Oxytocin therapy in children with autism spectrum disorder and co-occurring intellectual disability: examination of desirability, clinical efficacy and therapeutic augmentation by psychosocial training.

A Data Management Plan created using DMPonline.be

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Project abstract:

Intranasal administration of oxytocin is increasingly considered a new therapeutic resource for autism spectrum disorder (ASD). Prior oxytocin trials have however mostly excluded autistic individuals with co-occurring intellectual disability (ID) by design, despite making up 40% of the ASD population and
often displaying more severe symptoms. Therefore, we propose a RCT assessing the clinical effects of a multiple-dose oxytocin intervention (4 weeks of 3 times weekly intranasal administrations of 24IU) on core autism symptoms in 80 children with ASD+ID (7-12 years, IQ<75) (40 oxytocin, 40
placebo). In light of emerging insights that treatment outcome might be impacted by the context in which oxytocin is administered, administration will be paired with psychosocial training, allowing to further elucidate the potential of augmenting the clinical benefits by administrating oxytocin within a
socially stimulating context. Moreover, additional qualitative interviews with caretakers will allow novel understanding of the desirability, perspectives, expectations and experiences regarding oxytocin therapy for children with ASD. In summary, our quantitative and qualitative evaluation will provide first insights into oxytocin's clinical efficacy and mediation by context, its desirability and applicability in the pediatric ASD+ID population. These insights are essential for oxytocin's promising
implementation into the clinical practice for ASD within an early life developmental window.

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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**
Questionnaires about core autism symptims (ATEC, ABAS-3, RBS-R, DBC, PSS)	Informant-based-report questionnaires (parents and/or teachers) about core autism characteristics	Generate new data	Digital (through secure web-based application REDCap) & Physical (if paper version prefered)	Observational	tabular data .csv (comma-separated value)	+/- 5MB	Volume of paper versions difficult to estimate
Side effect report form questionnaire	Informant-based diary screenings on potential oxytocin-related side effects (safety monitoring by parents and teachers)	Generate new data	Physical (paper versions)	NA	NA	NA	NA
Semi-structured interaction: The Brief Observation of Social Communication Change (BOSCC)	Observation coding scheme + webcam video recordings	Generate new data	Digital	Observational	video data .mp3 (MP3 Format Sound)	<1GB	NA
Stress physiology recordings	Physiological measurements of cardiovascular stress response, electrocardiography (ECG) (heart rate variability, HRV more specifically)	Generate new data	Digital	Software	data from recordings .mat (matlab files)	Appr. 50 MB	NA
Audio recordings and transcripts from qualitative interviews	Interviews with informants/caregivers (e.g. parents and teachers) about their perspectives, expectations and experiences about the oxytocin nasal sprays for children with autism	Generate new data	Digital	Other	audio data .mp3 (MP3 Format Sound) and transcript data (pseudonymised word/pdf files)	<100MB	NA

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:

Not applicable. We will generate new data.

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 project has been ethically approved by the Ethics Committee Research UZ/KU Leuven, with reference number: S66832.

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

Yes, a PRET application G-2022-6027-R5(AMD) is submitted.
Collection of personal data of participants of the quantitative and qualitative part: children's and/or caregivers' personal information including age, biological sex, name, home address, date of birth, email, IBAN for financial reimbursement, telephone number, ASD symptom severity, IQ measurement. This information is necessary collected as part of the ICF procedure.
See further below under part 3 how these personal sensitive data will be managed carefully.

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).

- For questionnaires: Metadata (e.g. timestamp, electronic instructions) are automatically captured in REDCap.
- Standard operating procedures (SOPs) will be written to describe how to collect and analyse data from the measurements of stress physiology and social interaction coding scheme.
- 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.)
- Data obtained from informant-based questionnaires through paper versions will also be consistently complemented at REDCap.

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

- 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 electrocardiography (ECG) stress-recording device (BioSemi) generates metadata like the instrument settings and the timing of the measurements.

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

Where will the data be stored?

- Paper data (like the ICF forms and paper version questionnaires) will be kept in a locked cabinet in the office of the PI at KU Leuven.
- All research-relevant personal data will be de-identified and stored in coded form on the protected KU Leuven 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 accessible by the researchers of this study.
- 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 participants (both children and informants) and their allocated subject ID code (pseudonymization code), with a separate system for the participants of the quantitative part (children - subject for nasal spray ID) versus the qualitative part (informants - participant for interview ID) of the research project.

How will the data be backed up?

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 yes, specify concisely.
If no or insufficient storage or backup capacities are available, then 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. This volume is expected to be sufficient for the current project. A disaster recovery (mirror) copy of the data is included in this fee.

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 or participant for interview ID codes (i.e. pseudonymization). These data files will not contain information that would allow participant identification.
- Personal data collected on paper (e.g. ICFs, questionnaires) 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 the secured KU Leuven 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 PI (Kaat Alaerts) and support funds from the Rehabilitation sciences department.

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 generated research data will be archived for 25 years after study completion conform the Ethics Committee Research UZ / KU Leuven (EC Research) policy as well as good clinical practice guidelines for archiving clinical trial data.

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

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?

Pricing for data storage on the K-drive includes € 11,38 per 100 GB (with 50% of the cost covered by Group Biomedical Sciences). In view of the expected size of the database (including raw and pre-processed data), estimated cost of long-term data storage will be € 56,9 per year for 500 GB.

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

We plan to make (parts of) the de-identified, and pseudonymized raw data (from the quantiative or qualitative part) collected during the study available through the 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).

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 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.

When will the data be made available?

- Immediately after the end of the project
- Upon publication of the research results

We plan to make (parts of) the de-identified, and pseudonymized raw data collected during the study available through the 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.

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.

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

To be determined.

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.

6. Responsibilities

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

The involved PhD researcher Aymara Taillieu, together with colleagues Elise Tuerlinckx and Grazia Ricchiuti and PI Kaat Alaerts.

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

Back-up and immediate storage: Aymara Taillieu and colleagues Elise Tuerlinckx and Grazia Ricchiuti; Long-term storage: PI Kaat Alaerts.

Who will manage data preservation and sharing?

PI Kaat Alaerts

Who will update and implement this DMP?

Aymara Taillieu.