Effectiveness of Graston technique treatment on Pain, and Foot General Health of chronic Plantar Fasciitis patients

Protocol summary

Study aim
My study aim is to assess the effectiveness of Graston technique with taping on the treatment of chronic plantar heel pain, foot function and foot health related quality of life of chronic plantar fasciitis patients.

Design
Randomized, parallel groups, single blinded, randomized controlled trial

Settings and conduct
Medina Teaching Hospital, participants will be blinded so that they can not know either they will be in intervention group or in control group

Participants/Inclusion and exclusion criteria
Inclusion criteria
- Patients will be diagnose with chronic plantar fasciitis and Pain started before more than 6 weeks and less than 6 months
- Both gender age of 20 to 45 years were included
- Pain on first steps of walking out of bed in the morning or after prolonged standing, or sitting
- Pain located at the anterio-medial surface of heel or mid-foot and presence of an everted calcaneus greater than or equal to 2

Exclusion criteria
- No Previous history of severe vascular disease, cancer, joint disease, neurological disorders related to lower limb of affected side and pathological calcaneal spur
- Ankle and foot fracture or surgery before 6 months and stress fracture before 8 months
- Plantar having fascia release surgery done within 3 month back
- Diabetics and altered skin sensation or foot dermal conditions
- Who are already taking physical therapy treatment or any other treatment during 30 days of participation
- Pregnant female
- Who refuse to participate in the study

Intervention groups
There will be one treatment group and one control group. 30 participants will be randomized into treatment group and control group. 15 individuals will include into the treatment group which will GT group, 15 individuals will include into the control group which will control group randomly.

Main outcome variables
plantar heel pain, Foot function and General foot health

General information

Reason for update
Acronym
IRCT registration information
- IRCT registration number: IRCT20210111050005N1
- Registration date: 2021-02-01, 1399/11/13
- Registration timing: registered_while_recruiting

Last update: 2021-02-01, 1399/11/13
Update count: 0

Registration date
- 2021-02-01, 1399/11/13

Registrant information
Name
Noreen kiran
Name of organization / entity
The University of Faisalabad
Country
Pakistan
Phone
+92 41 5212044
Email address
noreen.kiran@tuf.edu.pk

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
- 2021-01-30, 1399/11/11

Expected recruitment end date
- 2021-04-04, 1400/01/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of Graston technique treatment on Pain, and Foot General Health of chronic Plantar Fasciitis patients

Public title
Effectiveness of Graston technique treatment on chronic plantar Fasciitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients diagnosed with chronic plantar fasciitis Patients having pain started before more than 6 weeks and less than 6 months Both male and female of age 20 to 45 years were included Patients having pain on first steps of walking out of bed in the morning or after prolonged standing, or sitting Patients having pain located at the anterio- medial surface of heel or mid-foot and presence of an everted calcaneus greater than or equal to 2

Exclusion criteria:
Patients having previous history of severe vascular disease, cancer, rheumatoid arthritis, or osteoporosis, neurological disorders related to lower limb of affected side, pathological calcaneal spur Patients having Ankle and foot soft tissue masses/bursitis, tendon pathology or scar, heel fat pad atrophy/hypertrophy Patients having Ankle and foot fracture or surgery before 6 months and stress fracture before 8 months Patients having pain or foot related complications after fracture or surgery Patients having fascia release surgery done within 3 months back Patients having Diabetics and altered skin sensation or foot dermal conditions Who are already taking physical therapy treatment or corticosteroid injections and who were not willing to quit such treatment during 30 days of participation Pregnant female Who refuse to participate in the study

Age
From 20 years old to 45 years old

Gender
Both

Phase
2

Groups that have been masked
- Participant

Sample size
Target sample size: 30

Randomization (investigator's opinion)
Randomized

Randomization description
Each patient of heel pain coming to the recruitment center will be screened. I will make a list of 30 patients according to the sequence as they are coming I will give them numbers 1 to 30 i.e. the first patient enrolled will be given number 1 and last patient enrolled will be given number 30. Every odd will be allocated into treatment group and every even number will be allocated into control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
I will give each participant a number, e.g 1 to 30, on the basis of these numbers I will make two groups, one will be treatment group in which all even numbers will be allocated, and one will control group in which all odd numbers will be allocated. In this way this way i could not know which participant will be in which group and participant will also not know who will be entered in which group.

Placebo
Not used

Assignment
Other

Other design features
Objective 1= To assess the effectiveness of Graston technique with taping on the treatment of chronic plantar heel pain in chronic plantar fasciitis patients, Objective 2= To assess the effectiveness of Graston technique with taping on foot function and foot health related quality of life of chronic plantar fasciitis patients

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee of The University of Faisalabad

Street address
Medina University near kea motors showroom, Sargodha road Faisalabad

City
Faisalabad

Postal code
38000

Approval date
2020-08-03, 1399/05/13

Ethics committee reference number
TUF/DR/MSPP/005

Health conditions studied

1

Description of health condition studied
Plantar fasciitis. Overloading and repetitive micro trauma results plantar fasciitis This is a health condition not a disease.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
pain

Timepoint
Before intervention, and 2, 4 weeks after intervention

Method of measurement
by using plantar fasciitis pain scale

Secondary outcomes

1
Description
General foot health status
Timepoint
before intervention and 2, 4 weeks after intervention
Method of measurement
by The Foot Health Status Questionnaire

Intervention groups

1
Description
It will receive baseline treatment (Therapeutic ultrasound, stretching exercises of calf and plantar fascia, taping ) and Graston technique by Graston tool. treatment will be of 2 sessions per week ( every 3rd day) for 4 weeks. Ultrasound protocol= Therapeutic ultrasound was given to the patients for 5 minutes(continuous mode, intensity of 1 W/cm2 with frequency of 1 MHz for five minutes in prone lying (Sankhe, et al., 2016). Stretching exercises of calf and plantar fascia= Stretching exercises of plantar fascia muscle and calf muscles, performed 10 stretches holding each for 10 seconds (DiGiovanni et al., 2006, Garret and Neibert, 2019). Taping method= low dye taping with calcaneal sling technique will be used. leukotape (type of tape) will be used for this purpose. taping will be applied on every 3rd day of week, after application patient will be guided to remove tape after 24 hours (Hyland et al., 2006, Weon, Kim and Jung, 2015).
Category
Treatment - Other

Recruitment centers

1
Recruitment center
Name of recruitment center
Madina teaching hospital
Full name of responsible person
Dr Kishwar
Street address
Medina Teaching hospital near kea motors showroom, Sargodha road Faisalabad
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
The University of Faisalabad
Full name of responsible person
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Email
Aisha.tabassum@tuf.edu.pk

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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<tr>
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<td>Noreen Kiran</td>
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<tr>
<td>Position</td>
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<td>Street address</td>
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<td>Phone</td>
<td>011925212044</td>
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<td>Email</td>
<td><a href="mailto:Noreen.kian@tuf.edu.pk">Noreen.kian@tuf.edu.pk</a></td>
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<tr>
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**Sharing plan**

- **Deidentified Individual Participant Data Set (IPD)**
  - **No** - There is not a plan to make this available
  - **Justification/reason for indecision/not sharing IPD**
    - Data is confidential
- **Study Protocol**
  - **No** - There is not a plan to make this available
- **Statistical Analysis Plan**
  - **No** - There is not a plan to make this available
- **Informed Consent Form**
  - **No** - There is not a plan to make this available
- **Clinical Study Report**
  - **Not applicable**
- **Analytic Code**
  - **Not applicable**
- **Data Dictionary**
  - **No** - There is not a plan to make this available