Plan Overview

A Data Management Plan created using DMPonline

Title: Symptom Management Essentials at Home (SMEtH)-study

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Template: UMC Utrecht DMP with DPIA

Project abstract:

Rationale: Despite the current national quality guidelines, symptom management in patients and family caregivers with a life-limiting illness, receiving domiciliary palliative care in the Netherlands, is still suboptimal. Barriers that have been identified are the identification of patients with PC needs, the collaboration with GPs and other caregivers, knowledge on quality of pc at home and optimizing autonomy, communication, and competences. To support nursing teams in the provision of palliative care, the method Palliative Reasoning has been developed, which is a systematic symptom management approach.

Objective: The aim is to determine the effect of the Palliative Reasoning methodology on perceived symptoms of patients and family caregivers dealing with a life-limiting illness and receiving palliative care at home by implementing this methodology in homecare nursing teams.

Design: Pragmatic open-label multicenter cluster randomized controlled trial.

Population: Patients (≥18 years) dealing with a life-limiting illness and with a life expectancy of less than one year, receiving palliative care by nursing teams working in homecare organizations and their family caregiver.

Primary study parameter: perceived symptom control of patients and family caregivers dealing with a life-limiting illness, after one month of implementing the SMEtH-intervention, measured with a one item question “Do you feel your symptoms are under control? Yes/No?”.

Statistical analysis: Mixed effects logistic regression analysis, controlled for age, gender, primary diagnosis, and performance status.

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Symptom Management Essentials at Home (SMEtH)-study

1. General features

1.1. Acronym/short study title

SMEtH-study

1.2 Division

- Julius Centrum (Julius Center)

1.3 Department

Department General Practice and Nursing Science

1.4 Path of the Research Folder

\\ds\data\JC\Datamanagement\Research\ Cancer\SMEtH

1.5 WMO/DEC

- non-WMO

1.6 ABR number (only for human-related research)

n.v.t.

1.7 METC number (only for human-related research)

n.v.t.

1.9 Research type(s)

- Use of questionnaires

1.10 Research design(s)

- Interventional

Cluster Randomized Controlled Trial

1.11 Mono or multicenter study (one choice)

- Monocenter

1.13 Which organisation is the sponsor of the study?

ZonMw

1.14 Name of datamanager consulted

Sander van Beekhuizen

1.15 Last check date by datamanager

2023-07-25

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)
- Nederlandse gedragscode wetenschappelijke integriteit
- Gedragscode Gezondheidsonderzoek (Dutch)
- Wet op de Geneeskundige Behandelingsovereenkomst (WGBO) or Medical Treatmants Contracts Act
- Algemene Verordening Gegevensbescherming (AVG) or General Data Protection Regulation (GDPR)

2. Data Collection

2.1 Give a short description of the research data.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format
Human	500	EPD	Secured server, Julius Centre	Quantitative data	.csv
Human	50	Questionnaires	Castor	Quantitative data	.csv
Human	100	Voice recordings	Secured server, Julius Centre	Qualitative data	m4.a
Human	100	Transcripts	Secured server, Julius center	Qualitative data	.doc
Human	25	observations/reports	Secured server, Julius Center	Qualitative data	.doc

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>

Nursing teams and the contact person working at Icare and AxionContinu select eligible patients --> nursing teams ask patients and their family caregiver to fill in the surveys --> surveys are handed out to the research team trough the contact person of each nursing team --> research team store the data in Castor and analyse the data with R and/or SPSS.

Alongside the effect study a process evaluation will be carried out. This process evaluation is not mentioned in the study protocol of SMEtH, but has its own individual protocol. The flow of the data for the process evaluation part of this study is as follows: Zorgbelang Inclusief will guide the discussions with the focus groups --> observations are made by the research team during the focus groups --> observations focus groups are reported in Word.

Individual nurses are approached by the contact person of each nursing team to participate in semi-structured interviews --> interview of around 45-60 minutes is carried out by means of a topic guide --> interviews are recorded (with permission of the nurse) with a certified voice recorder from the UMC Utrecht --> Interviews are transcribed verbatim by the research team in Word -->

transcriptions are analyzed by the research team in NVivo.

2.3 Estimated storage space for your project

- < 250 GB (e.g. questionnaires, textfiles)

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

- No, please specify

We do not reuse data. Quantitative data is gathered after the implementation of the Palliative Reasoning intervention by means of surveys that are filled in by patients, their family caregivers and the nursing staff.
To make sense of the survey results and understanding the process of the implementation of the intervention, semi-structured interviews and focus groups will be carried out. For this part of the study a separate protocol is developed.
All data that will be generated will therefore be new data.

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

#	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.	License fee Castor			ZonMw	
2.	Datamanager		ZonMw		
3.	Storage	x			
4.	Archiving	x			

2.8 Which contracts are in place?

Organization	Contract Type with UMCU	Role organization
AxionContinu	Consortium Agreement	Homecare organization where the intervention will be implemented and patients and family caregivers will be studied.
Zorgbelang Inclusief	Consortium Agreement	advisory and participatory role by guiding the conversation with the healthcare professionals as part of the process evaluation and by taking part in the development of end products.
Icare	Consortium Agreement	Homecare organization where the intervention will be implemented and patients and family caregivers will be studied.
ROC Midden Nederland	Consortium Agreement	advisory and participatory role by participating in guiding panels in to develop end products that are adapted to the education system
Hogeschool Utrecht	Consortium Agreement	advisory and participatory role by participating in guiding panels in to develop end products that are adapted to the education system
Integraal Kankercentrum Nederland	Consortium Agreement	advisory and participatory role by participating in the steering group and taking part in the development of end products.

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

Data will be collected by researchers of the EPZU research team. In collecting Data the research team will not be collaborating with other parties.

Contact persons in each nursing team will be in contact with all individual participants. If the decision is made to use local researchers to collect data from participants instead of researchers of the EPZU, in light of the feasibility of the study, a contract will be drafted that fit the tasks and responsibilities of that specific context. Consequently, this DMP will be adjusted according to the latest amendments.

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

Castor will be used to collect and store the data collected from the surveys and to collect patients' baseline measurements that will be asked.

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?

- No --> Skip to 3.6 if both 3.1 and 3.3 are No

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?
UMCU	Controller	NL	Yes
Castor	processor	EEA	Yes

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 contact participants, after being approached by the nursing staff and giving consent to participate in the study. The research team will inform the patients about the study.
Address	-
Telephone number	To contact participants, after being approached by the nursing staff and giving consent to participate in the study. The research team will inform the patients about the study.
Email	To contact participants, after being approached by the nursing staff and giving consent to participate in the study. The research team will inform the patients about the study.
Age (if fine grained)	Description of study population
Date of birth	-
Gender	Description of study population
Imaging e.g. MRI, pictures or video (can be health data)	-
Sound recordings (may be health data)	-
Location data (e.g. postal code)	-
Personal interests	-
Other -> describe below	Education level and employment status nurses, duration of current employment in order to successfully implement the intervention.

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

- Other --> describe
- Patients

Family caregivers of palliative 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.

All data will be pseudonymised through a code. The key file will be stored in the privacy research folder within the Julius data management environment. The content of this folder will be stored separately from the data containing the pseudonymised data and will only be accessible to the PI and datamanager.
Qualitative data consists of transcribed interviews, which also will be pseudonymised by means of a code (relevant) or X (irrelevant).

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

- Yes, I collect pseudonymized data from subjects in a questionnaire, I do not need to know the identity of the subject

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.

- SOPs about how to deal with a subject’s right on access, rectification, deletion and objection of their personal data
- Clear retention period(s)
- Role specific access to identifying data
- SOPs about who and how an employee has access
- Pseudonymization of data

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

- Yes, explain

Prior to the start of the study, informed consent will be obtained from all participants. The consent form will contain a section dedicated to the reuse of data for other research questions. Participants can consent to the reuse of data by checking the checkbox. This procedure will be submitted to the MREC of the UMC Utrecht.

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.

- 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,

The data are pseudonymised 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. The procedure can be found: Julius Center datamanagement.
Right of objection : informed consent is used for every substudy.
Right of rectification; during interviews, summaries will be used to provide the participants the chance to rectify what is understood by the researcher.

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

- We make use of the DRE, a cloudplatform with standard isolated workspaces that are only accessible to users with Multi-Factor Authentication (MFA). Access to data in workspaces is role dependent. The roles 'owners' and 'accountable' can download data directly. Who gets the role 'owner' is decided by the Accountable. This person is responsible for assigning the right role to the right person. The supplier anDREa B.V. does not have access to data in the workspaces. Only pseudonymized and anonymized data may be used.
- We make use of a certified Electronic Data Capture (EDC) tool (Castor), with user roles defined in such a way that user accounts only have access to patients from own center with the necessary role to add, view, edit and export data, except for the sponsor of the study
- 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

Type of data	Who has access
Direct identifying personal data	research teams, datamanager
Key table linking study specific IDs to patient IDs	PI, datamanager
Pseudonymized data	research team, datamanager

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. Reports and notes that are made in Word of the research process will also be stored in the secured Research Folder Structure of the UMC Utrecht. For analysis, data will be stored in DRE, because we need to install our own software. All files will be stored digitally.

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

All research data will be stored on UMC-Utrecht Networked drives, from which twice a day a backup is made automatically by the dIT.

4.3 Describe how you will take care of archiving and storage and associated costs.

For the storage and backup of the data the standard datamanagement facilities of the UMCU will be used. All data will be stored on a password secured server at the Julius Centre for Health Sciences and Primary Care.
the associated costs are yet unknown.

5. Metadata and Documentation

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

After the project we will place a description of our data in a metadata catalog. The metadata we will collect are raw data, data documentation, documentation of the research process (including documentation of all participants) and syntaxes. We have not yet made a choice as to which archive is most suitable for this type of data.

5.2 Describe your version control and file naming standards.

Project information can be found in the study protocol and in this DMP. In order to keep track on versions the following standards for filenames will be used: Each
file will name will follow a similar structure:
ResearchGroup_ ProjectName_ContentDescription_VersionNumber_Date.
For example, the following file name may be used: EPZU_SMEtH_DMP_V01_26-07-2023

6. Data Analysis

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

The following documents will be made available to make the data analysis procedure insightful for peers:
- Analysis plan
- Syntaxes/scripts
- Codebook
- Analyse notes
- Raw data

7. Data Preservation and Archiving

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

- the study protocol describing the methods and materials,
- the script to process the data, the scripts leading to tables and figures in the publication,
- a codebook with explanations on the variable names,
- and a ‘read_me.txt’ file with an overview of files included and their content and use.

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 10 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.

We still have to decide which archive we will use. We will probably use DataverseNL, however, this is still not completely decided. As soon we decided which archive to use, this DMP will be updated.

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

The archive we choose will determine which persistent identifier will be used. However, this is still unknown.

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.

The researchteam will be reusing the research data of SMEtH to generate new research questions.
The raw data might be of interest for other researchers in the field of palliative care. A request for verification or further investigation of the data can be submitted to the SMEtH-research group. All data will be made available, with the exception of traceable data. In the event that peers like to reuse our data, this can only be granted if the research question is in line with the original informed consent signed by the study participants. Every application will be screened upon this requirement. If granted, a data usage agreement is signed by the receiving party.

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)

1. As the data is privacy-sensitive, we will publish the descriptive metadata in the data repository with a description of how a data request can be made (by sending an email to the corresponding author). In the event that peers like to reuse our data, this can only be granted if the research question is in line with the original informed consent signed by the study participants. Every application will be screened upon this requirement. If granted, a data usage agreement is signed by the receiving party.
2. Our data 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.

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

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

- (Meta)data will be available after completion of project (with embargo)

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

1. We will use DataverseNL as a repository for our research data, we will follow the UMC Utrecht guidelines for publishing research data.