Plan Overview

A Data Management Plan created using DMPonline.be

Title: Exploring the mechanistic link between the oxytocinergic system and mindfulness training

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Template: KU Leuven BOF-IOF

Project abstract:

Individuals with Autism Spectrum Disorder (ASD) are at a higher risk of developing anxiety, stress and depression disorders compared to their neurotypical peers. Recent research has started to explore the potential of intranasal administration of oxytocin as a potential new therapeutic option for autism, related to its stress-regulating, prosocial effects. Oxytocin as stand-alone treatment is however anticipated to be suboptimal and may fail in consistently targeting the relevant neural circuits, if not administered in a therapeutic context that similarly stimulates stress regulatory states and behaviors. For facilitating stress-regulation, initial promising insights have emerged into the application of tailored mindfulness-based interventions for autistic individuals for promoting stress regulation and well-being. Furthermore, recent notions suggest that the neurophysiological-mechanistic underpinnings of stress regulation induced by oxytocin administration and mindfulness-based stress reduction programs may show considerable overlap. Here, an initial oxytocin clinical trial with 160 autistic adults is proposed to specifically explore the synergetic potential of combining oxytocin administration within a tailored mindfulness-based stress reduction program. The project is anticipated to yield important fundamental and clinical insights, facilitating novel ways for boosting efficacy and applicability of both oxytocin and mindfulness treatment approaches in clinical populations.

ID: 210435

Start date: 05-10-2025

End date: 08-10-2028

Last modified: 10-02-2025

Exploring the mechanistic link between the oxytocinergic system and mindfulness training

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
		Indicate: ***N****(ew data) or* *E(xisting data)*	Indicate: **D**(igital) or **P**(hysical)	Indicate: **A**udiovisual **I**mages **S**ound **N**umerical **T**extual **M**odel **SO**ftware Other (specify)		Indicate: <1GB <100GB <1TB <5TB >5TB NA	
PSS	Perceived Stress Scale	N	D	N	RedCap - online designer	<1GB	
DASS-21	Depression Anxiety Stress Scale	N	D	N	RedCap - online designer	<1GB	
SAAM	State Adult Attachment Measure	N	D	N	RedCap - online designer	<1GB	
SRS-A	Social Responsiveness Scale	N	D	N	RedCap - online designer	<1GB	
SCS-SF	Self-Compassion Scale-Short Form	N	D	N	RedCap - online designer	<1GB	
PSQI	Pittsburg Sleep Quality Index	N	D	N	RedCap - online designer	<1GB	
WHO-5	WHO-5 Quality of Life	N	D	N	RedCap - online designer	<1GB	
PTQ	Perseverative Thinking Questionnaire	N	D	N	RedCap - online designer	<1GB	
CHIME	Comprehensive Inventory of Mindfulness Experiences	N	D	N	RedCap - online designer	<1GB	
POMS	Profile of Mood State	N	D	N	RedCap - online designer	<1GB	
GQ-D	Group Questionnaire	N	D	N	RedCap - online designer	<1GB	
VAS-QL	Visual-analogue-scale quality of life	N	D	N	RedCap - online designer	<1GB	
RBS	Repetitive behavior scale	N	D	N	RedCap - online designer	<1GB	
stress physiology recordings: EEG		N	D	I	.mat, .mp4	approx. 50MB	
stress physiology recordings: ECG		N	D	I	.mat, .mp5	approx. 50MB	
stress physiology recordings: Skin conductance		N	D	I	.mat, .mp6	approx. 50MB	
stress physiology recordings: Respiration		N	D	I	.mat, .mp7	approx. 50MB	
oxytocin receptor (OXTR) gene methylation		Saliva samples with Salivette cotton swaps				small, individual kit: Oragene DNA (OG-500) kit	
Endogeneous oxytocin levels	Saliva samples with Salivette cotton swaps	N	P	O (small individual tubes)		Enzo Life Science Oxytocin ELISA assays (for oxytocin analysis); Salivary Cortisol Enzyme Immunoassay Kits by Salimetrics (for Cortisol analysis)	
PPG (photoplethysmography sensor)		stress physiology recordings	N	D	N	.mat	<1GB
stress reactivity in daily life: experience sampling		using mPath app on smartphone	N	D	N	via mPath	<1GB
stress reactivity in daily life: Muse S headband			N	D	N	JSON or CSV	<1GB
IC	Voluntary written informed consent of the participant or their legally authorized representative has been obtained prior to any screening procedures		N	D&P	O - tikbox 'Yes - No'	RedCap - online designer	
IC	Informed consent signed	N	D&P	O - tikbox 'Yes - No'	Physical format		
IMP	Trial medication	N	D	N	RedCap - online designer		

ConMed	concomitant medication	N	D	N	RedCap - online designer	
SF	Safety	N	D	N	RedCap - online designer	

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)? 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)

A PRET form has been submitted: G-2024-7933

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)

G-2024-7933
S68971
All personal data will be collected via electronic surveys like REDCap. Ordinary personal data: name of participant contact details will be used for communicating with the participants throughout the course of the study, will not be used for long-term storage. Names and other contact information will never be captured in REDCap.
Sensitive personal data: age, gender, medical information about participant's diagnosis and medication history,standardized questionnaires, Stress physiology recordings, ECG data data, respiratory data, skin conductance data and hormonal assessments.
All research-relevant personal data will be de-identified and stored in coded form on the protected L-drive (during study, transferred to K-drive after study completion) of KU Leuven or on
the independent and secured database and data management system (REDCap). This database is password-protected and only accesible by the researchers of this study.

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.

- 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

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).

For questionnaires: Metadata (e.g. timestamp, electronic instructions) are automatically captured in REDCap.
- Standard operating procedures will be written to describe how to collect and analyse data from the measurements of stress physiology and social reciprocity .
- Using RedCap, a Data Dictionary Codebook will be generated containing variable-level information for all captured information: Variable / Field name, Field Label (including question text) and Field Attributes (including Field Type, Validation, Choices, Calculations etc.)

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.

- No

REDCap offers the possibility to download a XML file of the metadata, which consists of the following information: User Roles, Data Access Groups, Data Quality Rules, Surveys and survey
settings, order of survey queue. REDCAp also keeps a log of when the questionnaires/surveys are filled in, when someone makes adjustments to the instruments or data. Also, metadata (e.g. timestamp, electronic instructions) are automatically captured during survey completion in REDCAp
The PGG device generates metadata like the instrument settings and the timing of the measurements.

Data Storage & Back-up during the Research Project

Where will the data be stored?

- Other (specify below)

Paper data like the ICF forms will be kept in a locked cabinet in the office of the PI at KU Leuven. Other pseudonumized data will be kept electronically in RedCap or in a secured folder on the KU Leuven L-drive.
The data will only be accesible by the researchers of this project. In a separate folder on the L-drive of the KU Leuven servers, a password protected document will be kept containing the patient identification log;
this will be the only link between the real identity of the participant and their allocated subject ID code (pseudonymization code).

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution

The data will be stored on RedCap and a central KU Leuven server (L:drive) with automatic daily back-up procedures.

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

RedCap is hosted on central ICTS webservices and provides unlimited capacity. The minimum for large volume storage provided by the KU Leuven ICTS-hosted L:drive is 5 TB. It is expected this volume is sufficient for the current project.

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

All included storage facilities (RedCap, L:drive) are incorporated within secured KU / UZ Leuven environments, are password-protected (including smartphone-based multi-factor identification) and are only accessible by registered collaborating researchers.
- All data files will be collected, processed and stored in a de-identified format by means of subject ID codes (i.e. pseudonymization). These datafiles will not contain information that would allow participant identification.
- Personal data collected on paper (e.g. informed consent forms) are stored in a locked cabinet onsite (during data collection: accessible only to study personnel; after data collection: accessible solely by PI of the study).

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

The price to set-up a RedCap projects is € 80 per year. Data storage on L:drive storage will result in a cost of € 569,2 per year (for max. 5 TB of data). Costs for data storage will be covered by personal funds of the involved co-PI (Kaat Alaerts) and support funds from the Rehabilitation sciences department.
total of 569,2 x 29 year = 16506,8€

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 25 years according to CTC recommendations for clinical trials with medicinal products for human use and for clinical experiments on humans

After finalizing the data collection, all data will be stored (at least 25 years after the end of the research) in pseudonymized format on password protected BIOMED L- and K Drive for large volume storage (secure facilities for data archiving). Saliva samples will be stored in secure freezers at the UZ KU Leuven Biobank.

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

- Large Volume Storage (longterm for large volumes)

the generated research data, the accompanying metadata and all documentation necessary to reuse the data will be transferred to the K:drive designed for long-term data archiving (managed by KU Leuven ICTS with automatic back-up procedures).

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

On average, one EEG recording is 0.35 GB
For 3 EEG recordings per participant across 120 participants(max.), this amounts to 126 GB
Including other types of data, the total storage required is expected to be around 150GB
On average, one PPG recording is 250 MB, ammounting up to 90GB for 3PPG recordings pp across 120 pp.

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.

- Yes, as open data

(Neuro)physiological data: PPG, EEG, ECG, skin conductance and respiration data
Biological data: saliva samples (to measure levels of oxytocin, cortisol and OXTR gene methylation)
self-report questionnaires to measure stress, anxiety, sociality, attachment, self-compassion, quality of life, perseverative thinking, mindfulness experiece, mood, repetitive behavior. Informant-report questionnaire to measure sociality
stress reactivity in daily life: experience sampling methods & muse s headband (heart rate + brain activity)

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

Sharing of de-identified, pseudonymized data upon request by email will be considered depending on the planned reuse. Only uses for research purposes will be allowed and commercial reuse will be excluded.

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

Where will the data be made available?

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

- Other (specify below)

In an Open Access repository

When will the data be made available?

- Upon publication of research results

We plan to make (parts of) the de-identified, and pseudonymized raw data collected during the study available through RDR online repository Open Science Framework (https://osf.io/) online repository or the recently launched KU Leuven Research data Repository. All clinical trial results will also be posted on the EUDRACT clinical trial study entry within 6 months after study completion (last visit of the last participant). "

Which data usage licenses are you going to provide?

If none, please explain why.

- Data Transfer Agreement (restricted data)

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.

- Yes, a PID will be added upon deposit in a data repository

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

Sharing on OSF and RDR are not anticipated to yield any additional costs.

Responsibilities

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

The involved researcher (Eimi van Weert) and Coordinating PI (Kaat Alaerts).

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

The main responsible person for the data management of the trial will be PI Alaerts and PI Van der Gucht (with delegation to the research team)

Who will manage data preservation and sharing?

Coordinating PI Kaat Alaerts

Who will update and implement this DMP?

The Coordinating PI (Kaat Alaerts) bears the end responsibility of updating and implementing this DMP