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A Pilot study to evaluate the effectiveness of eccentric exercise in the conservative management of Achilles Tendinopathy - a comparative trial

Submission date
30/09/2005

Recruitment status
No longer recruiting

Registration date
30/09/2005

Overall study status
Completed

Last Edited
18/10/2017

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
N0544160595

Study information

Scientific Title
A Pilot study to evaluate the effectiveness of eccentric exercise in the conservative management of Achilles Tendinopathy - a comparative trial

Study objectives
Is the rate of recovery in patients suffering from degenerative Achilles Tendon problems enhanced by beginning eccentric calf strength training exercises in standing from their first appointment?

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
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
The rate of recovery in patients suffering from Achilles Tendinopathy starting a loaded (standing) eccentric strength training program immediately is enhanced, in comparison to those who begin eccentric strength training in a non - weightbearing (lying) position.

Overall recovery will be better in patients suffering from Achilles Tendinopathy starting a loaded (standing) eccentric strength training program immediately is enhanced, in comparison to those who begin eccentric strength training in a non - weightbearing (lying) position.

The study will be conducted in the outpatient physiotherapy department, the natural setting for this type of intervention. Subjects will be opportunistically recruited from a sampling frame of patients referred for physiotherapy with a diagnosis of pain in the region of the Achilles tendon from September 2004 to December 2004 subject to Local Research Ethics Committee approval.

Potential subjects will be sent a letter inviting them to attend for an assessment for eligibility to join the trial. Subjects will be asked to telephone and express verbal consent to join the trail, these subjects will be sent an appointment date and a consent form to complete to bring with them to their first session. At their first session, the consent form will be collected, subjects will be given the VISA-A questionnaire to complete and a subjective and objective history will be obtained by the author (a chartered physiotherapist). Following this assessment, subjects will be offered the option to take part in the study based on well defined inclusion and exclusion criteria.

Subjects who do fulfil the inclusion criteria will be offered a follow up appointment to begin standard intervention through the normal booking procedure.

Consenting subjects will be randomly assigned to one of two treatment groups by computer generated block allocation:
1) The experimental group: eccentric exercise model 1- subjects will be taught eccentric exercises in lying using resistance band and building up to standing exercises as soon as they are comfortable at the highest level of resistance band.
2) The comparison group: eccentric exercise model 2- subjects will be taught eccentric exercises in standing from their first appointment.
Protocols describe the exact detail of the training methods will be used.

All subjects will be taught static calf stretches, ice massage and the exercises specific to their treatment group. Subjects will be given an exercise sheet to act as a memory aid with written advice on how to progress their exercises independently which will be discussed. Allowing the subjects to advance their exercises independently in this way reduces the potential for experimental bias which is unavoidable because the lead investigator is carrying out the research and is aware of the hypothesis.

Both groups will be offered further appointments at week 1, week 3 and week 5 with the expectation that the patients will practise the exercise programme at home independently.

A measurement of symptom severity will be evaluated 5 minutes prior to their first follow up appointments at week1, 3, 5, and 8 in all subjects using the Victorian Institute of Sports Association Achilles questionnaire- VISA- A, a validated and reliable condition specific measurement of symptom severity in Achilles tendinopathy. The questionnaire is self administered reducing any potential for observer bias.

Data collected will be anonymised and kept securely at all times. Results will be analysed on an intention to treat basis.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Change in the symptoms of pain, stiffness and function measured using the condition specific measurement: the VISA- A questionnaire.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2004

Completion date
31/12/2004

Eligibility

Key inclusion criteria
Study will be conducted in the outpatient physiotherapy department

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Ten subjects in the intervention group and 10 in the comparison group

Key exclusion criteria
1. Neurological problems
2. Bilateral symptoms
3. Any other foot and ankle problems
4. Under age 16, over age 65
5. Symptoms over 18 months in duration

Date of first enrolment
01/09/2004

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrookes NHS Trust
Cambridge
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Sponsor information

Organisation
Department of Health

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Sponsor type
Government

Website
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Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Cambridge NHS R&D Consortium - Addenbrookes NHS Trust (UK)

Funder Name
NHS R&D Support Funding (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