ROBUST: integrated ROBotic Upper limb sensorimotor rehabilitation after STroke to improve behavioural, objective and real-life outcome

A Data Management Plan created using DMPonline.be

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Project abstract:

Upper limb motor and somatosensory dysfunction after stroke negatively impacts on people's daily life. Knowledge from others and ourselves supports the hypothesis that integrated sensorimotor therapy is beneficial for patients with mild motor and residual somatosensory impairment. This project will evaluate this postulation. Firstly, we will validate our in-house developed sensorimotor robot-based protocol in 80 patients and 80 healthy controls. Secondly, a first therapy study (n=10) and subsequently pilot randomised controlled trial will be conducted in the chronic stage after stroke. The ROBUST trial will recruit 66 community-living patients receiving either 48 hours of integrated robot-based sensorimotor therapy (n=22) or 48 hours of conventional therapy (n=22) or usual care (n=22) in four weeks. Between-group comparisons up to three months post-intervention include clinical (behavioural), robot-based (objective), and wearable-sensor (real-life) measurements to unravel the effect of sensorimotor therapy on life after stroke.

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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 *Indicate: **N**(ew data) or **E**(xisting data)*	Digital or Physical data Indicate: **D**(igital) or **P**(hysical)	Data Type Indicate: **A**udiovisual **I**mages **S**ound **N**umerical **T**extual **M**odel **SO**ftware Other (specify)	File format	Data volume Indicate: <1GB <100GB <1TB <5TB >5TB NA	Physical volume
WP1_ICF	Signed informed consent forms	N	P	N.A.	N.A.	N.A.	60 pages (1 per participant)
WP1_Contact_details	Personal information to contact the participants (name, phone number, address)	N	P	N.A.	N.A.	N.A.	60 pages (1 per participant)
WP1_Screening	Data about inclusion- and exclusion criteria of all screened persons. Also screen failures will be collected.	N	D	N T	.xls .csv .xml (redcap)	<1GB	N.A.
WP1_Demographics	Demographical data: age, sex, dominant hand, type of stroke, time since stroke and affected side	N E	D	N T	.xls .csv .xml (redcap)	<1GB	N.A.
WP1_Clinical_paper	Clinical examinations of patients patients on worksheet	N	P	N.A.	N.A.	N.A.	1650 pages (60 participants x 25 pages and 25 participants x 6 pages)
WP1_Clinical_processed	Processed clinical examination of patient	N E	D	N	.xls .csv .txt .xml (redcap)	<1GB	N.A.
WP1_KINARM_raw	Data of robot (KINARM)-based assessments which are collected, directly from the assessments	N	D P	N	.xls .csv .txt .xml (redcap)	<1GB	340 pages (60 patients x 4 pages and 25 patients x 4 pages)
WP1_Scripts_analysis	Scripts for transformation of raw KINARM-data to analytical data (factor scores)	E	D	N SO	.R .txt	<1GB	N.A.

WP1_KINARM_processed	Data of kinematic assessments that can be interpreted	N E	D	N	.xls .csv .R .txt	<1GB	N.A.
WP1_Results	Results of the processed data	N	D	N	.xls .csv .txt	<1GB	N.A.
WP1_Reports	Presentation and discussion of results	N	D	I N T	.docx .pdf .jpg .ppx	<1GB	N.A.
WP2_ICF	Signed informed consent forms	N	P	N.A.	N.A.	N.A.	66 pages (1 per participant)
WP2_Screening	Data about inclusion- and exclusion criteria of all screened persons. Also screen failures will be collected.	N	D	N T	.xls .csv .xml (redcap)	<1GB	N.A.
WP2_Demographics	Demographical data: age, sex, dominant hand, type of stroke, time since stroke and affected side, stroke side in brain and medical history	N	D	N T	.xls .csv .xml (redcap)	<1GB	N.A.
WP2_Feasibility_paper	Data about feasibility and safety on worksheets	N	P	N.A.	N.A.	<1GB	Several boxes
WP2_Feasibility_processed	Processed data about feasibility and safety	N	D	N T	.xls .csv .xml (redcap)	<1GB	N.A.
WP2_Adverse_events	Adverse events during or caused by the novel therapy paradigm	N	D	N T	.xls .csv .xml (redcap)	<1GB	N.A.
WP2_Clinical_paper	Clinical examinations of patients patients on worksheet	N	P	N.A.	N.A.	N.A.	Several boxes
WP2_Clinical_processed	Processed clinical examination of patient	N	D	N	.xls .csv .txt .xml (redcap)	<1GB	N.A.
WP2_KINARM_raw	Data of robot (KINARM)-based assessments which are collected, directly from the assessments	N	D P	N	.xls .csv .xml (redcap) .txt	<1GB	264 pages (66 participants x 4 pages)
WP2_Scripts_analysis	Scripts for transformation of raw data to analytical data (factor scores)	E	D	N SO	.R .txt	<1GB	N.A.
WP2_KINARM_processed	Data of kinematic assessments that can be interpreted	N	D	N	.xls .csv .R .txt	<1GB	N.A.
WP2_Results	Results of the processed data	N	D	N	.xls .csv .txt	<1GB	N.A.

WP2: Reports	Presentation and discussion of results	N	D	I N T	.docx .pdf .jpg .ppx	<1GB	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:

We will reuse data of 80 healthy controls and 20 chronic stroke participants for WP1.
This data will be demographical data (WP1_Demographics), processed data from clinical assessments and assessments on the KINARM-robot (WP1_Clinical_processed and WP1_KINARM_processed), and scripts for transformation of the raw robot-based data to analytical data (WP1_Scripts_analysis).
This data was analysed for the first time in the study of Saenen et al. (2022) (S61997, https://doi.org/10.3390/brainsci12081005)
The data from this previous project is downloaded and collected on the secure KU Leuven network drive (L-drive), which is pass-word protected and only accessible by registered researchers.

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)

Data is retrieved from humans through screening (WP1_Screening + WP2_Screeing), demographical information (WP1_Demographics + WP2_Demographics), clinical tests and tests on KINARM (WP1_Clinical_paper, WP1_KINARM_raw, WP2_Clinical_paper, WP2_KINARM_raw), questionnaires about safety and feasibility (WP2_Feasibility), and questions about adverse events (WP2_Adverse_events)
WP1:

- PRET appliation: accepted (G-2023-7238)
- Ethical committee research UZ/KU Leuven: request in progress (S68470)

WP2: This study has not yet started, but no study will start without first obtaining PRET approval and ethical approval.

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)

PRET G-2023-7238
Several types of personal data will be gathered:
1. Personal data used for organizing the research (WP1 + WP2): i.e. name and surname, phone number, e-mail address, home address, identification card number and bank account number (for reimbursement of transportation costs). This data will not be included in the analysis.
2. Personal data for research purposes
a. Personal data processed during screening and collecting demographical data (WP1_Screening, WP2_Screening, WP1_Demographics, WP2_Demographics):

- Demographics: age, sex, hand, education level
- Data concerning medical status; dominant hand, type of stroke, time since stroke, stroke side in brain, brain location, affected side, current therapy, and medical history;

b. Personal data processed during collection of raw data (WP1_Clinical_paper, WP2_Clinical_paper, WP1_KINARM_raw, WP2_KINARM_raw)

- Namely data from clinical tests and data from tests on KINARM.

c. Personal data will be processed during collection of feasibility and safety questionnaires (WP2_Feasibility), and questions about adverse events (WP2_Adverse_events), for example medical symptoms.
All personal data will be pseudonymized. The file where the pseudonyms are linked to the personal data and identifiers will be stored

separately on the secured KU Leuven server, only accessible to the study staff.

ICFs, which also contain some personal data (e.g., name), will be stored in a locked cabinet within a room of Department Rehabilitation Sciences, Building De Nayer, KU Leuven. This room will be only accessible for study staff, since the PI (Geert Verheyden) has to give permission.

Any personal data shall be treated as confidential at all times including during collection, handling and use or processing, and the personal data (including in any electronic format) shall be stored securely at all times and with all technical and organizational security measures that would be necessary for compliance with EU and national data protection legislation (whichever is more stringent). The Sponsor shall take appropriate measures to ensure the security of all personal data and guard against unauthorized access thereto or disclosure thereof or loss or destruction while in its custody.

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 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).

At project level

- a READme txt file will be provided for each WP separately. We will use KU Leuven's template.
- For each WP separately, a detailed protocol will be provided, including research methods and instructions about the KINARM assessments for participants. Additionaly all clinical tests will be added to this document. This will be provided in a .pdf format.

At data level

- For each WP separately, a standardized case report form (CRF) will be completed during data collection, containing researchers notes, remarks concerning data quality, contextual information, deviations from the protocol,... These CRFs will be kept on paper, in the same folder as the research data that are collected on paper.
- For each WP separately, a user guide on data processing & handling will be provided as a .pdf file.
- For each WP separately, a data dictionary will be provided as a .csv file.

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

Metadata will be listed in a document which will be stored on the L-drive of KU Leuven.
The following documents will be provided:

- pseudonymized information regarding demographics, results on tests and information about feasibility and safety
- In the methodology section, information will be provided about how the data was collected and processed during this project

Furthermore, 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

Data Storage & Back-up during the Research Project

Where will the data be stored?

- Other (specify below)
- Large Volume Storage

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 (WP1_ICF + WP2_ICF) will be stored separately in a secured locker at the Department of Rehabilitation Sciences, Building De Nayer, of KU Leuven.Only authorized personnel will have access to this locked storage room as they will need to be granted access by the PI (Geert Verheyden).

Research data

1. The paper versions of the assessments (WP1_Clinical_paper, WP2_Clinical_paper, WP1_KINARM_raw, WP2_KINARM_raw) will be stored separately in a secured locker at the Department of Rehabilitation Sciences, Building De Nayer, of KU Leuven.Only authorized personnel will have access to this locked storage room as they will need to be granted access by the PI (Geert Verheyden).
2. 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 on 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 FreeFileSync tool will be used for regular back-up of active copies to the L-drive.
3. KINARM data will be transported from the KINARM-computer to the individual work pc of the researcher by a .txt file on a USB-stick. Data will be processed using MATLAB. Processed data will be saved on the secure KU Leuven Large Volume Storage network-drive (L-drive).

How will the data be backed up?

- Personal back-ups I make (specify below)

I will make a back-up of the data on my work computer (which is password locked) as well as on an external hard disk (which will be stored savely in a locked desk drawer).
Furthermore, I will use the standard back-up provided by KU Leuven ICTS.
The paper copies will be scanned and together with the digital data stored on the secure KU Leuven Large Volume Storage network-drive (L-

drive). This drive has also automatic daily back-up procedures.

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

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 5
TB, 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?

Identification data: The separate and password protected 'Subject Identification Code List', which matches identifying codes with the subject's names, will be managed by the PI (Geert Verheyden) and stored in a double-password protected digital file in a seperate folder on the L-drive.
ICF: The signed informed consent forms will be stored in a locked cabinet on-site in the Department of Rehabilitation Sciences, Building De Nayer (KU Leuven), only accessible by study personnel during data collection. After data collection, this cabinet is only accessible by PI (Geert Verheyden).
Personal data on paper: Personal data collected on paper will be stored in a locked cabinet in the Department of Rehabilitation Sciences, Building De Nayer (KU Leuven). The papers will be scanned in and stored on the secure KU Leuven network drive (L-drive).
Digital personal data: The digital, pseudonymized data (i.e. coded and containing no personal information) will be stored in a secure university environment (REDCap). This platform has the possibility of allowing detailed access control on file and folder level, in this way we can prevent access to data and modification of data by unauthorized persons. The digital data will additionally be stored on the L-drive. The PI of this project (Geert Verheyden) will be the only one who can grant access to this network drive.
A **back-up of the data** will be stored on the work pc of the doctoral researcher (which is password protected) and on an external hard disk (which will be stored within a locked desk drawer).

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

The Department of Rehabilitation Sciences provides an L-drive of 5TB for the NeuroRehabilitation Research Group, which was extended to 10 TB by the research group
itself, thereby covering the costs (i.e., €569.2/5TB/year). The price to set-up a RedCap projects is € 80 per year.

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 25 years according to CTC recommendations for clinical trials with medicinal products for human use and for clinical experiments on humans

Both raw data and finally processed data, as well as accompanying metadata and documentation, will be stored for 25 years after the end of the project, in line with the Belgian Law of 7 May 2004 related to experiments on humans.

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

- Other (specify below)

- Large Volume Storage (longterm for large volumes)

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).
Data collected on paper (e.g. informed consents) will be stored in a locked cabinet in a locked room at the Department of Movement Sciences. During data collection the
cabinet will only be accessible to study personnel.

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

The Department of Rehabilitation Sciences provides a K-drive of 5TB for the NeuroRehabilitation Research Group for archiving. The costs (i.e., €113.84/TB/year) will be covered by the department. In addition, the Group Biomedical Sciences sponsors 50% of this cost price. There is no charge for paper archiving.

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

Some data (such as results) will be available when published. This will be open data.
Raw data (WP1+2) and data analysis scripts (WP1+2), demographics (WP1+2) will be restricted data for reuse.
The full pseudonymized dataset will be made available as open as possible, as closed as necessary after publication of the data. This because of the type of data (sensitive and personal).
If the participant did not give consent for reuse of their data via the informed consent procedure, the data of that person will not be shared.
All of the above data that will be shared will be pseudonymized data.
Personal data (such as name and contact details) will be restricted available in a database of our research team to contact these persons for participating other studies. This will only be done if participants have given informed consent for reuse of this personal data.

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

Members of our own research group will have access to the data.
All participants will be asked whether the data gathered in the context of this project can be reused for other research purposes via an informed consent procedure. 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 (Geert Verheyden). Data will only
be shared if the research is approved by the ethical committee and participants will be informed regarding this secondary use.

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

All data originate from patients. Privacy regulations and ethical aspects restrict the sharing of these sensitive data, therefore pseudonymization of the full data set will be provided.
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 and based on a Data Processing Agreement (DPA).

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). 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 research results

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.

- 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

Not available yet.

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

There are no expected costs.

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 & metadata, under supervision of the PI (Geert Verheyden).

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

Data management, storage and back up will be performed by the PhD researcher associated with this project, under supervision of the PI (Geert Verheyden).

Who will manage data preservation and sharing?

The PI (Geert Verheyden) will be responsible for ensuring data preservation and reuse.

Who will update and implement this DMP?

The PI (Geert Verheyden) bears the end responsibility of updating and implementing this DMP.