

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

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/10/2017	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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 trial, 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 week 1, 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  
United Kingdom  
CB2 2QQ

## **Sponsor information**

**Organisation**  
Department of Health

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
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**Sponsor type**  
Government

**Website**  
<http://www.dh.gov.uk/Home/fs/en>

## **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