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Torque visuomotor feedback for the management of patellar tendinopathy

Submission date
09/07/2024

Recruitment status
Recruiting

Registration date
11/07/2024

Overall study status
Ongoing

Last Edited
17/02/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims

Tendons connect muscles to bones and help muscles to generate movement. When we exert repetitive movements for too long, tendons can become painful and are difficult to heal. Approximately 1-2% of adults present tendon pain on the leg during their lifetime and the knee tendon is one of the most common tendons to get injured. In the general population, the presence of knee tendon pain in the UK and worldwide is 1.6%, however, this number can increase up to 20% in athletes. The classic treatment offered by the NHS commonly involves exercises called ‘eccentric exercises’ (i.e., the muscle stretches while it contracts, like when you squat down). Unfortunately, these exercises do not have a clear effect on this injury, and it can take several months until people feel a reduction in pain. As a result, pain can persist and get worse over time, with approximately 50% of athletes experiencing this problem being forced to retire from their sport. Tendons need to be loaded to be able to heal. Knee tendon loading can be achieved, for example, by lowering weights from a standing to a squatting position. These components are observed in eccentric exercises; however, it is not easy to control how much load is received by the tendon. Moreover, these training interventions lack a clear progression, and programmes are normally not individualised to fit each person’s conditions. For this reason, we created a new intervention which first, can control the load received by the tendon, second, is adjusted and progresses according to each person’s own improvements and third, gives multiple information to the brain and muscles to enhance exercise performance. By using a specialised device for the assessment of muscle strength, this intervention uses each person’s own exerted force to provide feedback to control the knee movement during the rehabilitation programme, providing direct information on how to contract muscles during training. We have successfully employed this approach for the management of Achilles tendon pain (the tendon at the back of your ankle) and have observed significant improvements in pain and movement in as little as three weeks. Building up from this successful result, the aim of this project is to test this new rehabilitation programme for the management of knee tendon pain and compare it against the standard treatment offered by the NHS in a six-week training intervention.

Who can participate?

Inclusion Criteria for Tendinopathy Group

Participants in the tendinopathy group must be aged between 18 and 55 years, inclusive, and can be either male or female. They should have a documented history of patellar tendinopathy

for at least three months, with confirmation of the condition through ultrasound imaging showing increased tendon thickness and cross-sectional area. additionally, pain (pain of at least 2 /10 on a numeric rating scale, when performing a single leg eccentric squat) 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. Another inclusion criterion is a score of 80 or less on the Victorian Institute of Sport Assessment Scale-Patella (VISA-P), which assesses the severity of the condition. Furthermore, participants should not be receiving any NHS treatment for patellar tendinopathy at the time of the study.

Inclusion Criteria for Healthy Control Group
For the healthy control group, participants must be physically active males and females aged between 18 and 55 years. They should not have experienced any knee pain in the last 12 months to ensure the absence of current knee issues. Additionally, they must have no history of patellar tendinopathy to ensure they represent a healthy comparison group without the condition.

What does the study involve?
This study compares the effects of a novel intervention called visuomotor torque feedback training against another type of training commonly offered by the NHS, called eccentric exercise, on various aspects of patellar tendinopathy, including pain and your ability to perform daily activities. In addition, we will compare the neuromuscular adaptations (changes to the function of your brain and muscles) and modifications to the patellar tendon induced by these two types of training. We want to determine which exercise protocol has better results in this condition. As part of this study, we will assess your pain measured by a numerical rating scale (NRS), functional disability measured by the Victorian Institute of Sport Assessment - patella (VISA-P) questionnaire, level of physical activity analysed by the International Physical Activity Questionnaire (IPAQ) questionnaire, and kinesiophobia (fear of movement) through the Tampa scale of kinesiophobia (TSK) questionnaire. The architectural, morphological and structural properties of the thigh muscles and the tendon at the front of the knee will be assessed using ultrasound imaging and shear wave elastography (provides a 2D image of your tendon), and the electrical activity of your muscles will be evaluated using a non-invasive technique called high-density surface electromyography (HDEMG). The thigh muscle force will be assessed with a special device (dynamometer) designed to measure the movements of your knee. We will measure all of the above mentioned methods before the start of the intervention period, at the middle of the intervention period, and at the end. We will also check how well you have responded to each of the treatments, 6 weeks, 12 weeks and 18 weeks after the intervention, by asking your pain level and asking you to complete the VISA-P questionnaire.

What are the possible benefits and risks of participating?
Benefits:
This research aims to evaluate the effectiveness of a novel training intervention for managing patellar tendinopathy and seeks to identify the underlying mechanisms contributing to this injury. The successful implementation of this intervention will have direct benefits for both people suffering from patellar tendinopathy and clinicians involved in prescribing therapeutic exercises. Additionally, the findings from this research could have implications for managing other tendinopathies, as the proposed approach can be adapted to different joints.
Risks:
The risk from the procedures proposed within this project is minimal. There will be minor discomfort due to skin preparation for HDEMG, where the skin will be shaved and abraded. Similarly, there could be some minor discomfort when performing the knee extension tasks; however, participants will only be required to perform the task when the subjective numerical

pain rating is 5 out of 10. Soreness in the muscles of the leg and the patellar tendon might be experienced 24 to 48 hours after a training or testing session; however, this is entirely normal and does not pose a risk to the participant's well-being.

Where is the study run from?
The study will be conducted in a motor control lab at the University of Birmingham's Sport, Exercise, and Rehabilitation Sciences building.

When is the study starting, and how long is it expected to run?
June 2024 to June 2026

Who is funding the study?
Orthopaedic Research UK

Who is the main contact?
Dr Eduardo Martinez-Valdes, e.a.martinezvaldes@bham.ac.uk

Study website
https://www.birmingham.ac.uk/schools/sport-exercise/research/projects/patellar-tendinopathy-rehabilitation-project

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ORUK-574

Study information

Scientific Title
Torque visuo-motor feedback training versus standard eccentric exercise for the management of patellar tendinopathy, a randomised controlled trial

Acronym
TVM-PT

Study objectives
We expect the torque visuo-motor feedback intervention [TF] to be more effective in improving pain, functional abilities, and neuromuscular control than conventional interventions based on eccentric exercise [EE].

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/06/2024, The Science, Technology, Engineering and Mathematics University Ethics Committee (University of Birmingham, Birmingham, B15 2TT, United Kingdom; +44 (0) 1214143344; ethics-queries@contacts.bham.ac.uk), ref: ERN_2257-Jun2024

Study design
Single-centre interventional single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, University/medical school/dental school

Study type(s)
Treatment, Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Rehabilitation of patellar tendinopathy

Interventions
Current interventions as of 17/02/2025:
The sample will consist of two groups of individuals with patellar tendinopathy which will be randomly assigned (in a 1:1 allocation ratio to parallel groups using computer-generated simple scheme randomisation with REDcap (https://www.project-redcap.org/)) to a torque feedback [TF] group (n = 16); or eccentric exercise [EE] group (n = 16), with one control group consisting of healthy controls (n = 26), which will just be assessed at baseline.

A baseline assessment will be taken for all participants, and comparative analyses between the healthy controls and individuals with patellar tendinopathy on neuromuscular function and muscle architectural (muscle fibre arrangement; pennation angle and length), morphological (thickness) and tendon morphomechanical (thickness, cross-sectional area, and stiffness) properties will be conducted.

Post-baseline assessments, the TF and EE groups will undergo a six-week intervention. The TF group will perform a slow torque visuomotor feedback-based knee concentric-eccentric contraction task on an isokinetic dynamometer, while the EE group will perform a standard care of treatment offered by the NHS consisting of slow repetitions of unilateral eccentric squats to be done at home.

In addition to the baseline assessments (first experimental session), the participants' outcome measures will be assessed in the middle (3 weeks, second experimental session) and at the end of the intervention period (6 weeks, third experimental session). Pain and perceived disability will be also monitored 6 weeks and 12 weeks after the intervention.

The TF group will perform a torque feedback intervention using knee-extension isokinetic concentric and eccentric contractions on an isokinetic dynamometer based on a protocol that we successfully implemented for the management of Achilles tendinopathy (Contreras-Hernandez et al., 2022). The TF intervention will require participants to match a torque target presented on a computer monitor. The participants will be first asked to perform a warm-up consisting of three concentric and three eccentric knee-extension contractions at 25% of the maximum voluntary torque (MVT), followed by the TF protocol, which will consist of 2×15 eccentric contractions and 2 x 15 concentric contractions at 50% MVT. The range of motion will be 80° (from 10° to 90° of knee flexion, with 0° being full knee extension), time under tension of 10s, angular speed of 8°/s and 3 min rest between each series. MVTs and pain tolerance will be

measured weekly to adjust loads accordingly and will never exceed moderate pain levels (>5 NRS, Breda et al., 2021). If the participants exceeds a NRS >5, we will give them additional time to rest. If pain persists, the load will be reduced by 20% during contractions. Nevertheless, if, after this adaptation, the pain intensity is maintained, we will end the session.

According to NICE guidelines, participants in the EE group will receive treatment commonly employed in the NHS, which consists of eccentric resistance exercises to do at home. The training will consist of performing three sets of 15 slow repetitions of eccentric unilateral squats on a 25-degree decline board twice daily (morning and evening) for six consecutive weeks. The load will be increased weekly by adding a load on a backpack depending on pain tolerance (load that equates to a pain level of 5/10 on an NRS, Breda et al., 2021). The exercises will be performed at home, and we will provide the decline board to the participants. We will teach the participants how to do the exercises properly during the first experimental session, and we will monitor them in real-time through a training diary that they will fill in a shared One Drive Excel file every day. 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. Exercise performance will be rechecked during the second experimental session.

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 after their final assessment as part of their follow-up protocol, which will last up to six weeks (counted from the 6th-week assessment, i.e., 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 (i.e., 18 weeks from the start of the intervention period). The protocol will employ the same volume used by the home-based eccentric exercise group (i.e., 3 sets and 15 repetitions, twice daily), 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).

Previous interventions:
The sample will consist of two groups of individuals with patellar tendinopathy which will be randomly assigned (in a 1:1 allocation ratio to parallel groups using computer-generated simple scheme randomisation with REDcap (https://www.project-redcap.org/)) to a torque feedback [TF] group (n = 13); or eccentric exercise [EE] group (n = 13), with one control group consisting of healthy controls (n = 26), which will just be assessed at baseline.

A baseline assessment will be taken for all participants, and comparative analyses between the healthy controls and individuals with patellar tendinopathy on neuromuscular function and tendon morphomechanical properties will be conducted.

Post-baseline assessments, the TF and EE groups will undergo a six-week intervention. The TF group will perform a slow torque visuomotor feedback-based knee concentric-eccentric contraction task on an isokinetic dynamometer, while the EE group will perform a standard care of treatment offered by the NHS consisting of slow repetitions of unilateral eccentric squats to be done at home.

In addition to the baseline assessments (first experimental session), the participants' outcome measures will be assessed in the middle (3 weeks, second experimental session) and at the end of the intervention period (6 weeks, third experimental session). Pain and perceived disability will be also monitored 6 weeks and 12 weeks after the intervention.

The TF group will perform a torque feedback intervention using knee-extension isokinetic concentric and eccentric contractions on an isokinetic dynamometer based on a protocol that we successfully implemented for the management of Achilles tendinopathy (Contreras-Hernandez et al., 2022). The TF intervention will require participants to match a torque target presented on a computer monitor. The participants will be first asked to perform a warm-up consisting of three concentric and three eccentric knee-extension contractions at 25% of the maximum voluntary torque (MVT), followed by the TF protocol, which will consist of 2×15 eccentric contractions and 2 x 15 concentric contractions at 50% MVT. The range of motion will be 80° (from 10° to 90° of knee flexion, with 0° being full knee extension), time under tension of 10s, angular speed of 8°/s and 3 min rest between each series. MVTs and pain tolerance will be measured weekly to adjust loads accordingly and will never exceed moderate pain levels (>5 NRS, Breda et al., 2021). If the participants exceeds a NRS >5, we will give them additional time to rest. If pain persists, the load will be reduced by 20% during contractions. Nevertheless, if, after this adaptation, the pain intensity is maintained, we will end the session.

According to NICE guidelines, participants in the EE group will receive treatment commonly employed in the NHS, which consists of eccentric resistance exercises to do at home. The training will consist of performing three sets of 15 slow repetitions of eccentric unilateral squats on a 25-degree decline board twice daily (morning and evening) for six consecutive weeks. The load will be increased weekly by adding a load on a backpack depending on pain tolerance (never higher than > 5NRS, Breda et al., 2021). The exercises will be performed at home, and we will provide the incline board to the participants. We will teach the participants how to do the exercises properly during the first experimental session, and we will contact them once per week (via phone/email, according to their preference) to monitor their compliance with the treatment. Exercise performance will be rechecked during the second experimental session.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 17/02/2025:
At baseline, 3, 6, 12 and 18 weeks:
1. Pain assessed by a numerical rating scale (NRS)
2. Perceived functional disability measured by the Victorian Institute of Sport Assessment - patella (VISA-P) questionnaire

Previous primary outcome measure:
At baseline, 3, 6, 12 and 24 weeks:
1. Pain assessed by a numerical rating scale (NRS)
2. Perceived functional disability measured by the Victorian Institute of Sport Assessment - patella (VISA-P) questionnaire

Secondary outcome measures
Current secondary outcome measures as of 17/02/2025:
At baseline, 3 and 6 weeks:
1. Level of physical activity monitored with the IPAQ-SF scale
2. Level of Kinesiophobia measured with the Tampa scale for kinesiophobia (TSK)
3. Maximal knee extension strength - Peak knee extension torque (Nm)
4. Torque tracking accuracy - Coefficient of variation of torque (%)
5. Motor unit firing properties - Mean motor unit discharge rate (pps), discharge rate variability (%) and recruitment threshold (% MVT).

6. Quadriceps muscle connectivity/synchronization - Motor unit intermuscular coherence (Hz)
7. Thigh (Quadriceps) muscle thickness (mm), pennation angle (°), length (mm) measured with ultrasound imaging by placing the probe perpendicular to the skin above the three quadricep muscles (vastus lateralis, rectus femoris, vastus medialis).
8. Tendon thickness (mm) measured with ultrasound imaging, by placing the probe perpendicular to the skin directly above the tibial tuberosity in the sagittal (longitudinal) plane. A linear measurement (mm) will be taken at the proximal, middle, and distal portions of the tendon between the paratenon and epitenon.
9. Tendon stiffness (Kpa) and shear wave velocity (m/s), estimated via shearwave elastography

Previous secondary outcome measures:
At baseline, 3 and 6 weeks:
1. Level of physical activity monitored with the IPAQ scale
2. Level of Kinesiophobia measured with the Tampa scale for kinesiophobia (TSK)
3. Maximal knee extension strength - Peak knee extension torque (Nm)
4. Torque tracking accuracy - Coefficient of variation of torque (%)
5. Motor unit firing properties - Mean motor unit discharge rate (pps), discharge rate variability (%) and recruitment threshold (% MVT).
6. Quadriceps muscle connectivity/synchronization - Motor unit intermuscular coherence (Hz)
7. Tendon thickness (mm) measured with ultrasound imaging, by placing the probe perpendicular to the skin directly above the tibial tuberosity in the sagittal (longitudinal) plane. A linear measurement (mm) will be taken at the proximal, middle, and distal portions of the tendon between the paratenon and epitenon.
8. Tendon stiffness (Kpa), estimated via shearwave elastography

Overall study start date
01/06/2024

Completion date
01/06/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 17/02/2025:
Tendinopathy group
1. 18 to 55 years old
2. Male or female
3. History of patellar tendinopathy for at least 3 months. Signs of patellar tendinopathy on ultrasound imaging (i.e., increased tendon thickness and cross-sectional area).
4. Current pain (pain of at least 2/10 on a numeric rating scale, when performing a single leg eccentric squat) 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.
5. Score of less or equal to 80 on the Victorian Institute of Sport Assessment Scale-Patella (VISA-P).
6. Not receiving any NHS treatment for patellar tendinopathy in the preceding three months from the start of the study.

Healthy control group
1. Healthy physically active males and females aged between 18 and 55 years old.

2. Not have had any knee pain in the last 12 months.
3. No history of patellar tendinopathy

Previous inclusion criteria:
Tendinopathy group
1. 18 to 55 years old
2. Male or female
3. History of patellar tendinopathy for at least 3 months. Signs of patellar tendinopathy on ultrasound imaging (i.e., increased tendon thickness and cross-sectional area).
4. Current pain should be located only in the patellar tendon and experienced during physical activities such as jumping and squatting.
5. Score of less or equal to 80 on the Victorian Institute of Sport Assessment Scale-Patella (VISA-P).
6. Not receiving any NHS treatment for patellar tendinopathy.

Healthy control group
1. Healthy physically active males and females aged between 18 and 55 years old.
2. Not have had any knee pain in the last 12 months.
3. No history of patellar tendinopathy

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
58

Key exclusion criteria
1. Systemic or inflammatory conditions including rheumatic and neuromuscular disorders
2. Previously had lower-limb surgery without full rehabilitation
3. Known presence of inflammatory joint diseases
4. Familial hypercholesterolaemia
5. Daily use of drugs with a putative effect on the patellar tendon in the preceding 12 months (eg, fluoroquinolones)
6. Local injection therapy with corticosteroids in the preceding 12 months
7. Previous patellar tendon rupture
8. Inability to perform an exercise programme
9. participation in other concomitant treatment programmes

10. Signs or symptoms of other coexisting knee pathology on physical examination or ultrasound /MRI
11. Pregnancy

Date of first enrolment
15/07/2024

Date of final enrolment
19/01/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
School of Sports, Exercise and Rehabilitation Sciences
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Research organisation

Funder Name
Orthopaedic Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal, and presentation at international conferences.

Added 17/02/2025:
Study protocol available here: https://bmjopen.bmj.com/content/15/2/e092104.info

Intention to publish date
01/12/2026

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request from Dr Eduardo Martinez-Valdes at e.a.martinezvaldes@bham.ac.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Healthy group		11/07/2024	No	Yes
Participant information sheet	Patient group		11/07/2024	No	Yes

Protocol article	10/02/2025	12/02/2025	Yes	No