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Determining the feasibility of exercise therapy and activity modification for treating adolescents with heel pain: a study protocol

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ABSTRACT

Calcaneal apophysitis and Achilles tendinopathy are common overuse injuries characterised by insidious posterior heel pain with activity. Calcaneal apophysitis is commonly diagnosed in adolescents, although Achilles tendinopathy is understudied in the adolescent population and is therefore rarely considered until adulthood. Exercise therapy and activity modification have the highest level of evidence for treating Achilles tendinopathy, while calcaneal apophysitis is treated with anecdotal and passive treatment or complete rest. It remains unknown whether exercise therapy is effective for adolescents with heel pain related to either diagnosis.

This is a pilot and feasibility study. Thirty participants between the ages of 7 years and 17 years with posterior heel pain will be recruited from the local community and club sports team and local physicians, school nurses, and athletic trainers through flyers and social media. Participants will be asked to complete evaluations and treatment sessions every 4 weeks with three virtual visits every 2 weeks in between for 12 weeks. All participants will receive standardised treatment consisting of daily Achilles tendon loading exercises and education on pain-guided activity modification. Feasibility outcomes will include recruitment, enrolment, retention and compliance. Clinical outcomes will include the measures of symptom severity, quality of life, tendon morphology and lower extremity function.

This protocol will provide preliminary data to inform a larger clinical trial based on the feasibility of the proposed intervention and methodology. Additionally, the results will provide preliminary evidence on whether Achilles tendon injury occurs in the adolescent population.

The trial is registered with clinicaltrials.gov (ID:1652996).

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Heel pain related to Achilles tendon loading and loss of function is frequently diagnosed as Achilles tendinopathy in adults.
⇒ Calcaneal apophysitis is a clinical diagnosis that relies on the patient history of gradual onset of heel pain with activity in skeletally immature adolescents (under 18 years old).
⇒ Exercise therapy and activity modification is an effective treatment for Achilles tendinopathy but has not been evaluated in the adolescent population.

WHAT THIS STUDY ADDS

⇒ This study will determine whether prescribing exercise therapy and activity modification is a feasible intervention for adolescents with heel pain.
⇒ This study will also determine whether outcome measures commonly used for adults with Achilles tendinopathy can capture changes in symptom severity, tendon structure and mechanical properties, muscle-tendon function, and quality of life in response to treatment.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE AND POLICY

⇒ Exercise therapy and activity modification may be a superior alternative to the current treatment approach for adolescents with heel pain.
⇒ The findings of this study will justify whether replicating a larger clinical trial is feasible, whether the intervention is appropriate, and identify what barriers exist to participant recruitment, retention and treatment compliance.

BACKGROUND

Little is known about the development of Achilles tendon injury during adolescent years. Adolescents with insidious symptoms and pain at the posterior heel are commonly diagnosed as calcaneal apophysitis.[1] Calcaneal apophysitis is caused by repeated pull and strain at the cartilaginous growth plate where the Achilles tendon inserts.[2] The condition affects 3.7 per 1000 adolescents,[1] with the highest prevalence in boys aged 8–15 years and girls 7–13 years.[3] In adults, the same symptoms are clinically diagnosed as Achilles tendinopathy, defined by Achilles tendon pain with loading and loss of function.[4]

Calcaneal apophysitis may be the most common diagnosis for heel pain in adolescents because little evidence for the presence of Achilles tendon injury and the associated tendon structural alterations (tendon thickening, altered mechanical properties) exists in this population.[5 6] Calcaneal apophysitis is

a clinical diagnosis that relies on the patient history of gradual onset of heel pain with activity and the patient's age (<18 years old) relative to maturity.[7 8] Radiograph is considered uninformative due to the appearance of a separated apophysial plate, which is seen in all skeletally immature children. Therefore, a radiograph is rarely used to confirm the diagnosis.[9] Without imaging to confirm the diagnosis, the main distinction between a diagnosis of calcaneal apophysitis or Achilles tendinopathy is patient age and pain location. Considering chronological age and biological development are not equivalent,[10] it is plausible that Achilles tendon injury masquerades as calcaneal apophysitis in some adolescents. The lack of description regarding pain location in studies may also contribute to the historic disregard of Achilles tendon involvement in adolescents.[11] Few studies have used ultrasound imaging when evaluating adolescent patients with heel pain[2 12] despite the frequent use of ultrasound for adults with tendon injuries.[13 14] Determining the presence of Achilles tendon pain and/or altered tendon structure in adolescents diagnosed with calcaneal apophysitis is a critical concern considering that injury to either structure may prompt different treatment approaches.

A range of management recommendations are anecdotally supported, from complete immobilisation, which may inadvertently promote sedentary habits, to continued activity, which risks progressing pathology and may nullify any therapeutic intervention.[7 15 16] Only one randomised clinical trial has been conducted using an active treatment, finding no difference in outcomes between shoe inserts, physical therapy and no treatment ('wait and see'), although little description of physical therapy intervention was provided.[17] Exercise therapy has the strongest evidence for treating Achilles tendon injuries in adult patients.[18–20] Furthermore, when combined with pain-guided activity modification, exercise therapy is non-detrimental to recovery.[19] Although numerous research studies have examined the efficacy of exercise therapy for Achilles tendon pain in adults, this approach has never been evaluated for adolescents.[21–23]

The proposed study will determine the feasibility of recruitment, enrolment, retention and compliance for prescribing exercise therapy and pain-guided activity modification over 12 weeks for adolescents with heel pain. We will explore whether outcome measures commonly used for adults with Achilles tendinopathy can capture changes in symptoms severity, tendon structure and mechanical properties, muscle-tendon function, and quality of life in response to an intervention consisting of exercise therapy, pain-guided activity modification and load management. Additionally, we will provide preliminary evidence on whether Achilles tendon injury occurs in the adolescent population.

METHODS

Study design

This pilot and feasibility trial will recruit 30 adolescents with heel pain. This methodology and intervention have previously been used for adults with Achilles tendinopathy;[19 24 25] however, such a trial has not been attempted in the adolescent population.

Inclusion and exclusion criteria are shown in table 1.

Written parental permission and child assent will be required for all participants before enrolment. One parent will also be invited to consent to participate in the study by completing surveys. Participation is voluntary, and participants may withdraw from the study at any time. Concomitant care (ie, physical therapy, injection) will be prohibited throughout the intervention.

Participants will be evaluated at baseline and 4 weeks, 8 weeks and 12 weeks (figure 1). Data collection and supervised treatment will occur on the same day. Over the study course, participants will complete daily exercises using a standardised treatment protocol (box 1) and will be asked to modify activity as recommended using the pain-monitoring model. Additionally, participants will be asked to record all activities in a training diary.[19 24 25] Virtual treatment sessions will take place 2 weeks following each inperson visit to review the progress between the inperson visits (table 2). Both inperson and virtual visits will include patient education, supervised treatment and instruction, and a review of the training diary and home exercise programme prescription (online supplemental file). If a parent consents to participate, they will be asked to complete surveys at inperson and virtual visits. The Standard Protocol Items: Recommendations for Interventional Trials 2013 checklist was used to ensure our protocol's adherence to standardised reporting.[26] All supervised treatments and evaluation sessions will be completed at the University of Delaware Health Sciences Complex in Newark, Delaware. The same licensed athletic trainer or clinician will obtain informed consent and assent and conduct enrolment, evaluation and treatment precluding blinding. The physician reviewing all ultrasound imaging will be blinded from participant data.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1. Age 7–17 years 2. Insidious onset of posterior heel pain with running and jumping activities	1. Any other injury that limits the ability to participate in treatment and/or muscle-tendon function testing 2. Any lower extremity surgery or injection within with past 6 months 3. Any underlying medical condition predisposing heel pain (spina bifida, inflammatory spondyloarthropathy)

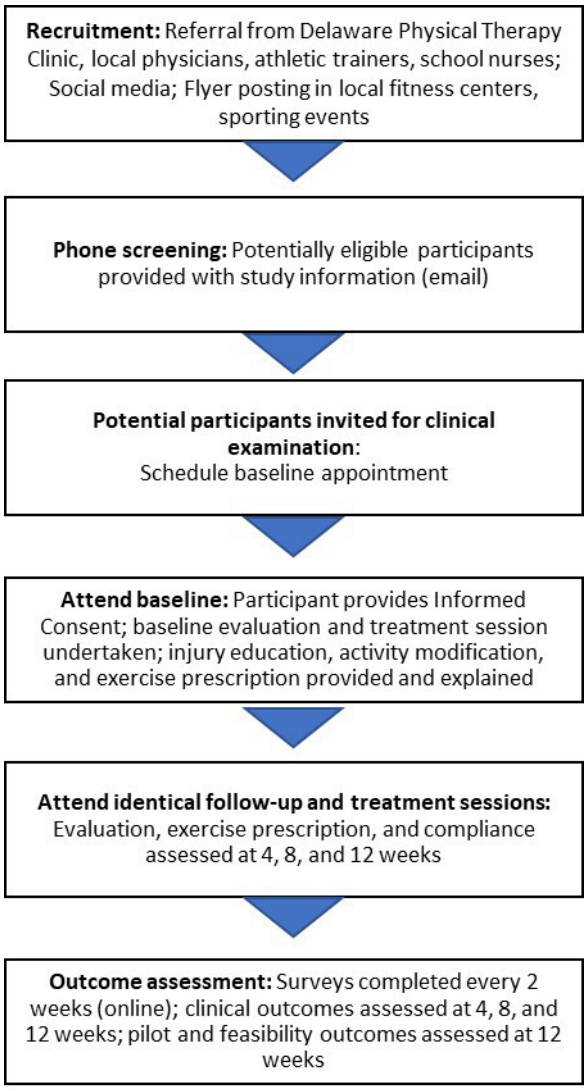

Figure 1 Study overview.

Patient and public involvement

Participants were not involved in the study design.

Setting

The trial will be conducted at the Delaware Tendon Research Lab at the University of Delaware, Newark, Delaware, USA. All data for this study will be recorded and stored using Research Electronic Data Capture (REDCap) (Vanderbilt University, Nashville, Tennessee, USA).[27]

Eligibility and screening

Potential participants will be recruited through our collaborators at local orthopaedic/podiatry offices, the University of Delaware Physical Therapy Clinic, as well as through local paediatricians and athletic trainers and nurses who work in middle schools and high schools. Social media advertisements will also be used. An online screening questionnaire will be accessible for interested individuals to complete a preliminary

Box 1 Treatment protocol

Phase 1: Weeks 1 to 2

Patient status

Pain and difficulty with all activities, difficulty performing 10 one-legged heel rises

Loading intensity

Progress loading up to 100% body weight with slow controlled motion. If needed, begin with aquatic therapy, bodyweight support or isometric plantar flexion

Goals

Start to exercise and understand the nature of the injury and how to use the pain-monitoring model

Treatment programme

⇒ Pain-monitoring model information and advice on exercise activity
⇒ Circulation exercise (moving foot up/down)
⇒ Two-legged heel rises standing on the floor (3×10–15 repetitions)
⇒ One-legged heel rises standing on the floor (3×10 repetitions)
⇒ Eccentric heel rises standing on the floor (3×10 repetitions)
⇒ Sitting heel rises (3×10 repetitions)

Phase 2: Weeks 2 to 5

If pain increases by more than 2 points when exercising while standing on the edge of a step, then perform exercises on a flat surface

Patient status

Pain with exercise, morning stiffness, pain when performing heel rises

Loading intensity

External loading should be introduced once patients can complete the bodyweight treatment programme without difficulty

Goals

Improve strength

Treatment programme

⇒ Two-legged heel rises standing on the edge of a step (3×15 repetitions)
⇒ One-legged heel rises standing on the edge of a step (3×15 repetitions)
⇒ Eccentric heel rises standing on the edge of a step (3×15 repetitions)
⇒ Sitting heel rises (3×15 repetitions)
⇒ Quick rebounding heel rises (3×20 repetitions)

Phase 3: Weeks 3 to 12

If pain increases by more than 2 points when exercising while standing on the edge of a step, then perform exercises on a flat surface

Patient status

Tolerates the recovery phase exercise programme well. No pain at the distal tendon insertion possibly decreased or increased morning stiffness

Loading intensity

Continue to progress with external resistance and speed of movement based on patient tolerance

Goals

Heavier strength training

Treatment programme

Perform exercises every day and with a heavier load two to three times per week:

⇒ One-legged heel rises standing on the edge of a step with added weight (3×15 repetitions)
⇒ Eccentric heel rises standing on the edge of a step with added weight (3×15 repetitions)
⇒ Sitting heel rises (3×15 repetitions)
⇒ Quick rebounding heel rises (3×20 repetitions)

Table 2 Schedule of enrolment, intervention and assessments

	Study period							
	Recruitment	Enrolment	Postenrolment					Close-out
Time point (week)		0	2	4	6	8	10	12
Enrolment								
Telephone screen	X							
Inperson screening		X						
Informed consent		X						
Intervention								
Injury education		X						
Exercise prescription		X	X	X	X	X	X	
Activity modification instruction		X	X	X	X	X	X	
Training diary review			X	X	X	X	X	
Exercise adherence			X	X	X	X	X	
Assessments								
Demographics		X						
Medical and procedure history		X						
Medication		X						
Sports participation history		X						
Physical activity before injury		X						
VISA-A Questionnaire		X	X	X	X	X	X	X
Foot and Ankle Outcome Survey		X	X	X	X	X	X	X
PROMIS Paediatric Physical Activity		X	X	X	X	X	X	X
PROMIS Paediatric Pain Interference		X	X	X	X	X	X	X
PROMIS Paediatric Global Health		X	X	X	X	X	X	X
Fear of Pain Questionnaire Child Report		X	X	X	X	X	X	X
Parent Surveys		X	X	X	X	X	X	X
Clinical Examination		X	X	X	X	X	X	X
Muscle-tendon function outcomes		X	X	X	X	X	X	X
Ultrasound imaging outcomes		X		X		X		X
Tendon mechanical properties outcomes		X		X		X		X
Global Rating of Change		X	X	X	X	X	X	X
Compliance with activity modification			X	X	X	X	X	X
Adverse events			X	X	X	X	X	X
Access to potential participants								X
Enrolment and recruitment rates								X
Safety								X

PROMIS, Patient-Reported Outcomes Measurement Information System; VISA-A, Victorian Institute of Sport Assessment- Achilles.

eligibility assessment and request to be contacted. After completing the screening questionnaire, a research team member will contact potential participants to clarify responses and schedule an inperson screening and informed consent. Access to potential participants and results of eligibility screening, recruitment sources, and reasoning for ineligibility or declined participation will be recorded in REDCap.

Treatment protocol and education

All participants will be treated with a standardised treatment protocol consisting of Achilles tendon-loading strengthening exercises for 12 weeks (box 1). Participants will receive standardised education and prescribed activity modification recommendations using the pain-monitoring model.[19] The treatment protocol was previously found feasible and effective in a randomised

control trial in adults.[19] Additionally, participants will be provided an 'Activity Ladder' at baseline as a visual aid to educate them on appropriate progression to return to full participation. Exercises will be prescribed once daily, and the volume and intensity will be based on the participant's status using the pain-monitoring model. The treatment protocol consists of three different phases (box 1). Progression occurs via increasing the number of repetitions, resistance, speed of movement or range of motion (from standing on a flat surface to standing on a step). In the event body weight, isotonic exercise (phase 1) is too painful in the early phase of treatment, isometric plantar flexion holds (30–45 s holds, 3–5 sets) may be used. In the later treatment phases, load progression can be achieved by performing the exercises off the edge of a step. However, if this additional range of motion increases pain <2/10, exercises should be performed on a flat surface.[19] Participants will be instructed to perform the exercises even if they experience pain and are only allowed to stop if the pain becomes intolerable. The pain-monitoring model will be used to adjust the exercise load consistent with previous studies.[19 25] When participants can complete the exercises with minor pain, the programme will be progressed by adding external load using a backpack, weight vest or weight machine. In phases II–III, participants will be prescribed to complete weighted exercises two to three times per week and bodyweight exercises for the remaining days.

Education

Education for the participant and parent will be standardised to address the following topics: (1) Understanding of their injury, (2) How to use the pain-monitoring model, (3) Rationale for treatment, (4) How to use the treatment diary (5) Proper exercise instruction, (6) Address questions from the patient or the parent. Participants will receive educational information both inperson and in written form (online supplemental material).

Evaluation and clinical exam Following enrolment, participants will complete a past medical history questionnaire related to their current symptoms and any previous lower extremity injuries. Self-reported location of symptoms with activity will be documented. The clinical exam will consist of a discriminatory palpation exam, in which participants will be asked to rate their pain (0–10 on a Numerical Pain Rating Scale). The purpose of the clinical exam is to record the frequency of participants with a chief complaint focal to the Achilles tendon, calcaneal apophysial plate or a combination (figure 2).

The evaluator will ask participants to 'rate pain on a scale from 0 to 10, with 0 being no pain and 10 being the worst pain imaginable' at the Achilles tendon osteotendinous insertion, the medial and lateral aspects of the retrocalcaneal bursa, and squeezing along the midportion of the Achilles tendon (2–6 cm proximal to the calcaneus). Special tests will also be performed, including the Heel Squeeze test, Royal London Hospital

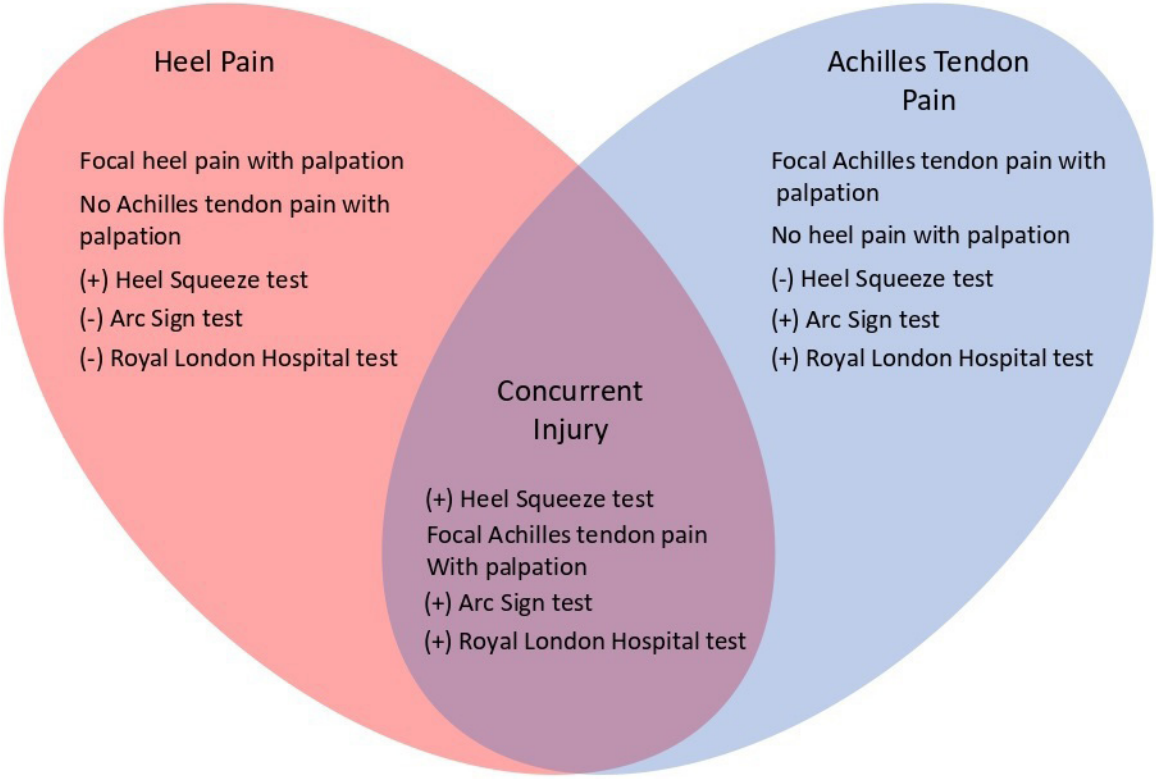

Figure 2 Criteria for clinical diagnosis of isolated heel pain, Achilles tendon pain and concurrent injury.

test and Arc Sign test.[28 29] The Heel Squeeze test is a pain provocation test in which the examiner squeezes the medial and lateral aspects of the calcaneus, confirming calcaneal apophysitis.[29] The Royal London Hospital and Arc Sign tests are sensitive and specific for the diagnosis of midportion Achilles tendinopathy.[28] Isolated Achilles tendon injury will be documented if the participant complains of isolated pain at the Achilles tendon insertion or midportion on palpation and with physical activity, has a positive Royal London Hospital or Arc Sign test, and has a negative Heel Squeeze test. Isolated calcaneal apophysitis will be documented if the pain is focal to the calcaneus, the Achilles tendon insertion and midportion are pain-free on palpation, and the Heel Squeeze test is positive. The concurrent injury will be documented if the location of pain on palpation is present at the Achilles tendon midportion or insertion and the Heel queeze test is also positive. An ultrasound exam will be used to record any abnormal findings. The presence or absence of hypoechoic regions in the Achilles tendon, tendon thickening (tendinosis), bursitis, intratendinous calcifications and neovascularisation (intratendinous or at the growth plate) will be recorded. When observable, the appearance of bony fragmentation and the status of the secondary ossification site of the calcaneal apophysial growth plate (open or closed) will be recorded. All findings will be reviewed by a physician who holds a Registered in Musculoskeletal (RMSK) sonography certification. Height, weight, shoe size and measure of the tibial length will be recorded at each inperson visit. Tibial length (cm) will be measured from the medial tibial plateau to the most inferior aspect of the medial malleolus.

Feasibility measures

Compliance, retention, safety

Participants will be given a training diary where they will document the exercises performed, other activities and their symptoms/pain level daily. This training diary has successfully been used in our previous study[19] and clinical practice. Each day, participants will rate their pain in the morning and the lowest and highest pain experienced that day, record their completed treatment exercises any other physical activity, and whether they participated in any running or jumping activities. Training diaries will be reviewed at each inperson visit. Participants who perform the heel rise exercises two or more times per week will be considered compliant with the exercise treatment programme. For each week, the frequency of days participants completed treatment exercises, days the training diary was filled out completely, days running or jumping activity was performed, and days in compliance with activity modification and pain monitoring will be recorded. Any missed follow-up visits, dropouts and adverse events will be recorded. Any adverse event occurring during a visit or reported outside of a visit that affects a participant's ability to participate in the study will be recorded.

Clinical outcomes

Symptom severity

Symptom severity will be measured using Victorian Institute of Sport Assessment- Achilles (VISA-A).[30] The Patient-Reported Outcomes Measurement Information System (PROMIS) Paediatric Pain Interference Scale is a 9-Likert item questionnaire that measures how pain interferes with functioning. The PROMIS uses a T-score metric in which 50 is the mean of the relevant reference population, and 10 is the SD of that population. Reporting a higher score equals more of the measured concept (more pain interference).[31] Additionally, parents who consent to participate will be asked to complete the PROMIS Parent Proxy Pain Intensity and Pain Interference Questionnaires as a secondary measure of symptom severity from the parent's perspective.[30]

Achilles tendon structure

B-mode ultrasound using a LOGIC e Ultrasound (GE Healthcare, Chicago, Illinois, USA) system with a wideband linear array probe (5.0–13.0 MHz) at 10 MHz will provide measures of Achilles tendon morphology, including maximal tendon thickness, cross-sectional area (CSA), degree of tendon thickening (thickest portion – thinnest portion), and Achilles tendon length (extended field-of-view images from calcaneal insertion to musculotendinous junction).[13 14] CSA will be measured at three locations along the free tendon between the calcaneal insertion of the Achilles tendon and a mark placed at 30% of tibial length to identify non-uniformity in tendon morphology. The calcaneal insertion will be confirmed with ultrasound and marked on the skin at the most proximal attachment point of the Achilles tendon on the calcaneus. Achilles tendon CSA measures will be taken at 10%, 20% and 30% length proximal from the calcaneal insertion. All imaging will be measured using Osirix MD imaging software (Pixmeo, Geneva, Switzerland). The presence or absence of hypoechoic regions, tendon thickening (tendinosis), bursitis, intratendinous calcifications, and neovascularisation will be recorded. When observable, the appearance of bony fragmentation and the status of the secondary ossification site of the calcaneal apophysial growth plate (open or closed) will be recorded. All images and measurements will be reviewed by a physician who holds a RMSK sonography certification.

Achilles tendon mechanical properties

Continuous shear wave elastography will be used to estimate the Achilles tendon mechanical properties using a Sonix MDP Q+ (Ultrasonix, Vancouver, British Columbia, Canada) ultrasound scanner with an L14-5/38 probe.[32 33] Participants will be asked to lie prone with their feet at rest, positioned against a platform at a fixed 10 degrees of dorsiflexion. The region of interest will be marked at 20% of the length

of the free tendon, proximal to the osteotendinous junction. A Minishaker Type 4810 (Bruel and Kjaer, Norcross, Georgia, USA) will deliver shear waves at 11 different frequencies (322 Hz, 339 Hz, 358 Hz, 379 Hz, 402 Hz, 429 Hz, 460 Hz, 495 Hz, 536 Hz, 585 Hz and 643 Hz) just proximal to the ROI on the posterior lower limb. Three trials will be performed on each limb. Postprocessing will be performed using a custom MATLAB Code that will produce two values representing mechanical properties, shear modulus (stiffness) and viscosity (rate-dependent stiffness), as described in detail by Cortes *et al* and Corrigan *et al*.[32 33] The average of three trials will be used for analysis.

Muscle-tendon function

Jump performance and calf muscle endurance will be measured by a single-leg countermovement jump (CMJ), drop CMJ (Drop CMJ), and the heel rise endurance test using the MuscleLab measurement system (V.19, Ergotest Innovation, Porsgrunn, Norway).[34] The CMJ will be performed on flat ground by asking participants to quickly bend their knee, immediately jump upward as high as possible and land on a single leg. The Drop CMJ will be performed by starting the participant standing on a single leg on a 20 cm high box. Participants will be instructed to 'drop' off the box and immediately rebound into a jump for maximal height. Participants will be asked to perform three trials, alternating between the right and left legs.[34] Participants must jump at least 1 cm for MuscleLab to register a valid trial. Participants will receive a zero for height if they cannot jump >1 cm for a trial. Participants who decline to attempt a jump for any reason will be assigned no value for that trial. Average jump height for the CMJ and Drop CMJ will be calculated from up to three trials per test. The heel rise endurance test will be performed on a single leg with the participant standing on a 10° incline box. A linear encoder will be affixed to the participant's heel with tape. Participants will be told to go as high as possible for each heel rise and return to the box to a metronome beep set to 30 heel rises/min and instructed to perform as many heel rises as possible.[34] Participants will be allowed to have two fingertips per hand against the wall for balance, placed at shoulder height. The test will be terminated when the participant stops, cannot maintain the metronome cadence, or can no longer perform a proper heel rise. Total heel rise work will be measured in joules (heel rise height × repetitions × body mass).[34] The examiner will demonstrate all tests before the participant attempts a trial. Participants will be instructed to stop any test if their heel pain exceeds 5/10. The jumping trials can resume after a short rest if the pain subsides, at the participant's discretion. We will ask participants to rate their heel pain following each test trial.

Quality of life

The PROMIS Paediatric Global Health questionnaire will be used to assess the self-reported impact of the injury on mental and physical health.[35] Parents will be asked to complete the PROMIS Parent Proxy Global Health Questionnaire as a secondary measure of the parent's perspective on the participant's mental and physical health.[31] The Fear of Pain Questionnaire Child Report will assess fear of pain and avoidance of activities. The Fear of Pain Questionnaire Parent Report will be used as a parent inventory to assess child pain-related fears.[36] Three subscales from the Foot and Ankle Outcome Score will be used to measure the foot and ankle-related quality of life, symptoms, and function in sport and recreation.[37]

Physical activity

The PROMIS Paediatric Physical Activity, Short Form questionnaire will be used to assess the self-reported capability of physical activities over 7 days.[30] Parents will be asked to complete the PROMIS Parent Proxy Physical Activity form. This will be used as a secondary measure of physical activity from the parent's perspective.

Self-reported improvement and satisfaction

The Global Rating of Change (GROC) Score will be used to assess the participants' perceived change in their overall status. The GROC is a 10-point Likert Scale (−5 to +5) ranging from 'very much worse' to 'completely recovered'. Participant satisfaction with the treatment intervention will be assessed on a scale of 0–10, where 0 is 'not satisfied', and 10 is 'very satisfied'.

Range of motion

Ankle range of motion in weight-bearing positions will be measured with a goniometer in full knee extension and knee flexion.

Statistical analysis

Sample size

We are planning to recruit 30 participants for this trial. A previous pilot trial using a similar intervention in adolescents with patellofemoral pain showed significant findings with fewer participants.[38] In the interest of treatment efficacy, a priori power analysis determined that 20 participants are required to detect a minimal clinically important difference in the VISA-A (6.5 points),[35] between baseline, 4 weeks, 8 weeks and 12 weeks with power=0.8, a medium effect size (partial η^2=0.06) and $\alpha = 0.05$. Considering this is a feasibility study to inform a larger clinical trial, 30 participants are justified.

Data analysis

A linear mixed model will be used to evaluate the main effect of time (treatment) on symptom severity, muscle-tendon function and quality of life from baseline to 4–8 weeks and 12 weeks. Frequencies of participants having isolated or concurrent Achilles tendon pain or calcaneal pain, presence or absence of Achilles tendon structural alterations (tendon thickening) or other pathological

findings (bursitis, neovascularisation, calcifications) will be reported descriptively. Differences in mechanical properties between limbs will be determined using limb symmetry indexes (LSI; % LSI = (most symptomatic limb value/least symptomatic limb value *100). Recruitment and retention outcomes, compliance with activity modification and patient satisfaction will be reported descriptively.

DISCUSSION

What does this study add?

The findings of this study will determine the feasibility of conducting a larger clinical trial for the treatment of adolescents with heel pain. We will determine the feasibility of participant recruitment and retention with the proposed strategies and resources and participant compliance with the treatment protocol. This pilot and feasibility trial will also help determine whether the proposed clinical outcomes are sensitive to capture any effect of exercise therapy and activity modification for adolescents with heel pain. Additionally, our findings will establish preliminary evidence to support whether Achilles tendon pain and/or pathology is present in adolescents with heel pain and warrants further investigation.

Future research

Determining whether this intervention is feasible and appropriate to conduct and assessing barriers to participant recruitment, retention and compliance is required before conducting a larger clinical trial to determine the treatment effectiveness and to determine whether the selected outcome measures should be retained, replaced or removed in a future trial. Should the presence of Achilles tendon injury be found, this pilot study will also provide estimates of the prevalence of an isolated and concurrent Achilles tendon injury in adolescents. A future direction will be to conduct a randomised controlled trial comparing outcomes between adolescents with calcaneal apophysitis and Achilles tendon injury. Additionally, it is plausible that the Achilles tendon's mechanical properties and morphology could change during the intervention due to normal maturation. Therefore it is of interest to determine the stage of development of participants in future research by calculating peak height velocity.[39]

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Contributors All authors contributed to planning the study and to the writing and submission of this protocol. SLH will conduct the study. All authors will contribute to the interpretation of the results.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the University of Delaware Institutional Review Board (ID: 1652996-4). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Data are available upon reasonable request to the corresponding author.

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