Aha BOOST. Arm-hand BOOST therapy to enhance recovery after stroke: clinical, health economic and process evaluation

A Data Management Plan created using DMPonline.be

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Project abstract:

Deficits in arm and hand movements after stroke are common and result in reduced independence in activities of daily living and quality of life. Implementable therapy in the subacute rehabilitation phase for improved arm and hand recovery long-term after stroke that demonstrates robust benefits for patient and society is still required. This is what our project will investigate, specifically whether for
P: patients after stroke, who are admitted to inpatient stroke rehabilitation, and who have the
potential to relearn,
I: an additional, comprehensive, arm-hand intervention (Aha BOOST)
C: when compared to dose-matched therapy for the lower limb,
O: enhances arm-hand activity and quality of life post-treatment and long-term, and is costeffective.
For this evaluation, a randomized controlled trial will be conducted in two independent Flemish rehabilitation centres, recruiting 80 patients in total. Our trial methodology is strongly based on a sound rationale, documented in a proof of concept that demonstrated 80% of patients achieving a clinical meaningful improvement in arm and hand function in the Aha BOOST intervention group compared to 0% in the control group after four weeks of therapy. In our definitive trial, 40 patients
per group are included and evaluated pre- and post-intervention, three months after intervention and 12 months after stroke to evaluate immediate, retained and long-term clinical effects and cost-effectiveness in the first year after stroke. Results include upper limb function, capacity, activity of daily living, participation and quality of life, health care utilisation and a dedicated process evaluation. Primary analysis and endpoint is the between-group difference in arm and hand ICF
activity level from pre- to postintervention. Utilisation objectives focus on the implementation of Aha BOOST in clinical practice, support management in embedding this new approach in routine setting and advocate integration in stroke care provision.

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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	Indicate: **N**ew or **R**eused	Indicate: **D**igital or **P**hysical	Digital Data Type Please choose from the following options: Observational Experimental Compiled/aggregated data Simulation data Software Other NA	Digital Data format Please choose from the following options: .por, .xml, .tab, .csv,.pdf, .txt, .rtf, .dwg, .gml, … NA	Digital data volume (MB/GB/TB) Please choose from the following options: <100MB <1GB <100GB <1TB <5TB <10TB <50TB >50TB NA	Physical volume
Informed consent files	Signed informed consent	N	P				80 pages (1 per participant)
Contact details participants	Personal information to contact the participants (name, phone number, address)	N	P				80 pages (1 per participant)
Clinical examinations_paper	Clinical examination of patients on worksheet	N	P				+/- 6800 pages (80 participants x 85p)
Clinical examinations_processed	Processed clinical examination of patient	N	D	Numerical	.xls/.csv /.txt/ .xml (redcap)	< 1 GB	
Patient questionnaire_paper	Questionnaires to patient on worksheet	N	P				+/-2800 pages (80 participants x 35p)
Patient questionnaire_proccessed	Processed questionnaires to patient	N	D	Numerical + textual	.xls/.csv /.txt/ .xml (redcap)	< 1 GB	

Patient diary_paper	Diaries to patient on worksheet	N	P				+/-8000 (80 participants x 100p)
Patient diary_processed	Processed diaries to patient	N	D	Numerical + textual	.xls/.csv /.txt/ .xml (redcap)	< 1 GB	
Therapy diary_paper	Therapy diaries (usual care and experimental interventions)	N	P				+/-2400 (80 participants x 30p)
Therapy diary_processed	Processed therapy diaries	N	D	Numerical + textual	.xls/.csv /.txt/ .xml (redcap)	< 1 GB	
Medical record data_paper	Demographic and stroke specific data	N	P				80 pages (80 participants x 1p)
Medical record data_processed	Processed demographic and stroke specific data	N	D	Numerical + textual	.xls/.csv /.txt/ .xml (redcap)	< 1 GB	
Adverse events_paper	Report of adverse events	N	P				80 pages (80 participants x1p)
Adverse events_processed	Processed adverse events	N	D	Numerical + textual	.xls/.csv /.txt/ .xml (redcap)	< 1 GB	
Therapy video's	Video recording of subsample (n=40) of experimental interventions (2 per participant)	N	D	Audiovisual + images	.mp4 / .mov	<5TB	
Observation schemes therapy video's (observation schemes)	Based on the video recordings, the observation schemes will filled in.	N	P				640 pages (40 participant's x 16)
Processed observations schemes	Processed observation schemes	N	D	Numerical + textual	.xls/.csv /.txt/ .xml (redcap)	< 1 GB	
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	<1GB	
Coded interviews	Coding of transcripts	N	D	Numerical + textual	.nvp (codes given in Nvivo)	<100GB	
Inpatient resource use	Data on costs of inpatient hospital stay (directly from rehabilitation hospital)	N	D	Numerical + textual	.xls/ .csv	<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

This study will investigate the effect of an intensive arm-hand program for subacute stroke patients and will include clinical assessments and questionnaires, analyzing cost-effectiveness and process evaluation. Because of the use of human subject data ethical approval will be requested.
Ethical approval: request in progress for project with registration number S68329

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

Several types of personal data will be gathered:
Personal data used for organizing the research: i.e. name and surname, hospitalization number, phone number, home address. This data will not be included in the analysis. Paper versions will be stored in a locked cabinet inside a locked room, only accessible to the study staff. Digital copies will be stored in a separate, password-protected file on the secured KU Leuven's servers, only accessible to the study staff.
Personal data for research purposes:
1. Demographics: date of birth, gender, accommodation pre-stroke, civil status, level of education; employment status and job, income, living arrangement, number of children living at home.
2. Data concerning medical status: Date of stroke, type of stroke, side of stroke, stroke localization, hand dominance, presence of neglect, relevant medical background, motor and functional ability in the upper limb, communication, cognitive status, level of independence, stroke impact (PROM), motivation, use of health care resources, patient experience with the program.

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

Within the AHA BOOST-RCT, data will be collected at two clinical sites: RevArte in Antwerp and K7 at UZ Gent. There is a subcontractor agreement (onderaannemersovereenkomst) between Jessa Hospital and these clinical sites, which describes the data processing agreement between them. The overarching project involves collaboration between three consortium partners: KU Leuven, Vrije Universiteit Brussel, and Jessa Hospital. According to the collaboration agreement (samenwerkingsovereenkomst), all consortium partners are data controllers, allowing shared data from the clinical sites to be distributed among all partners.

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

Details in Research collaboration agreement between consortium partners and subcontractor agreements.

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).

At project level: A README.txt file will be provided. We will use KU Leuven's template.
A detailed protocol will be provided, including the research methods, practices and instructions given to participants. This will be provided in a .pdf format.
At data level: 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, etc. These CRFs will be kept on paper, in the same folder as the research data that are collected on paper. Paper CRFs will be transcribed to REDCap. The use of REDCap ensures a data dictionary. A user guide on data processing & handling will be provided as a .pdf file.
Additionally, ManGO will be used for collecting the different pseudonymized, data forms from the clinical sites. In ManGO descriptive information about data objects and collection are stored as so-called AVU's (attribute-value-unit triples).

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

At project level: The RDR metadata format will be followed (see Data sharing & reuse).
At a data level:
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 are filled in, when someone makes adjustments to the data. Also metadata (e.g. timestamp, electronic instructions) are automatically captured during survey completion in REDCap.
For ManGO, automatically stored metadata as so-called AVUs (Attribute-value-unit triples). The attribute name represents the 'label' or name of some characteristic or property, while the value, naturally, indicates the value that said property takes for the item in question. The units are an optional field, meant for specifying measurement units. This metadata can be added using templates, via automatic metadata extraction or completely manually.

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

Where will the data be stored?

Personal data for organizing the research:
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).

Paper informed consent forms:
These paper forms will be collected and stored at the clinical sites.

Research data:
1) The **paper copies** of the descriptive data and questionnaires will be stored in a secured locker at the Department of Rehabilitation Sciences, Building The Nayer, of the KU Leuven. During data collection temporary storage is possible at building K on the health campus in Jette, of the VUB. Only authorized personnel will have access to this locked storage rooms as they will need to be granted access by the PI (Geert Verheyden, KUL) or prof. Koen Putman (VUB).

2) The therapy diaries and other pseudonymized data collected by the clinical sites will be uploaded on the **ManGO platform**. ManGO is an Active Data Management Platform based on the open source software IRODS. With this system it is possible to stroke data on reliable and secure systems hosted by ICTS KU Leuven, describe data and files using metadata, automating data workflows and share files with other users inside and outside the KU Leuven.

3) The different paper forms and data received via ManGO will be processed to **REDCap.** REDCAp is a secured and password-protected database and data capture system. The digital pseudonymized data on REDCap will be exported 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 or ZIVVER). 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.

How will the data be backed up?

We will use standard back-up provided by KU Leuven ICTS for my storage solution.

The paper copies will be scanned in and uploaded to the ManGO platform and together with the digital data stored on the university's secure network drive with automatic daily back-up procedures. 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

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 5TB, 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.

ManGO is hosted on central ICTS webservices and provides unlimited capacity. Data is stored securely in the data centers of KU Leuven. Of each file, two copies are stored: one in the datacenter of Heverlee, and one in the datacenter of Leuven. Per research project 1 TB of storage will be offered free of charge. When using more storage the cost will be €35/TB per year. There is funding available to obtain more storage if needed.

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 subjects' names, will be managed by the principal investigator (GV) and stored in a double-password protected digital file in a separate folder on the L-drive.

Informed consent: The informed consent files will be stored on the clinical sites in a locked cabinet, only accessible by study personnel.

Personal data on paper: Personal data collected on paper will be digitalized via ManGO and stored in a locked cabinet in the Department of Rehabilitation Sciences, Building The Nayer, of the KU Leuven. During data collection temporary storage is possible at building K on the health campus in Jette, of the VUB. Only authorized personnel will have access to this locked storage rooms as they will need to be granted access by the PI (Geert Verheyden, KUL) or Koen Putman (VUB).

Digital personal data: The digital, pseudonymized data (i.e. coded and containing no personal information) will be stored in a secure university

environment, i.e. REDCap and ManGO. Both platforms have 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 stored on the L-drive. The PI of this project (Prof Geert Verheyden) will be the only one who can grant access to this network drive.

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. The price to set-up a ManGO project is €35/TB per year, with the first 1TB per project free of charge.
Funding is available for data storage and backup.

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...).

All study 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.
All data collected for organization of the study (phone numbers, addresses) will be deleted immediately after the end of the study.

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

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 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. The informed consent forms will be stored on the clinical sites.

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.

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, …)

Yes, in a restricted access repository. 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 access is restricted, please specify who will be able to access the data and under what conditions.

All the data will be made available for other research purposes regarding the same pathology (stroke) of the consortium partners (KU Leuven, VUB and Jessa), this after approval of an ethical committee.
Additionally, the dataset could be made available for other doctors and institutions collaborating with the consortium partners after submitted a written request to the PI, approval of an ethical committee and based on a Data Transfer Agreement (DTA).

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

All data originate form patients. Privacy regulations and ethical aspects restrict the sharing of these sensitive data, therefore pseudonymization of the full data set will be provided. The informed consent form specifies that data will only be shared for research that is approved by an ethical committee and based on a Data Prosessing Agreement (DPA).

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

KU Leuven RDR.
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 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). The receiving party will be bound by 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

Not yet available.

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

No costs are expected.

6. Responsibilities

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

The PhD researchers and postdoctoral researcher associated with this project will be responsible for data documentation and 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 researchers and postdoctoral 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.