
TARGETING THE NEURAL MECHANISMS OF HUMAN SAFETY LEARNING

A Data Management Plan created using DMPonline.be

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Project abstract:

Anxiety disorders are amongst the most prevalent mental disorders worldwide, with almost a third of the population meeting diagnostic criteria sometime during their lives. Exposure treatment, based on the principles of inhibitory (extinction) learning, is the first-choice treatment for these disorders. Although proven effective in numerous experiments, exposure treatment has been rather prone to relapse and dropout. In addition, avoidance behaviours during and after exposure sessions can provoke the return of fear after treatment. To improve the efficacy of fear extinction, there has been growing scientific interest in employing counterconditioning techniques, which uses rewards during the omissions in extinction. Nonetheless, the effectiveness of counterconditioning in terms of reducing fear responses and avoidance behaviours remains inconclusive. Therefore, I will systematically assess whether we can experimentally enhance fear extinction and reduce avoidance behaviours by optimizing positive reinforcement techniques. First, I will assess several methods that could potentially enhance the effectiveness of counterconditioning interventions. Second, I will explore whether we can directly reinforce approach decision-making during extinction to reduce avoidance behaviours. Finally, I will study the effects of rewarded extinction techniques in a clinically anxious sample, to assess the potency of these interventions in a patient population for the first time. This includes assessing the neural mechanisms implicated in rewarded extinction, using 7 Tesla MRI imaging, focusing on neural prediction error signaling and fear responsiveness. Taken all together, this will give a first indication of how successful rewarded extinction can be in improving exposure treatment for anxious individuals.

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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
		<i>Indicate: N(ew data) or E(xisting data)</i>	<i>Indicate: D(igital) or P(hysical)</i>	<i>Indicate: Audiovisual Images Sound Numerical Textual Model Software Other (specify)</i>		<i>Indicate: <1GB <100GB <1TB <5TB >5TB NA</i>	
Online reward pilot	Study where 30 participants rated 109 stimuli on valence and arousal (online). Ratings on valence and arousal were collected. Data includes source data, processed data and analysis scripts, as well as the script for the task	E (Data collected during the first year of my PhD)	D	Numerical	Qualtrics ICF; exported as .csv Data: .csv / .log / .psydat Task programming: Python Script (.psyexp / .py) Data analysis: R Script (.r) / MATLAB scripts	< 1 GB	NA
Lab-based Partial Reinforcement study	60 participants are randomly assigned to three conditions (Full counterconditioning, partial counterconditioning, extinction) and undergo a fear conditioning and extinction paradigm in the lab while we also measure skin conductance and administer a battery of questionnaires (e.g. Anxiety Sensitivity Index, Depression Anxiety Stress Scale, Distress tolerance Scale, General Self-Efficacy Scale, Intolerance of Uncertainty Scale, Snaith-Hamilton Pleasure Scale & State Anxiety Index).	N (Data collection has recently started)	D/P	Textual Numerical	ICF, Exclusion Criteria and Adverse events from are on paper Questionnaires: Qualtrics, exported as .csv Data: .csv / .log / .psydat Psychophysiological Skin Conductance data: .acq / .txt Task programming: Python Script (.psyexp / .py) and MATLAB scripts (.m) Analyses: R scripts (.r) / MATLAB scripts	< 100 GB	1 folder with informed consent forms, exclusion criteria forms and adverse events forms (each form 1 sheet / participant)
Online reward learning study	Study where ~300 participants will perform a reward learning task as well as a counterconditioning experiment, and fill in questionnaires.	N (Data collection has not started yet)	D	Textual Numerical	Qualtrics/Pavlovian ICF and questionnaires; exported as .csv Data: .csv Task programming: Python Script (.psyexp / .py) and MATLAB scripts (.m) Analyses: R scripts (.r) / MATLAB scripts	< 100 GB	NA

Lab-based avoidance study	Study to validate an approach-avoidance paradigm	N (Study yet to be designed)	D/P	Textual Numerical	ICF, Exclusion Criteria and Adverse events from are on paper Questionnaires: Qualtrics/Pavlovvia/RedCap, exported as .csv Data: .csv / .log / .psydat Psychophysiological Skin Conductance data: .acq / .txt Task programming: Python Script (.psyexp / .py) and MATLAB scripts (.m) Analyses: R scripts (.r) / MATLAB scripts	< 100 GB	1 folder with informed consent forms, exclusion criteria forms and adverse events forms (each form 1 sheet / participant)
fMRI avoidance study	Study in patients (anxiety) and healthy controls, conducted at the University of Melbourne, Australia. Data will at least include task data, questionnaires, patient data, Ultra-High field 7T MRI recordings, skin conductance and eye tracking.	N (Study yet to be designed)	D/P	Textual Numerical Images	ICF, Exclusion Criteria and Adverse events from are on paper Questionnaires: Qualtrics/Pavlovvia/RedCap, exported as .csv Data: .csv / .log / .psydat fMRI images: dicom/.nii Psychophysiological Skin Conductance data: .acq / .txt Task programming: Python Script (.psyexp / .py) and MATLAB scripts (.m) Analyses: R scripts (.r) / MATLAB scripts	< 5 TB	1 folder with informed consent forms, exclusion criteria forms and adverse events forms (each form 1 sheet / participant)

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 existing data consists of pilotdata that I collected during the first year of my PhD already. The data has not yet been made available online.

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)

Online reward pilot and online reward learning study: G-2023-6525-R3

Lab-based partial reinforcement study: G-2024-7585-R2

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)

Yes, personal data in terms of demographic data and mental health questionnaire scores are and will be collected in accordance with the GDPR and KU Leuven guidelines:

Online reward pilot and online reward learning study: G-2023-6525-R3

Lab-based partial reinforcement study: G-2024-7585-R2

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.

- Yes

The third party consists of the participants themselves. They undergo an explicit informed consent procedure at the start of each experiment, which also consists of agreeing to the publication of anonymized results in scientific communications, as well as the publication of anonymized data on OSF and the (re)use of the data by other researchers.

Moreover, part of the data for my PhD project, being a joint PhD student, will be collected at the University of Melbourne, Australia. All data collected on the Melbourne site will be stored in Melbourne in accordance with the Australian national data and privacy legislations. In order to transfer the data to the KU Leuven, the data will be fully anonymized upon transfer to Belgium.

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).

Raw data files will be kept in a "RAW data folder" with individual data-files sorted and stored within participant sub-folders per dataset. Extracted and aggregated data will be stored in a "Processed data folder" with separate participant sub-folders/group data folder. All preprocessing, programming and analysis scripts that are generated will be saved within a "Scripts folder". All scripts and stimuli materials used for the task will be saved in an "Experiment folder".

Metadata will include the information about the experimental design, procedure and measurement characteristics, specification of the raw data file names, information about the variable codes. A working document is kept up to date for each study, including for instance information about important decisions, protocols and relevant literature.

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.

- Yes

Metadata will be stored as Microsoft Word/pdf/txt/csv file in each experiment parent-folder. We are currently not using a metadata standard, but will provide the necessary metadata in a structured manner. Currently, a working document is kept up to date for each experiment including important information about the study design, task and background. Whenever data is deposited on OSF, we will use their metadata standard to describe the data.

Data Storage & Back-up during the Research Project

Where will the data be stored?

- OneDrive (KU Leuven)
- Other (specify below)

All digital data obtained at the KU Leuven (demographical information, behavioural data, psychophysiological recordings, questionnaire answers, subjective ratings) will be stored on the KU Leuven OneDrive. Additional backups can be made and stored on personal drives, being encrypted and password protected back-up drives such as the PhD students own laptop or external hard drives.

Data in paper format (ICF, exclusion criteria forms & adverse events forms) are stored separately in a key-locked cabinet in a dedicated archive room of the research group.

After completing the project, the archive drive within the LBP (Laboratory of Biological Psychology) will be used to store all data for at least 10 years, in agreement with the university's data management policy.

As for the data collection at the University of Melbourne, all data will be stored on a password protected REDCap computer database on the University of Melbourne server. The data will be retained for a minimum of 5 years after publication of the results, in accordance with the Australian national data and privacy legislations.

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution
- Personal back-ups I make (specify below)

All data is stored on the central KU Leuven OneDrive that is backed up automatically on a daily basis. Copies are also backed-up on the external hard drives of the PhD student. These data are used for processing and analyses.

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

The PhD student has currently almost 2TB free capacity on their OneDrive environment, and has an external hard drive with a 4TB capacity to store and backup the data.

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

All data is stored on password-protected and/or encrypted drives, and all personal laptops are encrypted and password-protected. The OneDrive environment is further secured with a multifactor authentication process using the KU Leuven Authenticator app. Data in paper format will be stored in a key-locked cabinet in a dedicated archive room of the research group.

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

During the project, data will be stored in the free OneDrive environment of the PhD student and on a password-protected and encrypted external hard drive that has been purchased. No additional costs are therefore expected.

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...).

- All data will be preserved for 10 years according to KU Leuven RDM policy
- Certain data cannot be kept for 10 years (explain below)

The data that is collected at the University of Melbourne, Australia, will be retained for a minimum of 5 years after publication of the results, in accordance with the Australian national data and privacy legislations.

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

- Other (specify below)

Long-term storage will be ensured using the archive drive of the LBP, that is located in a separate building of the faculty (Van den Heuvel Institute), as well as on the dedicated external hard drive.

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

There are no additional costs expected in the retention period of 10 years.

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.**

- Other (specify below)

For the lab-based and online study, all anonymized data and scripts will be made available.

For the fMRI study: Defaced and anonymized data will be made available.

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

NA

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.

- No

Restricted personal data from human studies will never be shared beyond the researchers involved in the study. Other data will first be anonymized.

Where will the data be made available?

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

- Other (specify below)

Open Science Framework (OSF)

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.

- CC-BY 4.0 (data)

It is not sure yet what license we will use for the transfer of data from Melbourne to Leuven.

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.

- No

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

Public repositories such as OSF are free of charge, so no extra costs are estimated.

Responsibilities

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

KU Leuven: the PhD student, administrative/technical staff, and the co-PIs (Prof. Bram Vervliet, Prof. Tom Beckers) working on this project.
University of Melbourne: the PhD student, administrative/technical staff, and the co-PIs (Prof. Ben Harrison, Prof. Kim Felmingham, Dr. Trevor Steward) working on this project.

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

The PhD student and the administrative/technical staff.

Who will manage data preservation and sharing?

KU Leuven: the PI of this project (Prof. Bram Vervliet).
University of Melbourne: the PI of this project (Prof. Ben Harrison).

Who will update and implement this DMP?

KU Leuven: the end responsibility of updating and implementing the DMP is the PI of this project (Prof. Bram Vervliet).

University of Melbourne: the end responsibility of updating and implementing the DMP is the PI of this project (Prof. Ben Harrison).