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Research protocol to evaluate the effectiveness of shockwave therapy, photobiomodulation and physical therapy in the management of non-insertional Achilles tendinopathy in runners: a randomised control trial with elective cross-over design

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ABSTRACT

Background Achilles tendinopathy (AT) is a common overuse injury in runners. While the mainstay of treatment for AT is tendon loading exercises (physical therapy and exercise programme (EXER)), some patients have refractory symptoms. Extracorporeal shockwave therapy (ESWT) and photobiomodulation therapy (PBMT) have each been evaluated to facilitate tendon healing; the influence of combining treatments is unknown and limited studies have been completed in runners. This randomised control study, with an elective cross-over at 3 months, will evaluate the efficacy of three forms of treatment of non-insertional AT: (1) EXER (loading programme specific to Achilles tendon combined with physical therapy); (2) EXER and ESWT; (3) EXER, ESWT and PBMT. Sixty runners will be assigned using block randomisation into one of three treatment groups (n=20). After 3 months, each participant may elect a different treatment than previously assigned and will be followed for an additional 3 months. The EXER Achilles loading programme will be standardised using the Silbernagel at-home programme. The primary outcome of interest is treatment group responses using the Victorian Institute of Sports Assessment—Achilles (VISA-A) Score. Secondary outcomes include the Patient-Reported Outcomes Measurement Information System—29 questions, the University of Wisconsin Running Injury and Recovery Index, heel raise to fatigue test, hopping test and ultrasound measurements. We will also capture patient preference and satisfaction with treatment. We hypothesise that the cohorts assigned EXER+ESWT+PBMT and EXER+ESWT will see greater improvements in VISA-A than the EXER cohort, and the largest gains are anticipated in combining ESWT+PBMT. The elective cross-over phase will be an exploratory study and will inform us whether patient preference for treatment will impact the treatment response.

Trial registration number NCT04725513.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Non-insertional Achilles tendinopathy (AT) is commonly managed using exercise programmes, and studies have suggested the benefits of combined treatment with shockwave therapy.

WHAT THIS STUDY ADDS

⇒ This study will help understand the combined benefits of photobiomodulation therapy (PBMT) with shockwave therapy in managing non-insertional AT.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Results from this study may help justify the use of shockwave therapy in runners with non-insertional AT. The benefits of PBMT combined with shockwave therapy may help understand the clinical outcomes of adding this to treatment and clinical decision-making.

INTRODUCTION

Background and science

Achilles tendinopathy (AT) is a condition that represents a failed healing response from injury or an inability to remodel appropriately to maintain tendon health.[1–3] The result of AT is pain and limitations in performing physical activity. While AT is common in the general population, with a reported annual incidence rate of 2.35 per 1000 adults,[4] this injury is often seen in runners.[5] It has a lifetime prevalence estimated to exceed half of all male runners.[6 7] Notably, many of the general population may adopt running as a weight loss strategy and for general health,[5 8] potentially contributing to a higher incidence of AT. Runners may develop AT due to extrinsic risk factors (eg, increase in running volume,

changes in footwear) and/or intrinsic risk factors (eg, genetics or tissue quality).[8]

The treatment of AT is primarily non-surgical and typically focused on restoring tendon health and tolerance to load.[3 6] The highest level of evidence for the management of AT is progressive tendon loading programmes using eccentric and concentric exercises. Alfredson *et al* first described the paradigm shift to eccentric loading to treat AT in 1998.[9] In this study, 15 participants with chronic non-insertional AT were instructed to perform eccentric loading exercises of heel drops with added weighted backpacks to increase overall demands on the Achilles tendon and were instructed to exercise below the threshold of debilitating pain. All participants could return to sports participation and had improved measures of strength and minimal pain at 12 weeks of follow-up.

There are six commonly prescribed forms of loading programmes (referred to as exercise or physical therapy and exercise programme (EXER)) for the management of AT,[10] including eccentric only loading, heavy slow resistance training, or concentric and eccentric loading (Silbernagel protocol) programmes.[11] While tendon loading exercise programmes remain the mainstay treatment, recent work suggests that 40% of those with AT may not achieve symptom relief with EXER.[12] The mechanism for why some patients do not respond to exercise programmes is unknown; explanations for treatment failure include challenges with compliance,[1] the treatment programme not continued for a sufficient duration of months to achieve tendon changes and pain limiting the tolerance to the exercise programme.[13–15]

EXER loading programmes' success in managing AT may be enhanced through a combination of other interventions. Extracorporeal shockwave therapy (ESWT) has been studied in the management of tendinopathy and may induce healing through mechanisms of promoting tissue remodelling and modifying pain.[16] Radial ESWT generates pneumatic waves through a handheld device and has no reported cases of major complications such as tendon rupture in published literature.[16] Two recent network meta-analyses demonstrated that EXER combined with ESWT effectively treated AT in the longer term (>3 months). However, there are limited data to understand effectiveness before 3 months.[13 17] A case report documented success in treating mid-portion AT in a female runner with radial ESWT who was able to actively train for a marathon during treatment[18]; however, no high-level studies have been performed to document treatment success in a population of runners.

Using similar mechanisms as proposed for ESWT in the treatment of tendinopathy, photobiomodulation therapy (PBMT) has been proposed to increase cell proliferation and metabolism in plantar fasciitis[19] and it may provide benefits in the treatment of AT.[1] The effects of PBMT may be influenced by multiple variables, including wavelength and parameters of treatment.[19] A recent randomised, placebo-controlled trial compared four treatment arms and identified the greatest gains in Victorian Institute of Sports Assessment—Achilles (VISA-A) over 12 weeks observed in combined PBMT with EXER.[1]

Overall, studies have identified the potential effectiveness of EXER, ESWT and PBMT. However, no studies have evaluated the influence of ESWT combined with PBMT and EXER in managing non-insertional AT in runners. This protocol describes a research study to understand the best treatment option for runners with non-insertional AT.

Specific aims

The primary aim of this pilot study is to evaluate the effectiveness of combined treatment of ESWT and PBMT with EXER (ESWT+PBMT+EXER) compared with ESWT with EXER (ESWT+EXER) or Silbernagel programme with physical therapy as standard treatment (EXER) over 3 months using a randomised control trial (RCT) design. We hypothesise that the greatest gains in Achilles tendon function measured using the VISA-A will be observed in ESWT+PBMT+EXER compared with ESWT+EXER, and both treatment arms will be superior to the EXER group. We also anticipate that the greatest gains in secondary outcome measures will be observed in the ESWT+PBMT+EXER cohort, including less pain, improved functional measures in running and exercises, and sonographic changes suggesting healing of tendon structure.

A secondary aim is to evaluate the response of runners after 3 months who elect to cross-over to one of the other treatment arms. Each participant who completes the initial 3-month RCT will be allowed to choose a different treatment arm and complete similar measures over 3 months to document clinical improvement. The secondary aim is exploratory and intended to inform whether the patient preference for treatment influences treatment response.

MATERIALS AND METHODS

Study design

This protocol is for a RCT with an elective cross-over after 3 months and was designed using the Standard Protocol Items: Recommendations for Intervention Trials (figure 1).[20] The study is registered on ClinicalTrials.gov NCT04725513. The authors confirm that all ongoing and related trials for this drug/intervention are registered.

Sixty participants will be assigned using a randomisation block design to one of three treatment groups (each N=20). There is no power calculation as this is a feasibility study. The treatment groups are EXER, EXER+ESWT and EXER+ESWT+PBMT.

This study has been split into two parts. Figure 2 shows the intended path of the protocol. Part 1 is the initial RCT, and part 2 is the elective cross-over when the participants can select the treatment they want to receive if they are unsatisfied with their initial treatment.

Regardless of the treatment arm in which participants are randomised, they will be required to enrol in physical therapy at a location that is convenient to them and

		STUDY PERIOD						
	Enrollment	Allocation	Post-allocation					Close-out
TIMEPOINT	$-t_1$	0	t_{1wk}	t_{2wk}	t_{3wk}	T_{6wk}	t_{3mo}	T_{6mo}
ENROLLMENT:								
Eligibility screen	X							
Informed consent	X							
Allocation		X						
EXER		←	—	—	—	—	—	→
INTERVENTIONS:								
Weekly ESWT			X	X	X			
Weekly ESWT+ Twice weekly PBMT			X	X	X			
Elective Cross Over							X	
ASSESSMENTS:								
VISA-A	X				X	X	X	X
PROMIS-29		X			X	X	X	X
UWRI		X			X	X	X	X
Patient Goals		X					X	X
Treatment Choice							X	X
Patient Satisfaction							X	X
Heel Raises		X					X	X
Hop Test		X					X	X
Ultrasound Measures		X					X	X

Figure 1 Standard Protocol Items: Recommendations for Intervention Trials schedule of enrolment, interventions, and assessments. ESWT, extracorporeal shockwave therapy; EXER, physical therapy and exercise programme; PBMT, photobiomodulation therapy; PROMIS-29, Patient-Reported Outcomes Measurement Information System—29 questions; UWRI, University of Wisconsin Running Injury and Recovery Index; VISA-A, Victorian Institute of Sports Assessment—Achilles.

complete a log recording their return to running using the Silbernagel and Crossley's protocol.[21] Activities, including running, will be allowed as tolerated following published guidelines by Silbernagel and Crossley.[21] The EXER programme will be standardised in the loading programme of the Achilles tendons. Each participant will be prescribed physical therapy with a home exercise programme addressing individual strength deficits in proximal (spine and hip girdle) and distal (thigh, leg and foot/ankle) muscle groups following standard of care guidelines.

Participants

The participants will be runners aged 18–65 with a diagnosis of mid-portion AT, which can be unilateral or bilateral. Participants must be able to travel to Cambridge, Massachusetts, USA to complete the study visits. The inclusion and exclusion criteria are outlined in table 1.

In subjects with bilateral AT, the leg with the most severe symptoms (determined by the VISA-A) will be chosen as the primary data for the study. However, both legs will be treated consistent with the treatment group the subject was randomised into. Outcomes will be obtained for each Achilles tendon, regardless of treatment, using VISA-A at each data collection point. Participants will also be asked to complete a weekly log of running and their compliance with completing the EXER programme.

Recruitment method and screening procedure

We will use a multipronged approach to recruit participants, including posting on the Mass General Brigham study recruitment website and social media accounts, flyers, informing Mass General Brigham physicians, other providers who treat runners, and contacting running groups in the Greater Boston area.

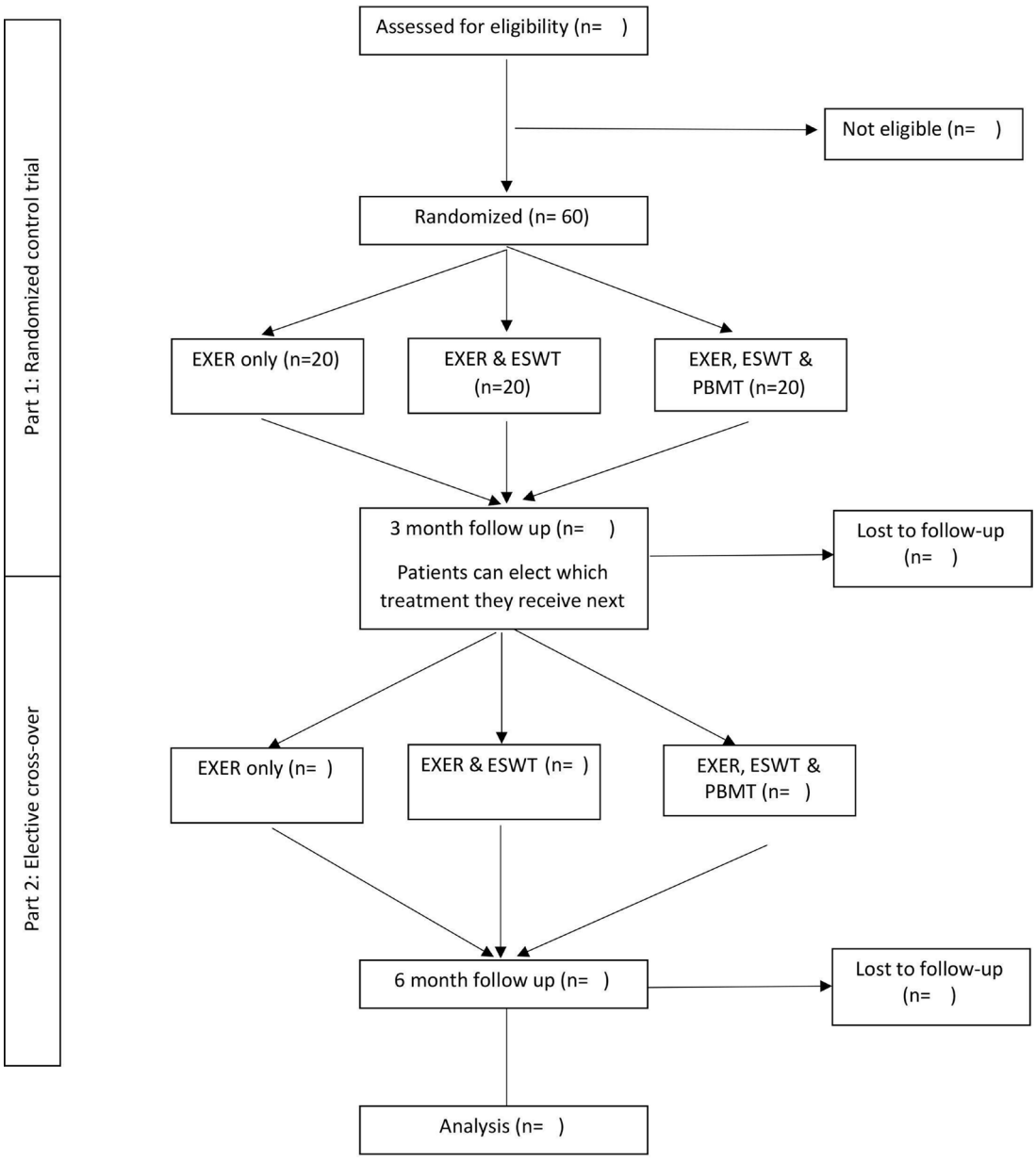

Figure 2 Flowchart of planned protocol. EXER, physical therapy and exercise programme; PBMT, photobiomodulation therapy; ESWT, shockwave therapy.

When a potential participant expresses an interest in the study, a study team member will introduce them to the study and determine if they meet the eligibility criteria. If the potential participant is eligible and remains interested in participating in the study, staff will obtain informed consent. Incentive payment of US$50 will be awarded following enrolment and completion of the assigned protocol for 6 weeks, 3 month, and 6 months for a total of US$150.

After it has been determined that a person is eligible and informed consent has been signed, the participant will be randomly assigned a treatment arm using block randomisation.[22] The assigned subject code will be used to identify data collected throughout the study. This is the treatment that they will receive for part one of the study.

In part two, an elective cross-over design will be used. It will allow each participant to choose one of the two alternative treatment arms to the prior treatment received (eg, a participant assigned EXER can elect to receive treatment with ESWT+EXER or ESWT+PBMT+EXER). Regardless of the choice of elective treatment, participants will be instructed to continue the EXER programme based on their current stage at the time of cross-over during months four through the conclusion of the study.

BLINDING

Due to the readily observable difference in nature of the treatment arms, blinding is impossible for the treating study staff and the participants.

Table 1 Inclusion and exclusion criteria

Inclusions criteria	Exclusion criteria (other contraindications to PBMT or ESWT)
1. Age 18–65	1. Less than 3 months of symptoms
2. Diagnosis of Achilles tendinopathy (either unilateral or bilateral)	2. Have received shockwave therapy within the past 3 months to their Achilles
3. Preinjury would run on average 10 miles or more a week	3. Currently enrolled in physical therapy for more than 4 weeks for this condition
4. Victorian Institute of Sports Assessment—Achilles of <80 at baseline	4. Primary insertional Achilles tendinopathy
	5. Prior injections in the past 3 months
	6. Diagnosis of rheumatological disease/connective tissue condition, symptomatic arthritis of foot and ankle, a primary running-related injury outside Achilles tendinopathy
	7. Pregnant women or women planning to become pregnant during the study due to unknown safety of extracorporeal shockwave therapy and external factor that would affect their ability to return to exercise
	8. Neuropathy diagnosis that would affect response to pain
	9. Known underlying cardiac condition 10. History of known Achilles tendon rupture 11. Use of fluoroquinolone or steroid at time of study enrolment

Treatment arms

Physical therapy and exercise programme (EXER) arm

All participants will be prescribed a standard loading programme designed by Silbernagel and Crossley.[21] The loading programme will be standardised; however, each participant will be evaluated by a physical therapist and recommended further home exercise programme to address any other lower extremity impairments known to contribute to mid-portion AT.[23 24] The standard EXER programme is described in box 1. Each participant will receive the exercise programme and instructions to complete the programme. Participants will be provided a University of Delaware Training Diary that we will ask them to complete. We will offer either an online or a paper version for them to complete (online supplemental appendix 1). Table 2 shows the patient visit schedule and phone call schedule for part one of the study, during which we will check in with physical therapy and EXER exercise protocol compliance.

ESWT treatment arm

The ESWT treatment protocol will include physical therapy and the EXER programme. Each participant assigned this treatment will receive one ESWT treatment and one telephone call weekly for 3 weeks, as shown in table 2. The ESWT will be performed by the principal investigator (AT) using the OrthoPlus Ultra 100/radial D-Actor. This Extracorporeal Pulse Activation Treatment device delivers radial ESWT and will be set to 3000 counts of treatment at 15 Hz using a minimum of 2 bars of air pressure with a focus applicator head over the mid-portion of Achilles using a clinical focusing technique (treatment over regions of maximal pain) and 3000 counts of ESWT using a minimum of 2.5 bars at 15 Hz using a broad oscillator to the myotendinous region and over symptomatic areas of the gastrocnemius and soleus, treatment will be applied distally to proximally to facilitate lymphatic return adjusting treatment air pressure and amount of force applied by applicator head by patient comfort. The maximum setting for each treatment applicator will be 4 bars of air pressure, and the first 500 counts using each applicator will be applied at 1.5 bars to help desensitise the tissue prior to increasing energy settings. The settings used for each participant will be recorded and followed in a similar approach to treatment.[25]

ESWT and PBMT treatment arm

Participants assigned this treatment arm will receive both ESWT and PBMT combined with physical therapy and the EXER programme (Box 1). ESWT will be administered using the same parameters outlined in the ESWT arm. Each participant will receive PBMT two times per week for 3 weeks, and ESWT will be completed following PBMT combined once weekly for 3 weeks, as shown in table 2. Participants will receive PBMT using the LightForce XPi 25W device with the Smart Hand Piece technology, which provides dual-wavelength (20% 810 nm/80% 980 nm) treatment and has a built-in accelerometer in the handpiece that controls the speed of light delivery to the treatment area. The therapy is delivered through a flexible optical fibre threaded through the handpiece containing a rolling glass massage ball. PBMT will be delivered at 10 J/cm^2 and applied in contact with the skin in a serpentine pattern to the calf from the fold in the back of the knee to the bottom of the leg including distal Achilles tendon and calcaneus. A member of the study team will calculate the treatment area according to a standard protocol and calculate the treatment time. The setting for treatment will be adjusted for skin pigmentation using the Fitzpatrick Scale and values recorded for each participant. Details on the measurements and calculation for the time that PBMT is applied are available in online supplemental appendices 2 and 3 with examples courtesy of staff from Enovis.

Box 1 Silbernagel At-Home EXER programme[2]

Patients may enter the program at any stage depending on the patient status.

Symptom management and load reduction phase: weeks 1–2
Patient status: pain and difficulty with all activities, difficulty performing 10 one-legged heel rises
Goals: start to exercise and understand the nature of the injury and how to use the pain-monitoring model
Treatment programme
1. Pain-monitoring model information and advice on exercise activity
2. Circulation exercise (moving foot up/down)
3. Two-legged heel rises standing on the floor (3×10–15 repetitions)
4. One-legged heel rises standing on the floor (3×10 repetitions)
5. Eccentric heel rises standing on the floor (3×10 repetitions)
6. Sitting heel rises (3×10 repetitions)

Recovery phase: weeks 2–5
If there is pain at the distal insertion of the tendon, continue standing on the floor
Patient status: pain with exercise, morning stiffness, pain when performing heel rises
Goals: start strengthening
Treatment programme
1. Two-legged heel rises standing on the edge of a step (3×15 repetitions)
2. One-legged heel rises standing on the edge of a step (3×15 repetitions)
3. Eccentric heel rises standing on the edge of a step (3×15 repetitions)
4. Sitting heel rises (3×15 repetitions)
5. Quick rebounding heel rises (3×20 repetitions)

Rebuilding phase: weeks 3–12 (or longer if needed)
If there is pain at the distal insertion of the tendon, continue standing on the floor
Patient status: tolerates the recovery phase exercise programprogramme well, no pain at the distal tendon insertion, possibly decreased or increased morning stiffness
Goals: heavier strength training, increase or start running and/or jumping activity
Treatment programme: perform exercises every day and with a heavier load 2–3 times per week
1. One-legged heel rises standing on the edge of a step with added weight (3×15 repetitions)
2. Eccentric heel rises standing on the edge of a step with added weight (3×15 repetitions)
3. Sitting heel rises (3×15 repetitions)
4. Quick rebounding heel rises (3×20 repetitions)
5. Plyometrics training

Return to sports phase: 3–6 months (or longer if needed)
If there is pain at the distal insertion of the tendon, continue standing on the floor
Patient status: minimal symptoms, not morning stiffness every day, can participate in sports without difficulty
Goals: maintenance exercise, no symptoms
Treatment programme: perform exercises 2–3 times per week
1. One-legged heel rises standing on the edge of a step with added weight (3×15 repetitions)
2. Eccentric heel rises standing on the edge of a step with added weight (3×15 repetitions)
3. Quick rebounding heel rises (3×20 repetitions)

The treatment with PBMT is safe based on prior work showing no clear histopathological changes induced by PBMT 4 hours following treatment.[26] Further, the use of the ESWT protocol has been performed in large cohorts of patients by the principal investigator with no serious adverse events observed.[25]

Table 2 Part 1 treatment schedule

	Baseline	Part 1					
	t	t+1 week		t+2 weeks		t+3 weeks	
Timepoint		Session 1	Session 2	Session 1	Session 2	Session 1	Session 2
Physical therapy and exercise programme	X	P	P	P	P	P	P
Extracorporeal shockwave therapy (ESWT)	X	X	P	X	P	X	P
Photobiomodulation therapy (PBMT)+ESWT	X	X	X	X	X	X	X

P, phone call; X, in-person visit.

Outcomes measures

All outcome measures will be performed at the baseline, 3-month and 6-month visits, with the VISA-A,[27] Patient-Reported Outcomes Measurement Information System—29 questions (PROMIS-29)[28] and University of Wisconsin Running Injury and Recovery Index (UWRI)[29] also collected at the 3-week and 6-week follow-up times. The return to sports log will be collected periodically after the initial treatment. This schedule is shown in online supplemental appendix 1. We will also collect data on how many drop out of the study before completion, record any adverse events and report them to the Mass General Brigham Institutional Review Board. The in-person study visits and evaluations will be performed at Spaulding Cambridge Outpatient Center.

Functional outcomes

Functional outcomes will be measured using heel-rises to fatigue and hopping tests. These will be measured in both limbs. The heel rises will be counted until the participant can no longer complete them with a metronome audible at 60 per min and the rate of heel rise performed at 30 per min based on published outcome measures for using this as an endurance test.[30] The hopping test will require the participants to complete 20 hops on each foot with arms at their side and perform at a rhythm that feels comfortable with a cue to hop 'like you are jumping rope on one foot' and then rate their pain using a visual analogue scale (0–10)[31] and a test that is associated with clinical improvement in a separate investigation.[32]

Measurement outcome/ultrasound

We will use ultrasound imaging to measure within-participant and treatment arm mean changes in the following: cross-sectional area, degree of thickening within the tendon at the site of maximal circumference and maximal pain, and presence and the number of neovessels visualised on colour flow doppler. We look at these changes as an exploratory outcome to understand the structural changes associated with clinical improvements.

Patient reported outcomes

Table 1 shows the time participants will be asked to complete different questionnaires. These include the VISA-A,[27] the PROMIS-29,[28] the UWRI,[29] patient goals, treatment preferences and patient satisfaction.

The VISA-A Questionnaire will measure the severity of symptoms specific to the Achilles. The VISA-A was designed to record the severity of AT in patients. It is an eight-question survey including questions on pain, function and activity. Each question is scored, and the cumulative score is out of 100. A patient without symptoms would score 100. The VISA-A is the only injury-specific outcome measure considered valid and reliable.[27] It is easy to use and has been used in other clinical trials.[33]

PROMIS-29 will be used to record non-AT-specific measures of health. This includes overall physical, mental and social health.[28] PROMIS-29 V.2 consists of 29 questions, which are answered on a scale of 1–5.

The UWRI is considered a valid and reliable patient-reported measure that assesses the longitudinal change in running ability in injured runners.[29] It consists of nine questions with multiple choice answers. The answers are then scored out of 36. A perfect score, 36, would be recorded when the patient has returned to their preinjury level of running.

Patient history, goals, the reason for a change of treatment and satisfaction will also be documented. We will also ask participants to record their return to running, following Silbernagel and Crossley's protocol.[21] To log this, they will track the date, exercise activity and pain level using the University of Delaware training diary (online supplemental appendix 1).

Monitoring of data quality

Study data will be collected and managed using Research Electronic Data Capture (REDCap) electronic data capture tools hosted at partners.[34 35] REDCap is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for data integration and interoperability with external sources. Questionnaires will be filled out on REDCap directly by the participant and reviewed by the study staff after the visit to ensure completeness. Objective measurements will be recorded by the study staff, checked and then entered into the REDCap system.

Data analysis

We will perform the Shapiro-Wilk test to evaluate the normality of data for both the primary outcome (VISA-A) and secondary outcomes (eg, PROMIS-29, UWRI, VAS, ultrasound measurements and functional tests). We will use the t-test and ANOVA test for the continuous data if the data is normally distributed. We will use the Mann-Whitney U test and Kruskal-Wallis to analyse analyse the data that is not normally distributed. We will use the X^2 or Fisher's exact tests for binary data to compare differences in proportions in response to a given outcome.

In the first phase of the study, the RCT, we will use a multivariable linear regression model to detect differences in our primary and secondary outcomes while controlling for potential dependent variables including sex, age, measured body mass index, medical condition (thyroid disease and diabetes) and prior or current tobacco use, along with prior steroid or fluoroquinolone class of antibiotics use. In part two, after the elective cross-over, we will use the models described above as repeated measure models to account for outcomes in treatment conditions selected by each research participant during the elective cross-over time of months 3–6.

Limited data sharing agreement was established with the Geneva Foundation, and data shared will include de-identified common demographic variables, including biological sex, marital status, year of birth, self-identified race and/or ethnicity, military status (civilian vs other aspects of prior or current military service), Fitzpatrick scale and injury location. The published study results will be shared with study participants. An interim analysis is planned after 30 participants are enrolled in the study for purposes of ensuring data quality and safety.

DISCUSSION

This research protocol aims to provide a framework to understand the difference between ESWT and PBMT combined with EXER in treating AT among runners. The novel elective cross-over design may help understand the influence of patient preferences on further outcomes and reflect clinical decision-making that helps apply findings to clinical practice. The non-invasiveness and safety of ESWT and PBMT allow for the safe implementation of these study findings.

While this study will advance our understanding of the management of AT in runners, there are limitations to this study. This is a pilot feasibility study, so we cannot do a power calculation to calculate the number of patients required to achieve statistically significant results. As a result of this study design, no sham ESWT or PBMT will be used in a separate treatment arm. Adherence to protocol and missing data are possible and will be accounted for using a patient report on the frequency of performing EXER exercise. PT will not be standardised as it is a clinical practice to individualise treatment plans and home exercise programmes based on the impairments of the individual patient; we will be minimising the influence of the EXER programme by using a standardised AT programme. Prior studies have measured meaningful clinical effects with sample sizes similar to what is proposed in our studies in the treatment of AT.[9 32] Results from this study may inform determining the effects of each treatment to determine power calculations for future work on this topic.

In summary, this research protocol outlines a pilot investigation into the management of AT in runners. The results of this study will inform clinicians of the potential benefits of ESWT and PBMT above standardised EXER loading for treating AT. Future studies may be informed by these findings, including consideration for the role of combined PBMT and ESWT in the management of other forms of AT (insertional), in other patient populations, including civilians and the military, and across other tendon and soft tissue conditions. Applying ESWT and PBMT may help address the burden of musculoskeletal disease and provide additional treatment options for patients.

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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 The study has been approved by the Mass General Brigham Institutional Review Board Protocol Number 2021P000025.

Provenance and peer review Not commissioned; externally peer reviewed.

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