Integrated care model for home-dwelling older patients with depression and physical multimorbidity (I-CONNECT)

A Data Management Plan created using DMPonline.be

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Project abstract:

Effective management of depression in elderly people with physical multimorbidity requires integrated care to be provided in a holistic manner. No evidence is available for integrated care models for the management of depression in older patients with physical multimorbidity, although more than two thirds of the older patients attending a psychiatric service have at least one physical comorbidity. The overarching goal of this research project is to develop and evaluate an integrated care model (I-CONNECT program) for home-dwelling older patients with depression and physical multimorbidity. We will conduct this research project in three phases: a development phase, a feasibility study, and an evaluation phase. The research project will be underpinned by the establishment of the Living Lab for Geriatric Mental Healthcare, to install an innovation culture that fosters the valorisation of research results.

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Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

Dataset name / ID	Description	New or reuse	Digital or Physical data	Data Type	File format	Data volume	Physical volume
		Indicate: ***N****(ew data) or* ***E****(xisting data)*	Indicate: **D**(igital) or **P**(hysical)	Indicate: **A**udiovisual **I**mages **S**ound **N**umerical **T**extual **M**odel **SO**ftware Other (specify)		Indicate: <1GB <100GB <1TB <5TB >5TB NA	
Scoping review	scientific articles	E	D	T	PDF	<1GB	NA
Focus group 1	IC forms and demographics	N	D + P	T	PDF	<1GB	50 pages
Focus group 2	Audio + Teams recordings	N	D	S + A	MP4 + WAV	<1GB	NA
Focus group 3	Transcripts	N	D	T	PDF	<1GB	NA
Focus group 4	Coding tree and concepts	N	D	T	Atlas.ti	<1GB	NA
Interviews 1	IC forms and demographics	N	D	T	PDF	<1GB	NA
Interviews 2	Audio recordings	N	D	S	MP4	<1GB	NA
Interviews 3	Transcripts	N	D	T	PDF	<1GB	NA
Interviews 4	Coding tree and concepts	N	D	T	Atlas.ti	<1GB	NA
Workshops 1	IC forms and demographics	N	D	T	PDF	<1GB	NA
Workshops 2	Posters and post-its	N	P	T	Paper	NA	15 posters with sticky notes
Feasibility 1*	IC forms	N	D	T	PDF	<1GB	NA
Feasibility 2*	EHR extractions	E	D	N, T	PDF	<1GB	NA
Feasibility 3*	Interviews IC forms and demographics	N	D	T	PDF	<1GB	NA
Feasibility 4*	Interviews audio recordings	N	D	S	WAV	<1GB	NA
Feasibility 5*	Interview transcripts	N	D	T	PDF	<1GB	NA
Feasibility 6*	Interview coding tree and concepts	N	D	T	Atlas.ti	<1GB	NA
Feasibility 7*	FIM questionnaire	N	D	T	PDF	<1GB	NA
CCT 1*	IC forms and demographics	N	D	T	PDF	<1GB	NA
CCT 2*	Patient questionnaires: P3CEQ, GFI, ACCI, PHQ-9, EQ-5D-5L	N	P	N	Paper	NA	3000 pages
CCT 3*	EHR extractions (polypharmacy, PIM, ED visits, hospital admission rate, QALYs, ...)	E	D	N, T	PDF	<1GB	NA
CCT 4*	Interview audio recordings	N	D	S	WAV	<1GB	NA
CCT 5*	Interview transcripts	N	D	T	PDF	<1GB	NA
CCT 6*	Interview coding tree and concepts	N	D	T	Atlas.ti	<1GB	NA
CCT 7*	Meeting reports	N	D	T	PDF	<1GB	NA
Living Lab*	Meeting reports	N	D	T	PDF	<1GB	NA

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

- The scoping review included 40 studies from MEDLINE, EMBASE, CINAHL and Cochrane Library. This review is currently submitted for publication.
- We will extract data from electronic patient records (EHRs) in this study, both in the University Psychiatry Hospitals in UPC KU Leuven campus Kortenberg, and UPC Duffel.

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, refer to specific datasets or data types when appropriate and provide the relevant ethical approval number.

- Yes, human subject data (Provide SMEC or EC approval number below)

For the focus groups, interviews and workshops, we obtained approval of the EC UZ Leuven under the number S66783.
For the feasibility study, we will submit a protocol to obtain ethical approval by November 2023. We first need the results of the first phases of the research project to be able to design the intervention, and thus the feasibility and mixed methods evaluation.
The protocol of the CCT will be written at the end of the feasibility study.

Will you process personal data? If so, please refer to specific datasets or data types when appropriate and provide the KU Leuven or UZ Leuven privacy register number (G or S number).

- Yes (Provide PRET G-number or EC S-number below)

S66783
+ approval for feasibility study and CCT to be obtained later

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type

where appropriate.

- No

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material or Data transfer agreements, Research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- No

Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g. in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, codebook.tsv etc. where this information is recorded).

- For qualitative data (from focus groups and interviews), we will make use of software to generate documentation and metadata. We will use Atlas.ti web version because this enables researchers to work together on a project in the cloud. (not possible with the NVivo version at KU Leuven) We will document the meaning of the codes, and make a list of our files.
- For the patient questionnaires, we will code every question as a variable. For every variable, we will define measurement units, missing data, and assign labels. These questionnaires will be given to patients on paper. Details about these questionnaires will be available later in the research project. The choice of questionnaires still can change, according to the results of the first phases of the project.

Will a metadata standard be used to make it easier to find and reuse the data?
If so, please specify which metadata standard will be used.

If not, please specify which metadata will be created to make the data easier to find and reuse.

- No

Data Storage & Back-up during the Research Project

Where will the data be stored?

- Shared network drive (J-drive)
- Other (specify below)

Redcap, a secure web application for building and managing online surveys and databases.

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution

Is there currently sufficient storage & backup capacity during the project?

If no or insufficient storage or backup capacities are available, explain how this will be taken care of.

- Yes

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

All digital data will be stored on the Shared Network Drive of KU Leuven or in the Redcap project software. Only the members of the research team will have access to the research data via their KUL username and password.
All physical data will be stored in labelled boxes in the archive of the Academic Center for General Practice at KU Leuven, which is a locked room.

What are the expected costs for data storage and backup during the research project? How will these costs be covered?

Shared Network Drive of KU Leuven: no cost
Redcap: €80 per year (covered by funding)

Data Preservation after the end of the Research Project

Which data will be retained for 10 years (or longer, in agreement with other retention policies that are applicable) after the end of the project?

In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

- Certain data cannot be kept for 10 years (explain below)

All data will be kept for 10 years, except the video and audio recordings of the qualitative studies (focus groups and interviews). These will be destroyed after data analysis. Only the verbatim transcripts will be preserved for 10 years.

Where will these data be archived (stored and curated for the long-term)?

- Shared network drive (J-drive)
- Other (specify below)

After the project has ended, all data from the Redcap project will be extracted and transferred to the Shared network drive.

What are the expected costs for data preservation during the expected retention period? How will these costs be covered?

Only Redcap license costs €80 per year. The project lasts 6 years, thus this will cost €480.
This cost is foreseen in the project budget.

Data Sharing and Reuse

Will the data (or part of the data) be made available for reuse after/during the project?
Please explain per dataset or data type which data will be made available.

- No (closed access)

If access is restricted, please specify who will be able to access the data and under what conditions.

The data will be accessible for the PI (Mieke Vermandere), the two PhD-students who will work on the project (Laura Tops, and the second one still to appoint), and the study nurse (also needs to be appointed in a later phase).

Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

Please explain per dataset or data type where appropriate.

- Yes, privacy aspects

All data will be handled with full confidentiality during the project. No personal data will be misused and only the information provided by respecting the law on the protection of privacy (08.12.92) will be stored. All personal information of the participants will be pseudonymised, and the collected data will only be used for data analysis related to this study purposes. Each participant will receive a numeric code. This code will only be used to link the research data to the demographic data, but not to identify the participants afterwards. After the data analysis, audio recordings will be destroyed. We will save the names and e-mail addresses of the participants (on the secured KU Leuven server) to send them the research paper(s) once it is published, but we will not save a key to link these names and e-mail addresses to the research data or the numeric codes of participants. Therefore, this is an anonymization process, and not a pseudonymisation. The list with names and e-mail addresses will be destroyed once the study results have been sent to the participants.

Where will the data be made available?

If already known, please provide a repository per dataset or data type.

- KU Leuven RDR (Research Data Repository)

When will the data be made available?

- Upon publication of research results

Which data usage licenses are you going to provide?

If none, please explain why.

- Other (specify below)

All files will be restricted because of privacy aspects (see above).
No licence will be granted.

Do you intend to add a persistent identifier (PID) to your dataset(s), e.g. a DOI or accession number? If already available, please provide it here.

- Yes, a PID will be added upon deposit in a data repository

What are the expected costs for data sharing? How will these costs be covered?

No expected costs.

Responsibilities

Who will manage data documentation and metadata during the research project?

The two PhD students who will work on the project, together with the research nurse, will manage data documentation and metadata during the research project.
The supervisor has the end responsibility and will manage long term preservation and sharing.

Who will manage data storage and backup during the research project?

The two PhD students who will work on the project, together with the research nurse, will manage data storage and backup during the research project.

Who will manage data preservation and sharing?

The supervisor of the project will manage data preservation and sharing.

Who will update and implement this DMP?

The supervisor of the project will update and implement this DMP.