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A randomised comparative trial of eccentric training versus static stretching in the management of chronic Achilles tendinopathy: Clinical and ultrasonographic outcomes

Submission date
29/09/2006

Recruitment status
Stopped

Registration date
29/09/2006

Overall study status
Stopped

Last Edited
05/05/2010

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0626161298

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Musculoskeletal Diseases: Achilles tendinopathy

Interventions
Subjects will pick an envelope containing a paper allocating the subject to either an eccentric calf loading training or static calf stretching regime. The researcher will then assign the subject to the appropriate state registered physiotherapist for commencement of the appropriate training regime. In each physiotherapy department participating within this study, one physiotherapist will be responsible for providing the care for participants undergoing the eccentric muscle training. A second physiotherapist will be responsible for providing the care for participants undergoing the static calf muscle stretching.

Added 05/05/10: trial stopped in 2007 due to lack of staff.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Clinical outcome: Victorian Institute of Sport assessment scale (VISA-A). A quantitative index of the clinical severity of Achilles tendinopathy which has proven reliability and validity (Robinson et al 2001). Scores range from 0-100, where 100 represents no symptoms and perfect function. A change of 25 points is considered clinically significant (Robinson et al 2001). The Consultant Musculoskeletal Physician who initially clinically asses the subjects at baseline will assess the same subjects at 12 weeks, six months and twelve months following the training regime. The Consultant Musculoskeletal Physician will be blinded to the treatment group, which the subject has participated. Patients will be instructed to withhold this information.
2. Ultrasonography: Achilles tendon evaluation form as designed by two Consultant Musculoskeletal radiologists in Leeds Teaching Hospitals NHS Trust. Similar grading schemes have been reported previously (Archambault et al 1997). The radiologists will scan both tendons of each individual and be blinded to the symptomatic side. Furthermore the radiologists will be blinded to the clinical findings, VISA-A scores and treatment regime undertaken by the patient. Patients will be instructed to withhold this information from the radiologists.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2004

Completion date
01/05/2006

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
Patients with Achilles tendon pain who have been referred to the Leeds Musculoskeletal Service by their GP or via secondary care will provide the study population. Patients referred will be screened clinically by a Consultant Musculoskeletal Physician. Those who meet the clinical criteria will be invited to take part in the study (visit 1). The first 60 patients who give consent will form the study sample. The sample size has been increased from the power calculation to allow for drop-outs from the study. Men and women aged between 25-65 years old.

Patients who meet the clinical inclusion criteria will be provided with an information sheet and consent form. After a minimum gap of 24 hours after receipt of the information sheet the patient will be contacted by the research coordinator, the study discussed and if the patient is happy to give consent the patient will provide three copies of the consent form which will be returned to the clinic base in a stamped addressed envelope. The researcher will sign the three copies of the consent form confirming that informed consent was received. One copy will be

retained in file by the research, one copy will be kept with the patients case notes and one copy will be returned to the patient.

Inclusion criteria:
1. Men and women aged between 25 and 65
2. Achilles tendon pain >3 month duration
3. Achilles tendon pain on palpation 2-6cm proximal to calcaneal insertion
4. Positive ardc sign - Tender area of intratendinous swelling that moves with the tendon (Mafulli, Kenward, Testa, Capasso, Regine and King 2003)
5. Positive Royal london test - Tender area of intratendinous swelling whose tenderness significantly decreases or disappears when the tendon is put under tension ie full ankle dorsiflexion or plantarflexion (Mafulli et al 2003).
6. VISA-A score <75
7. Tendinopathic changes present in tendon 2-6cm above Achilles insertion on calcaneus as imagined by ultrasound.

NSAIDs are allowed to be taken by the patient during their participation in the study, but their dose and use must be recorded.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Restricted ankle joint motion due to other injury/disease
2. Bilateral symptoms
3. Acute peri-tendinopathy
4. Insertional tendinopathy/tendinosis
5. Retrocalcaneal bursitis
6. Significant partial tearing of the Achilles tendon
7. Treatment to Achilles tendon within six months previous
8. Pregnancy
9. Previous Achilles tendon injection
10. history of rheumatic disease
11. Diabetes

Date of first enrolment
01/11/2004

Date of final enrolment
01/05/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Physiotherapy Department
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
Bradford South and West Primary Care Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration