Torque visuo-motor feedback training: A new way to manage patellar tendinopathy

Invitation

You are being invited to take part in a research study. Before you decide to participate, it is important you understand why the research is being done and what it will involve. Please take the time to read the following information sheet carefully and discuss it with the researcher or others if you wish.

What is the purpose of the study?

This study aims to compare the effects of a novel intervention called visuo-motor torque feedback training against another type of training which is the standard care of treatment 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 are going to compare the neuromuscular adaptations and changes to the patellar tendon induced by these two types of training. We want to determine which type of exercise protocol has better results in this condition. The structural properties of the tendon will be assessed using ultrasound imaging, the electrical activity of your muscles will be evaluated using a non-invasive technique called high-density surface electromyography (HDEMG), and thigh muscle force will be assessed with a special device (dynamometer), designed to measure the movements of the knee.

Why have I been chosen?

You have been chosen because we understand that you have experienced pain in the Patellar tendon at least for the last three months, or you have a diagnostic of patellar tendinopathy. The inclusion criteria to take part in the study is to be between 18 and 55 years old. The exclusion criteria include history of systemic or inflammatory conditions, chronic respiratory or neurological problems, cardiovascular diseases, lower limb surgery, currently receiving treatment for patellar tendinopathy in the NHS, and pregnancy.

We will ask you to complete a brief screening assessment to ensure you are eligible to participate. This will be performed by an experienced researcher and will include questions about your general health.

Do I have to take part?

You are free to decide whether you participate or not. You will be given an information sheet to keep, and you will be asked to complete a brief screening questionnaire and answer some questions. If you meet the criteria described above, you will be invited to sign a consent form before taking part in the study. If you do agree to take part, you are free to withdraw at any time up to 2 weeks following the data collection without giving a reason by communicating with any member of the research team by email. If you withdraw from the study, your personal data and all the data acquired until the point of withdrawal will be deleted and destroyed. Furthermore, the researchers will provide further information about the purpose of this study if you want, and you will be invited to leave your email address to receive the publication of the study results.

What will happen if I decide to take part?

Before you start the experiment, you will be asked to read and sign the informed consent form.

On the first session of the study, you will be randomly assigned to a visuomotor torque feedback group or an eccentric exercise group. If you are assigned to the torque feedback group you will visit our laboratory over six consecutive weeks for the experimental sessions (at week 1, 3, and 6) and training sessions (2-3 sessions per week). If you are assigned to the eccentric exercise group you will only visit our laboratory at week 1, 3, and 6 and the training sessions will be performed at home twice per day for 6 weeks. Each experimental session will last approximately 2 hours, and you will be given £60 or 6 research hours for completing the three experimental sessions. However, if you decide to withdraw during

the experimental sessions, we will proportionally give you the number of research hours or money that you dedicated to the experiments. Each training session will last approximately 30-40 minutes, but we will not compensate for your participation in these sessions. Finally, you will be contacted by email 6 weeks and 12 weeks after completing the study to report your level of pain and function.

The experimental sessions will be conducted before the treatment, on the third week and at the end of the treatment (immediately after week 6). The experimental sessions will include:

- Collection of anthropometric data (i.e., age, height, weight, and body mass index).
- Measurements of structural properties of the thigh muscles and Patellar tendon during rest with a technique called ultrasound imaging.
- Perform three maximal (full strength) isometric (you will push against resistance, but your knee will not move) knee extension (knee straightening) contractions.
- Assessment of the electrical activity produced by the thigh muscles during isometric knee extension contractions at different intensities with a technique called high-density surface electromyography.
- Measurements of the electromyographic activity (i.e., muscle electrical activity) of the thigh muscles during eccentric knee-extension contractions at different intensities (i.e., you will be asked to extend the knee, while the dynamometer moves your leg to the opposite direction).
- Assessment of the electromyographic activity of thigh muscles during concentric knee-extension contractions at different intensities (i.e., you will be asked to extend your knee, and the dynamometer will move the leg in the same direction).
- Complete questionnaires about your perceived fatigue and the current level of pain.

We will ask you to bring shorts that leave your legs accessible and to avoid any strenuous exercise (48 h) before the experimental sessions.

The training sessions will include:

Depending on your treatment group allocation you will perform:

- **Torque feedback training:** The exercise will consist of performing some knee strengthening exercises on a special device which is able to provide information on the way your muscle is contracting and producing force. We will teach you how to use this information to improve the way you move your knee during the training. Before you start with this training, you will perform a warm-up with the device. This warm-up will consist in performing three concentric (where you push against the pad fixed in front of your ankle, while your leg moves forward) and three eccentric (where you are resisting the fixed pad pushing against you, while your leg moves backward) contractions at 25% of your maximal force. Then you will perform the training protocol, which consists of performing 2 sets of 15 repetitions of eccentric contractions and 2 sets of 15 repetitions of concentric contractions at 50% of your maximal force at a very slow speed. The device will give you information of your performance while you perform the training. Maximal strength and pain tolerance will be measured weekly to adjust loads accordingly. All these training sessions will be supervised by one of our researchers and done in a laboratory at the School of Sport, Exercise and Rehabilitation Sciences of the University of Birmingham.

- **Eccentric exercise training:** The exercise will consist in performing three sets of 15 slow repetitions of eccentric unilateral squats, where you will lower yourself into a squat on one leg, and then push yourself back on two legs on a 25-degree decline board twice daily (i.e., morning and evening) for 6 consecutive weeks. The load will be increased weekly by adding load on a backpack depending on your pain tolerance. The exercises will be performed at home, and we will provide the incline board. We will teach you how to do the exercises properly, and we will

contact you once per week to support your treatment. We will revise your performance when you come to the second experimental session as well.

What are the potential benefits of taking part?

This research aims to evaluate the effectiveness of a novel training intervention for managing patellar tendinopathy and seeks to identify the underlying mechanisms that contribute 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 the management of other tendinopathies, as the proposed approach can be adapted to different joints. Should you wish to receive feedback about the findings of this study, we will communicate the findings/results of this study to you via email.

What are the potential risks of taking part?
The risk from the procedures proposed within this project is very small. You can stop the experiment at any time.

Non-invasive mounting/attaching procedures of surface electrodes (sticky patches) include slight discomfort from minor abrasion of the skin area. Prior electrode placement, the skin will need to be shaved to remove any hair. However, single use disposable razors will be used thus there is no expected risk from this procedure.

Concerning the risks during maximal contractions, we will require you to push against a fixed pad with the front of your ankle while your knee will be immobile (maximal isometric voluntary contraction), which will be less stressful to your knee compared to when you would be required to push against the pad while your knee moves (maximal dynamic voluntary contraction). Additionally, we will measure the maximum force you produce while pushing against the fixed pad, while your knee is immobile at three time points throughout the study (at week 1, 3, and 6), and we will use this value as a reference in all the different types of contractions/movements. Furthermore, we will use a restricted range of motion (i.e., the range at which your knee/lower leg will move) of 85° (from 5° to 90° of knee flexion, for reference; 0° is when your knee is fully straight/extended) in the dynamic contractions to avoid pain or discomfort at the end of the range of motion.

You might feel some level of muscle soreness up to 24 to 48 hours after the first experimental session, this is a normal response to exercise (similar to the muscle soreness felt after going to the gym), and your muscles will recover fully after this period.

You may experience some mild discomfort in the tendon while performing the contractions. Pain of less or equal than 5 out of 10 is expected during the treatment of patellar tendinopathy. Nevertheless, we will provide appropriate rest time throughout the experimental trials and training sessions to keep pain and discomfort at a minimum. Extra rest periods will be given at any time, if needed (in example, when you experience pain higher than 5 out of 10). If the pain persists, we will reduce the load by 20% during the contractions. If after this adaptation, the pain intensity is maintained, we will end the session and will monitor your symptoms closely. It is important to acknowledge that the potential pain experienced during the training sessions is usually observed during the first 2 weeks of training to then decay/declines throughout the treatment.

In the unlikely event that you suffer an injury, you should report this situation to any member of the research team, and then, we will contact an experienced physiotherapist for initial assessment. The physiotherapist will contact you by phone and monitor your symptoms over the next three days.

Furthermore, if you do not show any improvement over this period, we will schedule a clinical evaluation with the members of the research team, and we will stop your participation in our study.

Will my participation be confidential?
All information collected on you will be kept strictly confidential. Personal information will be retained, but only available to the researchers using password protected files. Data will be kept for 10 years in accordance with the EU General Data Protection Regulation (GDPR) 2018 and the University of Birmingham Research Guidelines. All data for presentation will be anonymized and aggregated, so your identity will not be revealed in any way. You can withdraw your data until two weeks from data collection. For more information on the University of Birmingham's data protection policy, please visit https://www.birmingham.ac.uk/documents/university/legal/university-of-birmingham-data-protection-policy.pdf

What will happen at the end of the research study?

The findings from this study will be presented in the form of presentations and scientific papers as appropriate. All data for presentation will be anonymized, which means your identity will not be revealed in any way.

Does the study follow ethics procedures?

This study underwent the ethical review processes of the University of Birmingham and received official approval from the Science, Technology, Engineering and Mathematics University Ethics Committee.

Who is organizing and funding the research?

The study has been designed and organized by Dr Eduardo Martinez-Valdes, Assistant Professor in Spinal and Musculoskeletal Physiotherapy e.a.martinezvaldes@bham.ac.uk (+44 (0)121 41 58187). The project has received funding from Orthopaedic Research UK.

What if I have a problem or concern?

If you have a concern about any aspect of this study, please speak with Dr. Eduardo Martinez-Valdes. Should you still have any concerns, you could also speak to the Head of School, Dr. Sarah Aldred s.aldred.1@bham.ac.uk (+44 (0)1214147284).

For further information please contact Ragul Selvamoorthy

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Thank you for your interest in participating in our study!