Plan Overview

A Data Management Plan created using DMPonline.be

Title: Sexual Rehabilitation in Couples Confronted with Penile cancer

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Template: FWO DMP (Flemish Standard DMP)

Project abstract:

Penile cancer, though rare, poses significant challenges to affected individuals, impacting physical, mental, and social dimensions of health. Current treatment involves surgery, affecting sexual well-being and quality of life. Psychosexual support is limited, and there is a lack of evidence-based strategies. This research project aims to fill this gap by developing and evaluating a personalized digital sex-counseling program for couples facing penile cancer.

The study, divided into four work packages, will explore relationship processes during sexual rehabilitation (WP1), investigate gender differences in the usage of existing digital programs (WP2), co-develop and improve a couple sex-counseling program (WP3), and explore real-time usage and effectiveness (WP4). The proposed digital program addresses the unique needs of patients who underwent genital surgery, involving partners, and aligns with current healthcare cost-cutting trends.

Methodologically, the project combines dyadic qualitative and quantitative analyses, involving patients and partners in a collaborative development process. The interdisciplinary approach incorporates inputs from urologists, sexologists, and patient representatives. A pilot trial, adopting web-based tracking and experience sampling, precedes a potential randomized controlled trial.

Anticipated outcomes include valuable insights into sexual challenges, risk factors, and the effectiveness of digital sex-counseling for penile cancer couples. If successful, the program could be a breakthrough in providing much-needed psychosexual support, aligning with professional guidelines, and adapting to the cost-cutting climate. Findings will be transferable internationally, contributing to a more comprehensive understanding of sexual rehabilitation in diverse patient populations.

This innovative project marks a crucial step towards improving the quality of life for penile cancer patients and their partners, emphasizing patient-centered care and addressing a significant gap in current healthcare practices.

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Sexual Rehabilitation in Couples Confronted with Penile cancer
FWO DMP (Flemish Standard DMP)

1. 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.

				Only for digital data	Only for digital data	Only for digital data	Only for physical data
Dataset Name	Description	New or reused	Digital or Physical	Digital Data Type	Digital Data format	Digital data volume (MB/GB/TB)	Physical volume
		Please choose from the following options: • Generate new data • Reuse existing data	*Please choose from the following options:* • Digital • Physical	*Please choose from the following options:* • Observational • Experimental • Compiled/aggregated data • Simulation data • Software • Other • NA	*Please choose from the following options:* • .por, .xml, .tab, .csv,.pdf, .txt, .rtf, .dwg, .gml, … • NA	*Please choose from the following options:* • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • NA	
WP1 Dyadic interviews	Audio and video recorded interviews in penile cancer patients and their partners Questionnaires on paper and later digitalized Audio and video recorded interviews Interview transcripts	Generate new data	Digital Physical	Observational	Audio data (.mp3) Video data (.mp4) Textual data (.pdf, .docx) Data analysis (.sav, .spv, .rda, .cvs, .xlsx, .nvpx)	<100GB	Paper questionnaires will be digitalized and stored digitally
WP1 Longitudinal survey	Longitudinal survey in penile cancer patients and their partners Questionnaires on paper and later digitalized	Generate new data	Digital Physical	Observational	Textual data (.pdf, .docx) Data analysis (.sav, .spv, .rda, .cvs, .xlsx)	<100GB	Paper questionnaires will be digitalized and stored digitally

WP3 Program co-development	Co-development and improvement of digital sex-counseling program for couples facing penile cancer Recorded online meetings Digital questionnaires	Generate new data	Digital	Observational	Audio data (.mp3) Video data (.mp4) Textual data (.pdf, .docx)	<100GB	
WP3 Think-aloud interviews	User experience interviews in penile cancer patients and their partners Questionnaires on paper and later digitalized Audio recorded interviews Interview transcripts	Generate new data	Digital Physical	Observational	Audio data (.mp3) Textual data (.pdf, .docx) Data analysis (.sav, .spv, .rda, .cvs, .xlsx, .nvpx)	<100GB	Paper questionnaires will be digitalized and stored digitally
WP4 Feasibility pilot	Experience sampling study with mPath: digital questionnaires Questionnaires on paper	Generate new data	Digital Physical	Observational	Textual data (.pdf, .docx) Data analysis (.sav, .spv, .rda, .cvs, .xlsx)	<100GB	Paper questionnaires will be digitalized and stored digitally

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:

Not applicable

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes, human subject data

Human subject data will be collected in all work packages.
(Survey data and Interview data)

Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes

Personal data will be processed during this research project. Only personal data relevant to the research will be collected and any personal data that is not necessary for further analysis of the data will be deleted. Ethical approval will be obtained before the start of each study.

Personal data used for organizing the research: (i.e. name, phone number, e-mail adress). This data will not be included in the analysis and will be stored separately from the research data.

Personal data for research purpose: for all workpackages participants will be asked to provide their demographics (e.g. age, sex, education), medical history related to research purpose (e.g. treatment type) and subjective experiences/variables (e.g. personal and relational variables, sexuality related variables). These data will be pseudonomyzed.

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.

- Yes

In the 3rd work package, an digital sex-counseling program will be developed and optimized with the goal of providing education and skills training for men faced with penile cancer and their partners during sexual rehabilitation after treatment. The content of the digital program will not consist of any personal data. Importantly, the main goal of the research project is not to commercialise this digital program, but to implement the program sustainably in the health care pathway, ideally free of cost for users.

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material/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

2. 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 documentation and Metadata purposes we will make use of:

- For each study, a study protocol is provided.
- A README file will be provided for each of the studies. We will use KU Leuven's template.
- Codebooks with information about study, files and variables
- All documentation will be stored in the folder where the dataset is stored.

Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type) which metadata will be created to make the data easier to find and reuse.

- Yes

Metadata standard will be automatically applied when depositing data in RDR of KU Leuven.

3. Data storage & back-up during the research project

Where will the data be stored?

Data will be stored on a shared OneDrive for Business folder during active research phases. OneDrive for Business is a Microsoft cloud solution to securely store documents and files. Multifactor authentication with the KU Leuven authenticator app OR additional encryption will be activated to ensure the safe storage of (strictly) confidential data. Only the PI can provide access to the OneDrive for study personnel.
A copy of the data will be stored on a shared network drive (J-drive), only accessible by registered collaborating researchers.

How will the data be backed up?

A back-up is provided via automatic version management of the files in OneDrive, maintaining up to 100 versions per file.
A copy will be kept on the departmental J-drive within the secure KU Leuven environment. Automatic version management of the files occurs when storing data in the KU Leuven datacenters. Version management is done using "snapshot" technology, where the previous versions of the changed files are kept online in a snapshot on the same storage system. A mirror (an exact copy) of the data is provided in the second ICTS data center for “business continuity” or “disaster recovery” purposes; a file is copied to the second data center as soon as it is written to a drive. ICTS can put the copy online within an hour in case of disaster with the primary storage.

**Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely.
If no or insufficient storage or backup capacities are available, then explain how this will be taken care of.**

- Yes

All KU Leuven personnel has access to 250GB of online data storage on OneDrive for business. As the estimated sizes of the datasets <100 GB, sufficient storage and backup capacity is available.
Our research group will have a shared J-drive for long term data storage with a big enough capacity to store the estimated sizes of the datasets at <100 GB.

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

Due to the personal nature of OneDrive, files that you do not explicitly share are not accessible to anyone else. As such, a separate folder will be created and encrypted for each dataset. Only the PI and registered collaborating researchers will have access to these folders via the encryption key.
KU Leuven network drive, specifically J-drive. The KU Leuven network drives are incorporated within secured KU Leuven environments, are password-protected (including smartphone-based multi-factor identification) and are only accessible by registered collaborating researchers. Only the PI can request access to the network drive for study personnel.

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

OneDrive for Business is free for staff and students of KU Leuven.
The Center for Biomedical Ethics and Law will provide a folder on a shared J-drive for data storage. As such, costs will be covered by the Center.

4. Data preservation after the end of the research project

Which data will be retained for at least five 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...).

Digital data: All digitally generated data and physical generated data that is later digitalized will be archived for minimally 10 years after study completion, in line with the KU Leuven RDM policy.

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

Digital data: The generated research data, metadata and documentation necessary to reuse the data will be transferred to the J-drive for long-term data archiving, managed by KU Leuven ICTS with automatic back-up procedures.

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

Digital data: Current costs for the J-Drive are approximately € 58/100GB/year, which will be covered by the research lab of the PI.

5. Data sharing and reuse

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

- Yes, in a restricted access repository (after approval, institutional access only, …)

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

Scientific researchers will have to motivate why they want access to the data:

- What topic are you studying?
- How is the data linked to your research domain?
- Why do you think you need this data?
- Which question/problem will the data help with?
- What do you expect the data to provide you with?

We will always ask to give credit to the original data creators when the data it is being used by other researchers

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 in the comment section per dataset or data type where appropriate.

- Yes, Privacy aspects

We work with personal and confidential data (e.g. name, sex, age, interview transcripts, several subjective perceptions,...). All data will be pseudonomyzed.

Where will the data be made available? If already known, please provide a repository per dataset or data type.

Via RDR, the KU Leuven institutional 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.

Data from the project that can be shared will be made available under a creative commons attribution license (cc-by 4.0), so that users have to give credit to the original data creators.

Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.

- Yes

A DOI will be available through RDR, but is not yet available

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

RDR is free for KU Leuven personnel, hence, no costs are expected for data sharing

6. Responsibilities

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

The PhD Researcher (Camille Roumieux) will be responsible for e for data documentation & metadata, under supervision of the PI (Eline Dancet).

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

Data management, storage and back up will be performed by the PhD researcher (Camille Roumieux), under supervision of the PI (Eline Dancet).

Who will manage data preservation and sharing?

The PI (Eline Dancet) will be responsible for ensuring data preservation and sharing.

Who will update and implement this DMP?

The PhD researcher (Camille Roumieux) will be responsible for updating this DMP. The PI (Eline Dancet) bears the end responsibility for updating and implementing this DMP.