
HIGH-INTENSITY INTERVAL TRAINING IN PATIENTS WITH GLAUCOMA (HIT GLAUCOMA)

A Data Management Plan created using DMPonline.be

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Project abstract:

Glaucoma is a chronic disorder of the optic nerve and is estimated to affect 120 million people by the year 2040. The only available treatment is to lower the eye pressure, either by surgery or medication. However, more than one third of glaucoma patients in Europe never experienced high eye pressures. Literature states these patients have microvascular abnormalities. Physical exercise training (high-intensity interval training) increases blood vessel health. Therefore, this project evaluates the therapeutic effect of physical exercise training in patients with glaucoma.

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Application DMP

Questionnaire

Describe the datatypes (surveys, sequences, manuscripts, objects ...) the research will collect and/or generate and /or (re)use. (use up to 700 characters)

The project will generate new data. The datatypes are the following:

- Observational
- Experimental
- Software

Specify in which way the following provisions are in place in order to preserve the data during and at least 5 years after the end of the research? Motivate your answer. (use up to 700 characters)

1. Designation of responsible person: Prof Dr Ingeborg Stalmans
2. Storage capacity/repository
 - during the research: 1TB
 - after the research: 1TB

What's the reason why you wish to deviate from the principle of preservation of data and of the minimum preservation term of 5 years? (max. 700 characters)

Data will be preserved for a period of at least five years from the end of the research project, except for clinical trial data that will be preserved for longer time. In accordance with the revised clinical trial regulation by the institutional ethical committee of UZ Leuven, all data (digital and physical) related to the clinical trials will be preserved for a period of 25 years (European Regulation 536/2014).

Are there issues concerning research data indicated in the ethics questionnaire of this application form? Which specific security measures do those data require? (use up to 700 characters)

The project will collect from human participants personal data, retinal images as well as ophthalmological and neuropsychological evaluation. Approval has been issued by the Ethics Committee of the University Hospitals Leuven, Ethische Commissie Onderzoek UZ Leuven/KU Leuven (reference number S67593).

Which other issues related to the data management are relevant to mention? (use up to 700 characters)

None

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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
		<i>Please choose from the following options:</i> <ul style="list-style-type: none"> Generate new data Reuse existing data 	<i>Please choose from the following options:</i> <ul style="list-style-type: none"> Digital Physical 	<i>Please choose from the following options:</i> <ul style="list-style-type: none"> Observational Experimental Compiled/aggregated data Simulation data Software Other NA 	<i>Please choose from the following options:</i> <ul style="list-style-type: none"> .por, .xml, .tab, .csv, .pdf, .txt, .rtf, .dwg, .gml, ... NA 	<i>Please choose from the following options:</i> <ul style="list-style-type: none"> <100MB <1GB <100GB <1TB <5TB <10TB <50TB >50TB NA 	
Participant details	Regular personal data, Ophthalmological and exercise capacity testing, 24h ambulatory blood pressure measurement, serum markers	Generate new data	Digital	Observational data	.csv, .xlsx	<100MB	
HSRI	Hyperspectral retinal images	Generate new data	Digital	Experimental	.TIF	<100GB	
FUNDUS	Fundus photography	Generate new data	Digital	Experimental	.TIF	<100GB	
OCT(A)	Optical Coherence Tomography (Angiography) images	Generate new data	Digital	Experimental	.E2E	<100GB	
DVA	Dynamic Vessel Analysis	Generate new data	Digital	Experimental	.avi	<1TB	

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:

N/A

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

The project will collect personal data, retinal images as well as ophthalmological and neuropsychological evaluation. Approval has been issued by the Ethics Committee of the University Hospitals Leuven, Ethische Commissie Onderzoek UZ Leuven/KU Leuven (reference number S67593).

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 regular and health data such as year of birth and age, medical test information (exercise capacity testing, serum markers, 24h ambulatory blood pressure measurements) and ocular data (retinal images) will be processed. All data are examined and kept in a coded format, with each participant assigned a unique anonymous identification.

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

Valorisation of research results is possible. For potential exploitable results, the tech-transfer office of KU Leuven will be contacted.

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.

- Yes

DTA with University of Basel in place, multicenter study. Meaning that data can be transferred as described in the protocol and publication only after approval both centers. Protocol approval has been issued by the Ethics Committee of the University Hospitals Leuven, Ethische Commissie Onderzoek UZ Leuven/KU Leuven (reference number S67593).

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).

A standard operating procedure will be created for the entire imaging procedure including preparation of the devices, settings used in programs, questions to ask the patient pertaining to their anamnestic data, a basic clinical examination to be conducted and naming strategies for all procedures which will be saved in separate files. There will be a logbook marking the names and pseudonyms of participants, as well as the researcher conducting the imaging, date of imaging, the informed consent process and at which time procedures were performed. The study protocol also includes a detailed description of the data collection process. Each retinal imaging dataset will be stored in a separate folder including a README.txt with all the relevant information. Scripts for data analysis will be written in Python or Matlab or R. Python scripts will be stored in Jupyter Notebooks (.ipynb format) while Matlab scripts will be stored as .m files. Regarding R scripts, they will include an Rd file. In all cases, each step of the analysis will be documented.

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

For images, a detailed acquisition protocol will describe how data was generated. The labelling of every retinal image will contain the study acronym, the patients id, the date of recording, the visit number, the eye region, the operator and the flash intensity.

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

Where will the data be stored?

We will utilise our institute's secure data storage system (University Hospitals Leuven servers). Numeric data will be saved in online servers (following GDPR legislation) in an online electronic case report form (eCRF), RedCap. Image data (Fundus, OCT(A), DVA) will be stored on the internal protected UZ Leuven Database.

How will the data be backed up?

We will utilise protected University Hospitals Leuven servers with automated onsite back-up and mirroring.

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

We will use the internal servers of the University Hospitals Leuven which can accommodate large amount of data. We currently have been allocated a 1 TB of space per year which is sufficient capacity.

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

We utilise our institute's secure data storage system (University Hospitals Leuven servers, databases). Data related to the clinical trials are solely stored on the servers of the University Hospitals Leuven, as mandatory by the UZ Leuven ethical committee. RedCap, the logged Electronic Case Report Form (eCRF) that is approved and supported by the UZ Leuven Clinical Trial Centre and Ethics Committee, ensures that the data are securely stored. Image data (DVA, Fundus, OCT(A)) are stored on the internal UZ Leuven Database, a secure environment for private data. All human data will be stored with a unique anonymous identifier for every subject that will be stored separately from the research data and only accessible for key researchers.

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

Back-up of data on the internal servers of the University Hospitals Leuven costs 200 euros per Terabyte per year. The corresponding 200 euros per year will be covered by the Research Group of Ophthalmology.

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...).

Data will be preserved for a period of at least five years from the end of the research project, except for clinical trial data which will be preserved for longer. In accordance to the revised clinical trial regulation by the institutional ethical committee of UZ Leuven, all data (digital and physical) related to the clinical trials will be preserved for a period of 25 years (European Regulation 536/2014).

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

Data will be stored for the long-term on the University Hospitals Leuven servers.

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

The expected cost is around 200 euros per Terabyte per year and it will be covered by the Research Group of Ophthalmology.

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, ...)

Research outputs will be made openly accessible, whenever possible, via existing platforms that support FAIR data sharing (www.fairsharing.org). Personal data will only be published after de-identification and identifiers will not be published. If, despite all efforts, it is not possible to protect the identities of subjects even after removing all identifiers, personal data will not be made public. Participants in the study are informed via consent forms about the policies regarding data sharing. The ethical aspects are covered in the context of the ethics review.

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

Personal data will only be published after de-identification and identifiers will not be published. If, despite all efforts, it is not possible to protect the identities of subjects even after removing all identifiers, personal data will not be made public. Participants in the study are informed via consent forms about the policies regarding data sharing. The ethical aspects are covered in the context of the ethics review. Requests for data will be evaluated on a per case basis.

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, Ethical aspects

The access will be restricted because personal data will only be published after de-identification and identifiers will not be published. If, despite all efforts, it is not possible to protect the identities of subjects even after removing all identifiers, personal data will not be made public.

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

Some journal request specific repositories therefore, the repository will be chosen at that point. However, whenever possible, RDR repository from KU Leuven will be chosen.

When will the data be made available?

Upon publication of research results.

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

Most data sets will be made publicly available (scientific articles, deliverables, software assets) in open repositories (such as Zenodo or KU Leuven RDR repository) with a Document Object Identifier (DOI) and following open licensing that enables distributing of the results to the community. Python, Matlab and R scripts will be licensed under MIT license. Exceptions will be made for those results protected by Intellectual Property Rights which will be further studied later in the project.

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

Intent to add Document Object Identifier (DOI), at least in scientific articles that will derive from the project.

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

There are no expected costs since deposition of smaller datasets in data repositories is usually covered by the repository.

6. Responsibilities

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

Prof Dr Ingeborg Stalmans, Jan Van Eijgen

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

Prof Dr Ingeborg Stalmans, Jan Van Eijgen

Who will manage data preservation and sharing?

Prof Dr Ingeborg Stalmans, Jan Van Eijgen

Who will update and implement this DMP?

Prof Dr Ingeborg Stalmans, Jan Van Eijgen

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GDPR

GDPR

Have you registered personal data processing activities for this project?

- Not applicable

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DPIA

DPIA

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

- Not applicable