**Neuromuscular and structural tendon adaptations after 6-weeks of either concentric or eccentric exercise in individuals with non-insertional Achilles 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 investigates the relationship between the neuromuscular control of the calf muscles and some characteristics of these muscles and the Achilles tendon in individuals with Achilles tendinopathy. Additionally, 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 the calf muscle force will be assessed with a special device (dynamometer), designed to measure the movements of the ankle.

**Why have I been chosen?**

You have been chosen because we understand that you have experienced pain in the Achilles tendon at least for the last three months, or you have a diagnostic of non-insertional Achilles 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, pain/injury within the lower limbs in the previous 6 months, lower limb surgery, 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.

Participants with non-insertional Achilles tendinopathy 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). 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 45 minutes, but we will not compensate for your participation in these sessions.

Due to the Covid-19 pandemic, we were forced to reduce the time of the experimental sessions. Thus, we will send you an email with a set of questionnaires 24 h before the experimental sessions. Please remember it is important to answer these questionnaires before you arrive at the lab.

**Covid-19**

For your safety we need to perform a covid-19 screening prior participation. Therefore, you will be contacted 24 hours prior to attendance to confirm that you are symptom free using the NHS COVID-19 Track and Trace App, or if this is not possible, a COVID-19 Symptom Screening questionnaire (i.e. https://www.sdcep.org.uk/wp-content/uploads/2020/05/Patient-COVID-19-screening-250520.pdf). Strictly no entry will be permitted for positive COVID-19 symptom screening. If you show positive COVID-19 symptoms, the testing can be rescheduled after a minimum of 14 days symptom-free have lapsed. Similarly, if you have been advised to isolate via a COVID-19 tracking system you must not enter the University building until your isolation period has expired.

Upon arrival to the School of Sport, Exercise and Rehabilitation Sciences, you will be re-screened using the COVID-19 Symptom Screening questionnaire in the atrium. If your screening is unsuccessful you will be politely asked to leave.

You will be asked to wash your hands on arrival at the building and wear a mask upon entry until departure (one will be provided by us on arrival). Where appropriate (i.e. medical exemption), a medical visor (i.e. face shield) will be provided with instruction on how to apply whilst behind Perspex glass. You are advised to wash hands before and after experiment.

We will provide a brief induction about the precautions required. We will carefully guide you to the laboratory and form the lab to exit, maintaining at least 2m distance at all times, to ensure safe and effective movement through the building complying with infection control and encourage avoidance of unnecessary touching of objects.

**What will happen if I decide to take part?**

After, covid-19 screening, we will move to the Centre of Precision Rehabilitation for Spinal Pain Laboratory (Room 218). Before you start with the experiment, you will be asked to read and sign the informed consent form (Session 1 only).

The experimental sessions will include:

* Collection of the anthropometric data (i.e., age, height, weight, and body mass index).
* Measurements of the structural properties of the calf muscles and Achilles tendon during rest condition.
* Perform three maximal (full strength) isometric (you will push against resistance, but your ankle will not move) plantarflexion (downward movement of the foot away from the leg, like pressing the accelerator pedal in a car) contractions and measurements of structural properties of the Achilles tendon during isometric contractions.
* Assessment of the electromyographic activity of the calf muscles during isometric plantarflexion contractions at different loads.
* Measurements of the electromyographic activity of the calf muscles during eccentric (i.e., you will be asked to try to do a plantarflexion movement, while the isokinetic device will move your foot to the opposite direction) plantarflexion contractions at different loads.
* Assessment of the electromyographic activity of the calf muscles during concentric (i.e., you will be asked to try to do a plantarflexion movement, while the isokinetic device will move your foot in the same direction) plantarflexion contractions at different loads.
* Evaluation of the electromyographic activity of your calf muscles during explosive (as hard and fast as you can) contractions.
* Complete questionnaires about rate of perceived exertion and the current level of pain.

The training sessions will include:

* Perform a warm-up protocol consisting of three eccentric or concentric plantarflexion contractions.
* Perform three maximal isometric plantarflexion contractions (every two weeks)
* Complete the eccentric or concentric training protocol. The eccentric protocol consists of 4 x 15 eccentric plantarflexion contractions at 50% of the maximal force with visual feedback of the exerted force in each contraction. Similarly, the concentric protocol will include 4 x 15 repetitions concentric plantarflexion contractions at 50% of the maximal force with visual feedback of the exerted force in each contraction.
* Complete questionnaires about rate of perceived exertion 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 calf muscles and the Achilles tendon, and the relationship with the neuromuscular control of these muscles during different types of contractions. Additionally, we will get a depth understanding of the effects of two different exercise protocols in this condition. Moreover, you will also get information regarding your calf muscles strength and control of force.

**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. You can feel up to moderate tendon pain during the first training sessions, which is normal during the treatment of tendinopathy. We will make sure that it does not reach levels equal or greater than 6 out of 10 during the sessions. Finally, you might feel some level of muscle or tendon soreness up to 24 to 48 hours after the experiment. This type of discomfort is usually observed after the first sessions in patients with non-insertional Achilles tendinopathy.

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.

Furthermore, we have applied a series of measures in order to prevent covid-19 transmission. Therefore, both you and the research team will:

* Use protective personal equipment
* Wash hands before and after the experimental procedures
* Maintain a 2m distance for most of the experiment

In addition, we will make sure that the experimental area and equipment is adequately sanitized before and after the measurements.

You will be provided with instructions on how to enter the building and will be informed about all the preventive measures taking place prior to the experiments.

**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 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.

**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 University Ethics Committee.

**Who is organizing and funding the research?**

The study has been designed and organized by Ignacio Contreras-Hernandez and is overseen by Dr. Eduardo Martinez-Valdes, Lecturer in Spinal and Musculoskeletal Physiotherapy (e.a.martinezvaldes@bham.ac.uk or +44 (0)121 41 58187).

**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 or Ignacio Contreras-Hernandez. Should you still have any concerns, you could also speak to the Head of School, Dr. Sarah Aldred (s.aldred.1@bham.ac.uk or +44 (0)1214147284).

**For further information please contact Ignacio Contreras Hernandez**

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**Thank you for your interest in participating in our study!**