Plan Overview

A Data Management Plan created using DMPonline.be

Title: Promoting healthy Achilles tendon behaviour in patients with Achilles Tendinopathy: a holistic approach to improve return-to-sport outcomes.

Creator: Laura Lecompte

Principal Investigator: n.n.

Affiliation: KU Leuven (KUL)

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Template: FWO DMP (Flemish Standard DMP)

Principal Investigator: n.n. n.n.

Project abstract:

Achilles tendinopathy induces Achilles tendon pain and functional limitations, leading to physical discomfort and social withdrawal, ultimately reducing quality of life. Currently, treatment resistance affects up to 61% of cases, with half of patients unable to return to their preferred sports or previous activity levels within 5 to 10 years of follow-up. This highlights the inadequacy of existing rehabilitation programs, where exercise therapy is seen as the golden standard. Understanding the healthy behaviour of the Achilles tendon and ways to modify pathological tendon behaviour is crucial. The Achilles tendon consists of three subtendons, which slide relative to each other. Reduced intra-tendinous sliding in pathological conditions and the potential to enhance this sliding through external foot positioning suggest promoting healthier tendon behavior. However, to improve patients' return-to-sport rates, we must look beyond the rehabilitation protocol itself. Considering the amount of physical activity patients engage in during and after the exercise therapy period is crucial, as it influences the tendon load as well. This proposal aims to: 1) investigate the effect of horizontal foot position on intra-tendinous sliding during dynamic exercises in healthy individuals and patients with Achilles tendinopathy cross-sectionally and over an extended training program and 2) explore the impact of physical activity during and after this training program on these treatment outcomes.

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Promoting healthy Achilles tendon behaviour in patients with Achilles Tendinopathy: a holistic approach to improve return-to-sport outcomes.

Application DMP

Questionnaire

The questions in this section should only be answered if you are currently applying for FWO funding.
Are you preparing an application for funding?

- No

Promoting healthy Achilles tendon behaviour in patients with Achilles Tendinopathy: a holistic approach to improve return-to-sport outcomes.
DPIA

DPIA

Have you performed a DPIA for the personal data processing activities for this project?

- No

Promoting healthy Achilles tendon behaviour in patients with Achilles Tendinopathy: a holistic approach to improve return-to-sport outcomes.

GDPR

GDPR

Have you registered personal data processing activities for this project?

- Yes

Promoting healthy Achilles tendon behaviour in patients with Achilles Tendinopathy: a holistic approach to improve return-to-sport outcomes.

FWO DMP (Flemish Standard DMP)

1. Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

				Only for digital data	Only for digital data	Only for digital data	Only for physical data
Dataset Name	Description	New or reused	Digital or Physical	Digital Data Type	Digital Data format	Digital data volume (MB/GB/TB)	Physical volume
		Please choose from the following options: • Generate new data • Reuse existing data	*Please choose from the following options:* • Digital • Physical	*Please choose from the following options:* • Observational • Experimental • Compiled/aggregated data • Simulation data • Software • Other • NA	*Please choose from the following options:* • .por, .xml, .tab, .csv,.pdf, .txt, .rtf, .dwg, .gml, ... • NA	*Please choose from the following options:* • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • NA	
Achilles Tendon Ultrasound Video's	Ultrasound images taken with the Arietta 650 Ultrasound machine during dynamic exercises in the lab.	• New	• Digital	• Experimental	• Raw .avi files. After analyzing these files, .avi, .mat and .xls files are created.	<100GB	
Motion Capture Data	During the dynamic exercises in the lab, the trajectory of 33 retroflective markers are recorded in combination with the ground reaction forces and EMG-measures.	• New	• Digital	• Experimental	• .c3d, .mot and .trc files as raw data files. After analysis, .mat files and .mat figures are created in combination with .xls files.	<100GB	

Matlab-Scripts	Multiple Matlab scripts are written to analyze data and create overview mean values and overview graphs.	• New	• Digital	• Software	• .mat scripts	<100MB	
Questionnaires	Multiple questionnaires are taken during this project: VISA-A, IPAQ, TAMPA-scale, SF-12 and FRESS and general questions concerning length, weight, birth date and gender.	• New	• Physical	• Observational	• Questionnaires are taken by paper during the measurement and afterwards, all data is put in REDCap. (As our ethical committe is EC UZ Leuven, this has to be done in REDCap).	3 pages per participant	
OpenSim Simulation Data.	Musculoskeletal modeling is performed in OpenSim.	• New	• Digital	• Simulation Data.	• .xml, .mat, .mot, .sto files and text documents.	<100GB	
File containing the information about the pseunomized data.	There is one excel file that has the information with the contact details of the participants and their assigned number (for example T1) that is used further in all other datasets.	• New	• Digital	• Other	• .xls file	<100MB	

Fitbit data	For WP3, participants will wear a Fitbit to record their physical activity pattern. Data is automatically saved via an application.	• New	• Digital	• Observational	• .xls files of the data can be downloaded from the Fitbit website. We will only focus on physical activity data (amount of steps taken, activity hours, types of physical activity). As the Fitbit will also store location data, which we are not interested in, this will not be downloaded. Also, we will create 'dummy accounts' online per fitbit, so that the fitbit gets a number and is not directly linked anymore to the participant him or herself.	<100MB	

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

Not applicable.

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes, human subject data

As we recruit both healthy controls and patients with Achilles tendinopathy, the ethical approval need to be done through the University Hospital UZ Leuven/KU Leuven.
For WP1, the ethics is already approved via UZ Leuven (S68515). For the other two work packages, one more ethical approval is needed, also to be obtained by UZ Leuven. As I have already done this and I know how long this procedure takes, I will make sure this will be obtained in time.

Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes

Personal data used for organizing the research (i.e. name, phone number, e-mail address). This data will not be included in the analysis and will be stored separately from the research data.

Personal data for research purposes: Participants will be asked to provide their demographics (age, gender, weight and height) and furthermore, some questionnaires will be takes that we have information about their physical activity level, Achilles tendinopathy severity, quality of life, fear of movement and return-to-sport information.

All these data will be pseudonymized.

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- Yes

From the data collected in WP2, we will have data about the load applied on the Achilles tendon during walking and other dynamic exercises in 50 patients. This could be transferred to an online application. By collection the type and amount of physical activity per day via an activity tracker and relating this to the experimental data collected in the lab, an overall load index per day could be given to the participant. This kind of information can be shared with their physiotherapist to adapt the training program if necessary.

This was also written down in the FWO proposal of the project. However, nothing of this is already start up and the new application would be made if results look promising. As the research has already experience with inventing applications, I'm convinced we're in contact with good people to make this work.

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material/Data transfer agreements/ research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- No

2. Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g., in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, Codebook.tsv etc. where this information is recorded).

For documentation and Metadata purposes, we will make use of:
At project level: A README file will be provided for each of the WPs. We will use KU Leuven's template. For each WP, a protocol is provided that explains in detail what should all be measured. This involves the standard instructions and the questionnaires that need to be taken off.
At data level: Matlab scripts will be used for data analysis. Comments will be included for others to be able to understand and use the code.

Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type)

which metadata will be created to make the data easier to find and reuse.

- Yes

At project level, the RDR metadata format will be followed (see Data sharing and reuse).

3. Data storage & back-up during the research project

Where will the data be stored?

KU Leuven network drive, specifically L-drive. Automatic version management of the files occurs when storing data in the KU Leuven datacenters. Version management is done using "snapshot" technology, where the previous versions of the changed files are kept online in a snapshot on the same storage system.
a. by default, 1 snapshot is taken daily and is kept for 14 days. So you can go back to previous versions of the file up to 14 days.
b. end users can restore older files themselves from within their Windows PC via the "previous versions | previous versions" functionality.
A mirror (an exact copy) of the data is provided in the second ICTS data center for “business continuity” or “disaster recovery” purposes; a file is copied to the second data center as soon as it is written to a drive. ICTS can put the copy online within an hour in case of disaster with the primary storage.
2. REDCap. When using KU Leuven REDCap, data is backed up as follows:
a. The web server backup regime is specified below:
i. An hourly backup, the last 6 versions of which are saved
ii. A daily backup, the last 7 versions of which are saved
iii. A weekly backup, the last 6 versions of which are saved
b. The database backup regime is specified below:
i. A nightly cold backup of all databases
ii. One month’s storage of the nightly cold backups
c. Data restore, upon request
3. To ensure that the master file remains up-to-date the FreeFileSync tool will be used for regular synchronization of active copies to the L-drive.

How will the data be backed up?

See answer above. During the PhD of Laura Lecompte, all data is also copied on her personal harddrive as extra back up.

Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely.
If no or insufficient storage or backup capacities are available, then explain how this will be taken care of.

- Yes

KU Leuven network drive, specifically L-drive. Our department has a L-drive with a capacity of 20 TB for active research data. As the estimated size of the dataset is XX TB sufficient storage and backup capacity is available.
2. REDCap. REDCap is hosted on central ICTS webservices and provides unlimited capacity.

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

1. KU Leuven network drive, specifically L-drive. The KU Leuven network drives are incorporated within secured KU Leuven environments, are password-protected (including smartphone-based multi-factor identification) and are only accessible by registered collaborating researchers. Only the PI can request access to the network drive for study personnel.
2. REDCap. When using KU Leuven REDCap, physical access to the data centers is logged and restricted to authorized KU Leuven Information Technology (IT) personnel, using badge identification. At the clinical database level only study team members, monitors and auditors/inspectors for whom the Coordinating or Principal Investigator (as applicable) has requested project-specific access, are granted data access. Upon successful training completion each user is centrally assigned a user role, associated with predefined system/data privileges, in accordance with CR DM-WI-001. The gatekeeper for UZL REDCap is UZL

CTC (ctc.datamanagement@uzleuven.be).
3. Data collected on paper. Data collected on paper (e.g. informed consents) will be stored in a locked cabinet in a locked room at the department of movement sciences. During data collection the cabinet will only be accessible to study personnel.

What are the expected costs for data storage and backup during the research project? How will these costs be covered?

KU Leuven network drive, specifically L-drive. The L-drive costs € 95.14 / TB / year. Our dataset is estimated at XX TB and the project will run for X years, resulting in a total cost of € XX. The department of Movement Sciences provides an L-drive of 20TB. As such, costs will be covered by the department. In case of insufficient storage (as the drive is shared by several projects), the drive can be extended. Additional costs could be covered by the FWO bench fee.
2. REDCap. A REDCap project costs €80/year. As the project will run for X years, costs are estimated at € XX. This will be covered by the fwo bench fee.
3. Data collected on paper. No costs are attached to storage of data collected on paper.

4. Data preservation after the end of the research project

Which data will be retained for at least five years (or longer, in agreement with other retention policies that are applicable) after the end of the project? In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

De studie valt onder experimentenwet en dus moeten data 25 jaar worden bewaard.
Digital data: All digitally generated data will be archived for minimally 25 years after study completion, in line with the Belgian Law of 7 May 2004 related to experiments on humans.
2. Paper files: All data gathered on paper, as well as informed consent forms will be archived for minimally 25 years after study completion, in line with the Belgian Law of 7 May 2004 related to experiments on humans.

Where will these data be archived (stored and curated for the long-term)?

Digital data: The generated research data, metadata and documentation necessary to reuse the data will be saved on the K-drive of the research group for long-term data archiving, managed by KU Leuven ICTS with automatic back-up procedures. Data will also be saved in Sharepoint of the Achilles Tendon Research group where other colleagues working on similar topics have access to (this is a SharePoint restricted to intern collegues that need permission of the PI Prof Vanwanseele).

What are the expected costs for data preservation during the expected retention period? How will these costs be covered?

The Department of Movement Sciences provides our research group with a K-drive. As such, costs will be covered by the department.

Paper files: No costs are attached to archiving of data collected on paper.

5. Data sharing and reuse

Will the data (or part of the data) be made available for reuse after/during the project? In the comment section please explain per dataset or data type which data will be made available.

- Yes, in a restricted access repository (after approval, institutional access only, …)

All digital data will be made available in a restricted access repository (RDR KU Leuven).

If access is restricted, please specify who will be able to access the data and under what conditions.

People that join the research group later and have similar projects will get access to the data. When this will be done, first an agreement related to EC UZ Leuven will be signed to do this in the right manner.

Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)? Please explain in the comment section per dataset or data type where appropriate.

- Yes, Privacy aspects
- Yes, Ethical aspects

Participants have to consent to data sharing in the informed consent forms. If they do not consent, their data will not be shared. Furthermore, the consent form specifies that data will only be shared for research that is approved by an ethical committee.

Where will the data be made available? If already known, please provide a repository per dataset or data type.

Via the KU Leuven repository, RDR

When will the data be made available?

Upon publication of research results / when data collection and analysis is finished.

Which data usage licenses are you going to provide? If none, please explain why.

Given the sensitive nature of the data, datasets will be published under restricted access, requiring the Custom KU Leuven license. This means that when access to the dataset is requested, a data transfer or sharing agreement will be drawn up by KU Leuven legal department in which the terms of use will be agreed upon with the requesting party.

Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.

- Yes

a DOI will be available through RDR once results have been published

What are the expected costs for data sharing? How will these costs be covered?

RDR is free for KU Leuven personnel, hence, no costs are expected for data sharing.

6. Responsibilities

Who will manage data documentation and metadata during the research project?

The PhD researcher (Laura Lecompte) will be responsible for data documentation & metadata, under supervision of the PI (Prof. Benedicte Vanwanseele).

Who will manage data storage and backup during the research project?

Data management, storage and back up will be performed by the PhD researcher (Laura Lecompte), under supervision of the PI (Prof. Benedicte Vanwanseele)).

Who will manage data preservation and sharing?

The PI (Prof. Benedicte Vanwanseele) will be responsible for ensuring data preservation and sharing.

Who will update and implement this DMP?

The PhD researcher (Laura Lecompte) will be responsible for updating this DMP. The PI (Prof. Benedicte Vanwanseele) bears the end responsibility for updating and implementing this DMP.