Sleep on it: The behavioral and neural effects of post-learning sleep and targeted memory reactivation for boosting motor memory consolidation in Parkinson's disease.

A Data Management Plan created using DMPonline.be

Creator: Letizia Micca

Affiliation: KU Leuven (KUL)

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Template: FWO DMP (Flemish Standard DMP)

Principal Investigator: Moran Gilat

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Project abstract:

Rehabilitation is a first line therapy for Parkinson's disease (PD), for which the ability to learn and retain novel motor skills is fundamental. However, PD patients often fail to consolidate new skills into long-term memory, thus reducing the efficacy of training. Interestingly, sleep facilitates motor memory consolidation in healthy adults, especially in combination with targeted memory reactivation (TMR). TMR works by adding task-related sounds during learning that are replayed during
subsequent sleep to reinforce the memory trace. Importantly, recent work suggests that sleep-dependent consolidation may be preserved in PD, but robust findings are lacking and have not
involved TMR. I will address this gap by investigating the effect of sleep and TMR on motor memory consolidation in PD. First, I will detail the impact of sleep impairment on memory consolidation in PD. Then, I will test the effect of TMR applied during sleep on consolidation using both a conventional TMR setup as well as a highly innovative closed-loop application that automatically sends stimuli at the specific up-phase of slow oscillations to achieve optimal learning. Finally, I will describe the neurophysiological processes underpinning these effects using state-of-the-art neuroimaging. Overall, this project will pave the way for new sleep interventions to boost rehabilitation for PD and will provide much-needed insight into how we can leverage sleep physiology to rescue core motor difficulties of PD.

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GDPR

GDPR

Have you registered personal data processing activities for this project?

- Not applicable

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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)

Collect:

1. Informed consent forms
2. Demographic data (e.g. age, gender, education)
3. Clinical characteristics (e.g. cognitive tests, manual dexterity measures, Movement Disorder Society Unified Parkinson's Disease Rating Scale, Medication intake)
4. Questionnaires (e.g. sleep quality scales, sleep diaries, quality of life, anxiety, depression)
5. Actigraphy data
6. Task-specific digitized measures (e.g. MSL and SRTT outcomes - .txt, .mat)
7. Polysomnography (raw .edf files, sleep stages and diagnosis obtained from the sleep technologist/medical doctor)
8. Neuroimaging data (e.g. electroencephalography (.eeg, .dat, .edf), functional magnetic resonance imaging (fMRI))

Overall data storage needed: 0.8-1 TB
Generate:

1. Manuscripts for publication in open access scientific journals
2. Presentations at scientific and public dissemination meetings
3. Scripts for data processing and analysis
4. Pseudo-anonymized datasets to be share upon consultation with the researcher (Letizia Micca) and principal investigator (Moran Gilat)

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 (If already designated, please fill in his/her name.)
2. Storage capacity/repository
    - during the research
    - after the research

PI prof. Moran Gilat (moran.gilat@kuleuven.be) and myself (letizia.micca@kuleuven.be) will be responsible for data management. De-identified hard copies will be stored in a secured locker inside a locked room, only accessible to study staff who receive access by the PI. The data obtained by computerized measures (all coded, containing no personal information) will be stored on protected and factor authenticated server file storages of the KU Leuven with automatic back-up. All de-identified data will be kept securely a total of fifteen years after completion of the study, in accordance with the requirements of FWO and KU Leuven. The storage capacity for the data of this project is guaranteed by our department for the total duration of fifteen years (both electronically and in the locked storage room).

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)

I have no reasons to deviate from the principle of preservation of data and of the minimum preservation term of five years.

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)

There are no issues of this sort in relation to the data collected for this project, which will all be pseudo-anonymized

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

There are no other issues to report. All study staff, including myself, have obtained the good clinical practice certification (ICH-GCP), as required by our University. The ICH-GCP course focuses on responsible conduct of research, informed consent, privacy and research data management.

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FWO DMP (Flemish Standard DMP)

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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	
PSG_screening_raw	This data set contains data on the polysomnography for the screening prior to WP1. This data are stored in the BIDS format. Contains: EEG data; sleep staging data; diagnosis and summary of findings written by a medical doctor; Actigraphy (data obtained with Actiwatch, used fro 7 consecutive days)	Generate new data	Digital	Observational	.edf .docx .csv	<1TB	

PSG_screening_processed	This data set contains: Processed EEG data on the polysomnography for the screening prior to WP1; Processed Actigraphy data	Generate new data	Digital	Compiled/aggregated data	.csv .txt	<100GB	
WP1_NAP_raw	This data set contains data on the experiment of work package 1. This data are stored in the BIDS format. Contains sections: Behavioural (collected at 3 time points); EEG data (collected over an 8-hour period overnight); Actigraphy (data obtained with Actiwatch, used between timepoints 2 and 3 during the experiment)	Generate new data	Digital	Experimental	.txt .mat .edf .mat .dat .csv	<100GB	
WP1_NAP_processed	This data set contains: Processed Behavioural data, collected at 3 time points; Processed EEG data collected over a 2-hour period overnight; Processed Actigraphy data ((worn between timepoints 2 and 3)	Generate new data	Digital	Compiled/aggregated data	.csv .txt .mat .Rda	<100GB	

WP2_TMR_raw	This data set contains data on the experiment of work package 2. This data are stored in the BIDS format. Contains sections: Behavioural; EEG collected over an 2-hour period overnight; Actigraphy (data obtained with Actiwatch, used between timepoints 2 and 3 during the experiment)	Generate new data	Digital	Experimental	.txt .mat .edf .mat .dat .vmrk .vhdr .eeg .csv	<100GB	
WP2_TMR_processed	This data set contains: Processed Behavioural data, collected at 3 time points; Processed EEG data collected over a 2-hour period overnight; Processed Actigraphy data (worn between timepoints 2 and 3)	Generate new data	Digital	Compiled/aggregated data	.csv .txt .mat .Rda	<100GB	
Paper-based questionnaires and case report forms	This data are stored in folders in a locked closet in a locked room. They include:general information (e.g., age, education) questionnaires and scales for neuropsychological examination; disease severity measures (patients with Parkinson's disease); sleep diaries; case report forms for WP1, WP2 and WP3	Generate new data	Physical	Observational			16 office folders
Paper-based questionnaires and case report forms - processed	Processed demographic, motor, cognitive, sleep quality scales and questionnaires	Generate new data	Digital Physical	Compiled/aggregated data	.csv .Rda	<1GB	

WP3_CLTMR_raw (ESTIMATION)	This data set contains data on the experiment of work package 3. This data are stored in the BIDS format. Contains sections: Behavioural (.txt, .mat), high-density EEG (.dat, .mat, .vhdr, .vmkr, .edf, .eeg); Actigraphy (data obtained with Actiwatch, used between timepoints during the experiment); fMRI data (resting state and functional connectivity)	Generate new data	Digital	Experimental	.txt .mat .edf .mat .dat .vmrk .vhdr .eeg .csv .nii DICOM	<1TB	
WP3_CLTMR_processed (ESTIMATION)	This data set contains: Processed Behavioural data, collected at 3 time points; Processed EEG data collected over a 8-hour period overnight + 2-hour habituation period Processed Actigraphy data (worn for 7 days prior experiment and for the time between timepoints 2 and 3) Processed T1, task-based fMRI,DWI, Fieldmap, reverse phase for fMRI and DWI	Generate new data	Digital	Compiled/aggregated data	.csv .txt .mat .Rda .nii DICOM .ison .h5 .simg	<5TB	
Scripts	Scripts to process behavioural, EEG and fMRI data	Generate new data	Digital	Software	.txt .py .mat .R	<1GB	

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

There are no other issues to report. Ethical approval has been obtained from the Medical Ethical Committee Research of the University Hospital Leuven for two of the three work packages of this project (study ID: S61792). The ethical approval for the third work package will be submitted in the year 2024. This project will not commence until ethical approval has been obtained. For all the work packages, written informed consent is obtained following an written informed consent procedure.

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

All the data will be pseudo-anonymized. Access to the data sets will be restricted to study staff on this project.
Personal data include the following:
Demographic statistics: age, gender, education level
Clinical characteristics: disease severity measures, cognitive measures,
Objective measures: Behavioral performance metrics, EEG, Actigraphy and fMRI data
Physical data will be stored in a locked cabinet in a locked room at the Department of Rehabilitation Sciences, KU Leuven, which is only accessible to study staff. Access to the data can be granted only by the PI (Moran Gilat)

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

Not applicable

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

Not applicable

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

Not applicable

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).

- README.txt files will be attached to the data sets, explaining the data formats, labels, and experimental conditions.
- Case report forms will be filled in during the experimental procedures and digitalised on a secure database managed by ICTS of KU Leuven. Importantly, only the Principal investigator (Moran Gilat) and dedicated study staff (e.g. PhD student LM) have access to this digital database.
- Scripts will be thoroughly commented to ensure interoperability

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

For all the data sets a RDR (KU Leuven's institutional research data repository for the publication of research data) standard will be used.
The Brain Imaging Data Structure (BIDS) will be used to facilitate finding and reusing of data. This data structure will be used for all the digital datasets.

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

Where will the data be stored?

Digital data will be stored on a secured Large Volume Storage (L-drive) of the KU Leuven with automated backup, for the duration of the project.
After completion of the project, this data will be migrated and archived on a secured Large Volume Storage (K-drive) of the KU Leuven, with automated backup that is specifically developed to archive large amounts of electronic data for long periods of time.
Additionally, copies can be made on the individual work pc of the researchers involved
in the project during data analysis, after which the data will be transferred to the L-drive.
The paper copies of the CRF's will be stored in a secured locker at the Department of Rehabilitation Sciences, Building The Nayer, of the KU Leuven. The paper copies that contain identifiable information (i.e. consent forms and subject identification logs) will be stored separately from the other data in a separate folder in a separate cabinet in a separate room. Only authorized personnel will have access to this locked storage room as they will need to be granted access by the PI (Moran Gilat).

How will the data be backed up?

The Case report forms and physical data will be digitalized on the ethically approved research team database on REDCap.
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

Yes, currently we have 1 TB free at our disposal for data storage on our Large storage drives. If this space proves insufficient, it is possible to purchase more storage space available on the KU Leuven servers for a price of €569.20/year/5TB. This costs, and the costs for current data storage, will be covered by the project.

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

The digital, pseudo-anonymized, data (i.e. coded and containing no personal information) will be stored in a secure university environment. The PI of this project (Moran Gilat) will be the only person who can grant access to this network drive via a request to ICTS. The separate and uniquely double pass-word coded "Subject Identification Register", which matches identifying codes with the subjects' names, will be managed by the principle investigator (Moran Gilat) and stored separately in a folder of the secure L-drive run by our university and only accessible by the PI.

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

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

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...).

Both raw data and finally processed data will be stored for a minimum of 15 years after
completion of the project, in accordance with KU Leuven RDM policy. The storage capacity for this project is guaranteed by the Department of Rehabilitation Sciences for the total duration of fifteen years (both electronically and in the locked storage room). After the completion of the project, the data stored on the L-Drive will be transferred to a long-term network drive (K-Drive) for archiving of large volume storage, provided by the KU Leuven servers.
The scripts will be made available and backed up also on a GitLab account , to allow for sharing upon publication.

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

Data will be archived on the secured university's long-term network K-drive.

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

The expected costs for the network drives, shared within the Neurorehabilitation Research Group, are of €569,20/year/5TB and will be covered by the Department of Rehabilitation Sciences.

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, …)

The pseudo-anonymized dataset will be made available after publication and upon request with the PI.
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.

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

All participants will be asked upon signing the Informed Consent Form whether the data gathered in the context of this project can be reused for other research purposes, both within the research group (closed data) or with other researchers inside or outside KU Leuven (open data).
Data of participants who granted permission for open data sharing will be shared with research groups who submitted a written request to the PI of this project (Moran Gilat) and who obtained ethical approval for use of this data. Data will only be shared if the research is approved by the ethical committee and following a data sharing agreement between the requesting party and KU Leuven.

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

The data collected is sensitive to privacy concern and will thus be pseudo-anonymized and only shared following ethical approval and a data-

sharing agreement for non-commercial purposes.

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

Among the possible options are:
RDR

When will the data be made available?

Upon publication

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

Creative Commons Attribution Noncommercial NoDerivatives 4.0 International,
CC-BY-NC-ND-4.0

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

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

No costs are expected. If any occur, they will be covered by the requesting parties

6. Responsibilities

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

The PhD researcher associated with this project will be responsible for data documentation and metadata, under supervision of the PI (Moran Gilat)

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

Data management, storage and backup will be under management of the PhD researcher associated with this project, under supervision of the PI (Moran Gilat)

Who will manage data preservation and sharing?

The PI (Moran Gilat) will be responsible for ensuring data preservation and reuse.

Who will update and implement this DMP?

The PI (Moran Gilat) bears the ultimate responsibility of updating and implementing this DMP.