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3T_the 10000 Tendons study

Submission date
14/08/2019

Recruitment status
No longer recruiting

Registration date
10/01/2020

Overall study status
Completed

Last Edited
07/01/2020

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Tendinopathy (also known as tendinitis) is a condition that causes pain in a tendon that joins bone to your muscles. It is a relatively common soft tissue injury and affects people of all ages, both athletes and non-athletes. Tendinopathy is common and problematic if it does not resolve. The study aims to find out why it does not resolve, and what the predictors of recovery are. Data will be collected from a large number of participants they will be followed up for one year to determine causal relationships between how people present and how they recover. At present, prediction of outcome is restricted to single or limited variables and no clinically relevant prediction models exist for these pathologies. To best inform the model, we will also collect data from participants with different problems in the same anatomical area. The main data collection will be questionnaires, with a questionnaire battery at the start and then brief monthly follow-ups. We will also collect clinical, imaging and biomechanical data for subsets of participants.

Who can participate?
Aged 18 years and above, with tendinopathy (Achilles, gluteal, patellar, rotator cuff tendinopathy or plantar heel pain), and matched healthy controls

What does the study involve?
The main part of the study will be completing online questionnaires via SmartTrial, the baseline questionnaires take 25-30 minutes to complete. Participants will then receive follow up emails for 12 months, every four weeks for shoulder, hip, ankle and foot and every three weeks for knee group. Follow up surveys take 4-5 minutes to complete. An optional clinical assessment can be completed (participants opt-in or out whilst completing the online questionnaires.

What are the possible benefits and risks of participating?
Benefits: The benefits of the study would be to improve the implementation of research findings for predictors of tendinopathies into practice. Participants would play an active role in shaping this development by taking part in the study, meaning that future patients will be treated with an effective evidence-based protocol from the start leading to an optimum management of their condition. Individual participants also stand to gain a deeper understanding of their condition which may help them to manage their symptoms better.
Risks:
Physical tests exacerbate existing symptoms:

In rare instances, clinical assessment process may cause pain, tightness or soreness or strain. Investigators will minimise the incidence of adverse events by recommending appropriate preparation and warm-up that will help prevent this. A physiotherapist will be present during the entire assessment process and will advise participants, in case of any injury possibility.
Clinical exam shows previously unrecognised pathology:
Clinical and US imaging may reveal previously undiagnosed pathology. This is likely with the clinical examinations when participants have not been previously assessed. Assessment will always be done by clinicians who can advise and refer as appropriate

Where is the study run from?
Queen Mary University of London in partnership with Barts Health NHS Trust, UK

When is the study starting and how long is it expected to run for?
December 2019 to June 2021

Who is funding the study?
1. Engineering and Physical Sciences Research Council, UK
2. National Institute for Health Research, UK

Who is the main contact?
Prof. Dylan Morrissey
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2019-003398-24

Protocol serial number

v1.0 23052019x

Study information

Scientific Title
3T_the 10000 Tendons study: outcome prediction for 5 tendinopathies: an international cohort study

Acronym
3T

Study objectives
The study aim is to build a usable clinical model that predicts the outcome for tendinopathy. The objectives are to:
1. Variably phenotype and follow a large number of patients with tendinopathy
2. Compare prognostic factors with data from people with other problems in the same area and healthy controls
3. Construct regression and Bayesian probabilistic models to predict recovery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/09/2019, London - City & East Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; +44 (0)207 1048033; nrescommittee.london-cityandeast@nhs.net), ref: 19/LO/1340

Primary study design
Observational

Study design
Observational cohort study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Tendinopathy

Interventions
Patients will be identified by clinicians at recruiting organisations and contact details sent, via a secure SmartTrial contact form to the researchers who will respond with a link to the correct database form for their problem area. They will then have as long as they require to peruse the PIS and complete the online ICF before carrying out the questionnaire battery.

The highest volume, lowest detail information set will include questionnaire data using an online Survey with the online SmartTrial electronic CRF from recruited patients. A pain drawing will be made using navigate pain. Data will include self-reported physical factors, psychosocial factors, health-related quality of life, condition-specific factors and activity level.

For people with shoulder pain, scapular dyskinesis will be examined via shoulder motion video recorded by participants. The video for scapular dyskinesis assessment will be collected via File Request system on Dropbox according to a filming guide.

The first survey takes just under 30 minutes to complete followed by very short monthly follow-ups of 1-2 minutes.

Entering the physical assessment and ultrasound imaging data is an optional extra depending on the choices made by the patient on the ICF. Medium volume, medium density data will further include clinical and imaging examination from 200 patients per tendon area, only of those with pathology, using clinical examination and ultrasound. Range of motion and muscle strength evaluation, palpation and other tests will be measured. All data entered on SmartTrial from clinical examination will have been performed as part of usual care.

For information only: The most detailed, low density data will include biomechanical testing of 60 people per tendon area comprising Kinetic and kinematic assessment using Force plate, surface EMG and motion tracking systems to measure ground reaction force, identify muscle activity and capture kinetic and kinematic features of joint moments, respectively. All data will be recorded within Coda-Motion Software system. This is covered by existing university ethics clearance and is not requests to be covered by this application.

Participants will be followed up for one year.

Once 50% of the data has been collected an interim analysis will be carried out to deign a retrospective model based on the data, to be tested prospectively with the second 50% of the data.

Analysis will be made for tendinopathy (all tendons), individual tendons, controls and for other conditions.

Intervention Type
Other

Primary outcome(s)
Symptoms/change in pain is measured using the global rating of change every four weeks via questionnaires on SmartTrial (every three weeks for knee), for 12 months. Except for the control group who are asked if they have any new symptoms/pain

Key secondary outcome(s)
1. Symptoms/change in pain is measured using the patient acceptable symptom state (PASS) every four weeks via questionnaires on SmartTrial (every three weeks for knee), for 12 months. Except for the control group who are asked if they have any new symptoms/pain
2. Symptoms/change in pain is measured using the single assessment numeric evaluation (SANE) every four weeks via questionnaires on SmartTrial (every three weeks for knee), for 12 months. Except for the control group who are asked if they have any new symptoms/pain

Completion date
01/06/2021

Eligibility

Key inclusion criteria
For all conditions to be studied AT, GT, PT, PHP, ST these inclusion criteria are the same:
1. Aged 18 and over
2. Having Achilles, gluteal, patellar, rotator cuff tendinopathy or plantar heel pain diagnosed by a relevant clinician (for the condition specific group)
3. Having other posterior calf, hip, foot, knee, shoulder diagnoses (for the 'other pathology' groups)
4. Healthy volunteers without any current foot and ankle, hip, knee, shoulder problems in the last six months (for the control group)

Specific inclusion criteria for PT:
1. Performing a jumping related sport such as volleyball, basketball, netball, athletics, football, handball, sprinting
2. Having a regular sports training schedule

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/12/2019

Date of final enrolment
01/06/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Mary University of London
Sports and Exercise Medicine

William Harvey Research Institute
Mile End Hospital
London
United Kingdom
E1 4DG

Sponsor information

Organisation
QMUL

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
Engineering and Physical Sciences Research Council

Alternative Name(s)
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, Science Research Council, Science and Engineering Research Council, EPSRC, SRC, SERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository

All data is encrypted and stored securely via SmartTrial and Navigate pain systems. This data is de-identified and stored separately from participant identifiable information. Only the study /research team have access to this system (individuals on the delegation log).
As per the UK Policy Framework for Health and Social Care Research, records will be kept for 20 years after the project has completed. As this study involving Barts Health NHS Trust patients, and sponsored by Queen Mary, University of London, the long-term storage of local records will be the Trust Corporate Records Centre. All research documentation will be archived in physical form.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No