Unraveling the twists and turns of Freezing of Gait in Parkinson's Disease - A multimodal neuroimaging investigation

A Data Management Plan created using DMPonline.be

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Project abstract:

Freezing of gait (FOG) is a complex and disabling symptom for people with Parkinson’s disease (PD). FOG is usually triggered in specific gait situations, with turning being the most provocative. So far, the reasons why turning causes gait breakdown are not yet known. Based on previous experimental work, high asymmetry and small step length are two candidates that may either separately or in combination, lead to FOG. To tease these apart, we independently manipulate asymmetry and step
size on a split-belt treadmill to study freezing-related deficits of motor control. Further, the neural correlates of turning-related asymmetric motor control have not been studied, owing to limitations of previous paradigms. We therefore propose a novel asymmetric foot movement task during functional MRI to study freezing-related brain network interactions during asymmetric motor control. Finally, we will link the functional networks underlying asymmetric motor control with the freezing-related
cortical brain activity measured during asymmetric upright walking. Combining novel behavioral and neuroimaging paradigms, this work will shed light on the precise motor control deficits in FOG. Importantly, we expect to provide concrete targets for future prospective and interventional work to detect risk and intervene optimally, and maximize the impact on FOG.

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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
		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	
VICON	Biomechanical data: foot marker positions during gait	Generate new data	Digital	• Experimental • Compiled/aggregated data	.c3d, .mat, .csv	<100GB	NA
APDM	Biomechanical data: trunk and leg acceleration, angular velocity and orientation during gait	Generate new data	Digital	• Experimental • Compiled/aggregated data	.h5, .csv	<100GB	NA
EMG	Biomechanical data: Muscle activation of lower limb muscles (electromyography	Generate new data	Digital	• Experimental • Compiled/aggregated data	.c3d, .mat, .csv	<100GB	NA

FNIRS	Neuroimaging of the brain: Near infrared spectroscopy to measure changes in oxygenated and deoxygenated haemoglobin concentrations in the cortical regions of the brain during walking	Generate new data	Digital	• Experimental • Compiled/aggregated data	.nirs, .mat, .csv	<100GB	NA
FMRI	Neuroimaging of the brain: Functional Magnetic Resonance Imaging to measure changes in deoxygenated haemoglobin during a foot movement task in the MRI scanner	Generate new data	Digital	• Experimental • Compiled/aggregated data	.dcm, .nii, .mat, .mif, .mgh, .csv, .tsv	<1TB	NA
Video	Video recordings: for annotation of freezing episodes	Generate new data	Digital	• Experimental • Compiled/aggregated data	.mp4, .csv	<100GB	NA
Audio	Audio recordings: responses to the Auditory stroop task are recorded to measure response time and accuracy	Generate new data	Digital	• Experimental • Compiled/aggregated data	.mp3, .csv	<100GB	NA
Health Data	Questionnaires to assess cognition, mood, disease severity, fear of falling and freezing severity	Generate new data	Digital	• Observational • Compiled/aggregated data	.csv	<1GB	NA
Contact	Personal data for contact purposes (name, address, email, telephone number)	Generate new data	Digital	Observational	.csv	<100MB	NA

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:

NA

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

Yes, we will collect health-related data in vulnerable people with chronic disease. Hence, the ethical considerations of such research will be assessed by an independent ethical committee (Ethical Committee Research UZ/KU Leuven). The file is yet to be

submitted, and research will only commence upon ethical approval.

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

Several types of personal data will be gathered:

1. Personal data used for organizing the research: i.e. name and surname, phone number, e-mail address, home address, identification card number (required for MRI scanning), bank account number (for reimbursement of transportation costs), name of neurologist (to verify diagnosis). This data will not be included in the analysis. Paper versions will be stored in a locked cabinet inside a locked room, only accessible to the study staff. Digital copies will be stored in a separate, password-protected file on the secured KU Leuven's L-drive, only accessible to the study staff.
Participants will be asked whether this personal information can be stored in a contact database for future research, via a separate informed consent procedure in
accordance with the General Data Protection Regulation (GDPR).
2. Personal data for research purposes

- Demographics: age, sex, years of education
- Data concerning medical status: Parkinson medication dosage, presence of deep brain stimulator, disease duration, disease severity, presence of freezing of gait, cognitive functioning and mood.
- Neuroimaging data consisting of two magnetic resonance imaging (MRI) sessions (including structural and functional scans).

Data will be pseudoanonymised and access to the data will be restricted. GDPR compliance has been assessed by the KU Leuven, and approved (reference number G-2023-6927).

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

The present project constitutes fundamental research and no commercial valorization will be undertaken.

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).

The following documentation will be provided to enable reuse of the data:

- In every subfolder of the database a ReadMe file will be added that contains information on the context in which the data were gathered, the origin of the data, and the content of the dataset.
- It will be documented in a text file in the subfolder how raw data have been processed into other forms of data (if applicable)
- Lab protocols are provided for the equipment used in this study. These document the parameters and instrument settings, provide a description of how to perform the assessments.
- The research protocol provides a detailed overview of all the variables that are collected and stored in the database.
- A data dictionary will be developed. This data dictionary provides detailed information about the variables collected within the project as well as their metadata such as standard definitions of variables, allowable values, formats, origin, etc

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 & reuse).

At a data level

- MRI data will be stored according to the international BIDS (Brain Imaging Data Structure) standard.
- MRI images will saved in both .nii and DICOM format, which includes structured metadata regarding the acquisition parameters and procedures.
- REDCap offers the possibility to download a XML file of the metadata, which consists of the following information: User Roles, Data Access Groups, Data Quality Rules, Surveys and survey settings, order of survey queue. REDCap also keeps a log of when the questionnaires are filled in, when someone makes adjustments to the data. Also metadata (e.g. timestamp, electronic instructions) are automatically captured during survey completion in REDCap

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

Where will the data be stored?

Research data

1. KU Leuven REDCap will be used to capture study related data. REDCAp is a secured and password-protected database and data capture system. The digital pseudonymized data one REDCap will be exported immediately and transferred to a secure KU Leuven Large Volume Storage network-drive (L-drive). This drive is specifically developed to store large amounts of data for long periods of time, immediately after collection from their respective research instruments. For data transfer, only secure methods will be used (KU Leuven's secured BelNet Filesender). For active use, copies from the master file on the L-drive can be made and kept on the individual work pc of the researchers involved in the project. To ensure that the master file remains up-to-date the SyncFree tool will be used for regular back-up of active copies to the L-drive.

2. fMRI data are temporarily transferred to the High Performance Computing (HPC) infrastructure of KU Leuven, which is part of the ‘Vlaams Supercomputer Center’, to
process MRI data. Upon completion these will be returned to the L-drive and individual work pc’s of the researchers involved

3. The paper copies of the descriptive data and questionnaires will be stored in a secured locker at the Department of Rehabilitation Sciences, Building The Nayer, of the KU Leuven. Only authorized personnel will have access to this locked storage room as they will need to be granted access by the PI (Moran Gilat).

Personal data for organizing the research

1. In a separate folder (i.e., not together with the research data) on the L-drive of the KU Leuven servers, a double-password protected document will be kept containing the patient identification log; this will be the only link between the real identity of the participants and their allocated subject ID code (pseudonymization code)

2. Paper informed consent forms will be stored separately in a secured locker at the Department of Rehabilitation Sciences, Building The Nayer, of the KU Leuven.
Only authorized personnel will have access to this locked storage room as they will need to be granted access by the PI (Moran Gilat). The ICFs will not be kept in the same binder as the paper research data.

How will the data be backed up?

The paper copies will be digitized and together with the digital data stored on the university's secure network drive with automatic daily back-up procedures.
Additionally, a mirror of the data is provided in a second ICTS data center for business continuity or disaster recovery purposes.

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

RedCap is hosted on central ICTS webservices and provides unlimited capacity. The minimum for large volume storage provided by the KU Leuven ICTS-hosted L-drive is 5TB, which will be sufficient for the data as described in part 2 of this DMP. If needed, there is funding available to obtain another 5TB of data storage

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

The digital, pseudonymized, data (i.e. coded and containing no personal information) will be stored in a secure university environment, i.e., the L-drive, and REDCap. The PI of this project (Prof Moran Gilat) will be the only one who can grant access to this network drive.
The separate and password protected "Subject Identification Code List", which matches identifying codes with the subjects' names, will be managed by the postdoctoral researcher (Dr. Nicholas D'Cruz) and stored in a double-password protected digital file in a separate folder on the L-drive.
Personal data collected on paper (e.g., informed consent forms) are stored in a locked cabinet on-site (during data collection: accessible only to study personnel; after data collection: accessible solely by PI of the study).

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

The costs for data storage are as follows:
L-Drive: EUR 113 per TB per year
Redcap: EUR 80 per project per year
Costs will be covered from the bench fee

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 generated research data will be archived for 25 years after the end of the project, conform the EC KU Leuven/ UZ Leuven and KU Leuven RDM policy.

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

The generated research data, the accompanying metadata and all documentation necessary to reuse the data will be transferred to the K-drive designed for long-term data archiving (managed by KU Leuven ICTS with automatic back-up procedures).

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

Archiving data on the central large volume drive (K-Drive) costs EUR 113 per TB per year. These costs will be covered by the PI for

the retention period. The Group of Biomedical Sciences, KU Leuven covers half this cost.

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, ...)

Pseudonymized datasets will be made available on RDR, the data sharing platform of the KU Leuven. A restricted-access policy will be in place for all datasets.

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

Sharing of pseudonymized data will be considered after a request is submitted explaining the planned reuse.
All study participants will be asked whether the data gathered in the context of this project can be reused for other research purposes, both within the research group or with other researchers inside or outside KU Leuven (restricted-access data) via the informed consent form.
Data of participants who granted this permission will only be shared with research groups who submitted a written request to the PI of this project.
Data will only be shared if the research is approved for secondary use by the ethical committee.
Transfer of the pseudonymized data will be performed via a secured method of transfer taking into account all applicable security arrangements and regulations (such as the European General Data Protection Regulation).
The receiving party will be bound by contractual agreement to keep the transferred data confidential at all times and to only process the data for the purpose of the Study. To this end, appropriate Data Transfer Agreements (DTAs) will be established.

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
- Yes, Privacy aspects

Yes, 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.

After publication of the results, the respective data will be made available via a suitable scientific repository, providing the necessary guarantees regarding GDPR compliance (i.e., KU Leuven repository, RDR). Importantly, only data of participants who granted their approval for re-use, either within the research group (closed data) or outside the research group (open data), will be made available. The dataset will be under restricted access.

When will the data be made available?

Upon publication of the research results, or as soon as possible thereafter.

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

The receiving party will be bound by contractual agreement to keep the transferred data confidential at all times and to only process the data for the purpose of the proposed study. To this end, appropriate Data Transfer Agreements (DTAs) will be established with help from colleagues of the KU Leuven Research & Development Department.

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

Not yet available

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

Storage upto 50GB are covered for free by RDR. Hence, we anticipate no additional costs for data sharing.

6. Responsibilities

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

Postdoctoral fellow and study coordinator Dr. Nicholas D'Cruz

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

Postdoctoral fellow and study coordinator Dr. Nicholas D'Cruz

Who will manage data preservation and sharing?

Prinicipal Investigator - Prof. Moran Gilat

Who will update and implement this DMP?

Postdoctoral fellow and study coordinator Dr. Nicholas D'Cruz will update and implement the DMP. End responsibility for its implementation lies with Prof. Moran Gilat.