Dietary intervention for disorders of gut-brain interaction: FODMAPs and beyond FODMAPs

A Data Management Plan created using DMPonline.be

Creators: Karen Van den Houte, n.n. n.n.

Affiliation: KU Leuven (KUL)

Funder: Fonds voor Wetenschappelijk Onderzoek - Research Foundation Flanders (FWO)

Template: FWO DMP (Flemish Standard DMP)

Principal Investigator: n.n. n.n.

Grant number / URL: 12B1B24N

ID: 206774

Start date: 01-11-2023

Project abstract:

Two of the most common disorders of gut-brain interaction (DGBI) are functional dyspepsia (FD) and irritable bowel syndrome (IBS), affecting 15% of the population worldwide. A diet with established efficacy in IBS is the low Fermentable Oligo-, Di-, Monosaccharides and Polyols (FODMAP) diet. During my PhD, a blinded reintroduction phase identified individual FODMAP triggers and the efficacy of the diet in FD showed promising results. The diet significantly reduced gastrointestinal symptoms, and this was associated with an improvement in duodenal mucosal permeability. In addition, our group observed improvement of FD symptoms and mucosal integrity with a 6-food elimination diet, which excludes the 6 main allergenic food proteins. Based on these observations, we introduced confocal laser endomicroscopy, a novel technique that allows to assess immediate duodenal mucosal responses and identify triggering food proteins even though the patients lack circulating IgE antibodies to these nutrients. In this research proposal, we will advance our understanding of dietary factors as a trigger for symptoms and improve the ability to use an elimination diet as a therapeutic approach in DGBI. We will conduct detailed interventional and mechanistic studies to assess the relationship between dietary intake, symptom occurrence, duodenal mucosal alterations and gut peptide signaling. In addition, we will unravel the basis of the allergy-like duodenal mucosal responses to food proteins in FD.

Last modified: 29-04-2024

Dietary intervention for disorders of gut-brain interaction: FODMAPs and beyond FODMAPs
Application DMP

Questionnaire

Describe the datatypes (surveys, sequences, manuscripts, objects …) the research will collect and/or generate and /or (re)use. (use up to 700 characters)

During this project, the following information will be collected for patients and healthy controls: spreadsheets with demographics (gender, age, weight, BMI), questionnaires on food-related and gastrointestinal symptoms, severity, psychosocial factors and quality of life impact and biological samples. We will also obtain duodenal biopsies during invasive gastro-duodenoscopy. Images will be made via the software related to confocal laser endomicroscopy in patients and healthy volunteers. This will lead to text notes and eventually manuscripts.

Specify in which way the following provisions are in place in order to preserve the data during and at least 5 years after the end of the research? Motivate your answer. (use up to 700 characters)

The collection and preservation of the data from patients will be the responsibility of the principal investigator. Only researchers involved in the study protocols can review data of patients. We will encourage patients to fill out questionnaires via online programs (Qualtrics/Redcap), which will limit questionnaires on paper. All data will be pseudo-anonymized before storage. The key for pseudo-anonymization will be kept in the secure servers of the University Hospital of Leuven. Afterwards, paper versions of questionnaires or study related material, will be stored via Oasis, an expert company in storage. The pseudo-anonymized data will be stored for at least 5 years.

What’s the reason why you wish to deviate from the principle of preservation of data and of the minimum preservation term of 5 years? (max. 700 characters)

There will be no deviation related to preservation in this project. The pseudo-anonymized data will be stored on the secure servers of UZ Leuven for at least 5 years.

Are there issues concerning research data indicated in the ethics questionnaire of this application form? Which specific security measures do those data require? (use up to 700 characters)

No issues identified based on the ethics questionnaires.

Which other issues related to the data management are relevant to mention? (use up to 700 characters)

No other issued identified related to the data management.

Dietary intervention for disorders of gut-brain interaction: FODMAPs and beyond FODMAPs
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	
Questionnaires	Online questionnaires will be filled out via qualtrics and RedCap. Afterwards, data will be exported via these systems in the form of excel files.	New	Digital	Observational	.csv	<100GB	
Urinary samples	Quantification of urinary histamine levels and N-methyl histamine excretion	New	Physical	Interventional			
Biopsy collection	Duodenal biopsies will be collected during a gastroscopy and stored in the -80 freezer.	Reuse and new	Physical	Interventional			

Ussing chamber experiments	Four duodenal biopsies will be mounted in ussing chambers to define TEER and flux.	New	Physical	Interventional			
EO and MC counting	Based on biopsies, H&E staining and c-kit will be done in order to count eosinophils and mast cells	Reuse and new	Physical	Interventional			
Medical history	Relevant medical history data will be collected via the CRF of each study	New	Digital	Observational	.csv	<1GB	
MRI images	Abdominal MRI acquisitions to quantify gastric emptying, nutrient progression into the small bowel	New	Digital/physical	Interventional/observational	.csv	<1TB	
Blood samples	genetic analysis and to define plasma levels of 5HT and gut peptides	New	Physical	Interventional			

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:

Reuse of my own data collected during PhD and collected in the same way as described above.

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

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

sex
age

date of birth
BMI
medical and surgical history
results of diagnostic tests

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/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).

The electronic database Sharepoint will be used to store data, where all involved researchers can find a clear overview of the data.
Data files will be pseudonimized and the study code numbers will be kept seperately in a clearly marked file (.csv).

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 will be created manually where appropriate (per study participant, per collected data). It will be used to describe date and time of data capturing, coding of questions in
database questionnaires. A clear description of what the data respresents and how it
was generated will be provided, including a description of materials, methodology
design, setup and parameters.

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

Where will the data be stored?

- Sharepoint
- KULeuven OneDrive

How will the data be backed up?

Sharepoint
KULeuven OneDrive

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

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

A password or authenticator log in is needed to enter the data.

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

KU Leuven provides online storage using Sharepoint for free up to 5TB, this will be sufficient for this research project

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...).

All data will be preserved for 10 years according to KU Leuven RDM policy.
All data that are at the basis of publications will be kept and preserved for 25 years.
Data that is likely to be reused within the research unit will also be preserved longer than 10 years.

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

Physical data will be collected at TARGID or biobank.
Paper data will be stored at TARGID and after publication via Oasis.

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

KU Leuven provides storage and back-up using Sharepoint for free up to 5TB, this will be sufficient for this research project

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 an Open Access repository
- 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.

No data transfer agreements at this moment regarding these work packages.

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.

- No

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

Not known at this moment.

When will the data be made available?

After publication.

Which data usage licenses are you going to provide? If none, please explain why.

KULeuven guidelines will be followed.

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

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

The budget will cover storage costs and long-term preservation costs.

6. Responsibilities

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

Karen Van den Houte

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

Karen Van den Houte

Who will manage data preservation and sharing?

Karen Van den Houte

Who will update and implement this DMP?

Karen Van den Houte