The bidirectional relation between threat (un)controllability and stress reactivity

A Data Management Plan created using DMPonline.be

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Project abstract:

Stress plays an undeniable part in our lives, but how we experience it depends on its characteristics, including controllability. Threat controllability is the actual or perceived ability to control an aversive event. Uncontrollable events are often experienced as more stressful and challenging than controllable events. Specifically, research has shown that uncontrollable experiences result in adverse outcomes (e.g., enhanced cortisol levels) and increase susceptibility to negative consequences of future aversive situations. Conversely, behavioural control over stressful events seems to protect against these effects. Exactly how threat (un)controllability impacts stress reactivity remains unclear, however, in part due to the unidirectional nature of research to date. The current project will explore the association between threat (un)controllability and stress reactivity from a bidirectional perspective. Furthermore, we will assess potential moderators (such as gender) and mechanisms (such as emotion regulation) contributing to their relationship. Finally, we aim to investigate whether exploiting threat controllability in a clinical context can boost the effect of interventions for anxiety disorders. Investigating threat (un)controllability and stress reactivity will thus help clarifying their role in the development and maintenance of psychiatric disorders.

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DPIA

DPIA

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

Question not answered.

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GDPR

GDPR

Have you registered personal data processing activities for this project?

- Yes

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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)

Question not answered.

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)

Question not answered.

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)

Question not answered.

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)

Question not answered.

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

Question not answered.

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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
Questionnaire data	Collected via online survey program (e.g., Qualtrics, LimeSurvey)	New data	Digital	*Observational*	*.csv .xlsx .txt .R .jasp*	<100MB	/
Experience sampling data	Daily diary assessment (7 days) via app installed on participants' phone (e.g., mPath)	New data	Digital	Observational	.csv .xlsx .txt .R .jasp	<100MB	/
Identification information data	1) Payment data (e.g., bank account number, address, first name, surname) 2) Signatures on the informed consent forms	New data	Digital (1) and Physical (2)	Observational	.csv .xlsx .txt .R .jasp	<100MB	Approximately 80-100 copies per study
Behavioural data	1) Computer task programmed with PsychoPy 3 software measuring button presses and perceived ratings responses 2) Fear and distress responses during the exposure sessions and behavioural approach tasks	New data	Digital (1) and Physical (2) but later transferred to digital files	Experimental	.csv .xlsx .txt .R .docx .jasp	<100MB	Approximately 80-100 copies per study
Physiological data	1) Electrodermal activity recorded with Biopac system and AcqKnowledge program 2) Blood pressure data recorded with a fully automated electronic sphygmomanometer (OMRON M2)	New data	Digital (1) and Physical (2). Physical data will be transferred to digital format after each testing session.	Experimental and Observational	.mat .acq .txt .xlsx	3-5 GB	NA
Sample analysis data (of salivary cortisol and salivary alpha-amylase)	Saliva samples collected with synthetic swabs Salivette®	New data	Physical	Experimental and Observational	/	/	Approximately 500 samples per study

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:

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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

The first study has been already approved by The Ethics Committee Research UZ/KU Leuven (S-number: S68015). Ethical approval will be obtained for all the next studies.

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

We will collect the following personal data:
1. Identification information (e.g. names, (email) addresses for payment purposes)
2. Personal details (e.g. age, gender, sex at birth)
3. Psychological details (personality, character traits)
4. Financial details (bank account details solely for payment purposes)
5. Data concerning (physical and/or mental) health such as medication use, physiological data (e.g., electrodermal activity, blood pressure measurement), data about mental health such as stress, depression, current mood, etc., menstrual cycle phase, wake-up, and sleep schedule time data
6. Human biological data such as saliva samples to measure salivary cortisol and salivary alpha-amylase
As the data contains sensitive personal information, the data will be treated with the necessary caution. As described in the application to the ethics committee (S68015) and PRET application (G-2023-6831):

- Experimental data will be collected, stored, and processed electronically in a format that does not allow connecting the experimental data to individuals. Specifically, all participants will be assigned a unique individual numeric code (e.g., P01). Experimental data will be stored and processed using those unique codes and will never be linked to participants' names.
- Participants will enroll themselves in the experiment via the EMS system with their EMS code. EMS-code and the participant's identity cannot be linked. The EMS code will **not** be used as a unique numeric code.
- Participants will be asked for their informed consent prior to each study.
- Participants will be asked for their informed consent to collect and share the non-identifiable data on the Open Science Framework (quote from the approved informed consent form by the Ethics Committee Research UZ/KU Leuven "*In the context of transparency in scientific research, the data of this research can be shared with others, for example with researchers from other universities or on the Open Science Framework (www.osf.io). In this case, only nonidentifiable data will be shared.*")
- Participants will indicate their names on the paper format data (informed consent form and adverse events form), which will be stored in a key-locked cabinet in the office of the main researcher (Michalina Dudziak), separate from the other data files. The paper data will **not** contain the unique individual numeric code.
- The payment information (EMS codes, bank account numbers) will be collected only for reimbursement purposes. The payment information will be stored electronically on the KU Leuven OneDrive account with additional password protection.

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

The obtained data have little potential for tech transfer and valorization.

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

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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

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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).

Each study will be preregistered on the Open Science Framework. The access to the preregistration will be open to everyone. The preregistration will include research questions and specific hypotheses, sample size rationale, recruitment strategy, exclusion/inclusion criteria, and study procedures (e.g., lab protocol). The data preparation and statistical analyses (including R code, and JASP syntax) will be documented and also available on the Open Science Framework. After the study is completed and accepted for publication, the pseudonymized dataset (with removed confidential information) will be uploaded on the Open Science Framework.

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

The following metadata will be added when uploading the completed dataset and R code file to the Open Science Framework:

- the lab protocol
- the explanatory comments in the R script
- ReadMe file explaining coding of specific variables (e.g., female/male coding, saliva samples codes)
- Description of the applied behavioural tasks

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

Where will the data be stored?

During the data collection, digital data files will be stored on a secure personal OneDrive linked to a KU Leuven account of the main researcher (Michalina Dudziak), which only project members can access. After the data collection is completed, the digital data will be transferred to SharePoint provided by KU Leuven. SharePoint provides safe storage of the data that can be accessed even when the individual researcher leaves the institution. The paper data will be stored in a key-locked cabinet in the office of the main researcher (Michalina Dudziak), separate from the other data files. The paper data will be retained for 10 years (KU Leuven RDM-richtlijn), after which they will be destroyed using dedicated university procedures for the destructing of sensitive documents (in the case of paper documents) or by the erasure of electronic files from the backup drive.
The biological human samples (e.g., saliva samples) will be stored in a low-temperature freezer (-18 to -21°C) at the Faculty of Psychology and Educational Sciences before shipping them to the laboratory (Dresden LabService GmbH) for processing. The details of processing, storage, and destination of saliva samples have been included in the Biobank application and approved by the Biobank manager Kristel Van Landuyt. The saliva samples will be destroyed by the Dresden Lab 2 weeks after the assay.

How will the data be backed up?

1. The raw and time-stamped master copy of the data will be stored in the university's secure environment (e.g., KU Leuven OneDrive) with automatic daily back-up procedures.

2. The pseudonymized copies of the data can be made and kept on the encrypted and password-protected work computer of the main researcher (Michalina Dudziak) during the data collection and data analysis process.

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

As the size of all data files do not exceed the available individual storage space of 2 TB (KU Leuven OneDrive) and the available shared storage space of 100 GB, there is sufficient storage and backup capacity during the project.

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

Multi-factor authentication is activated for the KU Leuven login of all researchers having access to the data.
Pseudonymized digital data will be stored in a folder on the main researcher's OneDrive which can only be accessed by an authorized link. Access to the data will be given to the supervisor, main data manager, and student researchers collecting data in the current project. Students will lose access to the data as soon as the project is completed and the data is analyzed.
Highly confidential digital data (e.g., payment information collected for reimbursement purposes) will be additionally password-protected and will be stored on the personal OneDrive of the main researcher. Access to the data will be given to the KU Leuven Finance Department which will complete payments for each participant.
After the completion of each study, digital data will be transferred to secured SharePoint. Access to data on SharePoint will only be given to the supervisor, the main data manager, and the main researcher (Michalina Dudziak).
Analogue data (e.g., informed consent forms, and adverse event forms) will be stored in a locked cupboard of the main researcher's office.

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

There are no costs expected as the size of the data files does not exceed the available storage space.

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...).

Participants' payment information, and raw (non-anonymized) data files containing highly confidential data will be deleted after the project is finished as they contain personal data that are not relevant anymore to the research project.
All other data will be preserved for 10 years according to KU Leuven RDM policy.
Saliva samples will be discarded 2 weeks after assay service provided by Dresden LabService according to the completed Saliva Order Form.

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

The digital data will be archived on the SharePoint.
The analogue data will be stored in the locked cabinet by the data manager of the research unit.

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

The cost for data preservation for ten years on our local research group storage will be around 36€. These costs will be covered by the supervisor and/or the research group.

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

Only pseudonymized datasets without direct participant identifiers will be available on the Open Science Framework. The datasets will include behavioral, biological, physiological, and questionnaire data. Confidential data such as payment information, addresses, names, and surnames will not be shared.

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

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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

Only pseudonymized data will be shared as participants will give their informed consent to share these data with other researchers. In this case, there are no restrictions to share the pseudonymized data as the data do not contain highly sensitive information.

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

The pseudonymized data will be shared in an Open Access repository (e.g., the Open Science Framework on European servers) as well as via internal Psychologisch Instituut Repository (Augias).

When will the data be made available?

Upon the publication of each study, the pseudonymized datasets will be uploaded and visible to the public on the Open Science Framework.

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

We will provide a Creative Commons Attribution 4.0 International (CC-BY-4.0) license that allows to share and adapt data while giving an appropriate credit and indication if changes were made.

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

Open Science Framework (OSF) allows to generate DOIs for datasets. Therefore, we will use DOI via OSF.

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

No costs for data sharing are expected.

6. Responsibilities

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

The PhD student (Michalina Dudziak) will manage documentation and metadata during the research project.

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

The PhD student (Michalina Dudziak) will manage data storage and backup during the research project.

Who will manage data preservation and sharing?

The PhD student (Michalina Dudziak) and the main supervisor (Prof. Tom Beckers) will manage data preservation and sharing.

Who will update and implement this DMP?

The PhD student (Michalina Dudziak) will update and implement this DMP. However, the end responsibility of updating and implementing this DMP after the PhD student is finished bears the main supervisor (prof. Tom Beckers).