Gastric interoception: Towards an improved understanding of interoceptive processes within and across organ domains in healthy individuals and patients with functional dyspepsia

A Data Management Plan created using DMPonline.be

Creator: Tabea Eimer

Affiliation: KU Leuven (KUL)

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Project abstract:

Functional dyspepsia (FD) is a prevalent functional somatic syndrome, which are defined by chronic debilitating bodily symptoms without known physiological cause. FD is characterized by medically unexplained gastric symptoms such as epigastric pain, putting a high burden on the individual. The mechanisms underlying the development and maintenance of such symptoms remain largely unclear. Impaired interoception, the process of how the nervous system integrates and represents information about the inner state of the body, has been proposed as a potential key mechanism. However, the objective assessment of gastric interoception remains difficult, and existing tasks are highly invasive or present numerous limitations. Consequently, there is a great demand for noninvasive and reliable tasks assessing gastric interoception to further our understanding in both healthy individuals and patients with FD. Moreover, a major, yet unanswered question is whether interoception is a general or organ-specific ability. This interdisciplinary proposal aims 1) to improve the measurement of gastric interoception, 2) to investigate on a perceptual and neural level whether interoception is a general ability, and 3) to examine how interoceptive processes in health and FD differ. The results will deepen our knowledge on body brain interactions and potentially direct new treatment approaches in FD.

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FWO DMP (Flemish Standard DMP)

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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
Personal data	Self-reported questionnaire: age, gender	Generate new data	Digital	Observational	.csv, .xlsx, .text, .psydat	<100MB	
Physiological data	EEG, stethoscope recording, respiratory flow	Generate new data	Digital	Experimental	.acq, .csv, .xlsx, .text, .log, .psydat	<1GB	
Imaging data	Fluoroscopy scans	Generate new data	Digital	Experimental	.dcm	<100GB	
Behavioral data	Perceptual responses: ratings	Generate new data	Digital	Experimental	.csv, .xlsx, .text, .log, .psydat	<100MB	
Psychological and physical functioning	Questionnaires	Generate new data	Digital	Experimental	.csv, .xlsx, .text, .log, .psydat	<100MB	

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:

N/A

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

PRET and ethical approval will be obtained before the start of data collection.

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

Names, email addresses, telephone number, bank account number (for inclusion (informed consent) and reimbursement)
Personal data + psychological and physical functioning: age, gender, data concerning physical and mental health (e.g., respiratory flow data, screening for psychological disorders, screening for gastrointestinal disorders)

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

The participants themselves are the only 3rd party. Agreements are thus part of the informed consent, mentioning the publication of results in scientific communications and the (re)use of data by other researchers.

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).

1. Data will be anonymized and uploaded onto the Open Science Framework (OSF) along with relevant code (see below for examples).
2. Raw data files will be kept in a common structure with individual data-files stored within participant sub-folders per experiment. Extracted data will be stored within separate participant sub-folders and aggregated data will be stored under the experiment parentfolder.
3. Physiological data – raw physiological data will be collected per participant and stored with a txt file with a clear description of what the data are and how they were generated (e.g., the input, frequency, run time, setting, etc.). R code that will be used to transcribe the data from its raw format to readable format will be stored and uploaded onto OSF.
4. Behavioral data – raw data from Psychopy (psychological software) will be collected for each participant and stored with a txt file containing the Psychopy python code used to generate the data. The python code will also be published on OSF.
5. Questionnaire data (Psychological and physical functioning) - A codebook will be generated containing study design, sampling methodology, variable-level information (label, question text, codes, frequencies), as well as attached copies of the questionnaire used along with the validation article and scoring criteria.
6. We will create and keep a Standard Operating Procedure (SOP) for the set up and analysis of the experiment.

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.

- No

Metadata will be stored as Microsoft Word/pdf, .txt or .csv file under each experiment parentfolder. In addition, all code and anonymized data will be uploaded to the Open Science Framework with corresponding metadata to aid in re-use by other researchers.

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

Where will the data be stored?

All digital data (questionnaire answers, subjective ratings, behavioral data, physiological

recordings, and neural recordings) will be stored on the KU Leuven Onedrive server of the researcher and will only be accessible by the identified KU Leuven researchers. In addition, the full database will be stored on ReDCAP. Data in paper format (informed consent forms, payment information forms, inclusion/exclusion criteria forms) will be stored separately in a key-locked cabinet in a dedicated archive room of the research group.

How will the data be backed up?

The data will be stored on OneDrive and RedCAP which both have automatic daily back-up procedures.

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

KU Leuven Onedrive allows 2 TB of data storage. RedCAP also allows at least 10 MB of storage.

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

- We will use two-factor authentication to protect the KU Leuven Onedrive account the data is stored on. In addition RedCAP is HIPAA compliant.
- Identifying information (e.g., name) will be replaced with a random unique number. The information that links individual to the unique number will be stored separately on the KU Leuven Onedrive server of the researcher, will be password-protected and will only be accessible by the identified KU Leuven researchers.
- All screens will be locked when not in use.

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

There is no cost associated with data storage and backing up. However, if unexpected costs arise, they will be covered via the bench fee.

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 retained for the expected 5 year period.

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

After completion of data collection, and until 25 years after the end of the project, all digital data will be stored on a secure Health-Psychology archival KU Leuven-based server. The log file linking participants' identity to their participant ID and the payment information form will be destroyed following data collection. Paper data will be destroyed at the end of the project.
Anonymized data will also be uploaded onto the Open Science Framework (OSF) where it can be accessed publicly

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

We expect no additional costs in the retention period of 5 years.

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

The dataset will be anonymized and uploaded to the Open Science Framework.

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

N/A

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.

In an Open Access repository:
The dataset will be anonymized and uploaded to the Open Science Framework.

When will the data be made available?

Immediately after the end of the project

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

Data usage license of type CC-BY-NC-SA will be used.

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

PIDs will be added to the datasets as this is the default on the Open Science Framework.

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

There are no expected costs for data sharing. The Open Science Framework is free of charge.

6. Responsibilities

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

The doctoral student (Tabea Eimer), administrative/technical staff and PI (Andreas von Leupoldt) working on this project.

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

The doctoral student (Tabea Eimer), administrative/technical staff and PI (Andreas von Leupoldt) working on this project.

Who will manage data preservation and sharing?

The PI (Andreas von Leupoldt) of this project.

Who will update and implement this DMP?

The PI (Andreas von Leupoldt) bears the end responsibility of updating & implementing this DMP.