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Investigating the effect of combined action observation therapy and eccentric exercises in the treatment of mid-portion achilles tendinopathy

Submission date
16/12/2020

Recruitment status
No longer recruiting

Registration date
23/12/2020

Overall study status
Completed

Last Edited
14/12/2022

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
Mid-portion Achilles Tendinopathy (AT) is a common condition that causes pain, swelling and stiffness of the tendon joining the heel bone and the calf muscles due to overuse. This condition can be both complex and difficult to treat. Exercise intervention has been shown to be effective for some individuals, however, a proportion of individuals will continue to have longstanding symptoms, including activity-related pain and movement limitations. Whilst, the tendon mechanical properties are targeted by the Strengthening exercises can improve the mechanical properties of the tendon, but may be unable to address changes to the nerves that can occur during injury.

Novel techniques have emerged that do address these nervous system changes, such as Action Observation Therapy (AOT). This technique involves the observation of movements followed by the physical practice of these same movements. Specific nerve cells called mirror neurones activate during the observation of the exercises, and have been shown to positively influence both the planning and execution of movement.

The aim of this study is to test the combination of AOT and strengthening exercises, including remote implementation of these techniques, and to evaluate the feasibility of a future larger scale trial to evaluate the effect on mid-portion Achilles Tendinopathy

Who can participate?
Patients aged 18-65 years old with mid-portion Achilles Tendinopathy.

What does the study involve?
The study involves the random allocation of participants to one of two groups. One group will follow a program of a combination of AOT and strengthening exercises, the other group will complete strengthening exercises only.

The strengthening exercises will be identical for both groups and involve two movements that lengthen muscle under tension. Participants in both groups will complete each movement for 15 repetitions, 3 sets, twice of day, for 12 weeks. All participants will have to view videos before each set of exercises. The AOT and exercise group will view two videos, one for each exercise, of a model performing the exercise. The models in the videos will match the participant for gender and side of injury. The exercise only group will view landscape videos prior to the performance of the same two exercises. These videos will be the same duration for both groups.

What are the possible benefits and risks of participating?
A possible benefit is a better treatment response to combined AOT and eccentric exercises.

The risks of participating are the risks that are associated with performing eccentric exercises with mid-portion Achilles Tendinopathy, a degree of pain is common during the exercises. The participant will be encouraged to keep pain levels below a self-rating of 5/10 and can stop performing the exercises at any stage.

Where will the study run?
The study is run from the University College of Dublin (Ireland). Due to the current restrictions imposed by COVID-19, the study will be conducted remotely via zoom at all stages.

When is the study starting and how long is it expected to run for?
From September 2020 to June 2022

Who is funding the study?
The study has been investigator initiated and funded

Who is the main contact?
Deirdre Ryan
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
The effect of combined Action Observation Therapy and eccentric exercises in the treatment of mid-portion Achilles Tendinopathy (AOTAT): a feasibility pilot randomised controlled trial.

Acronym
AOTAT

Study objectives
To conduct a power calculation to determine the numbers needed for a future large-scale randomised controlled trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved, UCD Human Research Ethics Committee (Office of Research Ethics, Roebuck Castle, Belfield, Dublin 4, Ireland; +353 (0)1 716 8767; research.ethics@ucd.ie), ref: LS-19-83-Ryan-OSullivan

Study design
Two-group parallel, blinded randomized controlled pilot trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mid-portion Achilles Tendinopathy

Interventions
Participants will be screened for the eligibility criteria in an online video call. This includes specific questions surrounding the location of pain using a pain map, the nature of the pain, morning stiffness and pain on a specific achilles tendon loading test.

Eligible participants will continue on to have baseline measurements assessed and will be briefed as to how to correctly perform the two exercises in the Alfredson protocol to ensure correct technique throughout the clinical trial. This programme consists of two achilles eccentric loading exercises to be performed twice a day, for 3 set of 15 repetitions. Both exercises require the participant to stand on the edge of a step with body-weight on the forefoot. The participant rises on the non-injured leg into plantar flexion and lowers eccentrically on the injury leg, so that

the heel lowers below the level of the step. The un-injured leg is then used again to return to the starting position of plantarflexion. Hands are placed on the wall or a railing for balance support. The first exercise is performed with the knee straight, whilst the second exercise is performed with the knee bent. Each participant will receive standard information regarding mid-portion Achilles Tendinopathy and exercise rehabilitation prior to commencing the intervention.

A member of the Research team not involved in the intervention or outcome measure assessments will randomly allocate participants to the intervention or control group. The randomization list will be generated online using a web-based randomization tool. The number will be placed in an opaque envelope which is given to the Researcher whom assigns the intervention or control programmes to each participant.

Action Observation Therapy (AOT) Group:
Participants in this group will have access to two videos in Salaso, an online application, one for each of the exercises to be performed. The videos will demonstrate a model performing 15 reps of the exercise, the model will match the participants for gender and side of injury. The videos will be observed prior to the physical performance of each set of exercises. The videos will be viewed twice a day, daily for 12 weeks. Participants will also log their compliance with the exercises programme in Salaso.

Control Group:
Participants in this group will have access to two landscape videos (with no human or animal content) in Salaso. The two landscape videos will be the same length as the exercise videos. This group will also receive a pdf file in their account with pictures and instructions as a reminder on how to correctly perform the exercises. The videos will be observed prior to the physical performance of each set of exercises. Participants will also log their compliance with the exercises programme on the Salaso.

Intervention Type
Other

Primary outcome(s)
1. Disability measured using the Victorian Institute of Sport Assessment Questionnaire (VISA-A) for Achilles Tendinopathy at baseline, 6, and 12 weeks

Feasibility outcomes:
1. Feasibility of daily Action Observation Therapy (AOT) twice a day from the participant's perspective using participant interviews at 6 and 12 weeks
2. Exploration of the relationship between Mid-portion Achilles Tendinopathy (AT), outcome measures, and AOT using participant interviews and specific outcome measures at 6 and 12 weeks
3. Exploration of the relationship between fear of movement, central sensitisation, and AOT using participant interviews
at 6 and 12 weeks
4. Reflection on the AOT intervention protocol and amend if indicated using participant interviews at 6 and 12 weeks
5. Piloting the methodological procedures, including remote implementation measured using participant interviews at 6 and 12 weeks
6. Recruitment rate and actual numbers recruited measured using at 6 and 12 weeks
7. Numbers needed for a future large-scale randomised controlled trial determined using a power calculation at 12 weeks

8. Participant experience of participating in a telehealth intervention trial, and assessment of trial procedures, interventions, and outcome measures along with satisfaction through a qualitative exploration at 12 weeks

Key secondary outcome(s))
1.Worst pain in the past week measured used the Numeric Pain Rating Scale (NPRS) at baseline, 6, and 12 weeks
2. Pain on loading measured with the hop test (with an aim to complete 25 hops on each leg) followed by rating pain using the NPRS at baseline, 6, and 12 weeks
3. Physical function capacity measured using the maximum number of single-leg heel raises on each side that individuals are able to perform at baseline, 6, and 12 weeks
4. Participation measured using the Lower Extremity Functional scale at baseline, 6, and 12 weeks
5. Psychological factors measured using the Pain Self-efficacy Questionnaire, a 10-item questionnaire, to assess an individual's level of confidence whilst completing certain activities; the Pain Catastrophising Scale, a multidimensional scale to assess an individuals' experience of magnification, rumination and helplessness; and the Tampa scale for Kinesiophobia, a 17 item questionnaire, to assess fear of movement, at baseline, 6, and 12 weeks
6. Central processing measured using the Widespread Pain Index and symptoms severity (these measures are part of the fibromyalgia diagnostic criteria, and this tool will be adopted to capture features of central sensitisation) at baseline, 6, and 12 weeks
7. Quality of life measured using the Euroqol-5 dimension questionnaire (which assesses health, mobility, ability to self-care, ability to undertake usual activities, anxiety, and depression) at baseline, 6, and 12 weeks
8. Patients belief about the efficacy of treatment measured using the Patient Global Impression of Change (7-point scale ranging from very much worse to very much improved) at 6 and 12 weeks
9. Patient satisfaction measured using the patient satisfaction questionnaire at 6 and 12 weeks

Completion date
01/06/2022

Eligibility

Key inclusion criteria
1. Unilateral pain in the mid-portion (2-7 cm proximal to insertion) of the achilles tendon
2. Pain lasting ≥3 months
3. Experiencing morning pain or stiffness
4. Have access to a smartphone, computer, laptop, or tablet
5. Competent in written and spoken English and be able to provide consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex

All

Total final enrolment
30

Key exclusion criteria
1. Clinical suspicion of achilles tendon rupture
2. Previous achilles tendon surgery in symptomatic leg
3. Bilateral or insertional achilles tendinopathy
4. Co-existing foot or ankle pathology such as triognum syndrome, retro-calanceal bursitis, superficial calcaneal bursitis, or Haglund's syndrome
5. Systemic disease such as ankylosing spondylitis or rheumatoid arthritis
6. Confounding lower limb injury
7. Metabolic or endocrine disorders, such as type I or II diabetes
8. Corticosteroid injection in/near the achilles tendon in the last 3 months
9. Condition that prevents the patients from executing an active exercise programme
10. Previously performed strength exercise rehabilitation for achilles pain
11.Use of fluoroquinoline antibiotics within the previous 2 years

Date of first enrolment
11/01/2021

Date of final enrolment
01/03/2022

Locations

Countries of recruitment
Ireland

Study participating centre
University College of Dublin
UCD Health Sciences Centre
Stillorgan Road
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Sponsor information

Organisation
University College Dublin

ROR

https://ror.org/05m7pjf47

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	outcome results	29/11/2022	14/12/2022	Yes	No
Protocol article		07/02/2022	09/02/2022	Yes	No