Plan Overview

A Data Management Plan created using DMPTuuli

Title: Understanding restoration of Achilles tendon function after rupture

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Project abstract:

Achilles tendon rupture (ATR) is a disabling condition with growing incidence in recent years. After rupture, whether treated surgically or non-surgically, patients have long-term deficits regarding symptoms, anatomy, function and physical activity level. The predictors of good recovery from ATR are currently poorly known. This study identifies factors that explain good recovery from ATR in a 1-year follow-up design. We will use the assessed patient-specific parameters in new biomechanical model to gain a better understanding of individual factors that lead to good recovery. Close collaboration between biomechanists and clinicians will enhance the understanding of long-term outcomes and prognosis by identifying areas of treatment and rehabilitation that need improvement in order to minimize permanent disability in this patient group. We may be able to create assessment tools for re-injury risk or develop algorithms to predict individual functional outcomes for patients after ATR.

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Understanding restoration of Achilles tendon function after rupture

1. General description of data

Date of the plan.

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1.1 What kinds of data is your research based on? What data will be collected, produced or reused? What file formats will the data be in?

Data will be collected by questionnaires and tests during visits to clinic and laboratory, and during daily living in participant's normal living environment.
Clinical data about type of pre-injury information, tendon rupture mechanism, tendon treatment and reruptures will be stored to the hospital electronic patient registry and data system (EFFICA, Exreport Patient Discharge database).
The research data (foot anatomy, heel-rise test, questionnaire-data) collected at the hospital will be stored in electronic research registry (Arkki) of Central Finland Health Care District in Excel format. Questionnaire data will be digitalized into Microsoft Excel worksheets. Upon digitalization and checking manual datasheets are destroyed as sensitive material.
In laboratory, analogue force and muscle activity data is collected and digitalized using 16 bit AD-board (CED, Cambridge, UK) before storing using Spike software as .smr format from which it can be exported as common data types (e.g. to Matlab). The obtained ultrasound image and video data are collected in DICOM (Aloka alpha 10, Japan) or .tvd format (Telemed, Lithuania). The DICOM videos and .tvd files will be processed into AVI files according to documented standard procedures. Outcome measures will be extracted from the images using Image J (National Institutes of Health, USA) and videos using custom-made programmes (Matlab, e.g. Cronin et al. 2011). Daily physical activity is assessed using accelerometry which provides .dat files that are processed using custom-made software. The .dat files contain either headerless binary data or binary data including a proprietary header in proprietary format. These files are not accessible without the assistance from the manufacturer. We have worked with the manufacturer to implement custom-written file readers which will not be made public because we do not have the manufacturer's consent. The .dat files are associated with a particular participant based on the folder name of the .dat file and a key file linking the folder names to participants. In data processing we can also utilize CSC services for large data management and processing.
Final data will be transferred to SPSS or other statistical programmes for statistical analysis.

1.2 How will the consistency and quality of data be controlled?

The research material will be carefully maintained, documented and stored in the servers of the Information Management Center of the University of Jyväskylä and Central Finland Hospital District. Quality of obtained data is ensured by training the persons performing the assessments. Researchers involved in data collection are given specific tasks to manage data documentation. All original data is kept untouched in designated folders and for processed data subfolders are created. Such folder structure is systematically used and explained in the metadata file. Processing of the data is described in Analysis instructions-folder for each data source that will be followed and kept up-to-date. Metadata description has its own folder.

2. Ethical and legal compliance

2.1 What ethical issues are related to your data management, for example, in handling sensitive data, protecting the identity of participants, or gaining consent for data sharing?

Clinical data and all other personal data are sensitive data. Each participant will be given ID number for pseudonymization during the research process. All data collected at the University, manual and digital, are pseudonym. For combining the sensitive data from hospital and university, the project will use CollabRoom or other secure ways for sharing sensitive data between the researchers. The project PI controls the access to the CollabRoom that is limited to researchers dealing with data collection and analysis. For non-sensitive data VPN connection is available.

2.2 How will data ownership, copyright and Intellectual Property Right (IPR) issues be managed? Are there any copyrights, licenses or other restrictions which prevent you from using or sharing the data?

Ownership of the data belongs jointly to Central Finland Hospital District and University of Jyväskylä and there are no limitations or third party rights regarding background or foreground of the project. Agreements about sharing and publishing data will be formalized. Vancouver protocol will be followed for authorships in publications.

3. Documentation and metadata

3.1 How will you document your data in order to make it findable, accessible, interoperable and re-usable for you and others? What kind of metadata standards, README files or other documentation will you use to help others to understand and use your data?

Metadata is described in Metadata_NoARK.txt file. We have prepared documentation about data collection, instrumentation, and analysis procedures where file-spesific analysis-flows and descriptions are contained. These information are in designated folders (Measurement and Analysis instructions, respectively). Progress master -file will contain information on data availability.

4. Storage and backup during the research project

4.1 Where will your data be stored, and how will it be backed up?

Clinical data will be stored in the hospital electronic patient registry protected by hospital firewall, username and password. The research data in electronic research registry of Central Finland Hospital is protected by username and password. Data collected at JYU will be stored on the University server and protected by individual username and password. Both the hospital and JYU have centrally managed backup system.

4.2 Who will be responsible for controlling access to your data, and how will secured access be controlled?

Access to the data collected at hospital is controlled by the PI of the NoARK clinical trial Juha Paloneva (until 5.3.2021) and Ville Ponkilainen (after 5.3. 2021) and access to the data collected at JYU is controlled by project PI Taija Juutinen. Access will be given to key researchers who will be analyzing and writing publications.

5. Opening, publishing and archiving the data after the research project

5.1 What part of the data can be made openly available or published? Where and when will the data, or its metadata, be made available?

Metadata (owners, project description, data collection and processing procedures, and list of variables) will be made available either in the form of publication or as information stored into database provided by the University (Converis). In addition, researchers aim to publish anonymized data that will be unique example about prospective cohort trial in Finland. Care will be taken that deanonymization is not possible and data included in the national patient registry is not included in case it may cause deanonymization.

5.2 Where will data with long-term value be archived, and for how long?

Question not answered.

5.3 Estimate the time and effort required for preparing the data in order to publish or to archive it.

Question not answered.