

Randomised, cross-over trial on the effect of isotonic and isometric exercise on pain and strength in proximal hamstring tendinopathy: trial protocol

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ABSTRACT

Background Proximal hamstring tendinopathy (PHT) is a condition that occurs at all ages and levels of sporting participation. Presenting as localised lower buttock pain with tasks such as squatting and sitting, it can cause disability with sport, work and other activities of daily living. Recent research has investigated the effect of isometric exercise on pain and strength with a range of tendinopathies but there are no published studies on PHT. This protocol paper details a study investigating the effectiveness of isometric compared with isotonic exercise on pain and strength in people with PHT.

Methods/Design The study is a prospective, cross-over randomised controlled trial (RCT). Twenty participants with PHT, recruited from the local community and sporting clubs will be recruited for the study. Participants will receive one session of isotonic hamstring strength exercises and one session of isometric hamstring exercise, with random allocation to the order of intervention. Primary outcomes will be hamstring strength measured with a dynamometer and pain with a functional task, assessed immediately following and 45 min after intervention. A secondary outcome will be pain with sitting assessed 24 hours after intervention.

The effect of isotonic versus isometric exercise on hamstring pain and strength will be determined using a repeated measures linear mixed model. Further analyses will determine the proportion of patients with clinically important pain and strength improvements, using relative risks, χ^2 testing and number needed to treat.

Discussion This RCT protocol will investigate the effect of isometric compared with isotonic exercise for PHT.

BACKGROUND

Proximal hamstring tendinopathy (PHT) affects the active populations, particularly those involved in sprinting, jumping, kicking or distance running sports. PHT can also occur in non-athletic populations.^{1,2} It was first described in 1988² as 'Hamstring Syndrome' and commonly presents as localised lower buttock pain, aggravated by prolonged sitting, running or walking (particularly uphill), lunging and squatting.^{3–5}

Studies on conservative treatment for people with PHT have investigated hamstring and agonist strengthening exercises,^{4 6–9} extracorporeal shockwave therapy (ESWT),⁴ soft tissue and manual therapy techniques^{8,9} and stretching.⁹ More recent clinical commentaries have recommended graduated strengthening programmes and load management as key treatments.^{3 5}

There is limited evidence suggesting that strengthening exercises are helpful for pain and function in a range of tendinopathy types,^{10–19} however, exercise with an eccentric component can have a side effect of delayed onset muscular soreness,²⁰ and a previous 3-week programme of isotonic exercise for PHT resulted in no change in pain or function.⁴ Additionally, tendon pain can interfere with the ability to undertake sport, work and other activities of daily living. The effect on work and social activity is particularly relevant for PHT, where pain with sitting is often the primary complaint.^{5 21}

Recent research has investigated the effect of isometric exercise on a range of tendinopathy types. The first published study investigated athletes with patellar tendinopathy demonstrating immediate reduction in pain on tendon loading and improved strength that was sustained for 45 min after isometric exercise.²² These improvements were reported as being potentially due to a decrease in intracortical inhibition as measured by transcranial magnetic stimulation.

However, subsequent studies of isometric exercise for tendinopathy have shown variable results in lateral elbow,^{23–25} Achilles,²⁶ rotator cuff,²⁷ gluteal²⁸ and patellar^{29–31} tendinopathies, as well as plantar fasciopathy.³² The effectiveness and mechanisms underpinning isometric exercise for tendinopathy remains unclear.

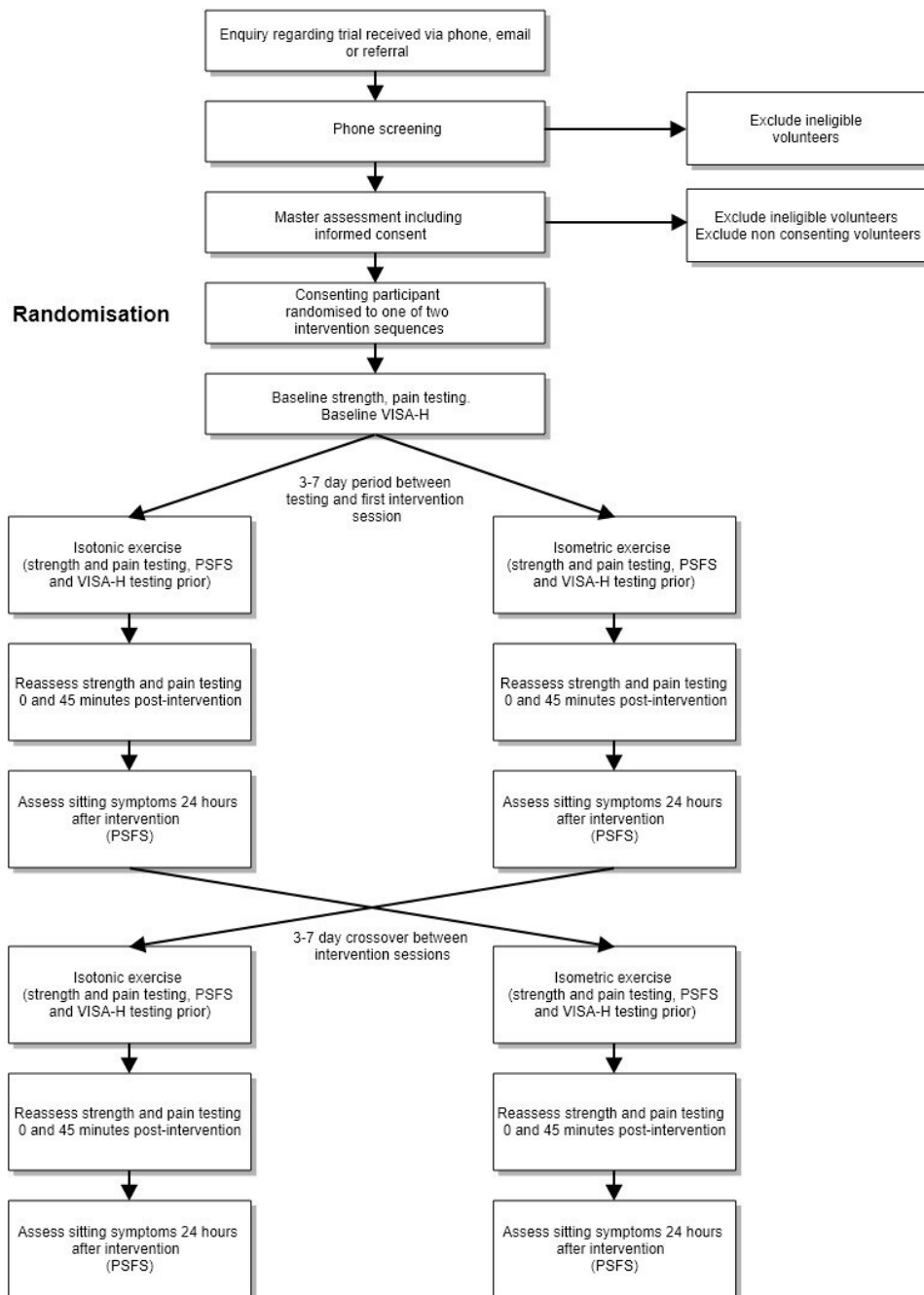


Figure 1 Overview of trial procedure. PSFS, Patient-Specific Functional Scale; VISA-H, Victorian Institute of Sport Assessment-Proximal Hamstring.

The primary aim of this paper is to describe a protocol for a randomised controlled trial (RCT) investigating the effectiveness (immediate and sustained) of isometric compared with isotonic exercise on pain and strength in people with PHT.

METHODS/DESIGN

Study design

This trial will be undertaken as a within participant, single-blinded, randomised, cross-over trial with two interventions (figure 1). A cross-over design has previously been used in trials comparing the effect isometric and isotonic exercise on pain and strength in patellar

tendinopathy^{22 31} and on pain in plantar fasciopathy.³² We are using this methodology to obtain a greater number of observations with the same cohort, given there was no evidence of carryover of intervention between sessions in previous trials of similar design.^{22 31 32} We used the Standard Protocol Items: Recommendations for Interventional Trials checklist when writing our report.³³

Patient and public involvement

As no resources were available for patient and public involvement, there was no formal involvement of participants in the study design.

Registration

Participants in the trial will provide informed written consent. The trial is registered with the Australian New Zealand Clinical Trials Registry (request ID 378609).

Setting

The trial will be conducted in the Neuroplasticity Laboratory at La Trobe University, Bundoora, Australia

Eligibility and screening

Participants will be sought via referrals from orthopaedic surgeons, sport and exercise medicine physicians and physiotherapists. Potential referrers will be informed of the trial and the referral process via formal meetings, personal correspondence, department lectures and trial information sheets. Advertisements will also be posted on social media.

Participants aged between 18 and 60 years old, with clinical features of PHT will be recruited. Potential participants will be screened for eligibility via telephone (box 1).

Participants who are eligible following phone screening will attend a baseline clinical assessment in which a detailed history and physical examination will be performed. To form a clinical diagnosis of PHT for eligibility for this trial, participants will be required to have reproduction of symptoms with modified arabesque (of $\geq 2/10$ on Visual Analogue Scale (VAS)) and two or more of prolonged sitting, a hamstring bridge or a modified hamstring stretch.

Intervention protocols

Testing, intervention and reassessment for this trial will be performed over three sessions (table 1), with sessions spaced 3–7 days apart. Participants will be requested to have a 48-hour period prior to each session where they avoid activity known to aggravate their symptoms to ensure stable loading prior to intervention.

The intervention protocol (table 2) will be based on the study investigating the effect of isometric exercise on patellar tendon pain and strength.²² Intervention in this study was well tolerated, with no adverse effects or dropouts (conversation with EKR, PhD, October 2020). A dynamometer (Biodex system 4 Pro, 1 Biodex Medical 2 Systems) will be used for both interventions. Both interventions will be performed in prone, with the hip in a neutral position. The isotonic contraction will be limited to 0°–60° of knee flexion, as force production is known to fall significantly at angles greater than 60° of flexion.³⁴ Informal pilot testing conducted in our lab prior to the study commencing was used to identify the most effective knee flexion angles for isometric testing and intervention, and to ensure that isometric and isotonic protocols were matched for perceived exertion.

No intervention will be undertaken in the first session, to enable familiarisation of protocol and equipment for the participants, and also to ensure that the baseline tests do not affect the outcome measures.

Intervention will be administered by the lead researcher (AR). Data from intervention sessions (Victorian Institute of Sport Assessment-Proximal Hamstring, VISA-H, strength

Box 1 Eligibility criteria

Inclusion criteria

Initial phone screening

1. Reports of relatively localised (defined as an area smaller than a tennis ball) ischial tuberosity region pain⁵ of gradual onset and at least 3 months in duration.
2. Willingness to participate in three sessions of testing and intervention as part of the trial, over a 9–21 days period.
3. Age between 18 and 60 inclusive.
4. Fluency in English sufficient to complete questionnaires and to enable understanding to the intervention.
5. Agree to refrain from other interventions for the treatment period of the trial, aside from consultation with medical practitioners and medication.
6. Agree to refrain from activity that would aggravate symptoms for 48 hours prior to each session.

Clinical examination screening

1. Positive findings (reproduction of lower buttock pain) with single leg arabesque AND with two or more of three additional diagnostic criteria.
 - Supine single leg bridge with heel on standardised height platform (bent knee).
 - Prolonged sitting <30 min.
 - Modified bent-knee hamstring stretch test.⁴⁹
2. A clear increase in activity levels precipitating onset of symptoms.

Exclusion criteria

Initial phone screening

1. Previous surgery to the hamstring complex, as we wish to study treatment effects independent to the effects of surgical procedures.
2. Previous injection to the hamstring tendon within the last 6 weeks, as we wish to study treatment effects independent to the effects of injections.
3. Previous imaging (MRI, ultrasound) performed since onset of symptoms showing normal hamstring tendon appearance, as a radiologically normal tendon is unlikely to be pain generating.⁵⁰
4. Treatment with extracorporeal shockwave therapy (ESWT) for PHT in the last 3 months,⁵¹ as we wish to study treatment effects independent to the effects of ESWT.
5. Current pregnancy or recent childbirth (within 6 months) as this could impair ability to undertake testing and intervention.
6. Diagnosis with autoimmune disease as we do not wish to evaluate tendon response where there is a potential autoimmune influence
7. Previous imaging (MRI, ultrasound) showing perineural sciatic nerve oedema as this suggests a pain generator that is not the proximal hamstring tendon

Clinical examination screening

1. Pain that is predominantly due to lumbar dysfunction including lumbar spine radiculopathy,⁵² or lumbar spine somatic referral.
2. Pain that is reasoned from clinical examination to be predominantly due to other structures or conditions, including sciatic nerve entrapment, ischiofemoral impingement, hip joint, local sciatic nerve irritation and adductor magnus tendinopathy (online supplemental file 1).

testing, pain testing) will be collected by a research assistant ensuring blinding of the intervention researcher.

Assessment

Primary outcome measures

Primary outcome measures will be assessed immediately, 45 min and 24 hours after the intervention (table 1). Pain



Table 1 Outline of sessions

Assessment/intervention component	Session 1	Session 2	Session 3
VISA-H	✓	✓	✓
Isometric strength testing	✓	✓	✓
Functional testing	✓	✓	✓
Sitting pain assessment (PSFS)	✗	✓	✓
Isometric strength intervention	✗	**	**
Isotonic strength intervention	✗	**	**
Isometric strength testing immediately postintervention	✗	✓	✓
Functional testing immediately postintervention	✗	✓	✓
Isometric strength testing 45 min postintervention	✗	✓	✓
Functional testing 45 min postintervention	✗	✓	✓
Sitting pain assessment 24 hours after intervention (PSFS) by phone call	✗	✓	✓
Functional testing 24 hours after intervention by video call	✗	✓	✓

✓component included, ✗=component not included, **=each component included in one of sessions two and three, order determined by randomisation.

PSFS, Patient-Specific Functional Scale; VISA-H, Victorian Institute of Sport Assessment-Proximal Hamstring.

will be measured with a VAS during a modified arabesque (figure 2) and strength with the Biodex dynamometer. An arabesque is recommended as a high-load clinical test for PHT,^{5 35} the VAS has been shown to be valid and reliable for chronic musculoskeletal conditions³⁶ and the Biodex dynamometer valid and reliable for testing of knee flexion strength.^{37 38}

Pain

Self-reported pain during a functional tendon loading activity will be assessed.^{22 25 26 29 30} Only one test (as opposed to five for the diagnosis of the condition for this trial) was used to reduce the effect of any pain with testing on the subsequent intervention.

An arabesque exercise was chosen due to its simplicity, clinical utility, as well as being functional for sporting and occupational activity (eg, picking up ball or lifting off ground, gardening). While reliability and validity of this test for PHT has not been performed, a similar movement (lifting object off the floor with knee straight) forms part of the reliable and validated VISA-H³⁹ and an arabesque is recommended by research and clinical experts for assessing this condition.⁵

All participants will be asked to undertake three, single leg arabesques. Participants will be able to hold on for

balance, asked to keep their knee at between 0° and 10° of flexion, maintain a neutral lumbar spine position and to have their rear leg off the ground.

Participants will be asked to perform the arabesque with their hand on the contralateral side reaching to the level of their ankle if possible. If all three repetitions could be completed, participants will be asked to quantify their pain on a 100 mm VAS. If participants can only perform one or two full repetitions, they will be asked about pain on those repetitions only and reassessed with the same number of repetitions after intervention. If participants cannot perform any full repetitions, their pain levels and depth of arabesque on their best repetition will be recorded. If all testing was pain free, the participants will score a 0.

Strength

All strength testing and strength intervention will be measured on the affected side using isokinetic equipment (Biodex system 4 Pro, 1 Biodex Medical 2 Systems).

Isometric strength testing will be performed in prone, with neutral hip flexion and 30° of knee flexion. This position was chosen to minimise compressive loading of the hamstring tendon on the ischial tuberosity and to maximise torque.^{34 40 41}

Table 2 Intervention description

	Prescription	Recovery between sets (min)	Loading bolus
Isometric	5 repetitions 45 s holds 45° knee flexion	2	50%–65% MVIC
Isotonic	5 sets of 9 repetitions 0°–60° knee flexion 2 s concentric and 3 s eccentric phase	2	100% of 9 RM (best effort across nine repetitions)

MVIC, maximal voluntary isometric contraction; RM, repetition maximum.



Figure 2 Modified arabesque.

Isometric strength will be tested with three efforts of five seconds. The maximal voluntary isometric contraction (MVIC) torque across all three efforts (measured in nM) will be recorded. If the third effort provides the highest MVIC torque, a fourth effort will be undertaken to ensure that maximal strength is accurately measured. All efforts will be undertaken with standardised vocal encouragement and instructions.

Secondary outcome measures

The secondary outcome measure will be pain during sitting, assessed using a Patient-Specific Functional Scale (PSFS).⁴² Participants will be asked to provide a rating before intervention and again 24 hours following intervention during a phone follow-up.

For the PSFS, participants will be asked to rate how much difficulty they were experiencing with sitting as a result of their hamstring condition, with a range from 0: 'Able to perform activity at same level as before injury or problem (no issues)' to 10: 'unable to perform activity (cannot perform)'. The PSFS is a valid and reliable measure for measuring change in functional tasks in the presence of musculoskeletal conditions.^{43–46}

Recruitment

Randomisation and allocation

All participants will be briefed on the research protocol and will be asked to sign a consent form before

commencing participation in the study. Participants will be randomly allocated to the order of intervention (isometric or isotonic first) via the use of envelopes. A computer-generated block randomisation sequence will be developed by an independent researcher who will have no contact with participants (AJH). The sequence will be transferred to sealed, opaque, sequentially numbered envelopes by the same researcher. As each participant is enrolled in the study, the next envelope will be opened by the treating therapist after the patient has been officially consented and enrolled.

Blinding

Participants will be blinded to the study hypothesis and therefore will not know which intervention was expected to have the most beneficial effect on pain and strength. The assessor completing the strength and pain testing after intervention will be blinded to treatment allocation.

Statistical analysis

Sample size

We are aiming to recruit 20 participants for this trial. As the first RCT to investigate the difference between isometric and isotonic strengthening for PHT, there were few data to calculate sample size. Trials in other tendinopathies have shown significant effects with similar or smaller sample sizes,^{22 29} while others have failed to show effects.^{31 32 47} In the absence of conclusive data relating to likely effects and variance in this population, combined with no data relating to feasibility of recruiting this population, a sample of 20 is justified. This sample size will only be sufficient to detect a large effect size of SMD >0.9 ($p=0.05$, power=80%). It is conceded that smaller effects might also be clinically important, and as such if the observed effect in the trial is smaller than SMD=0.9 then the trial will be underpowered.

Data analysis

Pain and strength data will be assessed for normality using visual analysis of histograms and a Shapiro-Wilks test. An assumption of negligible carryover effects from the intervention will be evaluated using paired t-tests to compare pain and VISA-H scores at the start of sessions 1 and 2 in each participant.

All analyses will be undertaken using repeated measures linear mixed models. Exercise type (isotonic vs isometric) and time (pre, immediately post, 45 min postintervention and 24 hours postintervention) will be independent factors, with pain, strength and PSFS the dependent variables.

Further analyses will be undertaken to compare the proportion of patients who demonstrated a clinically relevant pain reduction following each intervention, using relative risks (with 95% CIs), χ^2 testing and number needed to treat. We will define a clinically relevant difference in pain as 20 mm on a 100 mm VAS or two points on the PSFS, for these analyses.

DISCUSSION

What does this study add?

The use of isometric exercise in tendinopathy has only recently been investigated in a research setting. Despite early promising results,²² further studies^{23 27 31 32 47} have not found the same effects. The conditions for which isometric exercise is valuable for tendinopathy is also uncertain.⁴⁸

This study is unique in aiming to provide data on the effectiveness of isometric compared with isotonic exercise in a tendinopathy (PHT) that has not previously been investigated.

Future research

This RCT will be the first to compare isometric versus isotonic strengthening for people with PHT. This study will be essential to determine the feasibility of larger trials in the future and will also provide useful estimates of outcome effectiveness and variability to enable accurate sample size calculations for future trials.

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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 required.

Ethics approval Ethical approval from the La Trobe University Human Ethics Committee has been received (HEC20089).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data will be stored postproject on Research Online, La Trobe's institutional repository. Access to deidentified data will be available on request to the lead author.

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