Plan Overview

A Data Management Plan created using DMPonline

Title: Criterion and construct validity of the RISE device to assess movement behavior in community-dwelling people with stroke

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Template: UMC Utrecht DMP with DPIA

Project abstract:

To investigate:

1. The criterion validity of the RISE device in assessing movement behavior in community-dwelling people with a stroke in a laboratory condition.
2. The construct validity of the RISE device in assessing movement behavior in community-dwelling people with a stroke in real-world condition.

This study utilizes a combination of pre-existing and newly acquired data to address the research question. The pre-existing data is derived from the study conducted by Wondergem (2016-2017), which remained unpublished at that time due to a small sample size. Additional data was subsequently collected at Fontys Hogeschool in the summer of 2023 to supplement the sample size. The upcoming data collection will further enrich the dataset, supporting the comprehensive exploration of the study's objectives."

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End date: 21-06-2024

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Criterion and construct validity of the RISE device to assess movement behavior in community-dwelling people with stroke

1. General features

1.1. Acronym/short study title

Criterion and construct validity of the RISE device to assess movement behavior in people with stroke

1.2 Division

- Hersenen (Neurosciences)

1.3 Department

Brain

1.4 Path of the Research Folder

\\ds\GROUPS\HER\Onderzoek\Revalidatie\StudentenFW\Lauravanderheiden

1.5 WMO/DEC

- non-WMO

1.6 ABR number (only for human-related research)

not applicable

1.7 METC number (only for human-related research)

15-768/C

1.9 Research type(s)

- Clinical

1.10 Research design(s)

- Observational

1.11 Mono or multicenter study (one choice)

- Monocenter

1.14 Name of datamanager consulted

Dorien Huijser, Research Data Management Support, Utrecht University

1.15 Last check date by datamanager

2023-12-13

1.16 Indicate which laws and regulations are applicable for the project (please check all that apply)

- Richtlijn Kwaliteitsborging Mensgebonden Onderzoek (Quality Assurance for Research Involving Human Subjects)
- Medical Device Regulation
- Algemene Verordening Gegevensbescherming (AVG) or General Data Protection Regulation (GDPR)
- Gedragscode Gezondheidsonderzoek (Dutch)
- Nederlandse gedragscode wetenschappelijke integriteit

2. Data Collection

2.1 Give a short description of the research data.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format
Human	20	self-designed questionnaire	demographic data	Quantitative	.csv/.xls
Human	20	Barthel Index	assessment by trained healthcare professional	Quantitative	.csv/.xls
Human	20	Functional Ambulation Category	assessment by trained healthcare professional	Quantitative	.csv/.xls
Human	20	10-meter walking test	assessment by trained healthcare professional	Quantitative	..csv/.xls
Human	20	RISE device	RISE device activity monitor	Quantitative	.csv/.xls
Human	20	ActivPAL	ActivPAL activity monitor	Quantitative	.csv/.xls
Human	20	MoveMonitor	Dynaport MoveMonitor	Quantitative	.csv/.xls
Human	6	Video recording	JVC Camcorder GZ-R495BE	Video footage	MP4

Volume: the table above depicts the data yet to be gathered.

2.2 Describe the flow of the data (name systems used and/or third parties, recipients) <add link to location where diagram is stored in RFS>

The flow of data in the study involves multiple devices and software applications:

Newly collected data:

RISE device

1. Pseudonymization of personal information before Measurement

2. Measurement with RISE Device: Collect data using the RISE device.

3. Raw Data on RISE Device: unprocessed data on the RISE device.

4. Categorization into Movement Behaviors: Use 2M Engineering software to categorize data into movement behaviors

5. Secure USB Transfer to Research Folder: Transfer categorized data securely via USB to a research folder.

6. Compilation in Excel Files: specifying start and end times for each activity segment.

7. SPSS Analysis: Analyze compiled data in SPSS for further insights.

ActivPAL/MoveMonitor: The above steps outline the flow of data for both the RISE device and ActivPAL raw data, highlighting the specific processes involved in each stage of data handling and analysis.

Only other software: ActivPAL: software version 7 PAL technologies MoveMonitor: Dynaport MC.Roberts software (Online)

Video

1. **Pseudonymization of Personal Information Before Recording**
2. **Video Recording: video footage on camera**
3. **Storage on Research Folder Structure:** Save the recorded video footage in a designated location within the research folder structure. Ensure that the storage location is secure and follows ethical guidelines.
4. **Data Analysis - Categorization by Researchers:** Two researchers analyze the

pseudonymized video footage to categorize data into different movement behaviors.
5. **Compilation in Excel Files:** Compile the categorized data from the video analysis into Excel files. These files may include details about the identified movement behaviors.
6. **SPSS Analysis:** Further analyze the compiled data in statistical software such as SPSS for deeper insights and statistical exploration.

Barthel index/FAC score/10 meter walkingtest.

1. **Pseudonymization of Personal Information Before Measurement**
2. **Paper Form:** Use of paper forms for administering the Barthel Index, FAC score, and 10-meter walk test.
3. **Paper Record of Results:** Record the results of the assessments on the paper forms.
4. **Transfer to Excel on Secure Drive:** Transcribe the recorded results from the paper forms into an Excel spreadsheet. Save the Excel file on a secure drive, ensuring it is part of a protected folder or structure.
5. **Secure Storage of Paper Forms:** Store the original paper forms securely in a locked cabinet

Self-Designed Questionnaire:

1. **Paper Form**
2. **Patient Completion** Patients/researcher will fill out the paper form with their responses.
3. **Transfer to Excel on Research Folder Structure:** Transcribe the paper-based responses into an Excel spreadsheet. Save the Excel file on the secure drive within the research folder structure.
4. **Secure Storage of Paper Forms:** The physical paper forms are stored securely in a locked cabinet within the UMCU.

Reused Data: Accelerometer/Video/Barthel Index/FAC Score/10 Meter Walking Test/Self-Designed Questionnaire

Files are stored in the research data folder, protected by permission rights (UMC Utrecht O:drive ->revalidatie->studentenFW->lauravanderheiden-> reuse raw data collection). Paper forms are secured in a locked cabinet. The analysis process for the reused data follow the same procedures as the data to be collected.

2.3 Estimated storage space for your project

- 250GB - 1 TB

2.4 Can you reuse existing data? If so, list the data source(s)

- Yes, please specify

We utilize both previously collected data, sourced from the study conducted by Wondergem et al. (2016-2017), and from Fontys Hogeschool students in the period of April to July 2023. Additionally

data will be collected between dec 2023 and march 2024.
Previously Collected Data:
Source: Wondergem et al.'s study (2016-2017)
Participants: 12
Purpose: Criterion validity

Previously Collected Data:
Source: Fontys Hogeschool (april-July 2023)
Participants: 8
Purpose: Criterion and construct validity

Newly collecting data
Period: December 2023-March 2024
Participants: 6 participants will undergo assessment for both criterion validity and construct validity, while 14 participants will be involve only the construct validity assessment.
Purpose: Criterion Validity and construct validity

Total Participants:
Criterion Validity:
Previously Collected: 20 participants
Newly Collected: 6 participants
Total for Criterion Validity: 26 participants
Construct Validity:
previously collected: 8
Newly Collected: 20 participants
total for construct validity: 28 participants.

2.5 Describe how you will take care of good data quality.

1. The completeness of questionnaires and assessments will be checked after each measurement. If a question or part of the assessment is missing, it will be addressed at that point. If a question or assessment cannot be fulfilled, or if the participant chooses not to answer or perform the assessment, this will be documented.
2. data will partially checked by the PI, since this is no high-risk study.
3. The activity monitor data is obtained using the RISE device, ActivPAL, and MoveMonitor. They will be charged and set to record by the researcher and will be collected either personally by the main researcher or via postal service. Subsequently, via a secure USB stick, the data will be downloaded and safely stored in the secure data folder of the UMCU
4. The video data is obtained using a videorecorder. it will be set to record by the researcher during the laboratory protocol. data will be safely stored in the secure data folder of the UMCU.

#	Question	Yes	No	N/A
1.	Do you use a GCP-compliant Data Capture Tool or Electronic Lab Notebook?		x	
2.	Have you built in skips and validation checks?	x		
3.	Do you perform repeated measurements?		x	
4.	Are your devices calibrated?	x		
5.	Are your data (partially) checked by others (4 eyes principle)?	x		
6.	Are your data fully up to date?	x		
7.	Do you lock your raw data (frozen dataset)	x		
8.	Do you keep a logging (audit trail) of all changes?	x		
9.	Do you have a policy for handling missing data?	x		
10.	Do you have a policy for handling outliers?			x

2.6 Specify data management costs and how you plan to cover these costs.

#	Type of costs	Division ("overhead")	Department	Funder	Other (specify)
1.	data management such as storage during collection and analysis.	x			
2.	Time spend creating and upkeep the plan				voluntary
3.	additional costs: data collection (including written materials and activity monitors needed), data preparation for analyses, additional analyses programs.	x			
4.	data capture tool license fee Mc Roberts MoveMonitor	x			

The data capture tool for the MoveMonitor is the only paid component; software for the RISE device and ActivPAL is free

2.8 Which contracts are in place?

Organization	Contract Type with UMCU
MoveMonitor MC Roberts	Data Processing Agreement
Fontys Hogeschool	Consortium agreement

2.9 State how ownership of the data and intellectual property rights (IPR) to the data will be managed

Our dataset comprises activity monitor data, video footage, assessments, and questionnaires from individuals who have had a stroke, including data collected by Fontys Hogeschool under a consortium agreement. Fontys Hogeschool has contributed to the data collection but will not assume ownership of the collected data for this study. UMC Utrecht remains the owner of all data collected for this study. IPR is not applicable to this data. In the event of potential research collaboration projects, pseudonymized data may be shared after the formulation of a Data Transfer Agreement. Although IPR protection cannot be applied to our data, its intrinsic value will be considered when making the data available to others, when setting up research collaborations, and when drafting Data Transfer Agreements

2.10 Use of new technology. Does your study involve the implementation of a technology that has not been used before at UMC Utrecht?

- No

2.12 Will the study need/use personal data (directly or indirectly identifying) from the Electronic Patient Files (EPD; HiX), DNA, body material, images or any other form of personal data?

- Yes. You have indicated that you are using personal data in your project. The following chapter is the Data Protection Impact Assessment (DPIA) for research data. It is derived from the full DPIA, in accordance with the privacy office of UMC Utrecht. Answering questions in this chapter help to determine the risk of processing the personal data and what measures to take to minimize these risks.

3. Data Protection Impact Assessment (DPIA)

3.1 Are suppliers involved in the research project processing personal data from this study? (e.g. transcribe agencies, external laboratories, ICT helpdesk of eCRF, other EDCs (Castor, Redcap, Inform), DRE, Limesurvey, MS Forms)

- Yes

2M engineering b.v. (RISE device)
PAL technologies b.v. (ActivPAL)
Mc. Roberts b.v. (MoveMonitor)

3.2 Is the supplier already contracted by UMCU?

- Yes

3.3 Are there any other centers or organizations involved in the research with which personal data are exchanged?

- Yes

Yes, Fontys Hogeschool is also involved in the research, and there is a consortium agreement in place. The collected data is securely stored on their premises, and the information has been safely transferred to the secure data environment of UMCU.

3.4 Please indicate for each party involved in the dataprocessing, which role under the GDPR they have (controller, joint controller, processor, or sub processor)

Party involved	GDPR role in relation to UMCU	Location (NL, within EEA (not NL), outside EEA)	Is a security policy in place?
PAL technologies	processor ActivPAL data	NL	
Mc. Roberts	processor MoveMonitor data	NL	
2M engineering	processor RISE device data	NL	
Fontys Hogeschool	(joint) controller	NL	

3.6 What type of sensitive personal data will be used?

- Health data

3.7 What type of directly or indirectly identifying personal data will be used? Indicate why you need this data. Is this truly necessary?

Type of personal data	Reason for collecting these data
Name	to communicate with participants and give information, ensuring a personalized and responsive interaction throughout the research process while maintaining strict confidentiality and privacy standards.
Address	to do home visit for participants only involving construct validity
Telephone number	to get in contact with the participant, answer questions from the participant
Age (if fine grained)	to analyze and interpret the study results with consideration of potential age-based variations.
Gender	to analyze and interpret the study results with consideration of potential gender-based variations.
Imaging e.g. MRI, pictures or video (can be health data)	The necessity of collecting this data is typically linked to the research objectives, and in this case, it's for assessing the criterion validity of the intervention or methodology. Criterion validity often involves comparing the results of a measurement or diagnostic tool with a gold standard or reference, and in your case, video data serves as a reference point.
Length weight type of stroke infaction yes/no hemisphere right or left time since stroke	These measurements are related to the anthropometric characteristics of the participants and can be grouped for simplicity. They contribute to adjusting accelerometer data for individual body size. By collecting data on stroke characteristics, including type of stroke, infarction status, and affected hemisphere, we aim to enhance the generalizability of our study results to a more specific population. Understanding the nuances of stroke subtypes and affected hemispheres allows for a more nuanced interpretation of our findings, increasing the relevance of our results to individuals with similar stroke profiles.

3.8 Select any vulnerable groups from which you will collect data?

- Patients

3.9 Which legally prescribed personal number will be used? Note: it is NOT allowed to use BSN (or its international counterpart) for scientific research purposes.

- None

3.10 Can the purpose of the study be achieved with anonymous or pseudonymized data (while it is not currently used)?

- Yes, I reuse pseudonymized data, specify the source data

see 2.4
The pseudonymized data includes information such as age, gender, type of stroke, and other relevant participant characteristics. Each participant is assigned a random numeric code, and this code is used in data analysis. The key file, maintained separately, links these codes to the corresponding individuals without revealing personal information during the analysis process."

3.11 Which measures are taken to prevent the data from being traceable to the natural person? Also consider the measures taken to prevent data breaches.

- Role specific access to identifying data
- SOPs about how to deal with a subject’s right on access, rectification, deletion and objection of their personal data
- Minimalization of collected data points
- Encryption in case of data transfers
- Pseudonymization of data

Communication data is strictly separated from research data. Different team members, including the Principal Investigator and the research team, have distinct access levels. The Principal Investigator and research team have access to research data, while communication data may be accessible to specific team members involved in participant communication management.

3.12 Does the reuse of the data fit within the purpose for which they were originally collected?

- Yes, explain

The data were initially gathered during the study of Wondergem (2016-2017), which was not published at that time due to a small sample size. The reuse of this data, combined with additional data to be collected at Fontys Hogeschool in the summer of 2023, aims to supplement the sample size.

This collaborative effort not only adheres to the original objective of gaining insights into the validity of the RISE device in community-dwelling people with stroke but also contributes to enhancing the scientific value of the collected data.

Participants from the Fontys data collection are informed that their data will be shared with other institutions and have provided consent through ICPIF. Similarly, participants from the original study are aware that their data may be used by other researchers, such as in the current research, and have

given consent through ICPIF

3.13 What type of consent for using personal data is obtained?

- Study-specific or other type of Informed consent (e.g. broad consent, deferred consent)

3.18 Is there a dispute settlement or a party where the subject can go to with questions or complaints?

- Yes: this is described in PIF models and in objection explanation

3.19 Describe how you manage your data to comply to the rights of study participants.

- A subject can object to processing of their personal data or withdraw consent
- We inform the subjects about their rights of access, rectification and deletion of their data. In the information provision we describe the contact information in case a subject wants to exercise their rights,

3.20 Does the data collected concern data from which behavior, presence or performance (profiling) can be measured when this is not the purpose of the research?

- No

3.21 Are automated (i.e. without any human intervention) decisions made about the subjects based on the data?

- No

3.22 Describe the tools, procedures and transport methods that you use to ensure that only authorized people have access to personal data

- Patient digital imaging data for study purposes will be stored at the Research Imaging Archive (RIA) facility of the imaging division of UMC Utrecht. For safe processing of images, RIA will be

used (uses pseudonymization in order to guarantee safe processing). Only authorized personnel can access the (pseudonymized) imaging in the RIA container via personal login. The linkage table for the pseudonymized images will also be stored at the RIA. The container can only be accessed by users with the proper rights. Hospitals may transfer digital data into the RIA through secure connections. The RIA shields patient identifiable information through pseudonymized identifiers (i.e., study number) and only allows access to authorized researchers.

- We use the secured Research Folder Structure that ensures that only authorized personnel has access to personal data, including the key table that links personal data to the pseudoID

We use the secured Research Folder Structure that ensures that only authorized personnel (in this case, the PI and R) have access to personal data, including the key table that links personal data to the pseudoID.

Type of data	who has access
Accelerometer data	Data manager, PI and R: pseud. data only
Video footage	Data manager, PI and R: pseud. data only
Self-designed questionnaire/BI/FAC/10MWT	Data manager, PI and R: pseud. data only
Personal data participants	PI and R
Study ID codes description key	PI
Reused data accelerometer/video	Data manager, PI and R: pseud. data only
Reused personal data	PI
Data analysis: At inclusion the participant will recieve a individual study ID (e.g P01). the data files (video, text and excel sheet) will only contain the participant study ID	

PI: primary investigator

R: Research team

4. Data Storage and Backup

4.1 Describe where you will store your data and documentation during the research.

1. The data will be stored within the Research Folder Structure of the UMC Utrecht, situated within the UMC's firewall. Accessible through the network drive, the data will be located in a folder protected by permission rights (UMC Utrecht O: drive -> revalidatie -> studentenFW -> lauravanderheiden). All data will be stored in a pseudonymized format.
2. Personal information will be stored in a separate key file for an extra layer of security and privacy. Additionally a key file will be kept in a distinct folder with enhanced security measures. Access to this folder will be restricted, ensuring that it is not visible or accessible to everyone, thereby

maintaining the confidentiality of the key information.
3. Physical paper materials will be securely stored in a locked cabinet at the department.

4.2 Describe your backup strategy or the automated backup strategy of your storage locations.

1. All research data will be stored in the Research Folder Structure on the UMC Utrecht networked drives, benefiting from an automatic backup system. The dIT ensures that backups are made twice a day.

5. Metadata and Documentation

5.1 Describe the metadata that you will collect and which standards you use.

1. **Data Analyses Plan:**
    - A data analyses plan, version 1.0, specifically for assessing criterion and construct validity of the RISE device in capturing movement behavior among community-dwelling individuals with stroke, will be created.
2. **Data Management Plan:**
    - This data management plan will be developed to outline the procedures for collecting, storing, and analyzing data related to criterion and construct validity.
3. **Measurement Procedure Documentation:**
    - Detailed documentation outlining the measurement procedures for conducting criterion validity and construct validity assessments will be stored in a specific section of the research folder.
4. **README.txt File:**
    - A README.txt file will be included within the research folder. This file will provide essential context about the files within the folder, serving as a guide for researchers to understand the content and structure of the data.

5.2 Describe your version control and file naming standards.

1. File names will follow the convention of including the project acronym, measure moment, and version number.

2. Each different or updated version of the data set will be named using the date of the update to ensure no data is lost. When a newer version is saved the older version will be saved in a folder named 'previous versions'

6. Data Analysis

6 Describe how you will make the data analysis procedure insightful for peers.

1. **Data Analyses Plan:**
    - A detailed data analyses plan will be developed and stored in the research folder. This plan will serve as a comprehensive guide for peers, outlining the methodology and rationale behind the data analyses.
2. **SPSS Syntax with Comments/Explanations:**
    - The SPSS syntax used in the data analysis will be meticulously documented, including comments and explanations. This annotated syntax will provide a clear and detailed overview of the steps taken in the analysis, making it accessible and insightful for peers reviewing the procedures.
3. **Separation of Raw and Processed Data:**
    - Raw data and processed data will be stored in separate folders. This includes distinct folders for raw data, data analysis, final data, and output. This organizational structure ensures transparency in the data processing pipeline, making it easier for peers to track and understand the progression from raw data to the final analytical results.

7. Data Preservation and Archiving

7.1 Describe which data and documents are needed to reproduce your findings.

Criteria for determining data preservation for long-term access:

- Data and documents required for verification post-project completion or upon departure from UMC Utrecht.
- Data with potential for broader community reuse.
- Data that can enhance open-access publications.

All data and associated documents will be preserved long-term, approximately for 15 years:

1. All complete raw data and data prepared for analyses will be stored long-term.
2. The data analyses plan and its adjustments will be preserved long-term.
3. Demographic data, outcome variable data, and summary data of the activity monitor data and video footage, along with variable coding, will be preserved long-term.
5. The analyses output as used in the publication will be saved long-term.

7.2 Describe for how long the data and documents needed for reproducibility will be available.

1. Data and documentation needed to reproduce findings from this WMO study will be stored for at least 15 years.

2. In consideration of storage limitations, personal contact information, including residential addresses, phone numbers, and names, will be deleted upon the completion of the research.

7.3 Describe which archive or repository (include the link!) you will use for long-term archiving of your data and whether the repository is certified.

We will use Dataverse, which is hosted by UMC Utrecht
https://dataverse.nl/dataverse/UMCU

Further details on were data will be stored long term and who will be responsible will be added once available.

7.4 Give the Persistent Identifier (PID) that you will use as a permanent link to your published dataset.

Intention: We will be using a DOI-code and will update this plan as soon as we have the code. To be updated once relevance is determined and information is available

8. Data Sharing Statement

8.1 Describe what reuse of your research data you intend or foresee, and what audience will be interested in your data.

1. My peers will be reusing all research data in the final dataset to generate new research questions.
2. The raw data may attract the interest of other researchers; however, it will not be openly accessible, and only pseudonymized data will be provided.
3. Data will be shared with monitoring bodies as needed, such as internal audits conducted by UMC Utrecht.

8.2 Are there any reasons to make part of the data NOT publicly available or to restrict access to the data once made publicly available?

- Yes (please specify)

All data and documents included in the data package mentioned in 7.1 will be shared with restrictions. Due to the privacy-sensitive nature of the data, we will publish descriptive metadata in the data repository along with instructions on how to request the data (by sending an email to the corresponding author). Any request for data reuse by peers will be considered only if the research question aligns with the original informed consent signed by the study participants. Each application will be screened to ensure compliance with this requirement. If approved, the receiving party will be required to sign a data usage agreement

8.3 Describe which metadata will be available with the data and what methods or software tools are needed to reuse the data.

1. all data and documents in the data package mentioned in 7.1 will be shared under the aforementioned (8.2) restrictions.

8.4 Describe when and for how long the (meta)data will be available for reuse

- Other (please specify)

The data will be retained for 15 years. If, during this period, research questions are formulated by peers and collaborations emerge, including an agreement on data sharing, then pseudonymized data can be shared, provided that the research questions align with the informed consent signed by the participants

8.5 Describe where you will make your data findable and available to others.

since data will not be openly accessible the data will be stored as mentioned aboven. if all conditions for sharing pseudonomized raw data are met, a secrure method of granting access to the other researchers will be used.