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, as a healthy participant, might represent a normal individual of the population. 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, pain/injury within the lower limbs in the previous six months, 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?

You will be invited to attend once to one of our laboratories at the School of Sport, Exercise and Rehabilitation Sciences for the experimental session. The experimental session will last approximately 2 hours, and if you are interested, you will receive 2 research hours for completing the session (if you are a student).

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

The experimental session will include:

- Collection of the 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 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.

What are the potential benefits of taking part?
This study will provide important information about some properties of the thigh muscles, the Patellar tendon, and the relationship with the neuromuscular control of these muscles during different types of contractions. You will also get information regarding your thigh muscles strength and control of force. 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 potential risks from the procedures proposed within this project are minimal. Non-invasive mounting/attaching procedures of surface electrodes include that the skin of three small areas of the leg needs to be shaved (to remove any hair) and then cleaned with abrasive paste. This could produce slight discomfort from minor abrasion of the skin area. Finally, you might feel some level of muscle soreness up to 24 to 48 hours after the experiment, 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.

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

Ragul Selvamoorthy School of Sports, Exercise and Rehabilitation Sciences University of Birmingham B15 2TT	r.selvamoorthy@bham.ac.uk
Eduardo Martinez-Valdes School of Sports, Exercise and Rehabilitation Sciences University of Birmingham B15 2TT	e.a.martinezvaldes@bham.ac.uk +44 (0)121 41 58187

Thank you for your interest in participating in our study!