DMP_11N5622N

Project Name My plan (FWO DMP) - DMP_11N5622N
Project Identifier 11N5622N
Grant Title 11N5622N
Principal Investigator / Researcher Alice Nieuwboer
Project Data Contact Joni De Vleeschhauwer, 016324334, joni.devleeschhauwer@kuleuven.be
Description Manual dexterity is an integral part of daily life and crucial for touchscreen use. In people with Parkinsonâ€™s disease (PD) dexterity is compromised and medication only partially effective. Hence, structured training of manual skills is indispensable. Despite the dopamine deficiency in PD, some studies show beneficial effects of targeted motor learning with more efficient use of the intact neural networks. Still, the retention of practice often remains unstable. In healthy older adults, complex training proved to be beneficial for retention by recruiting a broader network. Currently, it is unclear whether a similar approach will be beneficial for motor memory retention in PD. Therefore, this proposal addresses the neural correlates of dual versus single task training on the retention of touchscreen skills, hypothesizing greater efficiency within compensatory networks after dual task practice. As PD is an enormously heterogeneous disorder and progressive, it is unlikely that all patients will benefit from dexterity training. Consequently, in a large prospective cohort study, we will identify the determinants for motor learning capacity and success, using a novel home training device. We will focus on compliance as a key factor, the nature of which is largely unknown in PD. We expect that compliance will interact mostly with the non-motor features of the disorder. Overall, this project will make a great step forward in developing individualized rehabilitation programs for PD.
Institution KU Leuven

1. General Information

Name applicant

Joni De Vleeschhauwer

FWO Project Number & Title

11N5622N: Towards individualized motor learning in people with Parkinson’s disease.

Affiliation

- KU Leuven

2. Data description

Will you generate/collect new data and/or make use of existing data?

- Generate new data

Describe in detail the origin, type and format of the data (per dataset) and its (estimated) volume. This may be easiest in a table (see example) or as a data flow and per WP or objective of the project. If you reuse existing data, specify the source of these data. Distinguish data types (the kind of content) from data formats (the technical format).

All data will initially be collected in a variety of file formats. All descriptive data will be collected on paper and entered in excel for WP1 and in REDCap (secured with two factor authentication) for WP2 and WP3. Below, an overview of all data is described for each work package.

Work package 1

Type of data	Format	Volume	How created
(A) Behavioral data	.txt / paper / .dif / .Prk / .xslx / .docx	2 MB	Touchscreen skills are assessed using different applications. Swipe-Slide Pattern tasks are automatically stored in a .txt file and in a .Prk file (latter inside scanner). These files are transferred to .xlsx format. Performance on a mobile phone task and on a fine motor skill assessment is recorded on paper and entered in .xlsx. Lastly, performance on basic touchscreen tasks is collected in a .dif file and transferred to an .xlsx file. Behavioral data on touchscreen skills will be collected at 4-5 different timepoints. .docx files are stored including instructions on how to collect data.
(B) Training data	.txt / .xlsx	Max. 1 MB	Training data consist of Swipe-Slide Pattern task performance for 4 days. This data is automatically stored in .txt files locally on the tablet as well as in a secure online database. The .txt files are then stored on protected server file storages of the KU Leuven (automatic back-up).
(C) Questionnaires	Paper / .xlsx	5 GB	Safety questionnaires for MRI are only important for screening prior to MRI scanning and will only be kept as a paper record in the University Hospitals Leuven. Questionnaires assessing disease specific characteristics, motor and cognitive function will be collected on paper and transferred to .xlsx files.
(D) Magnetic Resonance Imaging (MRI)	.NifTI / DICOM / .PAR / .REC	410 GB	MRI data of the participants' brain will be collected. This will include following types of MRI scans: • Anatomical scans (T1) • Task-based functional magnetic resonance imaging (fMRI) • Diffusion weighted imaging (DWI) • Fieldmap • Reverse phase scans for DWI and fMRI MRI scans will be collected at two timepoints.
(E) Processed data	.xlsx	5 GB	Processed data of all raw data sources described above, with the exception of MRI data, will be stored in .xlsx files

Work package 2-3

Type of data	Format	Volume	How created
(A) Behavioral data	.txt / paper / .dif / .Prk / .xslx / .docx	3 MB	Touchscreen skills are assessed using different applications. Swipe-Slide Pattern tasks are automatically stored in a .txt file locally on the tablet as well as on a secure online database. These files are stored in REDCap. Performance on a mobile phone task and on a fine motor skill assessment is recorded on paper and entered in REDCap. Behavioral data on touchscreen skills will be collected at 3 different timepoints. .docx files are stored including instructions on how to collect data.
(B) Training data	.txt / .xlsx	3 MB	Training data consist of Swipe-Slide Pattern task performance 10 days. This data is automatically stored in .txt files locally on the tablet as well as in a secure online database. The .txt files are then stored on REDCap.
(C) Questionnaires	Paper / .xlsx	5 GB	Questionnaires assessing disease specific characteristics or motor and cognitive function will be collected on paper and stored on REDCap.
(D) Processed data	.xlsx	5 GB	Processed data of all raw data sources described above will be stored on REDCap and summary data will be transferred to .xlsx files.

Data stored on paper will be stored in a locked cabinet inside a locked room, only accessibly to study staff.

3. Legal and ethical issues

Will you use personal data? If so, shortly describe the kind of personal data you will use. Add the reference to your file in KU Leuven's Register of Data Processing for Research and Public Service Purposes (PRET application). Be aware that registering the fact that you process personal data is a legal obligation.

- Yes

Privacy Registry Reference: WP 1: G-2021-2996-R2(AMD) / WP 2-3: G-2020-2683-R2(AMD) (both accepted).
Short description of the kind of personal data that will be used: for all work packages:

- Personal data used for organizing the research (name, phone number, e-mail address, home address; name of neurologist, general practitioner and physiotherapist). This data will not be included in the analysis and will be stored in a locked cabinet inside a locked room, only accessible to the study staff. Participants will be asked
whether this information can be stored in a database for future research, via a separate informed consent procedure in accordance with the General Data Protection Regulation (GDPR).
- Personal data for research purposes, including age, gender, years of education; and data concerning medical status (Parkinson medication dosage, presence of deep brain stimulator, disease duration, disease severity, presence of freezing of gait, cognitive function (global and subdomains) and mood. This data will be collected after acquiring a study-related informed consent procedure in agreement with the General Data Protection Regulation.
- Neuroimaging data consisting of two magnetic resonance imaging (MRI) sessions (including structural and functional scans).

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, add the reference to the formal approval by the relevant ethical review committee(s)

- Yes

The study (S62917) received ethical approval by the Ethical Committee UZ/KU Leuven on the 13th of September 2019.
Approved PRET application: G-2021-2996-R2(AMD)

The study (S64842) received ethical approval by the Ethical Committee UZ/KU Leuven on the 26th of March 2021.

Approved PRET application: G-2020-2683-R2(AMD)

Does your work possibly result in research data with potential for tech transfer and valorisation? Will IP restrictions be claimed for the data you created? If so, for what data and which restrictions will be asserted?

- No

Do existing 3rd party agreements restrict dissemination or exploitation of the data you (re)use? If so, to what data do they relate and what restrictions are in place?

- No

4. Documentation and metadata

What documentation will be provided to enable reuse of the data collected/generated in this project?

A detailed protocol will be written, including research methods, practices, etc., as well as a blank copy of the informed consent form for the different work packages. Also, a document containing all instruction for data collection has been written. These data will be stored in a Word file. Also, all questionnaires is available. All steps in the methodology will be logged in an Excel file.

For the MRI data, the brain imaging data structure (BIDS) will be used to save the data (https://bids.neuroimaging.io/index.html). This also includes detailed .txt files containing all information regarding the different imaging types.

The behavioral data of the Swipe-Slide Pattern task is saved in a .txt file, which also contains the exact time of performance. All data storage types will have clear instructions, naming and descriptions.

Will a metadata standard be used? If so, describe in detail which standard will be used. If no, state in detail which metadata will be created to make the data easy/easier to find and reuse.

- Yes

For the storage of MRI data, a standard structure (i.e., Brain imaging data structure or BIDS, see above) will be used. Moreover, metadata is also included in the MRI DICOM images, containing information regarding the acquistion settings.

However, for the majority of the data (not MRI), metadata will be provided as a readme, txt or word file. These files will contain all settings and descriptions of the collected data and performed tests/assessments.

5. Data storage and backup during the FWO project

Where will the data be stored?

1. The time-stamped master copy of the data will be kept on our research unit central storage facility. More specifically, digital data will be stored on a Large Volume Storage (L-drive) of the KU Leuven, which has been developed specifically for storage of large amounts of data for long periods of time. In addition, copies can be made and kept on personal devices of the researchers involved in the project.
2. Since we will be working with sensitive personal data that will only be pseudonymised as soon as possible. Only one record on paper and in an Excel file "Subject Identification Code List" links the pseudonym to the personal data, this paper is stored in a locked cabinet inside a locked room, only accessible for researchers involved in the project (see below), the digital file is password protected and will be managed by the PI (Alice Nieuwboer) and also stored on the secure L-drive.

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

4. Moreover, REDCap will be used to store the data of WP2-3. This online database is secured with a two-factor authentication and only accessible to researchers involved in the project.

How is backup of the data provided?

Data stored on paper will be digitized and stored, together with the digital data, on the university's secure network drive with automatic daily back-up procedures. Moreover, REDCap will be used to store the data of WP2-3. This online database allows for manual back-ups and is secured with a two-factor authentication and only accessible to researchers involved in the project.

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, we have more than 5 TB free at our disposal. This amount of storage will be sufficient for the data as described in part 2 of this Data Management Plan.

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

The expected costs are €569.20/year/5TB and will be covered by the project.

Data security: how will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

Since we will be working with sensitive personal, pseudonomyzed, data (i.e., coded and containing no personal information), the data will be stored in the university's secure environment for private data. Access to this secured network drive can only be granted by the PI of this project (Alice Nieuwboer). The document linking identifying codes to the subjects' names "Subject Identification Code List" is password protacted and managed by the PI and stored in a folder on the secure L-drive run by our university.

6. Data preservation after the FWO project

Which data will be retained for the expected 5 year period after the end of the project? In case only a selection of the data can/will be preserved, clearly state the reasons for this (legal or contractual restrictions, physical preservation issues, ...).

After the end of the project, both raw and processed data will be retained for the expected 5 year period.

Where will the data be archived (= stored for the longer term)?

Data will be archived on the secured university's network drive (with automatic back-up procedures) as described in part 5 of this Data Management Plan.

What are the expected costs for data preservation during the retention period of 5 years? How will the costs be covered?

The expected costs for the network drive are €569,20/year/5TB and will be covered by the department.

7. Data sharing and reuse

Are there any factors restricting or preventing the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

- No

Which data will be made available after the end of the project?

The full, anonymized, dataset will be made available after publication of the data and upon reasonable request with the PI. However, only data of participants who granted their approval for re-use of data will be made available. All participants are asked, via an informed consent procedure, whether the data collected within this project may be re-used for other research purposes inside or outside KU Leuven.

With regards to the neuroimaging data, which does not allow for full anonymization even after removing all personal information and defacing the images, data sharing will be restricted. However, upon reasonable request with the PI, data sharing will be considered.

Where/how will the data be made available for reuse?

- Upon request by mail

When will the data be made available?

- Upon publication of the research results

Who will be able to access the data and under what conditions?

Data of participants who gave written consent to data re-use (see above) will be shared with other research groups only after a written (and reasonable) request to the PI (Alice Nieuwboer). Only in case of ethical approval by the ethical committee, data will be shared and participants will be informed about this data sharing.

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

No costs are expected as the researchers primarily involved in this project will make sure the data is anonymized and prepared for data sharing. If any costs do occur, they need to be covered by the

requesting party/parties.

8. Responsibilities

Who will be responsible for data documentation & metadata?

Under the supervision of the PI (Alice Nieuwboer), the PhD researchers involved in this project will be responsible for data documentation and metadata.

Who will be responsible for data storage & back up during the project?

Under the supervision of the PI (Alice Nieuwboer), the PhD researchers involved in this project will be responsible for data storage and back up.

Who will be responsible for ensuring data preservation and reuse ?

The PI (Alice Nieuwboer) will be responsible for ensuring data preservation and reuse.

Who bears the end responsibility for updating & implementing this DMP?

The PI bears the end responsibility of updating & implementing this DMP.