High and low intensity speech intervention in children with cleft palate: perceptions of children, their caregivers and speech-language pathologists

A Data Management Plan created using DMPonline.be

Creator: Tara Mouton https://orcid.org/0009-0007-9923-8391

Affiliation: KU Leuven (KUL)

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Project abstract:

A cleft (lip and) palate (CP±L) is the most prevalent congenital craniofacial defect with significant societal impact, affecting speech, hearing, feeding, oral behaviour, dentition, and satisfaction with appearance. These consequences have a prolonged and adverse influence on social integration and well-being. The WHO highlights considerable financial costs, including morbidity, healthcare expenses, emotional issues and social exclusion for patients, their environments and society. The objective of this study is to compare high and low intensity speech intervention in children with CP±L based on the perceptions of the intervention providers (speech therapists in primary care) and intervention recipients (children with CP±L and their caregivers). Participation in this study includes taking part in a semi-structured interview. These interviews will be analyzed using both inductive and deductive approaches. After the interview, the participants are required to fill out a questionnaire regarding their demographics.

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DPIA

DPIA

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

- Yes

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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)

This research will collect data via questionnaires and semi-structured interviews. The collected data will be stored in databases. The data will be used to generate peer-reviewed manuscripts.
Digital datatypes will include audio data (from the interviews) and databases including processed quantitative and qualitative data. On paper data include informed consent forms and questionnaires.

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)

Responsible person: prof. dr. Greet Hens (ENT-specialist, PI of this project)
Storage capacity/repository:

- During the research: All the data will be stored on the internal KU Leuven OneDrive network. Non-anonymized/non-coded personal data will be stored in a digital vault/protected file
- After the research: Non-anonymized/non-coded personal data will remain in the digital vault/ protected file or will be transferred to another digital vault/protected file on the archive network of the KULeuven (L-Drive)

In both cases, only me and my supervisor will have access to the non-coded personal data.
A seperate file will be created with the key to the code assigned to each participant. This file will stored separately from the other databases and will only be accessible to the principal investigator or to his appointed replacement.
The key will be stored on the L-drive of the principle investigator.

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)

Not applicable

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)

All data will be coded (i.e. pseudonymized). There continues to be a link between the data and the individual who provided it. The subjects' identifiers will however be stored separately (site file) from their research data and replaced with a unique code to create a new identity for the subject. This code is stored on the UZ Leuven server which is password protected, but which also allows to consult the electronic medical chart of the patient stored on UZ Leuven Hospital servers, only if necessary. In addition, we will store all data on the central servers of the KU and UZ Leuven, which are protected against unauthorized access by firewalls.

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

Not applicable

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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
		Please choose from the following options: • Generate new data • Reuse existing data	*Please choose from the following options:* • Digital • Physical	*Please choose from the following options:* • Observational • Experimental • Compiled/aggregated data • Simulation data • Software • Other • NA	*Please choose from the following options:* • .por, .xml, .tab, .csv,.pdf, .txt, .rtf, .dwg, .gml, … • NA	*Please choose from the following options:* • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • NA	
D1	Survey	Generate new data	Digital and physical	Observational	.xml, .csv, .pdf, .txt	< 100 MB	350 pages
D2	Transcriptions	Generate new data	Digital	Other	.txt	< 1GB	
D3	Audio recordings	Generate new data	Digital	Other	.wav, .mp3, .mp4	<1TB	

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

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

Survey data and the data of the audio recordings will be collected.

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

- Data from/linked to the Electronic Patient File (EPD)
- Biometric data for the purpose of uniquely identifying a natural person, more specifically audio recordings of voices
- Data concerning health (cleft type, speech therapy history)

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).

All data and accompanying information will be stored exclusively on KU Leuven servers, Onedrive. All data will be accompanied with a README file or tab that outlines the exact data collection procedure, especially important for experimental data. All experimental work is prepared by extensive preparations, each step is logged. Standard operating procedures are written out in the lab and safely stored together with the experimental data in the same folders, to allow easy recovery of the metadata. All team members have access to these metadata.

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

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

Where will the data be stored?

All data are stored at the KU Leuven Onedrive. No data will be stored on local computers, hard drives etc.

How will the data be backed up?

All data stored in the central KU Leuven facilities are backed up automatically with version control and logging.

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

All KU Leuven personnel has access to 2 TB of data storage on OneDrive. As the estimated sizes of the datasets <2 TB, sufficient storage and backup capacity is available.

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

The data are stored on the KU Leuven servers, only accessible with double authentication.

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

All costs are covered by the departmental group, or otherwise through existing grant funding.

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 digitally generated data will be archived for minimally 10 years after study completion, in line with the KU Leuven RDM policy.

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

The same repositories as mentioned above will be used for long-term storage.

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

None

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)

Not applicable

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

Not applicable

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

Not applicable

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

Not applicable

When will the data be made available?

Not applicable

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

Not applicable

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

Not applicable

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

Not applicable

6. Responsibilities

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

The PhD researcher (Tara Mouton), under supervision of the PI (Greet Hens)

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

The PhD researcher (Tara Mouton), under supervision of the PI (Greet Hens)

Who will manage data preservation and sharing?

The PI (Greet Hens) will be responsible

Who will update and implement this DMP?

The PhD researcher (Tara Mouton) and the PI (Greet Hens), who has end responsibility for updating and implementing this DMP