Plan Overview

A Data Management Plan created using DMPonline

Title: Audio-recorded consultations in which physicians and patients use encounter patient decision aids aimed at improving shared decision making and integrating the personal perspective

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Affiliation: UMC Utrecht

Template: UMC Utrecht DMP

Project abstract:

Background: Shared decision-making (SDM) is the process in which a healthcare choice is made jointly by clinicians and patients. The third step in the process of SDM is to elicit the patient's relevant contextual information. To support the SDM process, a myriad of tools exist, for example encounter patient decision aids (ePDAs), such as the Dutch 'Consultkaarten'. Contextual information can be divided in to the medical context (physical characteristics of a disease) and the personal perspective, such as the social environment, values in life, mental health and activities of daily living. It is unclear if, and if so to what extent, the personal perspective is elicited during an encounter between a medical specialist and the patient while they use ePDAs. Objective: To examine if and to what extent the personal perspective is elicited during the clinical encounters as part of the SDM process wherein ePDAs are used, analyzed from the observer's viewpoint. Study design: For this prospective study we will use a qualitative design with observations of clinical encounters of medical specialists in outpatient clinics using audio recordings to analyze based on a observer's perspective and ask patients to fill the collaboRATE SDM instrument, a short questionnaire. Study population: The study population consists of patients with ovarian cysts, psoriasis, high blood pressure, or uveitis. Encounters are eligible for recording if the applicable ePDA was used during the consultation. Main study outcome: Whether the personal perspective was elicited analyzed from the observer's viewpoint. If yes, we're interested in which contextual factors were discussed as part of the personal perspective. Nature and extent of the burden associated with participation, benefit and group relatedness: Participating medical professionals are expected to attend a "kickoff meeting". Furthermore, during the preparation phase several observation days are planned which may require time of the participating medical professionals. Patients are asked to fill in a short questionnaire after the encounter in which the ePDA is used. No further action is required of the participating patient. Discussion: This study will gain insight whether and to what extent the personal perspective is discussed during clinical encounters while ePDAs were used. This will be studied based on the observer's perspective.

ID: 78630

Start date: 14-06-2021

End date: 31-12-2021

Last modified: 17-06-2021

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Audio-recorded consultations in which physicians and patients use encounter patient decision aids aimed at improving shared decision making and integrating the personal perspective

1. General features

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

DMP template version	29 (don't change)
ABR number (only for human-related research)	N/A
METC number (only for human-related research)	TBD
DEC number (only for animal-related research)	N/A
Acronym/short study title	ARC-SDM
Name Research Folder	xx-xxx_ARC-SDM
Name Division	Surgical Specialties
Name Department	Ophtalmology
Partner Organization	RadboudMC
Start date study	15-06-2021
Planned end date study	31-12-2021
Name of datamanager consulted*	Dax Steins
Check date by datamanager	02-06-2021

1.2 Select the specifics that are applicable for your research.

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

Audio opnames worden gemaakt.

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
human	20	audio opnames		audio	.mp3	0-10GB
human	20	questionnaire	LimeSurvey (certified by Radboudumc)	Quantitative	.csv	0-10GB

2.2 Do you reuse existing data?

- No, please specify

Er worden nieuwe audio opnames gemaakt en een vragenlijst afgenomen bij patiënten.

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

Type of data	Who has access
pseudomized data	research team
Key table linking study specific IDs to Patient IDs	PI (with care relationship to patient), 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

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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.	datamanager	x		
2.	Design of eCRF			RadboudMC
3.	Data Capture Tool license fee			RadboudMC
4.	Questionnaire license fee			RadboudMC
	Storage	x		
5.	Archiving	x		

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.

Eigenaarschap en intellectueel eigendom is vastgelegd in de Study agreement, opgesteld voor deze studie, tussen het UMCU en het Radboudumc. Het Radboudumc heeft de intellectual property rights (Zie study agreement) en is ook eigenaar van de data, m.u.v. de linking key file en informed consent formulieren.

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?

- No, go to 4.1

4. Data Storage and Backup

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

1. The digital files will be stored in the secured Research Folder Structure of the UMC Utrecht. We will need +/- 50 GB storage space, so the capacity of the network drive will be sufficient. Paper dossiers will be stored safely in a locked cabinet in a locked room in the UMC Utrecht. A project specific procedure is in place for access to the paper dossiers. Documentation of this procedure is stored in the Research Folder Structure.

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).

5. Metadata and Documentation

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

WE do not use metadata standards.

5.2 Describe your version control and file naming standards.

We will keep track of changes using descriptions of changes per datestamp for each file in a separate Word document.

6. Data Analysis

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

1. 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, so it is findable for my peers.

7. Data Preservation and Archiving

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

1. The data package will contain: the raw data, 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. These files are available on the secured servers (H-disk) of the RAdboudumc (and will not be stored on the UMCU servers)

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 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.

1. 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.

1. I cannot publish the dataset in an external repository. Therefore, I do not have a PID.

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. The raw data can be of interest for other researchers or for spin off projects.

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)

Privacy overweging van dokter en patient bij audio opnames; de ingevulde vragenlijsten zijn wel op te vragen.

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.

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

- Other (please specify)

Op aanvraag en na beoordeling

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

not available