated at the first week and fourth week of treatment in both the groups. **CONCLUSION:** The patients who receive Hip Abductor Strengthening intervention may have positive results compared to the MT intervention among patients with PF. This will be the first study to compare the effect of hip abductors strengthening and manual therapy. **TRIAL REGISTRATION:** Clinical Trial Registry- India. (CTRI/2020/04/024541)

**KEYWORDS:** Plantar fasciitis. Manual Therapy. Foot Function Index. Navicular Drop Test.

**RESUMO | INTRODUÇÃO:** A fascite plantar (FP) é uma causa comum de dor no calcanhar e deformidade da articulação do tornozelo. Mais de 11% -15% da população com sintomas nos pés precisa de cuidados de longo prazo. Foi comprovado que várias intervenções de fisioterapia com terapia convencional, que inclui terapia manual, ajudam nessa condição. **OBJETIVO:** Avaliar o efeito do fortalecimento do abdutor do quadril e da terapia manual (MT) em paciente com fascite plantar (FP). **MÉTODOS:** O desenho do estudo será um ensaio de controle randomizado de dois grupos, pré-teste e pós-teste. Um total de 30 participantes do sexo masculino e feminino com idade acima de 18-60 anos com dores provocadas pelos primeiros passos da manhã, dor na região plantar do calcanhar, serão alocados aleatoriamente em dois grupos - o Grupo A receberá terapia manual (TM) com fisioterapia convencional enquanto o Grupo B receberá fortalecimento dos abdutores do quadril com fisioterapia convencional. Ambos os grupos receberão 16 sessões de tratamento por 4 dias em cada semana durante 4 semanas. "Foot Function Index", "Podia scan", "Teste de queda do navicular" serão usados como medida de desfecho e serão avaliados na 1ª semana e na 4ª semana de tratamento em ambos os grupos. **CONCLUSÃO:** Os pacientes que recebem a intervenção de fortalecimento do abdutor do quadril podem ter resultados positivos quando comparados à intervenção de MT entre pacientes com FP. Este será o primeiro estudo a comparar o efeito do fortalecimento dos abdutores do quadril e da terapia manual. **REGISTRO DE ENSAIO:** Registro de Ensaios Clínicos - Índia. (CTRI / 2020/04/024541)

**PALAVRAS-CHAVE:** Fascite plantar. Terapia manual. Foot Function Index. Teste de queda do navicular.

## Introduction

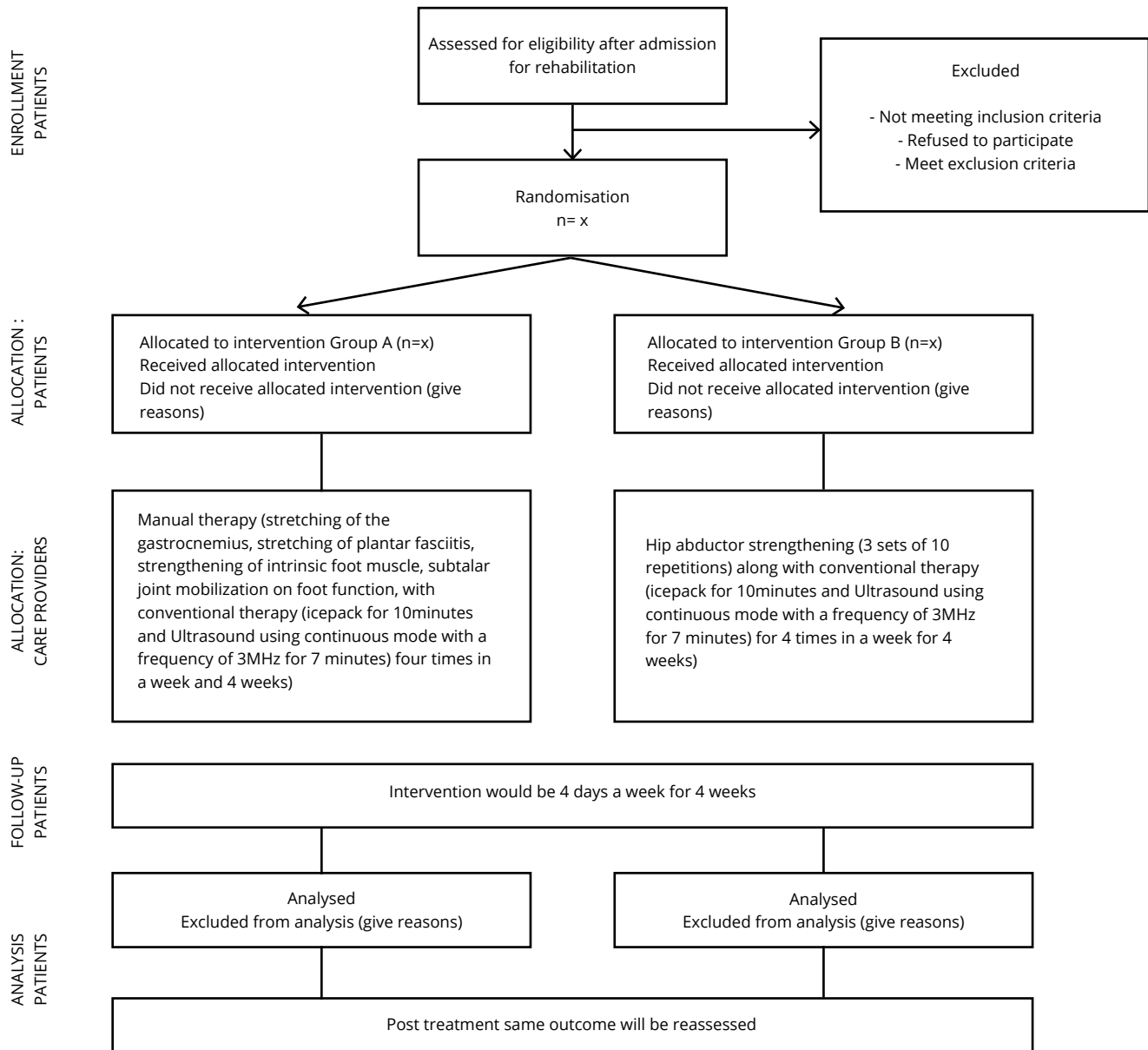
Plantar fasciitis (PF) is a common condition that causes pain on the bottom of the heel.<sup>1</sup> Previous literature had reported that PF might affect more than 1 million people globally per year. Nearly more than 10% of the population is affected by this condition. More than 11%-15% of foot symptoms need long-term care. Higher prevalence was seen in females between 40-60 years but affected all groups of age, sexes, and ethnicities.<sup>2</sup> The PF pain increase with the first step in morning.<sup>3</sup> PF etiology includes decreasing ankle joint dorsiflexion, poor shock absorption, high body mass index, or ill-fitting footwear, pes planus, excessive running.<sup>1-3</sup>

Several approaches have been used previously as a treatment for PF includes platelet-rich plasma injections, joint mobilization or manipulation, foot orthosis, non-steroidal anti-inflammatory drugs, corticoid injections, ultrasound, shockwave therapy but no strong evidence found.<sup>4,5</sup> Clinical studies have suggested manual therapy as an effective treatment

to reduce pain and function like stretching the tibialis posterior, lateral glide mobilization, plantar fascia stretch, soft tissue mobilization, and stretching calf muscle.<sup>6</sup> Many studies also showed and reported that hip muscle weakness is associated with ankle injuries and deformities.<sup>7,8</sup> There is a lack of mobility in the high arch foot in absorbing ground reaction forces, therefore unable to disperse the forces and increases the load on the plantar fascia.<sup>9</sup> In over-pronation, foot muscle weakness of the gluteus minimus, gluteus medius, tensor fascia latae, or quadriceps muscles can lead to plantar fascia pain and abnormalities.<sup>10</sup> Recently there is only one case study that reported that MT and strengthening of the hip abductors effectively reduce pain in fasciitis.<sup>1</sup> Therefore, the purpose of the study is to investigate the effect of MT and hip abductors strengthening exercise on functional, clinical, and biomechanical outcomes in plantar fasciitis patients. The patients who receive Hip Abductors Strengthening intervention may or may not have positive results compared to the MT intervention among patients with PF.

## Material and methods

Figure 1. Flow Chart of study protocol



## Trial registration

The Ethics Research Committee of the Maharishi Markandeshwar (Deemed to be University) has approved the protocol (protocol ID: MMDU/IEC/1539). In addition, the study protocol registry no- CTRI/2020/04/024541 has been registered in Clinical Trial Registry-INDIA and the World Health Organization International Clinical Trials Registry with a universal trial number (U1111-1248-4074). The study will be done following Helsinki Declaration revised in 2013 and National Ethical Guidelines for Biomedical Research involving Human Participants, 2017.

## Study Design

The study described here will be a two-group pretest-posttest randomized clinical trial where the participants will be blinded. The treatment will be given in the Outpatient department (OPD) of Maharishi Markandeshwar Hospital, Mullana, Ambala, India.

## Participants Recruitment

30 Participants of plantar fasciitis from the MMU Hospital at Mullana, Ambala, Haryana, will be recruited. All patients will be informed about the assessment and intervention procedure before signing the consent form. The therapist will endeavour to preserve patient confidentiality for records.

## Participant eligibility criteria

The Eligibility criteria include both female and male participants, aged above 18-60 years, Patients with a history of plantar heel pain for more than one month, Patients with hip abductor weakness, and those who need manual therapy. In addition, pain provoked by taking the first few steps in the morning; Participants must be willing to attend the assessment and treatment sessions.<sup>11</sup>

## Exclusion criteria

Pregnant women, patients who require medical aid, participants with diabetes mellitus, hypertension, renal disease, or cancer will be excluded. Also, with the Presence of peripheral vascular disease, chronic medical conditions like Malignancy, Systemic inflammatory disorders such as Rheumatoid arthritis, Ankylosing spondylitis, Septic arthritis, etc., Fracture of ankle and foot, that would disrupt the treatment will be excluded.<sup>4</sup>

## Randomization

30 participants before treatment will be recruited and randomized into two treatment groups via block randomization. Four blocks and eight rows for both the groups with matrix design  $4 \times 8 = 32$ . Allocation concealment will be established by sequentially numbered, opaque, sealed envelope (SNOSE) technique. Single blinding of Participants will be done and allocated to group A (Manual Therapy MT) and (Hip abductors strengthening exercise) group B. All the outcomes and procedures will be assessed by a physiotherapist, as shown in Figure 1.

## Interventions

Participants will be allocated to Group A (Manual Therapy) and Group B (Hip Abductor Strengthening) after collecting all measures such as demographic data (age, height, weight, gender, etc.) and outcomes includes pain associated with foot function (Foot Function Index), arch height (navicular drop test), Foot Pressure Distribution (Podiascan) prior and after treatment. A total of 16 sessions, four times a week on alternate days for four weeks, will be given to each patient.

## Manual therapy

Group A patients will be receiving manual therapy as mentioned in (Table 1)<sup>8</sup>, four times a week and for four weeks.

**Table 1.** Manual therapy intervention for Plantar Fasciitis

MT intervention (group A)	Details	Intensity
Stretching of gastrocnemius muscle	Patient in a supine lying position with the knee fully extended, therapist stabilizes the leg, holds the ankle joint, and stretches gastrocnemius muscle.	20sec hold 3sec relaxation for 3 repetitions.
Stretching of plantar fasciitis	In the prone position, with the knee extended, while therapist place fingers over the base of the patient toes, stabilize heel with another hand stretch the toes into dorsiflexion until a stretch is felt in the plantar fascia	20sec and tolerated by patient for 3 repetitions.
Strengthening of intrinsic foot muscles	In sitting position, with feet flat on the floor, lay the towel on the floor, instruct the patient to put the toes at the end of the towel and pull the towel.	10 sec hold, repeat 10times.
Joint mobilization (talocalcaneal joint)	Patient in a supine lying position with the heel hanging out of the table, therapist hold ankle joint, embrace the neck of the talus, distraction force is applied the talus is glided posteriorly to the tibia by pushing against the calcaneus.	5 repetitions, 20 Oscillations /min

## Hip abductor strengthening

Group B Patient will be receiving Hip abductor strengthening four days a week for four weeks. The patient will be made to lie in a side-lying position with a pillow placing below the head. Next, the patient will be asked to keep toes pointed forward and knees straight, lift one leg over the other, abducting the hip to a 45-degree abduction position; the ankle of the patient will be strapped with ankle cuff weight according to exercise protocol described in (Table 2) for three sets of 10 repetitions for four days for four weeks.<sup>12</sup> Hip abductor muscles contribute stability of the lower extremities, including the ankle joint.

**Table 2.** Hip strengthening protocol for Plantar Fasciitis

Week	Weight (Repetitive maximum, RM)
1-2	50% of 10 RM
2-4	70% of 10 RM

## Outcome measures

Primary outcome measures will be FFI (Foot Function Index) for Foot Function, while secondary outcome measures will be assessed using Navicular drop test for arch height and Podiascan for foot pressure distribution. Outcomes will be used for evaluation before and four weeks after the treatment.

## Foot Function Index (FFI)

FFI will be used to measure the impact of foot pathology on function in terms of pain, disability, and activity limitation. The patient will be asked to fill in this by self and an index consisting of twenty-three (23) self-reported items divided into three sub-categories of pain, disability, and activity limitation. The patient will be asked to score every question on a scale from 0 to 10. Where 0 defines (no pain or difficulty) and 10 (worst pain or so difficult) and total score range from 0 (no problem) to 230 (extreme problem). The Minimal Clinically Important Difference (MCID) value of FFI is 7. The inter-rater and intra-rater reliability is 0.96 to 0.73. The index will be used in first week of the intervention and the 4th week after intervention.<sup>4</sup>

## Navicular Drop Test (NDT)

NDT is used to measure navicular height in both flat foot and high arch foot in a plantar fasciitis patient. The ICC for NDT is 0.73 to 0.96. Each subject will be asked to sit in a relaxed position with hip and knee flexed at 90 degrees and the foot placed on the flat supporting surface of the ankle, and subtalar joints will be placed in a neutral position. The height of navicular tuberosity will be marked on the index card. The subject will then be asked to stand with equal weight on both feet. Then, the new height of Navicular tuberosity will be marked on an index card. Which will be compared with the normal navicular height that is between 3.6 and 5.5cm. The difference between the marks on the index card (NDT) will be measured with Vernier caliper.<sup>3</sup>

## Podiascan- diabetic foot care India Pvt limited

Foot pressure distribution or plantar pressure measurement systems identify and quantify areas of high pressure, helping us to diagnose the cause of lower extremity problems. Podiascan provides an efficient method to measure plantar foot pressure distribution. It produces instant and permanent high-resolution images of the pressure distribution across the plantar surface. The ICC for foot pressure distribution is more than 0.80.<sup>13</sup>

Firstly, the Harris Mat foot imprinter will be used for pressure distribution patient's foot will be cleaned after that, the therapist will apply ink for footprint, and the patient will walk freely over Harris Mat, then imprinter sheet will be scanned in podiascan and the high-pressure area will be shown.

**Figure 2.** SPIRIT- (Standard Protocol Items: Recommendations for Interventional Trials)

	Study Period						
	Enrollment	Allocation	Post-allocation (treatment)				Follow-up (evaluations)
Time point	0 week	0 week	1st week	2 <sup>nd</sup> week	3 <sup>rd</sup> week	4 <sup>th</sup> week	4 <sup>th</sup> week
Enrolment							
Eligibility screen	X						
Informed consent	X						
Clinical evaluation, inclusion and exclusion criteria	X						
Allocation		X					
Interventions							
Manual therapy			X	X	X	X	
Hip Abduction Strengthening			X	X	X	X	
Assessments							
Demographic data		X					
Foot Function Index (FFI)		X					X
Navicular drop test (NDT)		X					X
Podiascan		X					X

## Safety and Adverse Outcomes

The primary outcome measure used is FFI, and the secondary outcome measure used will be the Navicular drop test and podiascan. The outcome measure will be taken before and after the treatment. The therapist who will be providing the treatment will take care of all the adverse effects and harms of the same. As per the guidelines of WHO, all the safety measures will be taken by the therapist, such as wearing a PPE kit, mask, and gloves, while treating the patient. Proper safety measures will be maintained like social distancing, proper sanitization, the temperature of each patient will be monitored before entering the cabin. Sanitization of the cabin will be done from time to time after each treatment session.

## Data Monitoring

The researcher will perform the Statistical analysis and datasets, and the therapist will monitor the treatment sessions in both groups.

## Follow up

Patients will be expectant to come for the follow-up on the pre-decided dates. They will be called for the follow-up after the first treatment session for four weeks.

## Sample size estimation

Participants will be selected based on primary outcome measure Foot Function Index values to calculate the sample estimation. The effect size will be calculated using Mean post-and pre approaches values divided by standard deviation values with a 0.05 level of significance, a power of 90% ( $\beta=10\%$ ), and considering the rate of 30% dropout. A total of 30 participants, 15 in each group, will be required, and Statistical software will also be applied G-Power version 3.1.9.4.

## Data analysis

Data analysis will be performed using the SPSS version. 22.0. Outcomes will be measured before pre-and post-intervention for foot function, Arch height, and Foot pressure distribution by FFI (Foot Function Index), Navicular Drop Test (NDT), and Podiascan.

Shapiro-Wilk test will be used to check the data normality as the sample size is 30. Descriptive statistics will be expressed in mean±standard deviation if data follow a normal distribution, and if not, it will be expressed in median and intra-quartile ranges. For all the data analysis, the level of significance will be set as 0.05. Distribution of data either paired t-test or Wilcoxon signed-rank test will be used to compare the pre- and post-intervention score within the group and compare intervention score between the group's Independent t-test or Mann Whitney U- test will be used for FFI Questionnaire.

## Discussion

This randomized clinical trial aims to investigate the effect of hip abductors strengthening and manual therapy in patients with plantar fasciitis, seeking to lend a hand for physiotherapists, orthopedician, physicians, and other healthcare professionals in the clinical practice or for the decision-making process to recommend the use of hip abductors strengthening approach for patients diagnosed with plantar fasciitis. The primary purpose of the study is to evaluate the effects of MT and hip abductor strengthening with conventional physiotherapy in plantar fasciitis patients; this will be the first randomized clinical trial as no study has up till now evaluated in order to determine various changes in foot function, pain, quality of life in a patient with plantar fasciitis.

## Author contribution

Hooda K contributed to designing the methodology of the study and scripting the original manuscript. Goyal M and Samuel A have given the content of the review and correcting the manuscript. All the authors of the study helped in designing, conducting the research, and all the authors approve the manuscript of the study.

## Competing interest

No financial, legal, or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.



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