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# Effects of two different exercise protocols in individuals with non-insertional Achilles tendinopathy

**Submission date**
11/08/2021

**Recruitment status**
No longer recruiting

**Registration date**
13/08/2021

**Overall study status**
Completed

**Last Edited**
26/06/2025

**Condition category**
Musculoskeletal Diseases

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

## Plain English summary of protocol

Background and study aims
Achilles tendinopathy is a painful overuse injury of the Achilles tendon. This injury is frequent among people who practice running and jumping sports, but it is also present in the sedentary (inactive) population. Its symptoms include pain, swelling of the Achilles tendon, and loss of function. This study investigates the relationship between the control of the calf muscles and some characteristics of these muscles and the Achilles tendon in people with Achilles tendinopathy. The researchers also want to determine which type of exercise has better results in this condition.

Who can participate?
1. Healthy men or women aged 18 to 55 years old
2. Men and women in the same age range with pain in the Achilles tendon for the last 3 months or a diagnosis of non-insertional Achilles tendinopathy

What does the study involve?
The experimental sessions will involve completing questionnaires, collection of data (i.e., age, height, and weight), measurements of the structural properties of the calf muscles and the Achilles tendon during rest and lower force plantarflexion (downward movement of the foot away from the leg) contractions, and assessment of the electrical activity of the calf muscles during isometric (without movement), dynamic (with movement), and explosive (as hard and fast as the participant can) plantarflexion contractions. Participants with non-insertional Achilles tendinopathy will be randomly allocated into two different groups: eccentric (ECC) or concentric (CON) training. The training sessions will involve two different types of plantarflexion dynamic contractions. Each group will perform 4 x 15 repetitions at 50% of the maximal force 2-3 times per week over a period of 6 weeks.

What are the possible benefits and risks of participating?
The possible benefits of participating include obtaining important information about the Achilles tendon, calf muscle strength and control of force. Participants will receive an exercise program to reduce their symptoms. The potential risks from the procedures are low. To attach

surface electrodes the skin of three small areas of the leg needs to be shaved (to remove any hair) and then cleaned with abrasive paste. This could cause slight discomfort from minor abrasion of the skin area. In addition, participants can feel up to moderate tendon pain during the first training sessions, which is normal during the treatment of tendinopathy. The researchers will ensure that it does not reach levels equal to or greater than 6 out of 10 during the sessions. Finally, participants might feel some level of muscle or tendon soreness up to 24 to 48 hours after the experiment. This type of discomfort is usually observed after the first sessions in patients with non-insertional Achilles tendinopathy.

Where is the study run from?
University of Birmingham (UK)

When is the study starting, and how long is it expected to run for?
January 2020 to March 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Ignacio Contreras-Hernandez
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# Contact information

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Public, Scientific


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# Additional identifiers

**Clinical Trials Information System (CTIS)**
Nil known

**ClinicalTrials.gov (NCT)**
Nil known

**Protocol serial number**
AIP 17641

# Study information

**Scientific Title**
Neuromuscular and structural tendon adaptations after 6 weeks of either concentric or eccentric exercise in individuals with non-insertional Achilles tendinopathy

**Acronym**
AIP

**Study objectives**
Current study hypothesis as of 08/03/2022:

A 6-weeks training protocol based on either controlled eccentric or concentric contractions in individuals with non-insertional Achilles tendinopathy has similar results regarding changes in the gastrocnemius-soleus motor unit firing properties.
A 6-weeks training protocol based on either controlled eccentric or concentric contractions in individuals with non-insertional Achilles tendinopathy has similar results regarding changes in the level of pain and function and mechanical and structural properties of the Achilles tendon.
Gastrocnemius-soleus motor unit firing properties and mechanical and structural properties of the Achilles tendon differ between individuals with non-insertional Achilles tendinopathy and asymptomatic controls.

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Previous study hypothesis:

The mechanical and structural properties of the Achilles tendon and the gastrocnemius-soleus motor unit behaviour differ between individuals with non-insertional Achilles tendinopathy and asymptomatic controls.
A 6-weeks training protocol based on either controlled or concentric contractions in individuals with non-insertional Achilles tendinopathy has similar results regarding the level of pain and

function, mechanical and structural properties of the Achilles tendon, and gastrocnemius-soleus motor unit behaviour.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Current ethics approval as of 21/07/2022:
Approved 29/03/2021, Amendment approved 17/06/2022, University of Birmingham Science, Technology, Engineering and Mathematics Ethical Review Committee (Edgbaston, Birmingham, B15 2TT, UK; +44 (0)1214143344; S.M.Waldron@bham.ac.uk), ref: ERN_20-0604, amendment ref: ERN_20-0604A

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Previous ethics approval:
Approved 29/03/2021, University of Birmingham Science, Technology, Engineering and Mathematics Ethical Review Committee (Edgbaston, Birmingham, B15 2TT, UK; +44 (0) 1214143344; S.M.Waldron@bham.ac.uk), ref: ERN_20-0604

## Study design
Randomized clinical trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Non-insertional Achilles tendinopathy

## Interventions
Current interventions as of 08/03/2022:

Participants with non-insertional Achilles tendinopathy will visit the laboratory over six consecutive weeks for the experimental sessions (at week 1, 3, and 6) and training sessions (2-3 sessions per week). Before the first experimental session, individuals with non-insertional Achilles tendinopathy will be randomized by an independent researcher in a 1:1 allocation ratio to either eccentric (ECC) or concentric (CON) training using computer-generated simple scheme randomization. Healthy control participants will visit the laboratory once.

Participants in the ECC group will be asked to perform a warm-up consisting of three eccentric plantarflexion contractions at 25% of the maximal voluntary contraction (MVC); this will be followed by the eccentric training protocol. This protocol consists of 4 x 15 eccentric plantarflexion contractions at 50% of the MVC, range of motion of 30° (neutral position 0° to 30° of plantarflexion), time under tension of 10 seconds, angular speed of 3°/s and 3 minutes of rest between each series. Visual feedback of the exerted torque will be provided.

Participants in the CON group will perform a warm-up consisting of three concentric plantarflexion contractions at 25% of the MVC, and then, the concentric training protocol. This

protocol consists of 4 x 15 concentric plantarflexion contractions at 50% of the MVC, range of motion of 30° (neutral position 0° to 30° of plantarflexion), time under tension of 10 seconds, angular speed of 3°/s, and 3 minutes of rest between each series.

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Previous interventions:

Participants with non-insertional Achilles tendinopathy will visit the laboratory over six consecutive weeks for the experimental sessions (at week 1, 3, and 6) and training sessions (2-3 sessions per week). Before the first experimental session, individuals with non-insertional Achilles tendinopathy will be randomized by an independent researcher in a 1:1 allocation ratio to either eccentric (ECC) or concentric (CON) training using computer-generated simple scheme randomization. Healthy control participants will visit the laboratory once.

Participants in the ECC group will be asked to perform a warm-up consisting of three eccentric plantarflexion contractions at 25% of the maximal voluntary contraction (MVC); this will be followed by the eccentric training protocol. This protocol consists of 4 x 15 eccentric plantarflexion contractions at 50% of the MVC, range of motion of 30° (neutral position 0° to 30° of plantarflexion), time under tension of 14 seconds, angular speed of 3°/s and 3 minutes of rest between each series. Visual feedback of the exerted torque will be provided.

Participants in the CON group will perform a warm-up consisting of three concentric plantarflexion contractions at 25% of the MVC, and then, the concentric training protocol. This protocol consists of 4 x 15 concentric plantarflexion contractions at 50% of the MVC, range of motion of 30° (neutral position 0° to 30° of plantarflexion), time under tension of 14 seconds, angular speed of 3°/s, and 3 minutes of rest between each series.

## Intervention Type
Other

## Primary outcome(s)
Current primary outcome measure as of 08/03/2022:

Motor units mean discharge rate, discharge rate variability, recruitment, and de-recruitment thresholds of the gastrocnemius medialis, gastrocnemius lateralis, and soleus muscles all measured using high-density surface electromyography at baseline, weeks 3 and 6.

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Previous primary outcome measure:

1. Thickness, length, and cross-sectional area of the Achilles tendon measured using B-mode ultrasonography at baseline, weeks 3 and 6
2. Thickness, pennation angle, and fascicle length of the gastrocnemius medialis, gastrocnemius lateralis, and soleus muscles measured using B-mode elastography at baseline, weeks 3 and 6
3. Stiffness of the Achilles tendon measured using shear-wave elastography at baseline, weeks 3 and 6
4. Motor units mean discharge rate, discharge rate variability, recruitment, and de-recruitment thresholds of the gastrocnemius medialis, gastrocnemius lateralis, and soleus muscles all measured using high-density surface electromyography at baseline, weeks 3 and 6

### Key secondary outcome(s))
Current secondary outcome measures as of 08/03/2022:

1. Thickness, length, and cross-sectional area of the Achilles tendon measured using B-mode ultrasonography at baseline, weeks 3 and 6.
2. Stiffness of the Achilles tendon measured using shear-wave elastography at baseline, weeks 3 and 6.
3. Thickness, pennation angle, and fascicle length of the gastrocnemius medialis muscle using B-mode ultrasonography at baseline, weeks 3 and 6. Gastrocnemius lateralis and soleus muscles' thickness measured using B-mode ultrasonography at baseline, weeks 3 and 6.
4. Physical activity level measured using the International Physical Activity Questionnaire-Short form (IPAQ-SF) at baseline, weeks 3 and 6.
5. Achilles tendinopathy severity measured using the Victorian Institute of Sports AssessmentAchilles (VISA-A) questionnaire at baseline, weeks 3 and 6. Additionally, we will measure the severity of Achilles tendinopathy after 3 and 6 months of completing the intervention.
6. Physical function measured using the Foot and Ankle Ability Measure (FAAM) questionnaire at baseline, weeks 3 and 6.
7. Pain catastrophizing measured using Pain Catastrophizing Scale (PCS) questionnaire at baseline, weeks 3 and 6.
8. Fear of movement measured using the Tampa Scale of Kinesiophobia (TSK) questionnaire at baseline, weeks 3 and 6.
9. Pain level measured using the Numerical Rating Scale (NRS) at baseline, weeks 3 and 6. Additionally, we will measure the pain level after 3 and 6 months of completing the intervention.

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Previous secondary outcome measures:

1. Physical activity level measured using the International Physical Activity Questionnaire-Short form (IPAQ-SF) at baseline, weeks 3 and 6
2. Achilles tendinopathy severity measured using the Victorian Institute of Sports Assessment-Achilles (VISA-A) questionnaire at baseline, weeks 3 and 6
3. Physical function measured using the Foot and Ankle Ability Measure (FAAM) questionnaire at baseline, weeks 3 and 6
4. Pain catastrophizing measured using Pain Catastrophizing Scale (PCS) questionnaire at baseline, weeks 3 and 6
5. Fear of movement measured using the Tampa Scale of Kinesiophobia (TSK) questionnaire at baseline, weeks 3 and 6

### Completion date
31/03/2023

## Eligibility

### Key inclusion criteria
Men or women aged 18 to 55 years old will be recruited for the healthy control and Achilles tendinopathy groups

Inclusion criteria for those with Achilles tendinopathy:
1. Non-insertional Achilles tendinopathy determined by an experienced physiotherapist based

on defined clinical findings, VISA-A and NRS (Numerical Rating Scale) scores, physical examination, pain duration of at least 3 months and ultrasound evaluation
2. VISA-A scores less than 90 will be considered as a reference to identify individuals with Achilles tendinopathy
3. Ultrasound evaluation will include the identification of local thickening of the tendon and/or irregular tendon structure with hypoechoic areas and/or irregular fiber orientation

### Participant type(s)
Healthy volunteer, Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
55 years

### Sex
All

### Total final enrolment
39

### Key exclusion criteria
1. Systemic or inflammatory conditions including rheumatic, neuromuscular disorders, and malignancy
2. Current or history of chronic respiratory, neurological or cardiovascular diseases
3. History of lower limb surgery

Specific exclusion criteria for the participants with Achilles tendinopathy:
1. Patients participating in any other treatment or rehabilitation program for Achilles tendinopathy
2. Corticosteroid injections in the previous 12 months
3. Insertional Achilles tendinopathy

Specific exclusion criteria for the control group:
1. Pain/injury in the lower limbs within the previous 6 months

### Date of first enrolment
01/09/2021

### Date of final enrolment
15/02/2023

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**SportEx**
Edgbaston
Birmingham
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B15 2TT

## Sponsor information

### Organisation
University of Birmingham

### ROR
https://ror.org/03angcq70

## Funder(s)

### Funder type
Other

### Funder Name
Investigator initiated and funded

## Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
E.A.MartinezValdes@bham.ac.uk
Type of data: electronic data
Data availability: from 01/06/2023 to 31/12/2023 (6 months)
Data anonymisation: All information collected will be kept strictly confidential. Personal information will be retained but only available to the researchers using password protected

files. In addition, all data for presentations will be anonymized and aggregated, so the participants' identities will not be revealed in any way.
Ethical or legal restrictions: none

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | | 29/07/2022 | 01/08/2022 | Yes | No |
| Participant information sheet | Achilles tendinopathy group | | 12/08/2021 | No | Yes |
| Participant information sheet | Healthy control group | | 12/08/2021 | No | Yes |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Preprint results | | 22/06/2025 | 26/06/2025 | No | No |