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Torque visuomotor feedback training versus standard eccentric exercise for the management of patellar tendinopathy: protocol for a randomised controlled trial

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ABSTRACT

Introduction Patellar tendinopathy (PT) rehabilitation programmes frequently incorporate eccentric exercise (EE), where participants have limited control over the range of motion, speed, force production and load. Newly developed training protocols that employ visual feedback with specialised devices offer controlled management of loads, speeds and forces across the full range of motion, potentially providing greater benefits.

Objective This protocol outlines a randomised controlled trial designed to compare the effects of a visuomotor torque feedback (TF) protocol with a traditional EE protocol on the rehabilitation of PT over a 6-week period. Our primary objective is to evaluate whether the TF protocol reduces pain and disability more effectively than the EE protocol in individuals with PT. Secondary objectives include analysing structural and architectural changes in the patellar tendon and quadriceps femoris muscles, as well as examining motor unit discharge dynamics in response to EE and TF training. Lastly, we aim to compare these dynamics and structural changes between healthy controls and individuals with PT.

Methods Thirty two individuals with PT and twenty six healthy controls will be recruited. The PT group will be subdivided into an EE group, and a TF group, with both groups undergoing a 6-week training programme. The EE group will perform their exercises two times per day, while the TF group will do so 2–3 times a week. In individuals with PT, the primary outcomes will be the Victorian Institute of Sport-Patella (VISA-P) questionnaire to measure disability/physical function, and pain with a Numerical Rating Scale (NRS). To gain insights on mechanisms of action for potential improvements, motor unit discharge characteristics of the quadriceps femoris muscles will be assessed with high-density surface electromyography. Additionally, we will measure structural/architectural changes to the patellar tendon and quadriceps femoris muscles using B-mode ultrasonography and shear-wave elastography.

Ethics and dissemination This study was approved by the Science, Technology, Engineering and Mathematics Ethical Review Committee from the University of Birmingham (ERN_2257-Jun2024). The results of this study will be disseminated in peer-reviewed journals and at international conferences.

Trial registration number ISRCTN15821610.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The effectiveness of a novel rehabilitation approach using knee extension torque feedback will be assessed for managing patellar tendinopathy.
⇒ The tracking of longitudinal neuromuscular changes informs rehabilitation.
⇒ The participants' age (18–55) will decrease the generalisability of the study.
⇒ Torque feedback benefits from in-person support compared with the remotely supervised eccentric exercise.

INTRODUCTION

Patellar tendinopathy (PT) is a degenerative condition of the patellar tendon, affecting 7%–18.3%[1] of the sporting population and 1.6% of the general population.[2] This pathology can affect everyday movements and activities of daily living, leading to a reduced ability to carry out work-related tasks as well as performances in sports. Athletes competing in sports involving a high frequency of jumping, acceleration/deceleration, and those requiring rapid changes of direction such as volleyball[3] and basketball,[4] are more predisposed to PT. Some of the common symptoms of PT include pain in the patellar tendon during jumping/running activities, or pain evoked by palpation.[5] The unique challenge of rehabilitating PT lies in the length of time required for individuals to return to their normal levels of activity or sport, with some athletes even being forced to retire from their sporting careers due to the persistence of symptoms.[6] Furthermore, post-rehabilitation, individuals with PT may still experience pain and disability. This highlights the importance of identifying interventions that can offer the most effective rehabilitation for PT.

Common interventions used to rehabilitate PT have focused primarily on exercise based on eccentric contractions (ie, eccentric exercise) (EE). This type of exercise typically involves a single leg squat, where individuals are required to slowly lower themselves into a squat position, within a reasonable pain limit (a pain level of approximately 5/10 on a Visual Analogue Scale), and then returning to the standing position by contracting both limbs concentrically.[7] Eccentric exercises have been the standard of care recommended by the National Health Service in the UK (NHS).[8] However, EE with a decline squat can produce pain that may not be tolerated by all. This may be the result of participants experiencing a lack of control over the loads, speed, range of motion, and pain tolerance, with the potential for participants to employ altered movement patterns to minimise pain[9] potentially reducing the efficacy of the exercise. Additionally, eccentric single leg decline squats increase tensile loading on the patellar tendon, with low vastii muscle activation.[10]

Although tensile loading is required for tendon remodeling,[11] it also substantially elevates tendon pain. This increase in pain can inhibit neuromuscular activity,[12] particularly in protocols using pain-provoking eccentric decline squats with a pain intensity of =>5/10 on a VAS.[7] As a result, this approach can be challenging to adhere to, especially for individuals unaccustomed to regular exercise. Therefore, innovative training interventions using isokinetic dynamometry that enable individuals to produce force throughout the entire range of motion—with controlled external loads and visual feedback for adjusting knee extension force to a specified target may be a valuable alternative to traditional EE.[13] Furthermore, isokinetic dynamometer-based exercises facilitate greater muscle activation, particularly during concentric phases, while simultaneously loading the tendon. Moreover, the single-joint nature of these exercises enhances motor unit firing in the quadriceps to a greater extent than multijoint or closed kinetic chain exercises like squats.[14] This increased quadriceps activation promotes muscle strength, which is often reduced in individuals with patellar tendinopathy.[15] All of the abovementioned beneficial factors associated with isokinetic dynamometer-based exercises can further be enhanced with visual feedback, allowing for the participants to experience enhanced sensory, proprioceptive input which is normally reduced due to pain, due to the sensitisation of the patellar tendon, which perturbs the normal afferent activity of the muscle spindles and golgi tendon organs, affecting the control of muscle force.[16]

Rehabilitation for patellar tendinopathy primarily emphasises targeted tendon loading.[1] With insufficient or excessive stimulus, the patellar tendon is unlikely to recover effectively, which can delay the return to pain-free function.[1] This emphasises the need for individualising loads according to the participant's own strength/ability levels. A common issue for individuals with PT is the persistence of symptoms, including pain. Many continue to experience symptoms even after completing rehabilitation programmes involving EE, raising concerns about the effectiveness of EE-based training protocols.[11]

Current understanding of the aetiology of PT is based on studies that have used surface electromyography (EMG),[17–19] musculoskeletal ultrasonography,[20–22] Doppler ultrasonography[23] and shear wave elastography[24–26] to identify changes in muscle activation, and architectural (muscle fibre arrangement; pennation angle and length), morphological (muscle/tendon thickness and cross-sectional area) and structural (mechanical properties of the patellar tendon; stress and strain exerted on the patellar tendon) changes to the patellar tendon in PT. However, there is no consensus on the mechanisms that mediate PT and its recovery. One potential reason for the limited understanding of the pathology is the insufficient detail provided by current techniques, which may lack the resolution needed to investigate the neuromechanical determinants of the injury, such as motor unit, muscle and tendon relationships.

To date, no studies have used high-density surface EMG (HDsEMG) to investigate motor unit characteristics and adaptations in response to a training intervention in individuals with PT. HDsEMG is capable of measuring individual motor unit activity;[27 28] whereas, interference EMG measures can only detect the summation of muscle-fibre action potentials along the sarcolemma that is detected at the level of the skin.[29] HDsEMG data uses specialised algorithms such as blind source separation,[28] which could be valuable in detecting the underlying neuromuscular control of the knee extensors affected by PT, and their adaptations to a training intervention. Motor unit firing characteristics, such as mean firing rate and discharge rate variability, along with intrinsic motoneuron properties like persistent inward currents and synergistic muscle functional connectivity measured through inter-muscular coherence, can offer valuable insights into the neural control strategies used by individuals affected by PT. Additionally, the ability to track motor units across sessions can help provide deeper insights into the adaptations occurring within individual motor units.[30]

Similar to changes in neural control strategies mediated by motor units, architectural (muscle and tendon structure and arrangement), morphological (muscle/tendon thickness and cross-sectional area) and structural changes (mechanical properties of the patellar tendon; stress and strain exerted on the patellar tendon) to the knee extensor muscles and patellar tendon[24] are commonly observed in individuals with PT. These factors may lead to compensatory movement patterns that place uneven loads on the patellar tendon and cause instability in knee extensor control and muscle coordination, thereby increasing the risk of further aggravating PT. There is evidence for training protocols positively impacting changes in muscle and patellar tendon architecture, which are accompanied with enhanced control of the knee extensors during dynamic activities, emphasising the importance of a structured training programme to rehabilitate PT.[3 22 24]

With PT, the patellar tendon could become more compliant, and therefore, less efficient at transferring muscular force to the bone, which would necessitate increased neural drive to maintain a given torque level. Furthermore, reduced stiffness can alter sensory feedback to the central nervous system, potentially resulting in impaired control of the knee extensors. Therefore, training interventions should be designed with elements of motor control in addition to a sufficient stimulus load in order to improve rehabilitation outcomes.

The aims of this study are (1) to investigate the effects of a slow-speed visuomotor torque feedback training protocol on managing pain and disability in individuals with PT, compared with standard EE treatment. (2) Evaluate changes in motor unit characteristics and structural/architectural modifications in the vastus lateralis (VL), vastus medialis (VM) and rectus femoris (RF) muscles, and patellar tendon following the intervention. (3) Compare differences in motor unit characteristics and structural/architectural changes in the VL, VM and RF muscles, and patellar tendon between individuals with PT and healthy controls.

METHODS

Thirty two individuals with PT and twenty six healthy controls will be recruited using convenience sampling (advertisement via posters, leaflets, social media, email and word of mouth). Participant recruitment will start from 01/07/24 and will end on 19/01/2026.

We will recruit individuals aged 18 to 55; this age range has been chosen to avoid the inclusion of individuals with age-related patellar tendon degeneration, which may be a confounding variable. Healthy controls should not have experienced any knee pain during the previous 12 months and should have no prior history of patellar tendinopathy. Inclusion criteria for the PT group include a history of PT for at least 3 months and the verification of patellar tendinosis using ultrasonography (ie, increased patellar tendon thickness and cross-sectional area); additionally, pain located only at the patellar tendon during movement activities such as jumping and squatting, verified by using a single leg eccentric squat test, with the presence of a pain level of at least 2/10 on a VAS scale. Individuals should score 80 or less on the VISA-P scale. To ensure the generalisability of our findings, we have chosen to recruit participants of varying VISA-P scores, as it will allow our training intervention to be applicable to individuals with PT of varying disability levels. The prospective participants should not have received any treatment for patellar tendinopathy in the preceding 3 months prior to the start of the study. Finally, individuals with the following conditions will be excluded from participating: systematic or inflammatory conditions including rheumatic and neuromuscular disorders, previous lower-limb surgery without full rehabilitation, familial hypercholesterolaemia, daily use of drugs with a putative effect on the patellar tendon in the preceding 12 months (ie, fluoroquinolones), local injection therapy in or around the patellar tendon with corticosteroids in the preceding 12 months, previous patellar tendon rupture, inability to perform a knee exercise programme, participation in other concomitant treatment programmes, signs or symptoms of other coexisting knee pathology on physical examination or ultrasound/MRI, pregnancy.

Sample size

Based on power calculations performed using G*Power 3 software,[31] a total of 32 individuals with patellar tendinopathy are required for this study. Participants will be randomly assigned to either the eccentric exercise group or the torque visuomotor feedback group, with 16 participants per group. This sample size accounts for a power of 0.90, an alpha level of 0.05, a 20% attrition rate and an effect size (Cohen's d) derived from the study by Cannell *et al*[32] which reported approximately 2-point reductions in pain following both knee extension/curl exercises and drop squats after 6 weeks of training.[32]

Study design

This randomised controlled trial will be conducted from 01 July 2024 to 01 June 2026 at a laboratory within the School of Sport, Exercise and Rehabilitation, University of Birmingham. This study has been approved by the Science, Technology, Engineering, and Mathematics Ethical Reviewing Committee (ERN_2257-Jun2024) and has been registered as a clinical trial (ISRCTN15821610) (online supplemental appendix 1). The study will be conducted per the Declaration of Helsinki. The current study protocol was designed based on the SPIRIT 2013 statement.[33]

Online survey

Participant information is provided on the first page of a web-based online survey, via REDCap software. Once individuals confirm that they have read and understood the participant information, an eligibility form is displayed, allowing individuals to declare whether they are eligible or not. All eligible individuals are then asked to complete and sign an electronic consent form, embedded within the REDCap survey. Once consent is gained, demographic data (age, sex at birth) will be collected. Participants will then be asked to complete a series of questionnaires: VISA-P, International Physical Activity Questionnaire-Short Form (IPAQ-SF) and Tampa Scale for Kinesiophobia (TSK). Participants will be asked their resting pain levels, their current pain (during a single leg squat), as well as the lowest and worst pain they experienced over the preceding 24 hours through a Numerical Rating Scale (NRS). Additionally, we will assess the participant's pain during isometric, concentric and eccentric knee extension contractions.

Questionnaires

The questionnaires employed in this study (IPAQ-SF,[34] VISA-P[35] and TSK[36] aim to assess the level of physical activity, PT symptoms, physical function and fear of

movement. The most common questionnaire to assess physical activity is the IPAQ, a sensitive questionnaire that quantifies physical activity levels in 18–55-year-olds in different demographics.[37 38] Identifying the symptoms and impact of PT on physical activity using subjective measures can be achieved using the VISA-P form, and it is considered a simple, valid and reliable measure to evaluate the rehabilitation progress of individuals with PT.[35 39] As a result of injury, individuals tend to be fearful of generating movements that they would generally be comfortable with prior to injury; therefore, to assess the fear of movement and re-injury, we will use the TSK questionnaire, which is sensitive and reliable in individuals with chronic pain.[36]

Baseline session

Healthy controls and individuals in the PT group will then be asked to attend a university laboratory for a baseline measurement session (week 1). For healthy controls, the assessed leg will be randomly chosen, while for the PT group, the most symptomatic leg will be assessed. The leg with the most pain during manual palpation of the patellar tendon and an eccentric single leg squat will be considered as the most symptomatic leg for the PT group. Anthropometric data (height, weight, Body Mass Index and leg dominance) will be recorded on the participants' first experimental visit. Post-anthropometric data collection, participants will be asked to sit on a Cybex dynamometer with their knee angle set at 90°. A Logiq S8 GE (Logiq Healthcare, Milwaukee, USA) ultrasound (with B-mode imaging and shear wave elastography) will be used to assess the thickness, pennation angle, length of the fascicles of the RF, VL and VM in the sagittal plane. Then, the patellar tendon thickness will be assessed in the sagittal plane and cross-sectional area in the transverse plane. Finally, shear wave velocity will be recorded for the patellar tendon in the sagittal plane. Post-ultrasonography-based measurements, we will prepare the skin for the RF, VL and VM to place high-density surface electromyography electrodes in the same position and orientation as the ultrasound probe.

We will then record three knee extension maximal voluntary isometric contractions (MVC) for 5 s each, with a rest period of 1 min between repetitions, with the knee angle set at 90°. The highest MVC recorded will be used as a reference for the dynamic and isometric contractions in the experimental sessions. Post-MVC, we will measure motor unit characteristics using HDsEMG through a series of different contractions at varying loads, with the order of loads being randomised for each participant, maintaining the randomisation order throughout the study duration. Initially, we will conduct a series of isometric trapezoidal (torque template) contractions at intensities of 10% (sustained phase duration of 20 s), 35% (sustained phase duration of 15 s) and 70% MVC (sustained phase duration of 10 s), for two sets at each intensity, with 60 s between sets and intensity loads. The repetitions at different intensities will be completed in a random order. All trapezoidal torque template contractions will have a ramp-up and ramp-down phase of 10% MVC/s. Post the isometric trapezoidal torque template, we will then ask the participants to perform three isometric contractions matching a triangular torque template at 30% MVC with a speed of 3% MVC/s for the ramp-up phase and 3% MVC/s ramp-down phase (rest period of 60 s between sets), with no sustained phase between the ramp-up and ramp-down phases. Once all isometric contractions have been completed, we will provide the participants with 5 min of rest, after which they will undergo two sets of CON-ECC contractions at 25% and 50% MVC at 8°/s, with 60 s of rest between sets, followed by two sets of eccentric-concentric contractions at 25% and 50% MVC at 8°/s, with 60 s rest between sets. We will provide 1 min of rest between each loading condition for the dynamic contractions (eg, 25% CON-ECC and ECC-CON and 50% ECC-CON and CON-ECC).

All participants will be provided with a visual feedback on a computer screen, where a target torque will be provided based on the ramp contraction (torque template) to be performed; the participants will be required to match the torque output level through the duration of the contraction as accurately as possible. The dynamic contractions will be performed at a range of motion between 10° and 90° (ie, 80°) of knee flexion.

The PT group will be randomly allocated to either an EE group or visuomotor torque feedback (TF) group, with both groups undergoing a 6-week training period consecutively (two times per day for EE, and 2–3 sessions/week for TF), and an additional experimental lab visit at weeks 3 and 6 (figure 1). Each experimental session will last 2.5 hours. The weekly duration of each of the exercise protocols (EE and TF) will be approximately 120 min, with the TF group performing 40 min training sessions up to three times per week, and the EE group performing 14 training sessions lasting approximately 9 min each. This will ensure that the total weekly exercise volume is comparable across protocols.

We have chosen to have lesser training frequency for the TF group, as one of the common issues with tendon rehabilitation is participant adherence to the training protocol.[40] The EE protocol can produce significant tensile loading on the patellar tendon, with lower muscle activation of the vastii muscles,[10] causing substantial pain in the patellar tendon, which when coupled with a high training frequency can reduce participant adherence. Whereas in the TF protocol, there will be high tensile loading on the patellar tendon, accompanied with increased vastii muscle activity.[14] Additionally, the visual feedback of force will divert the attention of the participants away from the pain they experience, as they will be focused on proper exercise execution.[41] All the aforementioned factors associated with the TF protocol could potentially enhance tendon rehabilitation by reducing participant discomfort, thereby promoting greater training adherence. However, to mitigate and reduce the bias against the EE group, we will require the participants

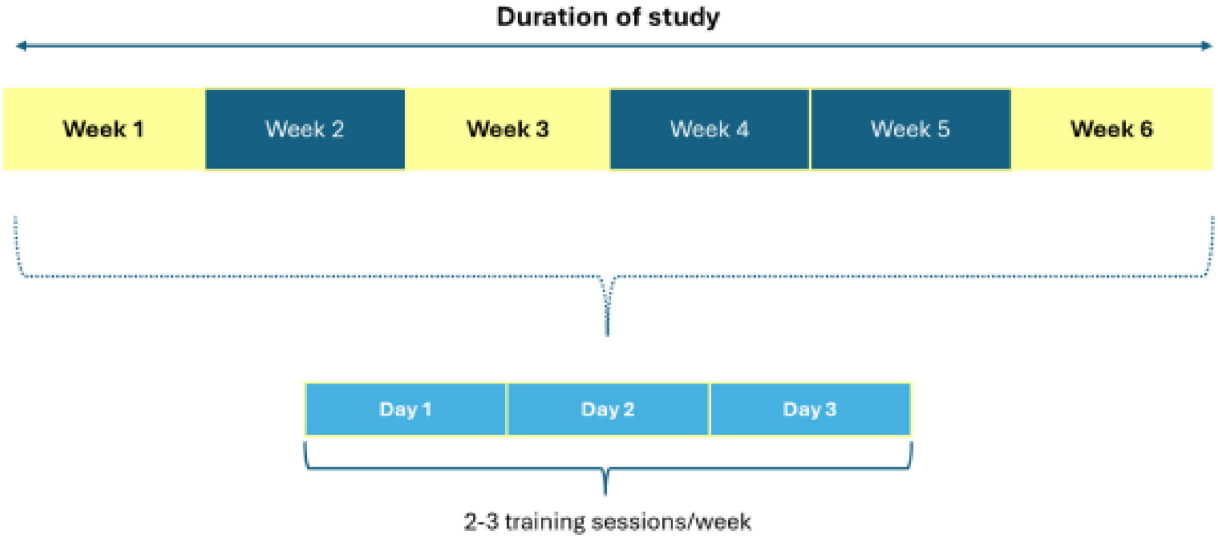

Figure 1 Schematic representation of study design. Yellow boxes indicate experimental sessions.

to fill in a training diary, which will be monitored in real-time daily. Where a participant does not adhere to a daily session, they will be contacted, and asked about their situation, and will be encouraged to resume exercise when possible. Additionally, at week 3, we will review their technique and loading, to ensure they are performing the exercises correctly and with adequate loads.

Training sessions

The EE group will be shown how to perform a unilateral decline board squat and provided with reference images and videos; this group will perform three sets of 15 repetitions (two times per day: morning and evening) for six consecutive weeks.[7 40] The intensity of the EE exercise will be increased weekly by adding a load in a backpack depending on pain tolerance (pain level of 5/10 on an NRS).[40] The EE exercise will be performed at home by the participants, and we will provide them with a standardised decline board to take home (25° of inclination). The EE group participants will be shown how to perform the exercise correctly in their first experimental session (figure 2). We will liaise with the EE group participants weekly via email/phone based on their preference to check compliance with the exercise programme. The exercise technique and performance of the EE group will be rechecked in their second experimental visit.

The training protocol for the TF group will be conducted in the laboratory, with the participants seated on a Cybex isokinetic dynamometer at a knee angle of 90° (0° being full knee extension); the exercise will be performed between 10° and 90° of range of motion (total of 80° range of motion). To warm up for subsequent tasks, the TF group individuals will be required to perform a warmup of three repetitions at 25% MVC eccentric and then 25% MVC concentric contraction. The participants will then perform two sets of 15 repetitions of 50% MVC eccentric contractions at 8°/s, and two sets of 15 repetitions of 50% MVC concentric contractions at 8°/s, with 3 min of rest between each set, with the knee returning to full extension or flexion passively at the end of every repetition for the eccentric and concentric contractions respectively. The participants will be provided with visual feedback (figure 3), with a target force level of 50% MVC to ensure they are performing both concentric and eccentric contractions at appropriate force levels throughout the entire range of motion.

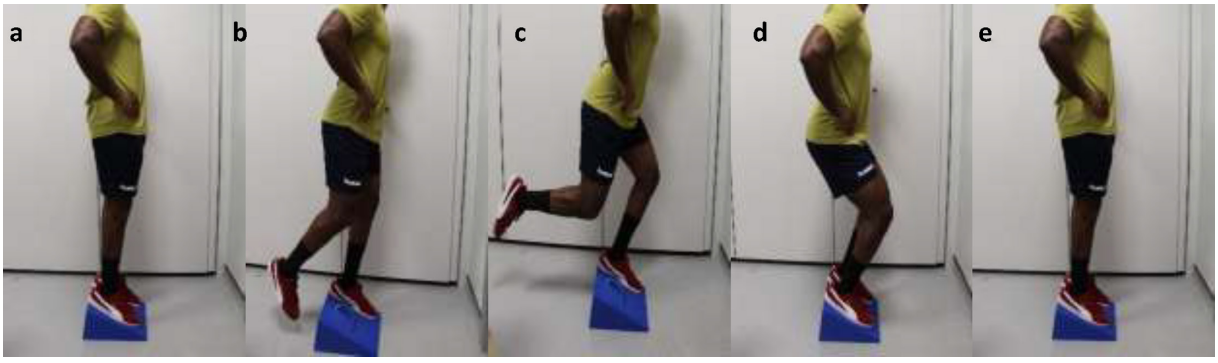

Figure 2 Eccentric unilateral squat. (a) Stance phase. (b) Unloading phase. (c) Unilateral eccentric squat phase. (d) Bilateral concentric squat phase. (e) Stance phase.

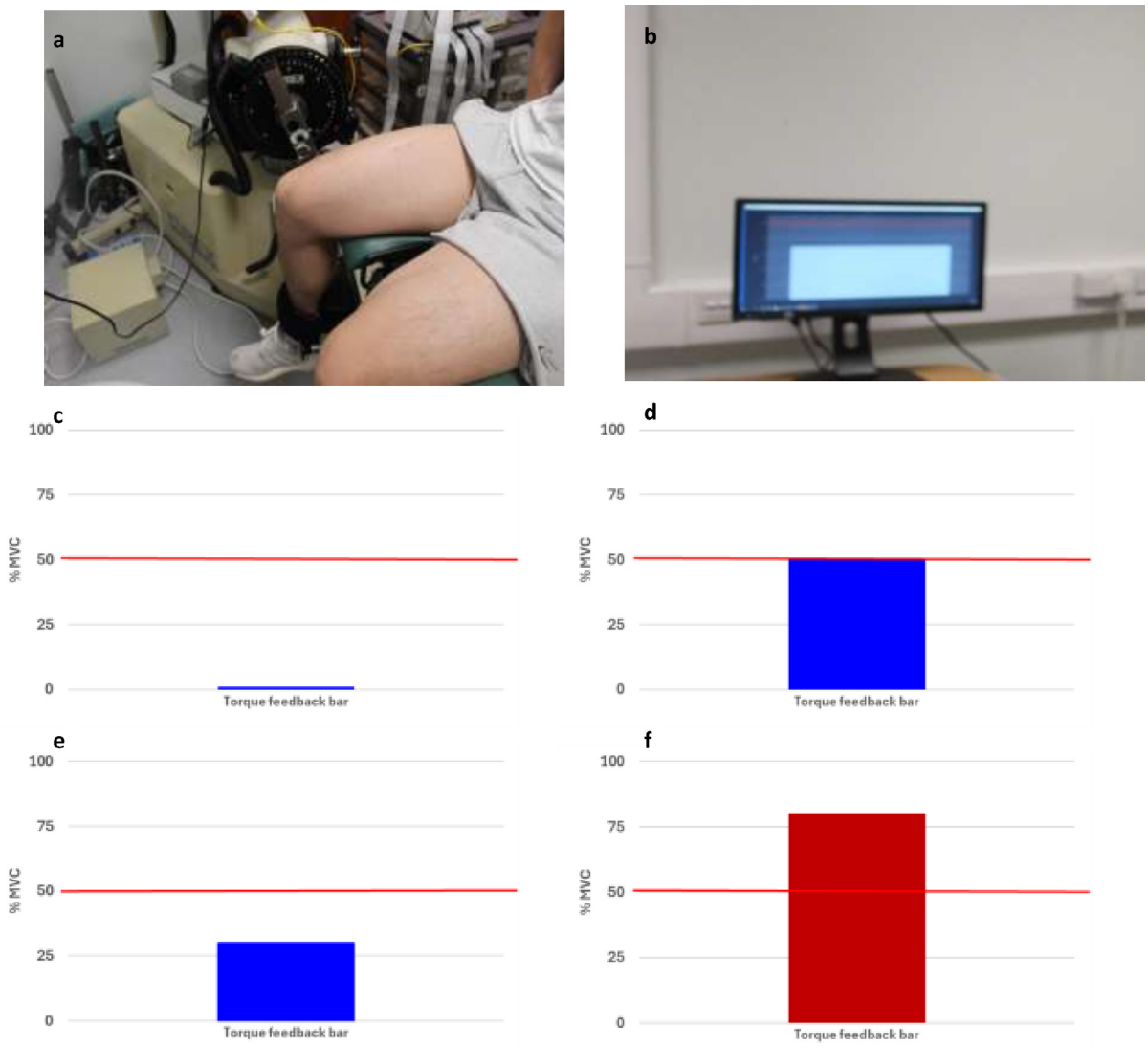

Figure 3 (a) A participant sat on a Cybex isokinetic dynamometer with a knee angle of 90° and (b) torque target feedback visual shown to participants. (c) No torque. (d) Torque correctly matched to target. (e) Torque under target. (f) Torque above target.

MVCs and pain tolerance for the TF exercise will be measured weekly to adjust loads accordingly and ensure the loads never reach an NRS value greater than 5.[40] During the intervention, if the participants experience pain greater than 5 on the NRS, we will provide them additional time to rest. Should the pain persist, we will reduce the load by 20% during contractions. Where necessary, adjustments will be made to reduce the participant's pain, and if pain persists, we will terminate all assessments.

Patients in both study arms will be instructed to perform exercises targeting risk factors for PT in addition to the allocated tendon-specific exercises.[7] These exercises targeting risk factors include flexibility exercises of the quadriceps, hamstrings, gastrocnemius and soleus muscles, strength exercises for the hip abductor muscles and hip extensor muscles using an elastic resistance band, calf-muscle strengthening exercises and core-stability exercises.

Follow-up protocol and surveys

Participants from both the torque visuomotor feedback and eccentric exercise group will be advised to perform decline board squats and continue with the exercises targeting risk factors[7] after their final assessment as part of their follow-up protocol, which will last up to 6 weeks (counted from the sixth week assessment, that is, 12 weeks from the start of the intervention period). Finally, we will have a 6-week follow-up period post-training cessation, where the participants' functional disability, pain and kinesiophobia will be recorded (ie, 18 weeks from the start of the intervention period). The protocol will employ the same volume used by the home-based eccentric exercise group (ie, 3 sets and 15 repetitions, two times per day), with the torque visuomotor feedback group performing half of the repetitions concentrically (standing up on one leg, and lowering themselves with both legs), and the other half eccentrically (lowering themselves with one leg, while pushing themselves up with both legs). At 6 and

12 weeks post-completion of the training protocol, the participants with PT will be sent an online REDCap survey and asked to report their pain (NRS) and perceived disability with the VISA-P questionnaire.

Outcome measures

Primary outcome measure

Changes in pain measured by NRS and perceived functional disability assessed by VISA-P will be the primary outcome measures of this study and will be assessed at baseline and then at 3, 6, 12 and 24 weeks from the baseline measurements.

Secondary outcome measures

At baseline, and then 3 and 6 weeks from baseline, the participants will be assessed on the following: level of physical activity monitored by an IPAQ-short form, level of Kinesiophobia measured with the Tampa Scale for Kinesiophobia, maximal knee extension strength (peak knee extension torque (Nm)), torque tracking accuracy (coefficient of variation of torque (%)), motor unit firing properties (mean motor unit discharge rate (pps), discharge rate variability (%), recruitment threshold (%MVC)), quadriceps muscle connectivity/synchronisation (motor unit intermuscular coherence (Hz)), patellar tendon thickness (mm) and CSA (cm^2), quadriceps femoris (VL, VM, RF) muscle thickness (mm), pennation angle (°), and fascicle length (mm), and estimated patellar tendon stiffness (Kpa and m/s).

Measurement set-up

For the experimental session set-up, the participants will be sat on a Cybex dynamometer with their knee angle set to 90°, post which ultrasound and elastography-based measures will be conducted. Then, the participants will be strapped onto the chair with two vertical hook and loop fasteners that will be secured through both participant's shoulders; we will then place an immovable ankle rest attachment that will be used to secure the opposite non-involved leg, to prevent compensatory knee extensions. The participant will be positioned so the dynamometer's rotational axis is directly parallel to their lateral epicondyle. The participants involved (measurement) leg will be securely strapped to the knee extension dynamometer attachment at the front of their ankle, and the knee attachment will be positioned and secured so the participant's knee angle is at 90°. The participant's dynamometer chair and settings will be saved to ensure the same settings are used in subsequent measures for reliable results.

Ultrasonography/shear wave elastography measurements

We will use a LOGIQ S8 ultrasound system (LOGIQ, GE Healthcare, Milwaukee, USA) equipped with SWE capabilities to capture both B-mode images and shear wave velocity recordings. B-mode ultrasonography images will be taken to assess quadriceps femoris muscle thickness (linear distance between the deep and superficial aponeuroses), pennation angle (angle between a fascicle and the deep aponeurosis), fascicle length (linear distance of a single fascicle from the deep aponeurosis to the superficial aponeurosis), and patellar tendon thickness and CSA using a 16-linear array probe (50 mm, 4–15 Hz), all B-mode ultrasound variables will be measured manually using ImageJ software (National Institutes of Health, Bethesda, Maryland, USA). Patellar tendon stiffness will be measured using a 9-linear array probe using the ultrasound's elastography option (44 mm, 2–8 MHz).

To measure patellar tendon thickness, we will measure patellar tendon thickness (figure 4a) based on an adapted protocol from Visnes *et al*.[42] We will identify the tibial tuberosity of the involved leg, after which the 16-linear array probe will be placed perpendicular to the skin directly above the tibial tuberosity in the sagittal (longitudinal) plane. A linear measurement will be taken at the

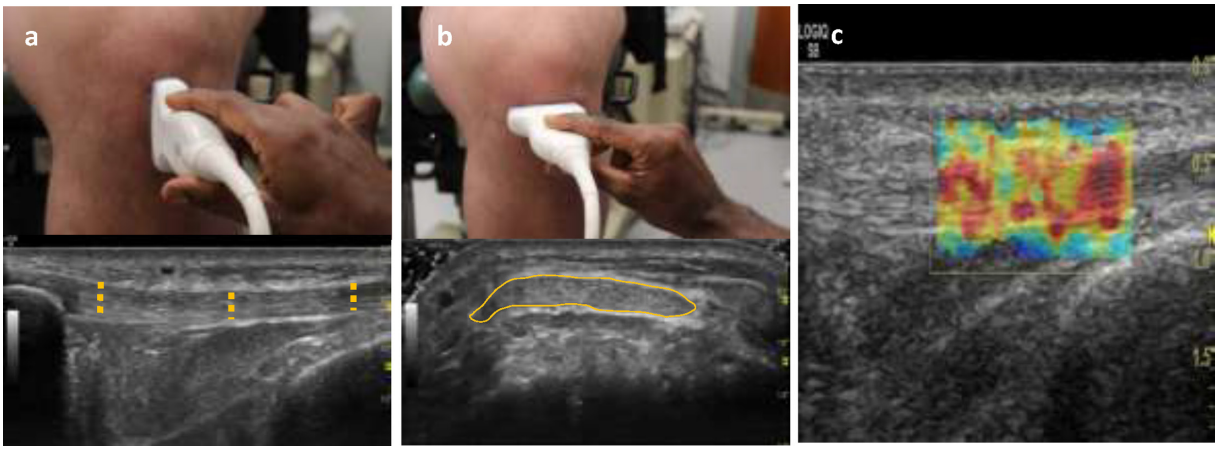

Figure 4 Patellar tendon probe placement/orientation. (a) Longitudinal plane for patellar tendon thickness measurement. (b) Transverse plane for patellar tendon CSA measurement. (c) Shear wave elastography of the patellar tendon, the heatmap represents the degree of stiffness in the tendon, with red indicating a stiffer tendon, and blue indicating a more compliant tendon. The yellow dashed lines indicate where tendon thickness measurements will be taken, while the yellow solid free-from line shows where tendon CSA measurement will be taken.

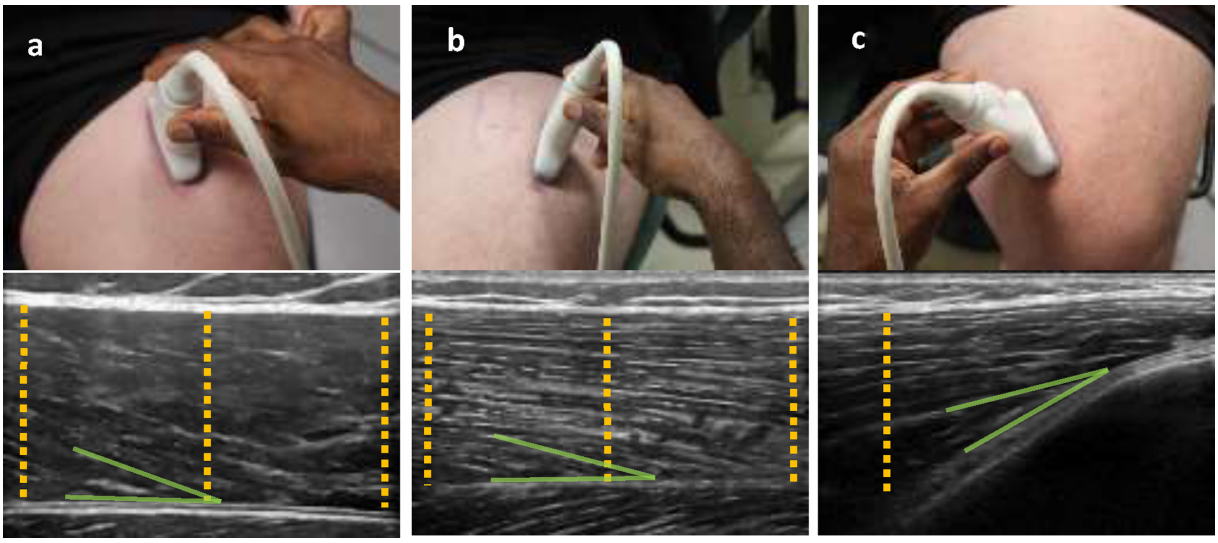

Figure 5 16-linear array probe placement/orientation and representative B-mode image on the (a) RF, (b) VL and (c) VM. The yellow dashed lines indicate the areas where muscle thickness measurements will be taken, while the green solid lines show an example location, where muscle pennation angle measurements will be taken from. RF, rectus femoris; VL, vastus lateralis; VM, vastus medialis.

proximal, middle and distal portions between the paratenon and epitenon, to identify patellar tendon thickness, the position of the probe will be marked at its centre and sides as a reference for the SWE measurements. Then, the 16-linear array probe will be rotated from the same position as where it was placed longitudinally into a transversal position to record the patellar tendon's CSA (figure 4b).

Subsequently, the quadriceps femoris muscles will be identified and marked; the RF muscle (figure 5a) will be assessed at 50% of the length between the superior portion of the patella and the anterior superior iliac spine.[43] For the VL (figure 5b), a site at 50% length between the lateral femoral condyle and greater trochanter will be used.[44] Finally, the probes will be placed medial to the superior border of the patella until an image of the VM (figure 5c) insertion point appears, and the probe will be adjusted such that the deep and superficial aponeuroses are oriented parallel to each other,[45] which should translate to 5% distance between the superior patellar border and anterior superior iliac spine. The ultrasound probe placement on the VL and RF muscles will be marked at the centre of the probe and the sides as reference points for the HDsEMG electrode placement.

For patellar tendon stiffness measurements, we will use the same position as the patellar tendon thickness assessment in the longitudinal plane using a 9-linear array probe (figure 4c) through the in-built elastography function of the Logiq S8 Ultrasound system (LOGIQ, GE Healthcare, Milwaukee, USA). We will then collect SWE frames with a region of interest focusing on the participant's patellar tendon for 15 s, ensuring that empty pixels from the SWE maps are avoided, where significant voids are present in the middle of the tendon, we will discard the captured frames, and recapture new frames. Finally, we will extract three images from the captured frames, post which we will apply a shear wave velocity and stiffness calculation function through the Logiq S8 system's in-built function over the entire region of interest to obtain mean shear wave velocity and stiffness.

HDsEMG and torque recording

For HDsEMG electrode placement, the skin will be shaved (where necessary), gently abraded using Nuprep skin preparation gel (Weaver and Company, Aurora, Colorado) and cleaned with water to reduce skin impedance. Three 13×5 (13 rows, five columns) equally spaced high-density electrodes (1 mm diameter, and 8 mm interelectrode distance; GR08MM1305, OT-Bioelettronica, Torino, Italy), attached with 2D electrode adhesive grids (FOA08MM1305, OT-Bioelettronica, Torino, Italy), will be used to record EMG activity of the VM, VL and RF muscles. We will apply AC-CREAM conductive paste (SPES Medica, Genova, Italy) into the cavities of the HDsEMG electrodes, which will be placed in the same position as the ultrasound measurements of the VL, VM and RF.

HDsEMG and torque signals will be converted from analogue to digital using a 16-bit converter (Quattrocento, OT-Bioelettronica, Torino, Italy) with a 2048 Hz sampling frequency and amplifier gain of 150. HDsEMG signals will be band-pass filtered between 10 Hz and 500 Hz at the source by the amplifier, and signals will be captured in monopolar mode, with reference electrodes (Ambu AS, Ballerup, Denmark) and conductive straps (Ws1-1, OT-Bioelettronica, Torino, Italy) placed on the participant's patella and shin. The three electrode grids and reference electrodes will be connected to the 16-bit converter (Quattrocento, OT-Bioelettronica, Torino, Italy). The torque produced by the participants will be recorded from the Cybex isokinetic dynamometer at a sampling rate of 2048 Hz (Humac Norm, Massachusetts, USA). The dynamometer will be synchronised with the

HDsEMG signals through an auxiliary input connected to the Quattrocento 16-bit converter (OT-Bioelettronica, Torino, Italy).

Signal analysis

To measure force steadiness (coefficient of variation of torque; SD torque/mean torque), a 15 Hz low pass filter will be applied to the torque signals, and peak knee extension strength (Nm) normalised to MVC (%MVC) will be analysed offline using a custom Matlab script, with the Matlab software version 2024a (Mathworks, California, USA). We will then decompose the monopolar HDsEMG signals into binary spike trains based on the convolutive blind source separation (BSS) algorithm.[28] BSS detects individual motor unit discharge patterns, by enhancing the heterogenous distribution patterns of the HDsEMG signals, which takes into account that no two motor units are likely to display homogenous firing patterns. Additionally, the BSS algorithm identifies motor units without an a priori knowledge of the nature of the signal, which makes it an unbiased algorithm.[46] We will use the BSS algorithm using a custom-made Matlab code, for the automatic identification of individual motor unit activity, with the accuracy of the decomposition being verified using a silhouette measure of >0.85.[28] The silhouette measure identifies the peak height of the decomposed spike trains relative to baseline noise, allowing for the accuracy of decomposition to be controlled. The signals will be decomposed for both the trapezoidal and triangular template contractions, and the discharge times will be transformed into binary spike trains. During the trapezoidal template contractions, the mean discharge rate and coefficient of variation of the inter-spike interval (discharge rate variability) will be assessed during the stable plateau phase of the contractions. We will estimate changes in motoneuron persistent inward currents throughout the entire duration of the triangular template contractions using a paired motor unit analysis method, where (ΔF) depicts the hysteresis of higher threshold motor unit discharge rates with respect to a lower threshold motor unit. ΔF will be quantified as the change in discharge rate in the recruitment and de-recruitment phases between a control/test unit (high threshold motor unit) and a reporter unit (low threshold motor unit).[47] Motor units will be semimanually edited to ensure that only high-quality signals/motor units are chosen for analyses, briefly, motor unit spike trains will be visually inspected, where erroneous spike trains (ie, non-physiological) will be removed, and incorrectly removed spike trains will be restored from the separation filter.[48] We will also track motor units across different sessions to understand how they adapt in response to a training protocol; briefly, post full BSS decomposition, we will apply a semiblind separation procedure that will focus on identifying motor unit action potentials (MUAP) that are similar in waveform/profiles to those extracted at baseline. Based on the semiblind separation procedure, two groups of motor units will be identified: the first group will consist of initially matched motor units based on similar MUAP profiles as those found at baseline, and the other group will consist of unmatched motor units that will be analysed in individual sessions but will not be matched to other motor units. Finally, we will apply a normalised cross-correlation function to verify the similarity between motor units of similar MUAP profiles, and only motor units with a cross-correlation factor of >0.8 will be used for tracked motor unit analyses. This technique has previously been validated.[30]

Adverse event management

Before participating in the study, all participants will be informed that they might experience pain and discomfort during and after the experimental and training intervention sessions. To ensure participants are performing the tasks in the experimental and training sessions with acceptable pain levels, we will continuously monitor their pain levels using an NRS and should their pain levels go past six (greater than moderate pain), we will provide them some time to rest. If the pain levels are maintained or increase, we will terminate and reschedule the session in the next 3 days. If post-accommodations and rescheduling for pain are insufficient, and the participants still experience considerable pain, they will be removed from the study, and this will be considered an adverse event and will be reported to the Science, Technology, Maths, and Engineering ethical review committee at the University of Birmingham.

Randomisation and blinding

Randomisation of participants with PT will be coordinated by Dr Eduardo Martinez-Valdes (E-MV) in a 1:1 allocation ratio to either the TF or EE group (parallel groups) through a computer-generated simple scheme randomisation (https://www.project-redcap.org/). EM-V will use a password-protected file to store the randomisation codes and ensure group allocation concealment. EM-V will provide the randomisation codes to Ragul Selvamoorthy (RS) and Michail Arvanitidis (MA) once all three experimental sessions are completed.

To achieve single-blinding, RS and MA will conduct the training interventions, collecting and providing obtained data to E-MV, who will mask the group allocation of the participants. Therefore, RS and MA will conduct statistical analyses without the knowledge of the participants' group allocation. Once all data has been analysed, E-MV will unmask the results.

Statistical analysis

R studio (R version 4.3) will be used for all statistical inferences of the data. Descriptive statistics presented in mean±SD will be used to interpret the data. A Shapiro-Wilks test will be conducted to analyse the normality of the data, and if the data is normally distributed, a group (TF, EE) × time (baseline, 3 weeks, 6 weeks) mixed ANOVA (repeated measures and independent measures) will be used to compare the outcome variables between

TF and EE group at baseline, 3 weeks, and 6 weeks post-training. Additionally, independent T-tests will be conducted for the outcome variables between the healthy controls and participants with PT at baseline. Where the repeated measures ANOVA are significant, we will use a Bonferroni corrected pairwise-t-tests. We will use relevant non-parametric tests if the data is not normally distributed. The partial eta squared (η_p^2) of the ANOVAs will be reported to examine the effect size of changes in outcome variable due to the training interventions. A η_p^2 of less than 0.06, 0.07–0.14, and greater than 0.14 will be classified as small, medium and large respectively. Statistical significance will be set at 95% (α=0.05), with 95% CIs reported.

DISCUSSION

This study will be among the first to investigate the use of a torque-based visual feedback training protocol that includes slow concentric and eccentric contractions and its effect on the management and rehabilitation of PT-related pain, functional disability and kinesiophobia. This protocol might provide a better alternative to standard treatments that involve unsupervised eccentric contractions. Additionally, this study will be the first to investigate changes in quadriceps motor unit activity, muscle architecture, and patellar tendon morphology and stiffness in people with PT against healthy controls, while also exploring changes in these variables following a 6-week training intervention.

One of the strengths of this study lies in the novelty of a torque-based visual feedback training protocol for individuals with PT, as visual feedback has previously been shown to improve both torque/force production, by reducing the variability of torque production, and maximum torque produced.[49 50] By providing a visual stimulus, the participants will be able to adjust their force levels according to the target force, whereas, without such stimulus, it is possible that participants would be less likely to produce the appropriate force levels, due to subjective pain-related limitations in force output and altered sensory feedback. In the TF task, the participants must actively perform concentric and eccentric contractions throughout an extensive range of motion, which increases the time that the patellar tendon and quadriceps femoris muscles are under tension, providing an optimal mechanical overload that can likely lead to enhanced remodelling of the injured patellar tendon.[1 51] Furthermore, the continuous contraction must be performed at an individualised target torque level (50% of the participant's MVC) using visual feedback. This provides unique proprioceptive input, helping participants become accustomed to the force output level associated with the exercise, thus improving performance across training sessions.[1 51] Additionally, the enhanced motor control strategies due to this protocol may potentially be mediated by enhanced corticospinal excitability, and the functional reorganisation of the central nervous system.[52] In contrast, the standard care of treatment involving eccentric unilateral squats can only be performed over a limited range of motion, with no feedback on the amount of force produced by individuals, along with the possibility of the muscle/tendon's active tension not being maintained towards the lower end of the movement (ie, dropping at the bottom of the squat, instead of holding the bottom position), due to pain, lack of mobility, or use of compensatory motor control strategies (eg, trunk flexion, lateral sway of the body, the tension in the calf).[9] The use of an isokinetic dynamometer further aids with the torque feedback-based training, as the loads will be individualised based on each participant's strength/ability levels, similarly, and contraction speeds can be controlled rigorously. Our protocol will limit the speed of both the eccentric and concentric contractions to 8°/s and the participants will only perform the contractions at individualised loads of 50% MVC, allowing them to have more control and less pain to perform the training intervention. Additionally, the visual feedback provides a reference force target level that allows the participants to actively adjust their effort levels to match the target, which may aid in developing optimal motor control strategies, as individuals with PT may not actively produce sufficient force during exercises to generate optimal adaptations in the tendon due to kinesiophobia.

Currently, there are no studies that have investigated individual motor unit characteristics in individuals with PT acutely or post an intervention targeting the rehabilitation of PT. Most studies have focused on analysing interference EMG[17–19] signals obtained from bipolar surface EMG, which does not provide clear information regarding the neural drive received by muscles.[29 53] Evidence suggests that an injured or damaged tendon may lead to altered activation of surrounding muscles as a compensatory mechanism for reduced tendon stiffness.[54] Therefore, it is important to assess how the nervous system adapts to these conditions by directly monitoring the neural drive received by the quadriceps muscles by studying motor unit firing properties. Therefore, another aspect that makes our study unique is the ability to compare individual motor unit characteristics acutely and longitudinally in comparison to healthy controls,[55] and in response to a training intervention.[56–58] This protocol will provide valuable knowledge that clinicians and practitioners can use to help inform their rehabilitation protocols.

Our study will analyse mean motor unit discharge rate, discharge rate variability, inter-muscular coherence, and the estimation of intrinsic motoneuron excitability via the analysis of persistent inward currents. Briefly, mean motor unit discharge rate indicates how often a motor unit discharges action potentials and is one of the main predictors of a muscle's capacity to produce force,[59] while discharge rate variability provides an index of the variation between action potential discharges of a motor unit and can represent the influence of synaptic input from excitatory/

inhibitory centres and the intrinsic properties of the motor unit.[60 61] Inter-muscular coherence assesses common modulations in motor unit discharge between synergistic muscles, identifying the presence of shared and independent synaptic inputs received by these muscles.[62 63] This information can be important in rehabilitating PT as a balanced activation of the knee extensor muscles could improve the control of knee extension force. Finally, the estimation of persistent inward currents (PIC) provides an indirect measure of persistent sodium channels and excitatory dendritic currents mediated by voltage-sensitive channels in the motoneuron that enhances the depolarisation of motor units and reduces the excitatory drive required for a depolarisation to occur. PIC represents the difference in the relationship between rate of force development and motor unit discharge rate.[47 64] It has previously been shown that PIC reductions occur in response to passive stretching of the soleus muscles,[65] which could be of interest to our study, as PT can decrease the stiffness of the patellar tendon (ie, increased compliance). Therefore, there is the possibility that we might see a change in PIC of the quadriceps femoris in our study, as a compensatory mechanism. Additionally, we will use different contraction types and loads to identify different motor unit populations, as lower and higher forces allow to compare the firing behaviour of lower and higher threshold motor units, which can be affected differently in the presence of pain.[27 66]

In addition to analysing motor unit properties, we will also study the architectural and structural properties of the knee extensor muscles and patellar tendon acutely and longitudinally. The assessment of the abovementioned variables will allow us to compare the differences between healthy controls and individuals with PT and to track the adaptations in knee extensor muscle,[67] and patellar tendon thickness/CSA,[3 20–22] and stiffness to a 6-week training programme.[7 24–26 68] The previously mentioned analyses are important given the degenerative condition of patellar tendinopathy, along with the long duration required for rehabilitation, and the persistence of pain and discomfort post-rehabilitation. The data on structural and architectural changes will provide further insight into the adaptations caused by the 6-week interventions in individuals with patellar tendinopathy. This will help determine whether neural and/or structural/architectural mechanisms underpin the positive rehabilitation of PT.

We acknowledge several limitations of our study. First, the duration of our training intervention will only last 6 weeks, which may not be an adequate period to cause a possible adaptation in the patellar tendon and associated structures, potentially requiring future studies to look at more extended training intervention periods to validate our hypotheses; nevertheless, it is important to test new protocols potentially inducing faster changes in pain and function[13] as current rehabilitation programmes use interventions lasting between 12 and 24 weeks, which are difficult to implement in athletic populations. Second, we will be unable to blind the participants to the nature of their intervention protocols, as adequate instructions will be required to ensure individuals can execute the training protocols safely; this limitation cannot be avoided. Moreover, we have chosen to exclude participants older than 55 years, as previous studies have shown age-related decline in patellar tendon architecture and stiffness, which limits our study's findings to individuals below the exclusion criteria. Finally, as only the TF group will perform their training interventions in the lab supervised by the researchers, they are likely to have higher training adherence compared with the EE group. To mitigate and reduce bias against the EE group, the participants will be required to fill in a training diary indicating the number of sets/sessions they have completed, which will be monitored in real-time daily. Where a participant is not adhering to the exercises, they will be asked about their situation, post which they will be encouraged to resume exercise where possible. Additionally, at week 3, the participant's technique and loading for the EE exercise will be reviewed, to ensure they are performing the exercises correctly and with adequate loading.

In conclusion, the current research study will provide novel insights into rehabilitating patellar tendinopathy through a torque feedback-based training intervention involving both concentric and eccentric contractions, compared with the standard care of treatment involving unsupervised EE. The study will potentially provide a protocol that reduces pain, discomfort and functional disability in individuals with PT while also providing insights into the neuromechanical nature of the intervention's adaptations.

Patient and public involvement

The research study's aims will add to literature that aims to investigate the efficacy of different training protocols for PT on pain and functional disability, besides the publication of the results of this study in peer-reviewed journals and presentations at conferences, we will promote the research study within the University of Birmingham's clinical physiotherapy academic programmes, and will present the results at the chartered society for physiotherapy meetings (Physiotherapy UK) as well as other European and Overseas Physiotherapy schools. We will also disseminate the results across clinical populations. A bi-monthly PPI event is normally held within our centre (University of Birmingham's School of Sport, Exercise and Rehabilitation Sciences) to promote our research with individuals suffering from a variety of chronic musculoskeletal complaints, which provides a unique opportunity to provide direct guidance and recommendations for the management of their pain, according to the results obtained from our research.

Post-termination of our study, we will hold a seminar within our research centre, and at the University of Southern Queensland's School of Medical and Health Sciences, to present the findings of our project and discuss the translation of this research into clinical practice. This workshop will provide an important link between practitioners (ie, physiotherapists, occupational therapists) and our research group, where we will provide a platform to apply our research to larger clinical populations. Patients and the public will not be directly involved in the analysis and data collection, but will contribute to the interpretation of the findings, and the production of a lay summary of findings. We will also aim to promote our research over a wide range of communication mediums such as public media outlets, as well as social media, to enhance the visibility and impact of our research to a wider audience. Finally, we will engage with our business engagement team to establish the necessary synergies to generate cost-effective devices for a wider implementation of the proposed intervention in the clinic.

ETHICS AND DISSEMINATION

The study's research protocol has been given ethical approval by the Science, Technology, Mathematics and Engineering Ethical Review Committee at the University of Birmingham (ERN_2257-Jun2024).

The research participants will be provided with information sheets regarding the nature of the research and what they will undergo, where they will have the opportunity to ask the researchers about the research protocol, post which they will be required to sign an informed consent form (online supplemental appendix 2). The participants will be informed that they can withdraw from the study at any time. All adverse events will be reported by the principal investigator to the ethical review committee immediately.

The results of this study will be submitted to a peer-reviewed journal and presented at conferences.

Confidentiality

All personally identifiable information will be strictly kept confidential. Personal information collected will be available to researchers only through a password-protected file. Additionally, all data for presentation will be anonymised and aggregated, to ensure the anonymity of the participants.

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Contributors E-MV is the guarantor for this research study. E-MV is responsible for the conception, design and development of the protocol. E-MV is the principal investigator for this research study. E-MV and MA have provided guidance on methodological and critical revision. RS will conduct the interventions/assessments and will conduct the data analyses and writing up of this study. All authors have revised/read and subsequently approved the final manuscript. RS, E-MV, MA, FN, PP, DE and E-MV contributed to editing, reviewing and approving the final manuscript.

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