
Plan Overview

A Data Management Plan created using DMPonline

Title: Meetinstrument voor Uitkomsten van REVALidatiebehandeling in Nederland (MUREVAN)
Prospectief cohortonderzoek

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Funder: ZonMw (Nederlands)

Template: UMC Utrecht DMP

Project abstract:

Rationale: Er is in de Nederlandse medisch-specialistische revalidatie behoefte aan een generiek meetinstrument waarmee de meerwaarde van (poli)klinische revalidatie op het niveau van de domeinen zelfredzaamheid, participatie, eigen regie en kwaliteit van leven zichtbaar kan worden gemaakt. In een eerdere fase van het onderzoek is een selectie van meetinstrumenten voor het meten van deze domeinen gemaakt.

Objective: (1) Wat is de test-hertest betrouwbaarheid van de geselecteerde meetinstrumenten bij revalidatiepatiënten? (2) Wat is de responsiviteit van de geselecteerde meetinstrumenten voor veranderingen tijdens de revalidatie?

Study design: Prospectief cohortonderzoek waarbij revalidanten bij de start de van de revalidatiebehandeling (klinisch of poliklinisch) en zes maanden later een vragenlijst invullen.

Study population: Klinische en poliklinische revalidanten met een recente aandoening afkomstig uit verschillende revalidatiecentra en revalidatieafdelingen van algemene en universitaire ziekenhuizen.

Intervention: niet van toepassing.

Main study parameters/endpoints: Test-hertest betrouwbaarheid en responsiviteit van de verschillende meetinstrumenten.

Nature and extend of the burdens and risks associated with participation, benefit and group relatedness: De belasting voor de deelnemers is laag en aan deelname zijn geen risico's verbonden. Deelname heeft ook geen directe voordelen voor de revalidant.

ID: 113549

Start date: 02-01-2023

End date: 01-12-2025

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Meetinstrument voor Uitkomsten van REVALidatiebehandeling in Nederland (MUREVAN) Prospectief cohortonderzoek

1. General features

1.1. Please fill in the table below. When not applicable (yet), please fill in N/A.

| | |
|--|---|
| DMP template version | 30 (don't change) |
| ABR number <i>(only for human-related research)</i> | NA |
| METC number <i>(only for human-related research)</i> | NA |
| DEC number <i>(only for animal-related research)</i> | NA |
| Acronym/short study title | MUREVAN |
| Name Research Folder | 22-000_MUREVAN |
| Name Division | Hersenen |
| Name Department | Revalidatie, Fysiotherapiewetenschap en Sport |
| Partner Organization | De Hoogstraat Revalidatie |
| Start date study | 1-2-2023 |
| Planned end date study | 1-12-2025 |
| Name of datamanager consulted* | Willem Broeder |
| Check date by datamanager | NA |

1.2 Select the specifics that are applicable for your research.

- Multicenter study
- Prospective study
- Non-WMO
- Use of Questionnaires

Het is een longitudinaal vragenlijst onderzoek. Gecoördineerd vanuit het KCRU (UMC Utrecht en De Hoogstraat). De verwachting is dat het onderzoek niet WMO-plichtig is. De check hiervoor loopt nog.

2. Data Collection

2.1 Give a short description of the research data.

| Subjects | Volume | Data Source | Data Capture Tool | File Type | Format | Storage space |
|--|--------|------------------------------------|--|-------------|--------|---------------|
| Klinische en poliklinische revalidanten met een recente aandoening afkomstig uit verschillende revalidatiecentra en revalidatieafdelingen van algemene en universitaire ziekenhuizen | 700 | Vragenlijsten: begin en eindmeting | Vragenlijsten worden afgenomen m.b.v. Castor of op papier (voorkeur deelnemer) | Kwanitatief | .sav | 0-5 GB |
| Klinische en poliklinische revalidanten met een recente aandoening afkomstig uit verschillende revalidatiecentra en revalidatieafdelingen van algemene en universitaire ziekenhuizen | 100 | Vragenlijst | Vragenlijsten worden afgenomen m.b.v. Castor of op papier (voorkeur deelnemer) | Kwanitatief | .sav | 0-5 GB |
| | | | | | | |

2.2 Do you reuse existing data?

- No, please specify

Data om onze onderzoeksvraag te kunnen beantwoorden zijn niet beschikbaar. Er moeten nieuwe data verzameld worden.

2.3 Describe who will have access to which data during your study.

| Type of data | Who has access |
|-------------------------|---|
| Persoonlijke data | PI, coördinerende onderzoeker en onderzoeksassistent van de instelling, datamanager |
| Sleutelbestand | PI, coördinerende onderzoeker, datamanager |
| Gepseudonimiseerde data | PI, coördinerende onderzoeker, onderzoeksteam, datamanager |

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

| # | Question | Yes | No | N/A |
|-----|--|-----|----|-----|
| 1. | Do you use a certified 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 | | |

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

| # | Type of costs | Division ("overhead") | Funder | Other (specify) |
|----|--------------------------|-----------------------|--------|-----------------|
| 1. | Licenties (Castor, SpSS) | Hersenen | | |
| 2. | Data opslag | Hersenen | | |
| 3. | Archiveren | Hersenen | | |
| 4. | | | | |
| 5. | | | | |

2.6 State how ownership of the data and intellectual property rights (IPR) to the data will be managed, and which agreements will be or are made.

Alle deelnemende centra en ziekenhuizen zijn eigenaar van hun eigen data. De data worden centraal vanuit het UMC Utrecht verzameld. Hierover worden met de deelnemende centra en ziekenhuizen afspraken gemaakt en deze wordt vastgelegd in contracten.

3. Personal data (Data Protection Impact Assessment (DPIA) light)

Will you be using personal data (direct or indirect identifying) from the Electronic Patient Dossier (EPD), DNA, body material, images or any other form of personal data?

- Yes, go to next question

I will process personal data. I have checked the full DPIA checklist and I do not have to complete a full DPIA. I therefore fill out this DPIA light and proceed to 3.1.

3.1 Describe which personal data you are collecting and why you need them.

| Which personal data? | Why? |
|--|---|
| Naam, huisadres, telefoonnummer en emailadres van deelnemers | om hen vragenlijsten toe te sturen en te contacten bij geen respons. |
| Geslacht, geboortedatum, nationaliteit, opleiding | om de studiepopulatie te kunnen beschrijven |
| Diagnosegebonden gegevens uit het EPD | om de studiepopulatie te kunnen beschrijven en om een case mix correctie uit te voeren. |

3.2 What legal right do you have to process personal data?

- Study-specific informed consent

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

1. The data are pseudonymized and the linking table to personal data is saved. An authorized person manages the linking table, can re-identify study participants when necessary and deliver, correct or delete the data.

| | |
|-----------------------|--|
| Right of Access | Research data are coded, but can be linked back to personal data, so we can generate a personal record at the moment the person requires that. This needs to be done by an authorized person. |
| Right of Objection | We use informed consents. |
| Right to be Forgotten | In the informed consent we state that the study participant can stop taking part in the research. Removal of collected data from the research database cannot be granted because this would result in a research bias. |

3.4 Describe the tools and procedures that you use to ensure that only authorized persons have access to personal data.

1. 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.
2. We make use of a certified Electronic Data Capture (EDC) tool (Castor). To send surveys, email address will be used in the EDC, but this is encrypted for the users in such a way that users can send emails to subjects without seeing the actual email address. No personal data other than email address will be used in the EDC.

3.5 Describe how you ensure secure transport of personal data and what contracts are in place for doing that.

1. We will not transport any personal data outside the UMCU network drives.

4. Data Storage and Backup

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

The digital files will be stored in the secured Research Folder Structure of the UMC Utrecht.

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

All (research) data is stored on UMC Utrecht networked drives from which backups are made automatically twice a day by the division IT (dIT).

During data collection, automatic backups will be made in the Electronic Data Capture Tool Castor. Upon completion of data collection, all data are exported and saved in the Research Folder Structure where they are automatically backed up by the UMC Utrecht backup system.

5. Metadata and Documentation

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

For the data collected in Castor, a codebook of my research database is available in Castor. We do not use metadata standards yet.

5.2 Describe your version control and file naming standards.

We will distinguish versions by indicating the version in the filename of the master copy by adding a code after each edit, for example V1.1 (first number for major versions, last for minor versions). The most recent copy at the master location is always used as the source, and before any editing, this file is saved with the new version code in the filename. The file with the highest code number is the most recent version and older versions are moved to a folder OLD.

6. Data Analysis

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

I have written an analysis plan in which I state why I will use which data and which statistical analysis we plan to do in which software. The analysis plan is stored in the project folder (research protocol).
We will be using SPSS, version 25, for statistical analysis of the data. The syntax will contain comments, such that every step in the analysis is documented

7. Data Preservation and Archiving

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

Onderzoeksprotocol, vragenlijsten, ruwe data, codeboek van de vragenlijsten en SPSS syntax.

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

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

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.

After finishing the project, the data package will be stored at the UMC Utrecht Research Folder Structure and is under the responsibility of the Principal Investigator of the research group. When the UMC Utrecht repository is available, the data package will be published here.

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

NVT

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.

Er zijn geen plannen om de data te herbruiken, maar vanuit de subsidieverstrekker ZonMw bestaat de wens om data vindbaar, toegankelijk en herbruikbaar te maken (FAIR principes).

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)

4. Our data (personal data is extracted from the dataset) will be shared with third parties after approval of the Principle Investigator. The criteria and time period will be determined on a case-by-case basis.

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 restrictions.
2. Along with the publication, the codebook of the data and scripts of analysis in SPSS/Matlab/R/Python will be available.

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

- (Meta)data will be available upon completion of the project

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

EASY (DANS)