STUDY PROTOCOL

Official Title:

The Role of Instrumental Soft Tissue Mobilization and Foam Rolling in Managing Plantar Fasciitis: A Randomized Controlled Trial

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Study protocol summary with Statistical Analysis Plan

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Background

Plantar fasciitis is one of the most common causes of heel pain and functional limitation. The plantar fascia is a thick band of connective tissue extending from the calcaneus to the toes and plays an important role in maintaining the medial longitudinal arch of the foot. Repetitive stress and microtrauma can lead to degeneration and inflammation of the plantar fascia, resulting in pain during the first steps after rest and reduced functional capacity.

Various physiotherapy interventions have been proposed for the management of plantar fasciitis, including stretching exercises, strengthening exercises, orthoses, and manual therapy techniques. Instrument-Assisted Soft Tissue Mobilization (IASTM) has gained popularity in recent years due to its ability to improve soft-tissue mobility and promote tissue healing through controlled micro-trauma and stimulation of fibroblast activity. Foam roller therapy is another widely used intervention that applies self-myofascial release to soft tissues. It is believed to improve flexibility, increase blood flow, and reduce muscle tightness.

Although both interventions have shown beneficial effects individually, there is limited evidence comparing the effectiveness of IASTM and foam roller therapy in individuals with plantar fasciitis. Therefore, this study will be conducted to compare the effects of these two treatment approaches on pain, range of motion, strength, quality of life, and functional disability.

Objective

- To compare the effectiveness of Instrument-Assisted Soft Tissue Mobilization and Foam Roller therapy in reducing pain and improving ankle range of motion in individuals with plantar fasciitis.
- To evaluate the effect of IASTM on pain, range of motion, muscle strength, and quality of life.
- To evaluate the effect of foam roller therapy on pain, range of motion, muscle strength, and quality of life.
- To compare improvements in foot function and disability between the two interventions.

Methods

Study Design

This study will be a Randomized Controlled Trial conducted as an experimental comparative clinical study involving two intervention groups. Participants diagnosed with plantar fasciitis will be recruited and allocated into two groups receiving different physiotherapy interventions. Outcome measures will be assessed at baseline and after completion of the treatment protocol.

Study Setting

The study will be conducted across physiotherapy outpatient settings across Delhi NCR, India.

Participants

A total of 56 participants diagnosed with plantar fasciitis will be recruited and allocated into two groups. Group A: 28 participants and Group B: 28 participants.

Eligibility Criteria

Participants will be eligible for inclusion if they are between 18 and 45 years of age, experiencing pain on palpation at the medial tuberosity of the calcaneus, and reported pain during the first steps in the morning that decreased after walking. Individuals with symptoms persisting for more than one month will be included in the study. Both male and female participants meeting these criteria would be

considered for participation. Participants will be excluded if they have a history of foot surgery, inflammatory rheumatic disease, previous steroid injection in the affected region, or radiculopathy affecting the lower limb.

Interventions

Participants in Group A (Instrument-Assisted Soft Tissue Mobilization (IASTM)) would receive IASTM applied to the plantar fascia, gastrocnemius, and soleus muscles using specialized stainless-steel instruments. The therapist will use scanning and stroking techniques to identify and release soft-tissue restrictions. Treatment will be administered for approximately 5–10 minutes per session, followed by cryotherapy for 10–15 minutes. IASTM sessions will be provided on alternate days for three weeks.

Participants in Group B (Foam Roller Therapy) Participants in this group will perform self-myofascial release using a foam roller applied to the calf muscles and plantar fascia. The foam roller will be moved back and forth along the muscle groups while maintaining controlled pressure. Each session shall consist 45 seconds of rolling followed by 15 seconds of rest for five repetitions.

Both groups would also follow a standardized exercise program consisting of stretching and strengthening exercises targeting the calf muscles and plantar fascia. The stretching component included gastrocnemius stretching, soleus stretching, and plantar fascia stretching, with each stretch held for 30 seconds and performed for three repetitions. The strengthening program shall comprise toe curl exercises, ankle invertor strengthening, ankle evertor strengthening, and heel raise exercises to improve foot and ankle muscle function. The intensity and progression of the exercises will be adjusted according to the individual participant's performance and tolerance to ensure safe and effective rehabilitation.

Outcome Measures

The outcomes of the study include pain intensity, ankle range of motion muscle strength, quality of life, and foot function. Pain intensity will be assessed using the Numeric Pain Rating Scale (NPRS), an 11-point scale ranging from 0 (no pain) to 10 (worst imaginable pain). Ankle range of motion will be measured in degrees using a universal goniometer. Quality of life will be assessed using the Short Form-36 (SF-36) questionnaire, which evaluates physical and mental health domains. Foot function and disability related to plantar fasciitis were measured using the Foot Function Index (FFI) questionnaire.

Study Duration

The intervention protocol shall last for three weeks, with outcome measures recorded before and after the treatment period.

Statistical Analysis

Statistical analysis will be conducted to compare pre- and post-intervention values within each group and between the two groups. Paired t-tests will be used to assess within-group changes. Unpaired t-tests will be used to compare outcomes between the two groups. Statistical significance will be considered at $p < 0.005$.

Ethical Considerations

Ethical approval has been obtained from the institutional ethics committee before commencement of the study. Participants will be informed about the study procedures and shall provide written informed consent prior to participation.