DISSECTING AGITATION IN DEMENTIA BY MULTIMODAL SENSING (DADS)

A Data Management Plan created using DMPonline.be

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Project abstract:

With the increasing age of the global population comes a significant increase in the number of people with dementia (PwD). Behavioural and psychological symptoms of dementia lead to the decision to institutionalise PwD, ahead of the cognitive decline. Specifically, agitation is the most critical behavioural problem seen in dementia and is present in 50-80% of PwD. Agitation leads to dire consequences for PwD, their environment and society. However, there is limited understanding what happens physiologically during agitation, there is currently no way to robustly detect agitation and there is a clear need to understand what causes agitation in each person with dementia. In this research project, we propose a multimodal sensing platform for non-obtrusive in-depth analysis of agitation in PwD. We aim to discover digital markers for measuring agitation objectively, safely and continuously and identify triggers for agitation both on an individual and population level.

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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 / ID	Description	New or reuse	Digital or Physical data	Data Type	File format	Data volume	Physical volume
		*Indicate: **N**(ew data) or **E**(xisting data)*	Indicate: **D**(igital) or **P**(hysical)	Indicate: **A**udiovisual **I**mages **S**ound **N**umerical **T**extual **M**odel **SO**ftware Other (specify)		Indicate: <1GB <100GB <1TB <5TB >5TB NA	
clinical	clinical, contextual, demographic data	E	D	T	.doc/.xlsx/.csv	<1GB	10 pages per participant(informedconsent,...)
physiological	physiological data (skin temprature, heart rate, actigraphy, electrodermal activity)	N	D	N	.csv/.xlsx	>5TB	
environemntal	data on the living environment of the particpant	N	D	I/N	.csv/.xlsx/.jpeg./.gif	>5TB	

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:

Some data from the KWS patient file will be used as part of this research project.

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, refer to specific datasets or data types when appropriate and provide the relevant ethical approval number.

- Yes, human subject data (Provide SMEC or EC approval number below)

S62882 was approved by the EC UZ Leuven and EC UPC KU Leuven.

Will you process personal data? If so, please refer to specific datasets or data types when appropriate and provide the KU Leuven or UZ Leuven privacy register number (G or S number).

- Yes (Provide PRET G-number or EC S-number below)

S62882 was approved by the EC UZ Leuven and EC UPC KU Leuven.

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

Commercial valorization could be possible in the future. We will consult LRD when appropriate.

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material or 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

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).

Protocols and details related to data collection and processing will be recorded and transcribed to Word or Excel files. Data folders containing raw and processed data will be hierarchically organized and labelled based on the source of the data, the type of experiment, the date of data generation, and the different experimental conditions analysed.
Data analysis methods and particularities (including metadata) will be described in text documents and Excel files included in these folders.
Research methods and practices (including the informed consent process) will be fully documented. Details on the setting of the data collection and the selection of participants will be documented. An overview of all steps taken to remove direct identifiers (e.g. name, date of birth) in the data will be added to the documentation.
The codebook will contain information about the study, files and variables. It will also provide instructions on how to read, analyse, interpret and verify the data.
All files will be stored on REDCap (secured).

Will a metadata standard be used to make it easier to find and reuse the data?
If so, please specify which metadata standard will be used.

If not, please specify which metadata will be created to make the data easier to find and reuse.

- No

Data Storage & Back-up during the Research Project

Where will the data be stored?

- OneDrive (KU Leuven)

- Shared network drive (J-drive)
- Personal network drive (I-drive)
- Large Volume Storage

Data will be stored on KU Leuven/UZ Leuven/UPC KU Leuven and if necessary imec secure servers.
Copies (of parts of the data) can be made and kept on personal devices in accordance with the level of authorisation of the user and the data security level of their device. Sensitive personal data concerning the study participants will be stored in a KUL/UZ secure environment. We will use KUL/UZ managed storage and file-sharing facilities as well as the REDCap platform for active use of the data during the project
REDCap will be used to build the database of this project. We will ensure secure data storage at the start of the project and this for the full duration of the project and 5 years thereafter. A centralized network folder at KU Leuven servers will be used.

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution

Automatic backups for the disk capacity will consist of “snapshot” technology, where all incremental changes in respect of the previous version are kept online. It is standard procedure that 1 snapshot is made per day and that these snapshots are kept for 14 days. The end user can personally restore previously dated files from his or her Windows PC by using the “previous versions” function. Security groups can be set up to enable user management (by the local IT administrator). A mirror (an exact copy) of the data is provided in the second ICTS data center for “business continuity” or “disaster recovery” purposes. A file is copied to the second data center as soon as it is written to a drive. ICTS can put the copy online within an hour in case of disaster with the primary storage. The operating and maintaining of the storage solution is performed by ICTS.

Is there currently sufficient storage & backup capacity during the project?

If no or insufficient storage or backup capacities are available, explain how this will be taken care of.

- Yes

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

To access the original data (i.e., not the backed-up copies), one would need access to the systems. This can be either digitally, which would require knowledge of the IP adresses and login credentials, or physically. It is the candidate's responsibility to make sure these credentials are not only kept safe but of sufficient strength to deter any unwanted data manipulation.

Data-stored on UZ Leuven-managed personal computers are protected via password access to the computers, as set up by the UZ Leuven IT department. Off-site access to REDCap data is available from UZ Leuven personal computers and is password protected.

Personal data will be pseudonymised by the investigator. All data will be treated confidentially and with due care during the project always in line with the guidelines of UZ Leuven regarding access to and use of patient data. The data from the medical file will be collected in a structured manner in a secured computer document. This file will be stored in a team-specific storage location on a server of KU Leuven or UZ Leuven. Data enabling patient identification will be pseudonymised. This means that the personal data will be processed in such a way that it can no longer be used attributed to a specific person without the use of additional information.

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

For data storage: 1200 euro (4 years x 300 euro/year).
For the storage of digital data using REDCap there will be a cost of 80euros/year.
The costs that are associated with storage will be covered by our funding.

Data Preservation after the end of the Research Project

Which data will be retained for 10 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 will be preserved for 10 years according to KU Leuven RDM policy

The digital data will be stored on the university's central servers (with automatic back-up procedures) for at least 10 years, conform the KU Leuven RDM policy.

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

- Large Volume Storage (longterm for large volumes)
- Shared network drive (J-drive)

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

For data storage: 3000 euro (10 years x 300 euro/year).
The costs that are associated with storage will be covered by our funding.

Data Sharing and Reuse

Will the data (or part of the data) be made available for reuse after/during the project?
Please explain per dataset or data type which data will be made available.

- Yes, as restricted data (upon approval, or institutional access only)

The type of data that will be made available will be determined on an ad hoc basis and in adherence with the informed consent of the participants and advice from the relevant ethics committees.

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

Published data will be available to everyone.
Research/experimental data will be available only for people from the lab of the PIs.
Access will be granted upon written request to the creators of the dataset.
Commercial reuse is not allowed.

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 per dataset or data type where appropriate.

- Yes, privacy aspects
- Yes, ethical aspects

The project will make use of demographical, clinical, physiological and contextual data of patients. Pseudonimyzed data can be made available for further analysis in line with the terms of the ICFs and following advice from the relevant local ethics committees and LRD (Leuven Research and Development).

Where will the data be made available?

If already known, please provide a repository per dataset or data type.

- KU Leuven RDR (Research Data Repository)
- Other data repository (specify below)
- Other (specify below)

- In a restricted access repository
- Upon request by mail
- Other (specify): Different data types will be made available by different means according to the nature of the data and request. For example, pseudonymised pre-processed results may be shared with collaborators for new analyses, spreadsheets with pseudonymised data can be made available on request. Publications relating to the study will be provided in open access via Lirias 2.0.

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.

- CC-BY 4.0 (data)
- Data Transfer Agreement (restricted data)

Do you intend to add a persistent identifier (PID) to your dataset(s), e.g. a DOI or accession number? If already available, please provide it here.

- Yes, a PID will be added upon deposit in a data repository

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

Expected costs associated with data sharing will mostly include publications costs. Publication costs will depend on the type of platform we will use. If we aim to publish in an open access journal, we expect a publication cost from around 3000 to 5000 euros per article.
These costs will be covered by our funding.

Responsibilities

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

PhD candidates (Hannah Davidoff, Marta Bono and others attached to the project) will be responsible for their own data.
PIs of the project are prof. Maarten Van Den Bossche and prof. Maarten De Vos.

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

PhD candidates (Hannah Davidoff, Marta Bono and others attached to the project) will be responsible for their own data.
PIs of the project is prof. Maarten Van Den Bossche.

Who will manage data preservation and sharing?

This responsibility will lie with the PI, as this requires a long-term commitment most likely extending beyond the tenure of the PhD candidates.

Who will update and implement this DMP?

The end responsibility for updating and implementing the DMP is with the supervisor (promotor).
To this end, the PhD candidates commit themselves to keeping the supervisor informed about the status of their respective data backup and preservation.