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Achilles tendinopathy exercise rehabilitation using the PhysViz app

Submission date
19/11/2024

Recruitment status
Recruiting

Registration date
21/11/2024

Overall study status
Ongoing

Last Edited
16/12/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
The Achilles tendon connects the calf muscle to the heel bone. Tendons must be strong enough to transmit forces generated during physical activity or sports. Achilles tendinopathy (AT) is a painful injury which is often caused by cumulative, high-load activities such as running, and is usually accompanied by a loss of tendon strength.
Most people with AT recover slowly (over several weeks or months), but the condition can cause persistent symptoms (pain, swelling) for some people which may last for months or years.
Exercise-based rehabilitation is considered the best treatment for AT, and one of the benefits of this treatment is rebuilding the strength of the Achilles tendon. However, it can be difficult to find the right intensity of exercise which is strong enough to stimulate tendon strengthening, but without aggravating symptoms.
To help people recover from AT and regain their tendon strength, researchers have developed a new exercise software (app) for Achilles tendinopathy called PhysViz. The PhysViz app is connected to a Bluetooth force monitor which is incorporated into a home-based exercise conducted using a fabric strap that participants push against with their muscles. The PhysViz app displays individualized feedback on a phone screen while participants engage in rehabilitation exercises at a precise dose which promotes tendon strengthening.
This study aims to measure Achilles tendon strength before and after a 12-week exercise program using the PhysViz. The researchers will use MRI, ultrasound imaging and functional tests to assess whether Achilles tendon strength and function improve over 12 weeks.

Who can participate?
Patients aged between 19 years or older with Achilles tendinopathy affecting the middle part of the tendon (on either one or both sides of the body) by a health professional (MD or physiotherapist), with symptoms that have persisted for 3 months or greater. These symptoms include tendon pain during activity, tendon is tender when touched or squeezed, and pain is worsened by activities like hopping or raising up on their toes.

What does the study involve?
The study involves two data collection visits and an exercise program; visits are scheduled for before and after the exercise program to determine how effective the treatment is.
Data collection visit 1 (3 hours):

1. Fill out several questionnaires about symptoms and current activities
2. Undergo an MRI scan of both Achilles tendons. Participants will be oriented in a standing position in the open upright MRI - the scanning process should take no longer than 60 minutes.
3. Non-invasive tendon testing. The researchers will place motion capture markers on the participant's foot that can detect movement using cameras (similar technology to how many films and video games are made). They will take an ultrasound video of the muscles and tendons in the participant's leg – this is a common and painless procedure (similar to that used during pregnancy). They will record the activity of the calf muscles using electrodes placed on the skin – this is a common and painless procedure but will require a small area of skin to be shaved to remove any hair that may influence the signals recorded. The researchers will ask participants to contract their calf muscles to push against a Biodex dynamometer footplate. This is a seated device, where the participant's foot is placed against a platform to push against, to determine the amount of strength generated by the muscle. The researchers will ask participants to perform hopping tests on a force platform. This is a device that sits on the floor (like a bathroom scale) and measures the centre of pressure and the amount of force that participants are able to generate while doing specific movements. The researchers will ask participants to perform heel rises (i.e. rising up on their toes).
4. Receive instruction on how to use the PhysViz app, and how to complete the Achilles-strengthening exercises. The researchers will show participants how to install the PhysViz app on their phone and connect it to the load cell. If participants do not have a phone, we will supply them with one for the duration of the study. Participants will be required to sit on the floor or exercise mat with legs stretched out in front of them and push as hard as they can against a stirrup placed under their foot. The stirrup will be attached to a fabric strap which wraps around the participant's lower back or around a chair to stabilize, while their foot pushes against it.
12-week exercise program, during which participants will be asked to:
1. Take the exercise equipment home with them.
2. Perform home-based PhysViz exercises 3-4 times per week for the 12-week period (~6 minutes per session, 36-48 sessions)
3. Perform 5 sets of 4 isometric contractions at the prescribed exercise load, which will be reassessed weekly depending on participant tolerance
4. Communicate with research staff weekly (via email or phone).
Data collection visit 2 (3 hours):
1. Fill out several questionnaires about symptoms and current activities
2. Reperform the tendon MRI scanning procedures and testing protocols from Visit 1
3. Participants will be asked to provide any feedback they would like to share about their experience with the PhysViz or with the exercises.
Follow-up questionnaire at 24 weeks (phone call, 5-10 minutes):
4. The researchers will contact participants at 24 weeks post-enrollment with a questionnaire to determine how they have fared since finishing the PhysViz exercise program. Questions will help determine the effectiveness of the exercise protocol by identifying the participant's current tendinopathy status and relative impact on their work/lifestyle.

What are the possible benefits and risks of participating?
With adherence to the exercise protocol, most participants are expected to experience improvements to the Achilles tendinopathy symptoms. However, not every participant may experience improvement. Indirect benefits of participating include learning about musculotendinous structures and how they relate to strength and movement.
The MRI is an open MRI so there is no risk of claustrophobia. All scanning protocols are designed to answer research questions for studies approved by the Protocol Proposal Committee and UBC ethics. Research scans are typically not designed for clinical diagnosis, therefore, scans will NOT be routinely reviewed by a radiologist. If a finding is incidentally identified by the MRI technologists or investigators, a radiologist will review the scans and take the following actions

when the finding is of potential clinical significance and follow-up is needed:
1. Notify the Principal Investigator or designate.
2. The Principal Investigator or designate will explain that an incidental finding has been identified, and with the participant's permission, contact their family physician.
Participants may feel mild discomfort when tapes and markers used to position equipment on the skin are removed at the end of the testing sessions, this will be no worse than removing a band-aid. Allergies to adhesive tape will be verbally asked before application. There is a risk of discomfort or pain in the Achilles tendon or calf muscle from the exercise protocol, Biodex muscle contraction trials, hopping or heel rises. Participants may experience a temporary increase in tendinopathy symptoms. As part of the exercise program, we will ask participants to generate a controlled amount of force through their injured leg. We believe that this maneuver (voluntary generation of muscle force through an injured tendon) carries a larger risk than if the tendon were uninjured. However, we are not aware of any evidence of injury during Achilles tendon rehabilitation. Likelihood of risk and discomforts: temporary increase in symptoms during exercise (pain/discomfort): very common (approximately 80%). Temporary increase in symptoms after exercise is complete (pain/discomfort): less common (5-20%). Temporary increase in symptoms after exercise is complete (swelling/stiffness): uncommon (2-5%). Muscle or tendon injury: rare (less than 1-2%, not quantified based on available evidence).

Where is the study run from?
The study data collection visits will be run from the Centre for Aging SMART at VCH, part of the University of British Columbia - Faculty of Medicine (Vancouver, Canada). The exercise program will be a home-based treatment, the researchers will send participants home with all necessary equipment to perform the exercises correctly and safely.

When is the study starting and how long is it expected to run for?
April 2024 to November 2026

Who is funding the study?
This study is funded by a WorksafeBC Exploratory Research grant RS2024-ER01, which covers research stipends for non-salaried employees, research supplies and services. WorksafeBC had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
UBC CREB H24-02396

Study information

Scientific Title
High load exercise with biofeedback and dose monitoring for Achilles tendinopathy: a quasi-experimental feasibility study using the PhysViz system

Study objectives

It is hypothesized that a 12-week progressive, biofeedback-enabled isometric exercise program using the PhysViz app will be feasible for people with persistent Achilles tendinopathy. The researchers further hypothesize that after a 12-week exposure to progressive, biofeedback-enabled, isometric exercise using the PhysViz system, the following outcomes will be altered:

Increased:
1. Achilles tendon stiffness (load tolerance)
2. VISA-A
3. Tendon energy storage and release
4. Calf muscle function (heel rise)
5. Maximal and submaximal muscle-tendon force output
6. Tendon structural organization (MRI)

Decreased:
1. Hysteresis
2. Tendon water content
3. Tendon thickness or cross-sectional area
4. Pain during hopping
5. Average pain during last week immediately after activity (type of activity specified by the participant)

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/11/2024, UBC Clinical Research Ethics (Room 210, Research Pavilion, 828 West 10th Avenue, Vancouver, V5Z 1M9, Canada; +1 (0)604 875 4149; pia.ganz@ubc.ca), ref: H24-02396

Study design
Quasi-experimental feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Achilles tendinopathy

Interventions
The protocol is based on Radovanović et al, 2022, a 12-week Achilles tendinopathy rehabilitation program using high-loading isometric contractions of the triceps surae.

Participants will connect their phone (must be Android) or a study phone to the Bluetooth sensor (Tindeq) using the PhysViz software, and be oriented to the different software functions. Participants will be seated on the floor or a gym mat with straight legs, and back leaning comfortably against a support (e.g. pillows or bolster). The shod foot will be placed against a stirrup connected to a sling in which the load sensor has been inserted. The sling will be tightened to facilitate maximal isometric plantarflexion with the ankle as close to 90 degrees as possible. The injury prevention strategy relies on instructing the individual to specifically

contract the calf muscles (and not other muscles such as the quadriceps which could lead to a patellar dislocation) and to gradually build up to the maximum voluntary contraction with 3-5 submaximal warm-ups (3-s contraction, 3-s rest, 1 min rest between sets). Two to three maximum voluntary contractions will be elicited, and the force (kg) recorded: the training load will be set at either 90% of the MVC, or at a load where pain is no more than 5/10 (whichever is lower). After a 10-minute rest, the exercise intervention will begin, consisting of 5 sets of 4 isometric contractions at the set training load. Each contraction is 3 s in length, followed by a 3-s rest, followed by a 1-minute rest, 3-4 times per week for 12 weeks. Participants will take the exercise equipment (sling, stirrup) home with them. Every week, the training load will be reassessed and/or increased by using the same method described above (90% of MVC or pain level of no more than 5/10). The researcher will adjust the load target accordingly in the PhysViz app, which will adjust the participant's biofeedback target. For people with bilateral symptoms, the intervention will be applied to the worst (most symptomatic) side and outcomes collected from that side. If the participant wishes, they may also elect to do the exercises on their other side (optional).

The training load will be reduced in the following scenarios: If the pain experienced during the exercise is too high (>5/10 or deemed too high by the participant), if the pain does not subside after the exercise or if pain/swelling is still increased the next day, or if other symptoms such as stiffness or swelling are worsened. The number of sets, repetitions, and frequency of sessions (3-4 times were week) will be maintained if possible even if the training load (kg) is reduced. If baseline pain during normal daily activity (e.g. walking) is already high (equal to or greater than 5 /10), then an initial week of exercise at low load (e.g., 30-40% MVIC) will be trialled, with a gradual ramp-up to the target of 90%. Participants will also be instructed to consider other strategies to reduce pain in consultation with a healthcare provider as necessary, such as ice, pain medications or shoe inserts such as a heel cup.

Achilles tendon and feasibility outcomes will be assessed pre- and post-intervention.

Intervention Type
Behavioural

Primary outcome(s)
1. Program implementation:
1.1. Withdrawals and lost to follow-up: Will be tracked in the CONSORT flowchart, with reasons, and reported as a % of the total number of people enrolled. The feasibility target is 80% retention in the study; measured at week 12.
1.2. % prescribed time under tension and % force achieved (area under curve): Each prescribed repetition for the 12 weeks will be totalled and used as the denominator. The numerator will be the actual time spent loading the tendon or area under the curve (force x time), extracted from the PhysViz data; measured weekly, calculated at week 12.

2. Practicality:
2.1. Self-reported adverse events: Identified at the weekly check-ins or by emails or other messages sent to research staff. An arbitrary threshold would be a low rate of adverse events (<10%) and that those events are not serious in nature (e.g. causing significant injury); identified weekly, baseline to week 12.
2.2. Prescribed exercise sessions attempted and completed: The exercise session will be categorized as attempted if the session was started as indicated by PhysViz app data. It will be categorized as complete if all repetitions are initiated, even if not every repetition hits the target force level or duration. Reported as percentage of sessions attempted and completed;

measured weekly from baseline to week 12.
2.3. System Usability Survey (SUS questionnaire): Usability questionnaire for rating the equipment experience, rated with a 10-item questionnaire (0-100 point scale); measured at week 12.

3. Acceptability:
3.1. Mobile application rating scale (UMARS): App usability questionnaire with 16 attributes (1 [inadequate] to 5 [excellent]).
3.2. Pain and pain tolerability of rehabilitation exercise: Researchers will report on the number of sessions in which people found their pain during exercise to be intolerable; measured weekly from baseline to week 12.
3.3. Semi-structured interview: Qualitative interview/debrief for experience with PhysViz app and exercise program at week 12.
3.4. Follow-up questionnaire: Qualitative interview, questionnaire to determine intervention durability and tendinopathy evolution 12 weeks after the conclusion of the exercise program; measured at 24 weeks.

Key secondary outcome(s))
Preliminary efficacy outcomes:
1. Achilles tendon strength: In vivo Achilles biomechanics estimation (load [N] and deformation [mm], stiffness [N/mm]) with ramped maximum voluntary contractions using a combination of real-time ultrasound, motion capture and dynamometry; measured at baseline and week 12.
2. Achilles elastic energy storage-release: In vivo Achilles hysteresis measurement (energy lost, %) during hopping using a combination of real-time ultrasound, motion capture and dynamometry; measured at baseline and week 12.
3. Morphology imaging: Achilles MRI imaging (cross-sectional area [mm2] and water content [total content]); measured at baseline and week 12.
4. VISA-A questionnaire: Achilles tendinopathy severity evaluation (0-100 point scale); measured at baseline and week 12.
5. Weekly average pain: Participant specified (0-10 point scale) weekly during exercise program; measured at baseline, weeks 0 to 12, and week 24.

Completion date
01/11/2026

Eligibility

Key inclusion criteria
1. Male or female aged 19 years or older
2. Fluent in English
3. Diagnosis of unilateral or bilateral, midportion Achilles tendinopathy by a health professional (MD or physiotherapist)
4. Diagnostic criteria: Pain located in the midportion of Achilles tendon, pain during activity, the tendon is tender to palpation, pain is worsened by loading tests (e.g. heel rises or hopping)
5. Tendinopathy symptoms 3 months or greater
6. Willing to dedicate 30-40 minutes weekly to PhysViz exercises
7. VISA-A <80

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
19 years

Sex
All

Key exclusion criteria
1. Insertional tendinopathy
2. BMI greater than 35.0 kg/m2
3. Previous or current diagnosis of Achilles tendon rupture
4. Chronic pain syndrome or systemic inflammatory diseases
5. Received corticosteroid injections in the Achilles region <3 months ago
6. Taken fluoroquinolones within the last 5 months
7. Unable to give informed consent
8. No home Wi-Fi or mobile internet
9. Severe vision impairment
10. Failed MRI screening

If participants have any of the following, they will not be able to participate in the study:
11. Cardiac pacemaker, wires, or defibrillator
12. Metal fragment in the eye or orbit
13. Steel brain aneurysm clip
14. Pregnancy
15. Stainless steel Intrauterine Device (IUD)
16. Surgery or tattooing (including makeup tattoos) within the past 6 weeks

If participants have any of the following, the individual's case will be reviewed by the MR Technologist or Radiologist:
17. Artificial heart valve
18. Ear or eye implant
19. Brain aneurysm clip, titanium
20. Implanted drug infusion pump
21. Electrical stimulator for nerves or bones
22. Coil, catheter or filter in any blood vessel
23. Orthopedic hardware (artificial joint, plate, screws, rods)
24. Other metallic prostheses
25. Shrapnel, bullets, or other metallic fragments
26. Medical procedures within the past 6 weeks

Date of first enrolment
01/01/2025

Date of final enrolment
01/05/2026

Locations

Countries of recruitment
Canada

Study participating centre
Centre for Aging SMART at VCH
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Sponsor information

Organisation
University of British Columbia

ROR
https://ror.org/03rmrcq20

Funder(s)

Funder type
Other

Funder Name
WorkSafeBC

Alternative Name(s)
WorkSafe British Columbia, Workers' Compensation Board of BC

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

The anonymized datasets generated during and/or analysed during the current study will be stored in a publicly available repository. The distinct repository is currently unknown but will be shared at a later date.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes