The perpetuum mobile of semi-starvation in anorexia nervosa : the causal impact of microbiota on food choices

A Data Management Plan created using DMPonline.be

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Project abstract:

Patients with anorexia nervosa (AN), suffer from alterations in motivational and appetitive functioning, making food choices difficult and re-nourishment a negative experience. This project investigates the impact of the diet-sensitive microbial ecosystem in the gut (microbiota) plays a key role on food choices en stress reactivity in these patients. We specifically want to explore the causal relationship of the composition of microbiota and short-chain fatty acids (SCFA) levels (fatty acids produced from dietary fiber in the gut by its microbiota), with alterations in endocine stress responses and eating behavior. To do so, we will conduct a triple-blind, placebo controlled randomized clinical trial, to investigate the effect of SCFA administration on arousal, positive valence and food choices.

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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)

- Questionnaire data
- Food choice task (computer task) data
- Wearables data (autonomic nerveus system signals)
- Saliva samples (cortisol)
- Faecal samples
- Plasma samples (SCFA)

All samples will be gathered and registered at the biobank of UZ/KU Leuven.

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)

Data will be stored according to the Research Data Management (RDM) policy of KU Leuven.
(1) All data is collected and stored in eCRF in secure encrypted webserver REDCap (http://projectredcap.org/). Data will be pseudonymized, with a key, only accessible to the (co)promotors and PhD student. Data gathered outside REDCap will be collected under the pseudonym and will later be added to REDCap. All physical data (i.e., informed consent, etc.) will be stored in a locked archive closet (Biobank, UZ Leuven).
(2) Metadata will be made to ensure findability of the data.
(3) All deleted data will be justified and documented.
(4) All data will be retained for 25 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)

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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)

/

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

/

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DPIA

DPIA

Have you performed a DPIA for the personal data processing activities for this project?

- Not applicable

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GDPR

GDPR

Have you registered personal data processing activities for this project?

- Not applicable

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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
Questionnaire data		*Please choose from the following options:* • Generate new data	*Please choose from the following options:* • Digital	*Please choose from the following options:*	*Please choose from the following options:* • • NA	*Please choose from the following options:* • <100MB •	
Food choice task (computer task) data		• Generate new data	• Digital	• Observational	• NA	• <100MB •	
Wearables data (autonomic nerveus system signals)		• Generate new data	• Digital	• Observational	• NA	• <100MB •	
Saliva samples (cortisol)		• Generate new data	• Physical	• Observational	• NA	• <100MB	
Faecal samples		• Generate new data	• Physical	• Observational	• NA	• <100MB	
Plasma samples (SCFA)		• Generate new data	• Physical	• Observational	• NA	• <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:

/

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

- Questionnaire data
- Food choice task (computer task) data
- Wearables data (autonomic nerveus system signals)
- Saliva samples (cortisol)
- Faecal samples
- Plasma samples (SCFA)

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

- Questionnaire data
- Food choice task (computer task) data
- Wearables data (autonomic nerveus system signals)
- Saliva samples (cortisol)
- Faecal samples
- Plasma samples (SCFA)

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).

Data will be collected per participant and immediately stored according to the Research Data Management (RDM) policy of KU Leuven:
(1) All data is collected and stored in eCRF in secure encrypted webserver REDCap (http://projectredcap.org/). Data will be pseudonymized, with a key, only accessible to the (co)promotors and PhD student. Data gathered outside REDCap will be collected under the pseudonym and will later be added to REDCap. All physical data (i.e., informed consent, etc.) will be stored in a locked archive closet (Biobank, UZ Leuven).
(2) Metadata will be made to ensure findability of the data.
(3) All deleted data will be justified and documented.
(4) All data will be retained for 25 years

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

The metadata tells us:
- what the data resource contains
- where the data resource comes from
- the quality controls that have been applied.

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

Where will the data be stored?

Data will be collected per participant and immediately stored according to the Research Data Management (RDM) policy of KU Leuven:
(1) All data is collected and stored in eCRF in secure encrypted webserver REDCap (http://projectredcap.org/). Data will be pseudonymized, with a key, only accessible to the (co)promotors and PhD student. Data gathered outside REDCap will be collected under the pseudonym and will later be added to REDCap. All physical data (i.e., informed consent, etc.) will be stored in a locked archive closet (Biobank, UZ Leuven).
(2) Metadata will be made to ensure findability of the data.
(3) All deleted data will be justified and documented.
(4) All data will be retained for 25 years

How will the data be backed up?

All data is collected and stored in eCRF in secure encrypted webserver REDCap (http://projectredcap.org/). All physical data (i.e., informed consent, etc.) will be stored in a locked archive closet (Biobank, UZ Leuven).

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

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

Data will be pseudonymized, with a key, only accessible to the (co)promotors and PhD student. Data gathered outside REDCap will be collected under the pseudonym and will later be added to REDCap. All physical data (i.e., informed consent, etc.) will be stored in a locked archive closet (Biobank, UZ Leuven).

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

yearly cost storage redcaps and biobank UZLeuven

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 25 years.

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

All data is collected and stored in eCRF in secure encrypted webserver REDCap (http://projectredcap.org/). All physical data (i.e., informed consent, etc.) will be stored in a locked archive closet (Biobank, UZ Leuven).

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

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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.

- No (closed access)

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

Data will be pseudonymized, with a key, only accessible to the (co)promotors and PhD student.

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.

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When will the data be made available?

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

All data is collected and stored in eCRF in secure encrypted webserver REDCap (http://projectredcap.org/). All physical data (i.e., informed consent, etc.) will be stored in a locked archive closet (Biobank, UZ Leuven).

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.

- No

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

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6. Responsibilities

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

Data will be pseudonymized, with a key, only accessible to the (co)promotors and PhD student on the project.

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

The (co)promotors and PhD student on the project.

Who will manage data preservation and sharing?

The (co)promotors and PhD student on the project.

Who will update and implement this DMP?

The (co)promotors and PhD student on the project.