Impact of an intensive rehabilitation programme integrating advanced technology for adults with central neurological disease: A randomised controlled rehabilitation study in the chronic phase

A Data Management Plan created using DMPonline.be

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Project abstract:

Rehabilitation brings the patient to a certain level of functioning. For hospitalized patients who are subsequently admitted to a rehabilitation program, this level is not the level of functioning that they had before the pathology. Therefore, restrictions are still present when patients are discharged from the rehabilitation centre to the home situation. And although further improvement is possible in this chronic phase, rehabilitation options are limited. This results in little to no further progress and negatively impacts life after stroke and spinal cord injury .

Advanced rehabilitation technology enables intensive rehabilitation and positively affects upper and lower limb function. However, several economic factors, including the lack of adequate evaluations of cost-effectiveness and current reimbursement models, are hampering the widespread use of this innovative technology in rehabilitation. This makes rehabilitation in the chronic phase inaccessible and ineffective.

This project will consist of 1 large clinical trial with 2 core concepts: (1) Clinical benefits of an intensive rehabilitation programme using advanced technology, compared to the control group; (2) A full health economic evaluation combined with model-based estimation of costs and benefits; (3) A process evaluation.

Knowledge about these core concepts of intensive rehabilitation using advanced technology will allow us to develop a better rehabilitation package for patients after stroke and spinal cord injury and will have an impact on the implementation of advanced technology within rehabilitation.

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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.

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 **O**ther (specify)		Indicate: <1GB <100GB <1TB <5TB >5TB NA	
Informed consent files	Signed informed consent	N	P	Textual	/	/	+/- 100 pages
Questionnaires	Several questionnaires are administered that measure: - achievement of personal goals (GAS) - Patient's self-perception of performance (COPM) - Fatigue (FSS) - experiences during physical strain (BORG) - individuals' confidence in carrying out activities of daily living (SSEQ)	N	P --> D	Numerical, textual	.xls/.csv /.txt/ .xml (redcap)	< 1 GB	+/- 5000 pages
Questionnaires (REDCap)	Several questionnaires are administered only in REDCap (via mail) that measure: - Quality of life (EQ-5D-5L) - Direct and indirect medical costs (Health economic questionnaire)	N	D	Numerical, textual	.xls/.csv /.txt/ .xml (redcap)	< 1 GB	/
Clinical Tests	Several clinical tests are administered that measure: - independence in daily functioning (FIM) - Cardiovascular fitness (6MWT) - Arm function (ARAT) - Performance-based impairment index (FMA) - Independence of walking (FAC) - max. walking speed (10MWT)	N	P --> D	Numerical, textual	.xls/.csv /.txt/ .xml (redcap)	< 1 GB	+/- 5000 pages
Therapy diary	frequency, fatigue, and content of therapy	N	P --> D	Numerical, textual	.xls/.csv /.txt/ .xml (redcap)	< 1 GB	+/- 12000 pages
Health economic diary	Direct and indirect medical costs	N	P --> D	Numerical, textual	Xlsx.	< 1 GB	+/- 6000 pages
Therapy log (KWS)	Information of KWS (patient file)	N	D	Numerical, textual	Xlsx.	< 1 GB	/

Observation schemes	Observation about the protocol (n = 12)	N	P --> D	Numerical, textual	.xls/.csv /.txt/ .xml (redcap)	< 1 GB	+/- 100 pages
Qualitative interviews	Interview with subsample (n=16) of study participants + health care providers	N	D	Sounds	.mp3	<100 GB	/
Transcribed interviews	Transcribed form of the interviews	N	D	Textual	.pdf	< 1 GB	/
Coded interviews	Coding of transcripts	N	D	Numerical, textual	.nvp (codes given in Nvivo)	<100GB	/

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

A PRET (G-2022-5696) application was submitted and approved on 24 Apr 2023.
Ethical approval reference number: S67164, approved on 13 Jun 2023.

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

A PRET (G-2022-5696) application was submitted and approved.
Ethical approval reference number: S67164, approved on 13 Jun 2023.

Short description of the kind of personal data that will be used:
Ordinary personal data: name, contact details, address
--> only acquired for communicating with the participants throughout the course of the study, will not be used for long-term storage. This will not be captured in REDCap, but will be recorded on a separate file (patient identification form) and stored separately from other research data.
Sensitive personal data: age, gender, stroke/SCI related information (onset, lesion location...) relevant medical history, socio-economic data (work status, Education level, home situation, Marital status), standardized questionnaires/tests, therapy diary, patient file (hospital).
All research-relevant personal data will be pseudonymisized and stored in coded form on the protected L-drive (during study, transferred to K-drive after study completion) of KU Leuven or on the independent and secured database and data management system (REDCap). This database is password-protected and only accessible by the researchers of this study.

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

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

A Clinical Trial Agreement (which includes a Data Processing Agreement) between KU Leuven en AZ Herentals is signed. VUB is also mentioned in this Agreement as third party.

The parties have expressly agreed that any and all data as collected and prepared in the context of the Study shall be the property of all parties. Parties shall give each other all rights necessary to fulfil its obligations towards RIZIV as well as to make the PhD research and publication possible.

Parties agree that all parties have the right to transfer or license, as it sees fit, the Results to third party VUB for use for any and all purposes, including the right to sublicense, in consultation but without compensation for the Participating Site.

Neither Party shall publish or present any results of the Study (either in part or in total) to the public (e.g. abstracts in journals or newspapers, oral presentations at professional meetings, etc.) and/or present abstracts of such results at professional meetings until the study has been completed and the final study results have been published unless a written approval has been obtained from the other parties. Any publications of the results, by either party or their representatives will also be the subject of pre-submission peer review and comment by the other parties. Parties will not withhold their consent unreasonably for publication of a doctoral thesis or any other publication in the framework of a doctoral research based on this Study.

All Parties will be named author on any publication. In most instances, the order of the subsequent authors is to be based on significant scientific input to the study.

Authorship and other related publications questions shall be addressed in accordance with the Protocol and the principles of the ‘Uniform Requirements for Manuscripts Submitted to Biomedical Journals’ and in accordance with the requirements of the respective medical journal.

Another Agreement between KU Leuven and VUB was drafted: Data Transfer Agreement with a reference for the processing of data to the 'Framework agreement regarding (joint) processing of personal data between the Flemish Universities signed on 27/05/2020'. In implementation of this Framework Agreement, the Parties specify that KU Leuven assumes the role of Controller and the VUB will assume the role of Processor. The notification obligation will be fulfilled by the Controller.

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.

- Yes

Parties (AZ Herentals and KU Leuven) have agreed that any and all data as collected and prepared in the context of the Study shall be the property of all parties.

Parties shall give each other all rights necessary to fulfil its obligations towards RIZIV as well as to make the PhD research and publication possible.

The Participating Site (AZ Herentals) and Investigator shall have the right to use the data that the Participating Site prepared in the context of the Study for teaching and internal research purposes and patient care.

Parties agree that all parties have the right to transfer or license, as it sees fit, the Results to third party VUB for use for any and all purposes, including the right to sublicense, in consultation but without compensation for the Participating Site.

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).

Demographic + questionnaires/tests + therapy diaries:

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/surveys are filled in, when someone makes adjustments to the instruments or data. Also, metadata (e.g. timestamp, electronic instructions) are automatically captured during survey completion in REDCAp.

A separate field will be made for remarks that are useful to know about the participant/ circumstances during the assessment (e.g. important

notes of the patient file (KWS).

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

1. In every subfolder of the final database a **ReadMe txt 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.
2. A **data dictionary** in Excel format 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.

- No

- 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/surveys are filled in, when someone makes adjustments to the instruments or data. Also, metadata (e.g. timestamp, electronic instructions) are automatically captured during survey completion in REDCAp.
- Using RedCap, a Data Dictionary Codebook will be generated containing variable-level information for all captured information: Variable / Field name, Field Label (including question text) and Field Attributes (including Field Type, Validation, Choices, Calculations etc.)

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

Where will the data be stored?

- Pseudonymized data will be kept electronically in RedCap or in a secured folder on the KU Leuven OneDrive for Business for active use of the data during the project (processed and raw data). The data will only be accesible by the researchers of this project.
- The paper data will be stored in the office of the research team in a cupboard (cupboard locked). It will be stored inside the KU Leuven in the research group room where only the research team has access to and in a locked Paper data from other sites: will be transfered as quickly as possible to the cupboard in KU Leuven.
- In a separate folder on the KU Leuven OneDrive, a 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).
- The master copy of the data will be stored on a Large Volume Storage (L- drive) of the KU Leuven, specifically developed to store large amounts of data for long periods of time.

How will the data be backed up?

- OneDrive for Business takes automatic backups.
- The university's central servers has automatic daily back-up procedures.
- Authorized members of a study team can use existing REDCap features to create backups of study data and For example, prior to making significant changes to study design. These features include one or more of the following: exporting study data, downloading the data dictionary and download an XML backup.

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 OneDrive storage capacity is 2TB and provides sufficient storage for the active use of the data.
- The minimum for large volume storage provided by the KU Leuven ICTS-hosted L:drive is 5 TB. It is expected this volume is sufficient for the current project. A disaster recovery (mirror) copy of the data is included in this fee.

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

- All included storage facilities (RedCap, L:drive, OneDrive) are incorporated within secured KU Leuven environments, are password-protected (including smartphone-based multi-factor identification) and are only accessible by registered collaborating researchers.
- All data files will be collected, processed and stored in a de-identified format by means of subject ID codes (i.e. pseudonymization). These datafiles will not contain information that would allow participant identification.
  Personal data collected on paper (e.g. informed consent forms) are stored in a locked cabinet on-site at KU Leuven (during data collection: accessible only to study personnel; after data collection: accessible solely by PI of the study)
- Additionally, a clean desk policy and an office key policy will be strictly followed. Computer screens will be locked using Windows L-button. Documents with personal data will be dropped in locked containers for shredding.

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

- OneDrive is covered by KU Leuven.
- The research group foresees space on the L drive.
- RedCap costs 80 euro per year, which will be covered by the RIZIV funding (working costs)

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 stored on the secured KU Leuven's central servers (with automatic back-up procedures) for at least 25 years, conform to the recommendations of the ethical committee UZ/KU Leuven.

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

The generated research data (both raw and processed 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?

Pricing for data storage on the K:drive includes € 11,38 per 100 GB, with 50% of the cost covered by Group Biomedical Sciences. In view of the expected size of the database (including raw and preprocessed data), estimated cost of long-term data storage will be €5,65 per year for 100 GB (since the minimum is 100 GB).

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 full dataset will be pseudonymized and will be shared upon request, after approval of the PI, and for clearly defined research purposes.

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 in RDR explaining the planned reuse. The PI will have to approve this. Only uses for research purposes will be allowed, and commercial reuse will be excluded.

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

Data sharing can only happen when it is not for commercial use, or it doesn't reveal the identity of the participants. All data collected in the context of the study is the property of all parties.

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).
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). The dataset will be under restricted access.

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.

Data Transfer Agreement (restricted data).
The receiving party will be bound by a 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

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?

No costs for data sharing 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?

All researchers associated with this project and our CRA will be responsible for data documentation under supervision of the PI.

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

Back-up and immediate storage: All researchers associated with this project will be responsible for data storage under supervision of the PI.
Long-term storage: PI

Who will manage data preservation and sharing?

The PI will be responsible for ensuring data preservation and reuse.

Who will update and implement this DMP?

The PI bears the overal responsibility for updating & implementing this DMP.