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Effect of Achilles tendon stretching in individuals with plantar fasciitis

Submission date
20/11/2015

Recruitment status
No longer recruiting

Registration date
14/12/2015

Overall study status
Completed

Last Edited
09/08/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims:
Plantar fasciitis (PF), or heal pain, is a common foot condition. It is usually experienced as an intense pain when placing weight on the heel (for example, when walking). The condition usually builds up gradually, getting worse over time and is generally worse in the morning or after not walking for a while. It can be eased by gentle activity, such as walking and made worse by stairs, hills, running, jumping, or barefoot activities. Rest, elevation (raising the feet of the floor) and massage often provides pain relief. A review of the literature has shown that stretching the Achilles tendon and plantar fascia (the tough band of tissue that runs under the sole of the foot) is good at being able to reduce the pain experienced in patients with plantar fasciitis. Stretching exercises increase range of motion (ROM) and circulation, reduces risk of injury to the muscles, joint, tendons and ligaments, and reduces muscular soreness and tension. This study is looking at a new tool being created (the continuous passive stretching instrument: CPS) to stretch the Achilles tendon and the plantar fascia at the same time. The aim of this study is to compare the CPS tool with standard Achilles tendon stretching for patients with plantar fasciitis.

Who can participate?
Patients aged between 40-60 with PF

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 receive the standard Achilles tendon stretching treatment, twice a day, 5 days a week for a period of four weeks. Participants in group 2 are given the CPS treatment, twice a day, 5 days a week for a period of four weeks. All patients are followed up after the 4 week period and again after 3 months, where the amount of pain they are experiencing, is measured.

What are the possible benefits and risks of participating?
Participants may experience a reduction in pain. There are no known risks to participating.

Where is the study run from?
Physical Therapy clinic, Faculty of Allied Health Sciences, Bangkok (Thailand)

When is study starting and how long is it expected to run for?
December 2015 to July 2016

Who is funding the study?
Allied Health Sciences Research Fund

Who is the main contact?
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Effect of Achilles tendon stretching in individuals with plantar fasciitis: a randomized controlled trial

Study objectives
Continuous passive instrument can improve plantar fasciitis symptoms when compared with stretching exercises.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Review Committee for Research Involving Human Research Subjects, Health Science Group, Chulalongkorn University, Thailand, 01/10/2015

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Plantar fasciitis

Interventions
Participants are randomly allocated to one of two groups.

Group 1: Achilles tendon stretching: Standing and facing to the wall, the patient lean forward, with the affected foot furthest away from the wall while keeping the heel on the floor with knee straight. Holding for 20 sec./set, 5 sets/time, 2 times/day, 5 days/week, for 4 consecutive weeks

Group 2 Continuous Passive Stretching (CPS) Instrument group: The CPS is the innovation passive stretching instrument. The base of CPS is made of wood, it is 30x24 cm adjustable slope to 5 levels from 0-60 degrees for Achilles tendon stretching. Two bases of CPS are independently, each base can adjust for appropriate degree which is controlled by remote. The base surface will be placed with Bene-feet mat and attaches the modified goniometer at the side of base. Subject will stand with bare feet on CPS with hip and knee straight. The CPS will be raised up until the patient feels pain triggering at Achilles tendon or calf muscle then it will be lower down from the tighten point. For the sound side, CPS will be raised at the same degree as the affected side in order to maintain and balance both sides. Compensation such as knee or hip

bending will be eliminated at appropriate degree. A fascia will be relaxed by surface of board. The holding phase will be 20 seconds/set and 20 seconds for resting period. The subject will receive a treatment every day for 4 consecutive weeks (5 sets/time, 2 times/day, 5 day/week). 3 months follow-up with VAS and VAS-FA for both groups will be performed.

Intervention Type
Mixed

Primary outcome(s)
VAS-FA score (the visual analogue scale-foot and ankle questionnaire).

VAS FA consists of question 20 items. The questions are divided into three sections, 4 items relating to pain, 11 items relating to function, and the patient complaints for 5 items. Visual Analogue Scale (VAS) ranged of 0-100 points is applied each question. Thus, 20 questions will be in the range 0-2000 points and the final score is divided by 20, so the score with the range from 0-100 points. In Thai version, method of scoring is taken from English version. By using the visual inspection of the question which has the length of 10 cm (100 mm). Subjects draw “X” along a line based on individual feelings for each question. The left side, the minimum score is 0 points, which represents the most severe of symptoms. For the right side, the maximum score is 100 points, which represents the minimal symptoms or severity.

Measured at baseline, after 4 weeks and, again, after 3 months.

Key secondary outcome(s))
1. Pain intensity (pressure algometer for pain): Pressure algometers is designed to measure the level of pain from pain thresholds or tenderness resistance. Participants will be asked during giving the pressure on the area of pain and must be able to separate pain out of discomfort: once the subject says “stop”, investigator will record the value of pressure force. The pressure algometer will be applied in this study to investigate the level of pain change after the stretching techniques at tenderness point of plantar fascia
2. ROM (range of movement) of lower back (BROM): The BROM will be used as outcome measurement in this study since we consider the continuation of the muscle and fascia along the superficial back line of human body. For the measuring of sagittal plane motion of lumbar, the inclinometer will be used. An inclinometer with L-shaped is attached on the subject’s sacrum with self-adhesive straps to hold the device in center position and can record the degree of measuring. It is used to measure the distance between the spinous process of T12 and S1, and the motion of the lumbar flexion and extension. Measure can be done in a standing position, even in the standing position is not limited pelvis. However, the device over S1 pelvic component allows only lumbar motion without pelvic motion. Range of motion is recorded in degrees from the side of the device
3. ROM of ankle dorsiflexion (goniometer): The degree of ankle will be performed to determine the improvement of Achilles tendon tightness and plantar fascia shortening by standard goniometer in supine position
4. Patient's satisfaction, measured by the global perceive effect questionnaire

All outcome measures will used at baseline and the end of 4th week, other than patient's satisfaction as the questionnaire will be given only at the end of treatment only.

Completion date
31/07/2016

Eligibility

Key inclusion criteria
1. Plantar heel pain that increases in the morning with the first steps after waking up (VAS≥4)
2. Symptoms decreasing with slight levels of activity, such as walking
3. Localized pain on palpation of the proximal plantar fascia
4. The symptoms worsened after weight bearing for a long time

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Red flags (i.e., tumor, fracture, rheumatoid arthritis, osteoporosis, severe vascular disease, etc)
2. Fracture of lower extremities within 6 months
3. Prior surgery of lower extremities within 6 months
4. Nerve involvement lower extremities, diabetes mellitus, pregnancy

Date of first enrolment
01/12/2015

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
Thailand

Study participating centre
Chulalongkorn University
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Sponsor information

Organisation
Chulalongkorn University

ROR
https://ror.org/028wp3y58

Funder(s)

Funder type
Research organisation

Funder Name
Allied Health Sciences Research Fund

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		02/08/2017	09/08/2017	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes