LittleNIRVANA 2.0: een digitaal multifunctioneel pijn- en angstbeheersingssysteem voor kinderen

A Data Management Plan created using DMPonline.be

Creators: Babs Weyn, n.n. n.n.

Affiliation: KU Leuven (KUL)

Funder: KU Leuven (KUL)

Template: KU Leuven BOF-IOF

Principal Investigator: n.n. n.n., n.n. n.n.

Grant number / URL: C3/22/033

ID: 199992

Start date: 01-03-2023

End date: 28-02-2025

Project abstract:

Painful and stressful medical procedures such as vaccinations or needle procedures are a major burden for children. In this context, KU Leuven and partners developed a prototype of a new, innovative, multisensory pain & anxiety toolkit for children. This prototype was tested on more than 150 children undergoing needle-related medical procedures, with excellent results. In this project, we aim to rework and extend the current little NIRVANA 1.0 solution into a modular, multi-application little NIRVANA 2.0 solution for pediatric dentistry. To this end, we will build on the needle application software and extend it for dentistry by modifying and extending its content and design. A field study of the system in a real environment will be part of the validation in the second year of the project. In this field study, we will test the new prototype on pediatric patients undergoing dental procedures at UZ Leuven.

Last modified: 31-05-2023

LittleNIRVANA 2.0: een digitaal multifunctioneel pijn- en angstbeheersingssysteem voor kinderen

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	
little NIRVANA dental software	software to run the little NIRVANA dental application	N	D	SO	source code and compiled code (text based format)	<100 GB	NA
prototype study: patient data (recorded via research app)	• Patient age • Patient first name	N	D	T	SQL XLS SAV	<1GB	NA
usage logs	automatically recorded usage log of the little NIRVANA software (duration, #clicks, user preferences, ...)	N	D	T	SQL	<1GB	
prototype study: Likeability and usability questionnaires for children & parents (recorded via research app)	Questionnaires for pediatric patients and their parents evaluating the usabiliy and likebility of the little NIRVANA dental application	N	D	T	SQL XLS SAV	<1GB	NA
prototype study: Likeability and usability questionnaires for Health Care provider (dentist)(recorded via research app)	Questionnaire for dentists evaluating the usabiliy and likebility of the little NIRVANA dental application	N	D	T	SQL XLS SAV	<1GB	NA
prototype study:rating tools and questions to evaluate 1) general well-being, 2) distress, 3) anxiety, 4) pain and 5) preparedness	• Pain: FLACC (Face, Legs, Activity, Cry and Consolability; Merkel ea, 1997) and Faces Pain Scale Revised (Hicks ea, 2001) • Anxiety: CAM (Child Anxiety Meter; Ersig ea 2013), OSBD-R (Observational Scale of Child Distress-Revised); anxiety scale of the Child Behavior Checklist (Achenbach and Rescorla, 2001) and PPQ (Perception of Procedure Questionnaire; Kazak ea 1996)	N	D	T	SQL	<1GB	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:

NA (we are not reusing data)

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)

EC approval was obtained for the previous little NIRVANA study (needle-related procedures), with S number S64654. EC approval will be requested for this study through an addendum on this study.

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).

- No

During the field study, no personal data will be collected. The patients age and first name will be the only data that are collected. The first name (or Nickname) is optional but can be used to personalize the software (which is liked by the children).

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.

- Yes

The intention is to create a new non-profit spin-off based on all the little assets of NIRVANA (including the earlier needle-related procedures project). LRD is actively involved in the preparations. All data types and datasets will contribute to this initiative; the software is IP from KU Leuven, the results of the field research are important for the validation of the software and services of this new entity.

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.

- Yes

Yes, the software that will be created in this project will build on the previous software for needle-related procedures. The latter is jointly owned by RISE (Research Institutes Sweden) and KU Leuven. LRD is currently in negotiations to transfer the rights of this initial software from RISE to KU Leuven.

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).

software: all code is extensively documented. This is part of the ongoing software transfer agreement currently being discussed by RISE and KU Leuven.
README files: data will be described according to category (questionnaires) and structured according to several identifiers: title, year, location, author/creator, file type, key words, ...
Results of the prototype study (questionnaires and rating instruments): all recorded data are stored in a DB, including the questionnaires and rating instruments themselves. Thus, the answers to the questionnaires and the results of the rating instruments are self-explanatory and understandable to all.
Through a clear folder structure located on the One Drive, existing data and developed material will be organised in order to simplify retrieving and consulting the overall documentation. Produced material will adopt meaningful filenaming starting with the date (year/month/day, e.g. 230331_), description of its content and, when applicable, ending with the initials of the creator.

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

The data and data structure is very simple and it is easy to find and reuse data. Therefore, no metadata standard is required.

Data Storage & Back-up during the Research Project

Where will the data be stored?

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

Questionnaires will be completed on a research tablet (via a research app) and - after completion - sent to OneDrive. Note: data cannot be collected directly on a server because network functionality cannot be guaranteed in all medical cabinets.
User logs are automatically stored on a KU Leuven research PC (or tablet) running the little NIRVANA software. Usage logs are automatically sent to OneDrive when a network connection is established.
Back-ups of Software is stored on KU Leuven's OneDrive. Software will be deployed on KU Leuven tablets and PC's.

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution
- Other (specify below)

In addition to the standard back-up procedures, the standard back-up system of the Medical Image Research Center (MIRC) will also be used. This is managed by the IT manager of the MIRC.

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

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

KU Leuven's standard procedures (IT and MIRC) are followed to store and secure the data. Since no personal data is collected, the level of confidentiality is low (privacy is high).
Normally no physical data are collected, but in case of failure of the research app, tablet or PC, we will print a copy of the questionnaires (as a backup). These printed questionnaires will be stored in locked cabinets in the MIRC. The MIRC itself has a restricted access policy.

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

The data volume is extremely small (especially compared to the volumes which the MIRC is used to handling). Therefore, no additional hardware or software needs to be purchased to store the data. The data will be placed on the current MIRC servers. A (very small) fee is paid to IT for this purpose. The MIRC will bear the cost of this fee through their operating budget.

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

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

- Other (specify below)

Data will be stored for long-term use on research servers of the MIRC (managed by the IT manager of the MIRC).

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

The expected costs are extremely low considering the limited volume. It is estimated that this cost is < 100 Euros. Costs will be covered through the operating budget of the MIRC.

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 restricted data (upon approval, or institutional access only)

Data might be made available to other researchers for research purposes under strict conditions and under the FAIR principle
Data and data rights can also be transferred to the new spin-off entity in collaboration with LRD.
Data of prototype study will be made available by congress abstract, paper publication and further dissemination by seminars, workshops.

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

Access to data is restricted to all researchers, promoters and co-promoters of the C3 project. If access to data is requested and deemed valuable/necessary by the current research team, advice will be sought from LRD for drafting legal agreements to control access and rights.

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.

- Yes, intellectual property rights

The software is IP from KU Leuven.

Where will the data be made available?

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

- KU Leuven RDR (Research Data Repository)

There is no disciplinary repository for the project data types, so KU Leuven RDR will be used for data regarding the prototype study. Regarding software: only compiled code will be made available. Source code will not be shared.

When will the data be made available?

- Other (specify below)

Data will be made available after requests of the 3rd party and after finalization of the legal agreements for sharing.

Which data usage licenses are you going to provide?

If none, please explain why.

- Other (specify below)

The license type will need to be discussed with LRD based on the specific requests for data sharing.

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?

There a no expected costs for data sharing

Responsibilities

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

The researchers from the C3 project will manage the documentation. The co-promotor and promotor share that end responsibility. They also will manage the storage and sharing.

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

The IT manager of the Medical image Research center in collaboration with the IT management of KU Leuven

Who will manage data preservation and sharing?

Data preservation: the IT manager of the Medical image Research center in collaboration with the IT management of KU Leuven
Data sharing: the promotor of the C3 project in collaboration with LRD (for agreements). After finalization of the agreements: the IT manager of the Medical image Research center in collaboration with the promotor of the C3 project.

Who will update and implement this DMP?

The promotor and co-promotors of the C3 project