Gastmans Initial DMP

Project Name Electronic Tracking Devices in Dementia Care: An Ethical Analysis
Grant Title G0A5822N
Principal Investigator / Researcher Chris Gastmans
Project Data Contact Jared Howes; +3216372182; jaredmichael.howes@kuleuven.be
Description The project goal is to develop an ethical framework for the design, development, and use of electronic tracking devices in dementia care. The project uses empirical-ethical approach, combining qualitative and conceptual research methods. The nature of collected data will include content analysis of electronic tracking device company websites, personal data as part of a qualitative interview study, and personal data as part of a focus group study. These data will be used to directly inform and shape the development of the final framework.
Institution KU Leuven

1. Data Description
What data will you collect or create? Fill out the table below and/or describe.

Type of data	Format	Volume	How created?
WP1. Archived websites	PDF of websites.	300 - 500 MB	Included webpages will be saved as PDF's by using the print function of the Firefox web browser.
WP2. Qualitative interview data: 20 interviews	Audio-recorded and stored uncompressed Mp4 format; transcribed into MS word format	10-15 GB	Interviews conducted over Microsoft Team meetings.
WP3. Systematic review - Academic articles	PDF files stored and catalogued in an Endnote library	300-500 MB	Collected via systematic review methods.
WP4. Qualitative focus group data: 3 focus groups of 10 persons	Audio-recorded and stored uncompressed Mp4 format; transcribed into MS word format	10-15 GB	Three separate focus groups conducted in person.

Do you intend to reuse existing data?
No. All data used in this project will be collected by the researcher.

Do you use personal data (i.e. all data possibly identifying an individual)?

- Yes

The interview study (WP2) and focus group study (Wp4) involve personal data.

The interview study (WP2) methods and protocol have undergone ethical review at KU Leuven Sociaal-Maatschappelijke Ethische Commissie (SMEC): reference number: G-2021-3903

2. Documentation and Metadata
Describe the documentation that will be created for the data. This section deals with the way in which you will document how the dataset was created and subsequently processed.

Overall, each study meta-data will be stored on the institutional OneDrive account of the Senior Researcher. A read me file will be created for the saved data describing the contents and how they are organized. This will include a glossary of acronyms used in the file system.

1. For the systematic review, the methodology and methods will be reported in detail within a word document (e.g., the inclusion and exclusion criteria). The search strings used will be preserved in individual word documents named after the database for which the string is meant (e.g., Embase search string.docx). Individual conceptual schemes will be provided for each included article, and a combined overall conceptual scheme will be preserved in a Miccrosoft Word document. The overall scheme and demographics of the included articles will be stored as tables in a Microsoft Excel workbook.

2. For the website content analysis: a detailed description of the website selection process,

including the date on which websites were archived will be recorded in a Microsoft Word file. A full PDF image of each included webpage will be made and preserved.

3. For the interview study: A codebook will be created that will contain the following information - Label or name of the code, name of the person that has conducted the coding, date of the coding, definitions and descriptions of codes and concepts, information on the relations between the codes and concepts that will be used. The codebook will be created in Excel, and descriptions will be integrated into the excel workbook itself. Additionally, a short report will be created detailing the conditions of the interview. A pseudonymous transcript will be made from the recorded interviews (note: audio files will be destroyed at conclusion of study and not preserved) and preserved in a Microsoft Word document. Each participant will receive a code and the related reports and transcripts will be placed into a folder named after their code.

4. For the focus group studies: A codebook will be created containing the following information- label or name of the code, name of the person that has conducted the coding, date of the coding, definitions and descriptions of codes and concepts, information on the relations between codes and concepts that will be used. The codebook will be created in excel and given a descriptive file name (e.g., KUL ETD interview codebook). Pseudonymous transcripts will be created of each focus group (note: audio files will be destroyed at conclusion of study and not preserved) in a Microsoft Word document. Data created from each focus group will be stored together under a file with the name and date of the focus group (e.g., Focus group 1 - 19/02/2022).

Describe the metadata for the data. This section deals with metadata: information contained in your dataset about the research data.

The metadata will be reported following the KU Leuven research data repository template in a read me file.

The read me file will consist of at minimum: Title of the data set, Authors of the data set (including family names, ORCID ID's, organization affiliation (e.g. Associatie KU Leuven), and department/faculty affiliation. The FWO grant associated with the collection of the data set. Contact information for the senior researcher will be included. A description with a summary of the purpose, nature, and scope of the data set, a list of defining key terms used in the data set. A full bibliographic citation to any publications that are based on the data set. Additionally, the technical format of included files (e.g., .docx, .xml, .pdf) will be included.

3. Ethical, Legal and Privacy Issues
Are there any ethical issues concerning the creation and/or use of the data?

WP2 (interview study) and WP4 (Focus group study) include research involving human participants and therefore certain ethical issues.

There are two issues related to data storage and preservation. First, all data will undergo a pseudonymization process whereby identifying data (e.g., name or place of employment) will be permanently removed from the transcript and other documents and replaced by a unique random code. The key to the data will be stored separately from the pseudonymized data and will be only available to the primary researcher. The key is preserved in the case a participant wishes to exercise their rights to access, rectify, or erase data.

Participants have the right to withdraw their consent to participate any time before, during, or after participation; however, the data is being processed under the GDPR on the basis of public interest and therefore relevant data may be utilized if essential to the study.

Collected, pseudonymized data will be stored for a length of ten years, in accordance with the policies of KU Leuven.

As of June 7th, 2022, the interview study has undergone ethical review by the Sociaal-Maatschappelijke Ethische Commissie (SMEC) (see file: G-2021-3903). The focus group study will be submitted to SMEC when appropriate.

Did you consider all issues about copyrights and IPR?

The data will not contain trade secrets, patentable inventions, or be viable for commercial exploitation.

Are the collected data considered to be â€œdata containing personal informationâ€ and are all the requirements about the collection of these data met?

The interview study and the focus group study will involve collecting personal data: name, business address, email, phone number, age, sex, and professional history. Additionally, data defined as "special category data" under the GDPR may also be collected. During an interview or during a focus group, if participants decide to discuss them, philosophical or religious positions may be collected and included in the transcript.

All participants will be informed of the personal and special data that will or may be collected during their participation, they will be informed that their data will be stored for a period of 10 years after the end of the study, and that collected data may still be used if they withdraw their consent.

As of June 7th, 2022, the interview study (WP2) has undergone ethical review by the Sociaal-Maatschappelijke Ethische Commissie (SMEC) (see file: G-2021-3903). The focus group study (WP4) will be submitted to SMEC at the appropriate moment.

4. Data storage and Backup during Research
How and where will the data be stored during research?

- In a cloud service offered by the university

During research activities, data will be stored on the PhD student's KU Leuven institutional Microsoft OneDrive cloud storage account.

Which back-up procedures are in place?

During research activities, data will be stored on the KU Leuven OneDrive cloud storage account of the PhD student, this service takes automatic backups of data.

Describe the data security procedures and who has access to the data.

To ensure data security, KU Leuven standard procedures and good practices of data management will be strictly followed. Additionally, only the PhD researcher, conducting the interviews, will have access to personal identifying information of participants in the interview study (WP2) and focus group study (WP4).

5. Data selection and Preservation after Research
What is the long-term preservation plan for these dataset(s)?

The data will be stored on the university's central servers, with automatic back-up procedures, for at least 10 years in conformity with the KU Leuven RDM Policy.

Data Selection: Which data will have long time value for the research and will be preserved?

Archived websites, conceptual schemes and merged conceptual schemes from WP1. Transcripts, conceptual schemes, merged conceptual schemes, coded transcripts, and code books from both WP2 and WP3.

6. Data Sharing
Are there any restrictions for sharing the data?

Audio recordings of interviews (WP2), and focus groups (WP4) will be destroyed at the conclusion of each study as participants do not give consent for the data to be kept beyond the individual work package.

If there are no restrictions, which mechanisms will be in place to assure that the data are discoverable, accessible and intelligible?

Question not answered.

How will you share the data?

- Repository

Data will be stored in the KU Leuven Research Data Repository.

With whom will the data be shared?

- On request

Access to data will be considered upon receipt of a request explaining the planned reuse. Only uses for research purposes will be allowed. Commercial reuse will be excluded.

7. Responsabilities and Resources

Who is responsible for Data Management during the project? This will be the person who might receive questions on the data management aspects of the research project.

Jared Howes will be responsible for updating and implementing the DMP during the course of the project.

Which additional resources are needed for the execution of the Data Management Plan?

There are no additional costs or resources anticipated in the execution of this data management plan.

Did you read the KU Leuven Data Management Policy? (find the link to the policy in the guidance).

- Yes