Plan Overview

A Data Management Plan created using DMPonline.be

Title: The ACHIEVE-project: Advancing Cardiovascular and ocular Health In Eye patients: EffectiVeness and mechanisms of Exercise.

Creator: Marie Renier

Affiliation: KU Leuven (KUL)

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Template: FWO DMP (Flemish Standard DMP)

Project abstract:

Glaucoma often coexists with uncontrolled hypertension, increasing cardiovascular risk. Current pharmacological therapies fall short, underscoring an urgent need for safe alternatives for blood pressure (BP) management in patients with glaucoma. While aerobic endurance training (AET) and isometric resistance exercise (IRE) show promise in lowering BP, direct comparisons in the hypertensive population are lacking. Additionally, in glaucoma patients effectiveness of exercise in BP control remains unknown. This project seeks to address these gaps by introducing exercise alongside usual care. Our ACHIEVEproject will for the first time in glaucoma patients with hypertension 1) employ two randomized controlled cross-over trials in 60 individuals to asses which exercise modalities and timing are safe and effective to use in a chronic exercise program, 2) enrol 125 patients into a randomized controlled exercise trial comparing AET and IRE for improved BP control, 3) investigate long-term sustainability of exercise-induced BP changes and 4) obtain an in-depth assessment of exercise-induced changes in vascular function, alongside changes in inflammation and oxidative stress to elucidate key pathways underlying better BP control. In summary, ACHIEVEment of the integration of structured exercise will induce a paradigm shift in glaucoma care. The use of exercise to target BP can potentially transform outcomes in these patients, fostering healthier hearts and eyes in the long-term

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The ACHIEVE-project: Advancing Cardiovascular and ocular Health In Eye patients: EffectiVeness and mechanisms of Exercise.

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.

Dataset Name	Description	New or reused	Digital or Physical	Digital Data Type	Digital Data format	Digital data volume (MB/GB/TB)	Physical volume
WP 1: randomized controlled crossover trial							
Informed Consent Forms	Informed consent forms printed and signed at the start of the RCT	Generate new data	Physical data which will be digitally archived by scanning paper-based archival documents	Other	.pdf	<100MB	60 informed consent forms
Demographics, medical history and medication	Information on demographics (age, sex), medical history and current medication use	Reuse existing data	Digital	Observational	Data captured by the research team and directly entered into electronic database (Redcap)	NA	/
Anthropometrics ,office and home Blood Pressure (BP)	Anthropometrics (Weight, height), 3 office BP readings, 10 home BP readings	Generate new data	Digital	Observational	Data captured by the research team and directly entered into electronic database (Redcap)	NA	/
Vascular function	Information on endothelial function. Flow-mediated dilation, Flow-mediated slowing and dynamic retinal vessel analysis.	Generate new data	Digital	Observational	Raw software files (.data) and processed .xlxs files	TBD	
Cardiopulmonary exercise test (CPET)	Data collected during CPET (1 per participant)	Generate new data	Digital	Observational	Raw software files (Jaeger CPX, SentrySuite) and processed .xlxs files	TBD	
Physical activity	7-days (1 per participant) and 24-hour (4 per participant) physical activity readings	Generate new data	Digital	Observational	Raw GT3x files processed by Actilife6 software(.csv)		

Dataset Name	Description	New or reused	Digital or Physical	Digital Data Type	Digital Data format	Digital data volume (MB/GB/TB)	Physical volume
Questionnaires	Results from Morningness-Eveningness Questionnaire (MEQ) (1 per participant)	Generate new data	Digital	Observational	Online text survey via survey application in RedCap		
Ambulatory blood pressure measurement (ABPM)	ABPM readings (4 per participant)	Generate new data	Digital	Experimental	Raw software files (.data) and processed .xlxs files		
Eye pressure	Results from eye pressure readings (4 per participant)	Generate new data	Digital	Experimental	Data captured by the research team and directly entered into electronic database (Redcap)		
WP2 and WP3: Reuse data from an already ongoing RCT within our research group							
Demographics, anthropometrics, exercise data, physical fitness, physical activity vascular function, ABP	Database generated from completed Hit-Glaucoma Trial.	Reuse existing data	Digital	Observational	.csv, .xlxs generated from recap		
Blood chemistry	Additional analysis on collected serum during HIT-Glaucoma trial.	Generate new data	Digital	Experimental			

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:

WP2 and WP3 will reuse existing data that becomes available following the completion of the HIT-Glaucoma trial (S67593, doi: 10.3389/fphys.2024.1349313).

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

WP2 and WP3 form a substudy within the HIT-Glaucoma trial. The study has been approved by the Ethics Committee of Northwestern and Central Switzerland (EKNZ) (Project-ID: 2023-01397) and the Ethics Committee Research UZ/KU Leuven (EC Research) (Project-ID: S67593). Ethical Approval from the Ethics Committe UZ/KU Leuven for WP1 (ACHIEVE, S69872) is currently ongoing.

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

Two types of personal data will be collected:
1) Personal information for contact purposes (e.g. name, phone number, e-mail) which will not be used in any further analysis.

2) Personal information for research purposes: socio-demographic data (e.g. sex, birth year), data concerning medical status (medical history, medication use), health related physical fitness data (cardiopulmonary exercise test), data on cardiovascular health (blood pressure, vascular health), blood biochemistry data, physical activity data.

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.

- No

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).

All data will be coded. A README.txt file will be placed in a dedicated ACHIEVE folder on the J-drive to provide an overview of the management of all collected data.

Approved ethical commission/funding application: detailed overview of the study protocol for each work package (.pdf)

Informed consents forms (ICF): original blank copies (.pdf) and signed hardcopies
(printed paper)

Standard operating procedures (SOPS): Comprehensive explanation of data collection methods (measurement procedures) and data generation (software, materials, setup, settings), as well as the subsequent storage and processing of data (software, protocols, guidelines) (.docx)

Clinical report forms (CRF):

An electronic Case Report Form (eCRF), developed in REDCap, will be used.

Raw experimental data includes the storage of original physical records and digital files in their native specific software formats. These raw data files are systematically stored in a dedicated project folder on the J-drive (working drive) or L-drive (large storage drive), hosted by KU Leuven servers. Within this folder, data are organized into subfolders based on the experiment or method type (e.g., physical activity registration, cardiopulmonary exercise test) and further categorized by assessment points. Each raw data file is also uploaded to the REDCap database, where a corresponding link (key identifier) to its backup on the J-drive/L-drive is maintained.

Processed data are managed within the REDCap database, which contains a comprehensive data dictionary, measurement units, and key identifiers linking to the original data files.

The Patient Identifier Record (PIR) is stored separately from subject recruitment files on a different location within the KU Leuven server to ensure the protection of private data, under the supervision of the Principal Investigator (PI).

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.

- No

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

Where will the data be stored?

1. Data on anthropometrics, vascular function, physical fitness, eye pressure, blood pressure,...will be immediately digitalized by entering the values in the RedCap database hosted on the KU Leuven servers. Only researchers working on the ACHIEVE project will have access to the RedCap for the duration of the project.
2. A copy of KU Leuven digitalized files will also be stored on the J-drive of the KU Leuven CVEP research group (hosted by KU Leuven servers) within the password protected ACHIEVE folder.
3. Paper copies, including informed consent forms will be stored in a secured locker at the offices of O&N4 (Herestraat 49; lokaal 04.419 - 3000 Leuven) for KU Leuven after being digitalized (scanned) and saved in the RedCap database and the J-drive.
4. Large data files (ABPM data, vascular health imaging data) will be stored on large storage L-drive hosted on KU Leuven server.

How will the data be backed up?

Paper documents will be digitized and then uploaded to both the REDCap database (hosted on KU Leuven servers) and the J-drive on the KU Leuven server network. The original paper copies will also be securely stored in a locked cabinet. This ensures that three versions of the data are consistently maintained. Both the REDCap database, J-drive and L-drive are automatically backed up through KU Leuven's IT services.

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

Currently, 4 TB of storage space is available, with additional budget allocated should further capacity be required. However, based on current projections, no additional storage is expected to be necessary.

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

The pseudonymised digital data—meaning it is coded and contains no directly identifying personal information—will be securely stored within the University infrastructure, specifically in the REDCap database hosted on KU Leuven servers. Access to this database is strictly controlled by the Principal Investigator (Véronique Cornelissen), who determines access permissions and user roles. Similarly, access to the J-drive is exclusively managed by the PI. The subject identification code list, which links participant names to their unique codes, is protected by a dual-password system, stored separately, and solely managed by the PI.

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

The costs for the REDCap database are 80 euro/year and will be covered by the bench fee of the PhD-student. The J-drive is covered partially by departemental funding (CVEP-drive) and partially (300 euro/year) by the research group (CV imaging data) of which the research team is part of.

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...).

All data related to the project will be retained for 20 years after completing the trial.

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

The data will be stored on the KU Leuven central servers (with automatic back-up procedures) for 20 years.

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

The REDCap database that will be compiled within this research project will be hosted on the servers of the KU Leuven at a cost of 80 euro's/year. These cost are covered with the FWO bench fee of the PhD-student.
The back up of all raw files (except large data files) on the J-network drive are 156,6 euro/TN and will be covered by the department.
All large data files (ABPM data, vascular health imaging) will be stored on the large volume drive at the KU Leuven server at a cost of 641,95 EUR/year and will be covered by the department.

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, …)

Data will be available on written request after signing a data sharing agreement. Data will only be shared after setting up a new research collaboration and if the research is approved by the ethical committee. The full anonymized dataset will be made available after publication of the data and upon request with the Steering Committee composed by the PI (Véronique Cornelissen), the co-promotors and PhD-student of this project.

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

The anonymised transcripts will be made available through RDR, the KU Leuven institutional repository. Access will be considered after a written request is submitted explaining the planned reuse. Only uses for research purposes will be allowed and commercial reuse will be excluded. Data will only be shared if the research is approved by the ethical committee.

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

Personal data will not be made available under any circumstance, as required by law.

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

All anonymised transcripts will be made available through RDR, the KU Leuven institutional repository.

When will the data be made available?

Data will be available after an embargo period. After the end of the project an embargo of 5 year will be applied to the data to allow the consortium to process and analyse all available data.

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

The RDM support desk will be contacted to draw up a Data Transfer Agreement (DTA).

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 assigned at a later stage via the RDR system.

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

Minimal costs are expected. If they occur, they will be covered by the requesting parties. Additionally the use of RDR entails no costs for KU Leuven personnel.

6. Responsibilities

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

The PhD-researcher (Marie Renier) associated with this project will be responsible for data documentation and metadata, under supervision of the PI Véronique Cornelissen.

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

Data storage will be performed by The PhD-researcher (Marie Renier) under supervision of the PI Véronique Cornelissen. Back-ups will be automatically performed by KU Leuven ICT / Biomedical science group.

Who will manage data preservation and sharing?

The PI (Véronique Cornelissen) will be responsible for ensuring data preservation and reuse with support from ICTS and Gbiomed-IT staff.

Who will update and implement this DMP?

The PI (Véronique Cornelissen) bears the end responsibility of updating and implementing this DMP.