Plan Overview

A Data Management Plan created using DMPonline

Title: Copy of Evaluation of the additional effect of continuous ultrasound bladder monitoring in urotherapy for children with functional daytime urinary incontinence. The SENS-U trail

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Project abstract:

In this project, we want to study the cost-effectiveness of the SENS-U (continuous ultrasonic bladder monitoring) within standard urotherapy and specific urotherapy (3rd line). Lower urinary tract dysfunction (LUTD; functional incontinence) is a common condition with a prevalence of 10-20% in 7 year-old children. First line treatment according to the International Children's Continence Society (ICCS) is urotherapy. Urotherapy is a noninvasive, nonpharmacological treatment, defined as bladder re-education or rehabilitation aiming at correcting the filling and voiding function of the bladder-sphincter unit. Urotherapy is not always sufficient. If the initial success rate of urotherapy increases by addition of the SENS-U, health care efficiency will be obtained with less need for other expensive, invasive and/or time consuming treatments. Furthermore, the possible psychological stress associated with complex medical treatment (like surgery) is prevented. The SENS-U is a wearable ultrasound device that continuously measures bladder filling and gives an alarm at a preset bladder filling (e.g. 80% filling). The SENS-U provides biofeedback that teaches the child at which feeling of the bladder (e.g. the feeling corresponding with 80% filling) the child has to void. We hypothesize urotherapy with additional SENS-U to be 15% more effective (15% more continent children after treatment) than urotherapy without SENS-U. A multicenter RCT was conducted comparing urotherapy alone, with SENS-U, and with sham device. Children are randomized per center. There are four participating centers including children aged 6 to16 years with functional daytime urinary incontinence eligible for urotherapy. Study duration is 4 years. Primary outcome is the percentage of continent children after 3 months of urotherapy. Secondary outcomes are long term outcomes, subjective experiences, adherence, voiding frequencies, post-void residuals and volume, uroflowmetry curves, and quality of life. The effectiveness of urotherapy is approximately 54% (continent children). The sham device is believed to have the same effect. We expect 15% additional effect with the SENS-U. Sample size is based on three pairwise comparisons of continence proportions between the 3 groups. With a = 0.05, power = 0.80, and 33% lost to follow-up we need 160 children per group (1:1:1 randomization). This results in a total of 480 children divided over 4 centers (120 children each center).

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Copyright information:

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1. General features of the project and data collection

1.1 Project leader contact details

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1.2 I have composed my DMP with the assistance of a data stewardship (or management) expert. List his or her name, function, organisation/department, phone number and email address.

- The expert is connected to my department or institution (please explain his/hr expertise related to data stewardship)

Marten Onnink
Function: data steward at Radboudumc
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Radboud universitair medisch centrum, Radboudumc Technology Center Clinical Studies Intergraal Team. Postbus 9101, 6500 HB Nijmegen (115). Philips van Leydenlaan 15 (route 392)

1.3 In collecting data for my project, I will do the following:

- Generate new data

1.4 In my research, I will use:

- A combination of quantitative and qualitative data

Quantitative data about number of wetting accidents and frequency voiding chart parameters
Qualitatie data: interviews with subjects about user-friendliness of the device and experiences with wearing alarm systems

1.5 I will be reusing or combining existing data, and I have the owner's permission for that.

- No, I will not be reusing or combining existing data

1.6 In collecting new data, I will be collaborating with other parties.

- Yes, we have reached agreements on the user rights of the data used in the project

The valorisation department of the Radboudumc is involved. They will help to conduct a consortium clinical trial agreement and data transfer agreement.

1.7 I am a member of a consortium of 2 or more partners. Clear arrangements have been made regarding data management and intellectual property. (also consider the possible effect of changes within the consortium on issues of data management and intellectual property)

- Yes, clear arrangements have been made regarding data management and intellectual property through a consortium agreement

A consortium agreement is conducted with the help of the Valorisation department.

1.8 I can give an estimate of the size of the data collection; specifically, the number of participants or subjects (“n=”) in the collection and its size in GB/TB

- Yes (please specify)

480 children in total, 120 children in each center (4 centers).
With a 1:1;1 randomization 40 urotherapy alone, 40 urotherapy + sham device, 40 urotherapy + SENS-U
In total an expected <5GB of data will be generated

1.9 The following end products I will make available for further research and verification (please elaborate briefly)

- Data documentation
- Raw data
- Audiovisual material/ Images
- Syntaxes
- Documentation of the research process, including documentation of all participants

Raw data of source data is EPIC (electronic patiënt files) and will be available for 15 years. Data generated by the SENS-U device will be filed in EPIC as PdF files.
Documentation will be provided containing information about the data and procedures
Data sharing will only be made possible under the condition that it can be pseudonymized and other agreements part of the data transfer agreement.

1.10 During the project, I will have access to sufficient storage capacity and sites, and a backup of my data will be available. (please elaborate briefly)

- Yes, I will make use of my institution's standard facilities for storage and backup of my data

Data will be stored in a project specific folder on a network attached storage that is password protected and behind a firewall. All data on the network storage system is backed up overnight.

2. Legislation (including privacy)

2.1 I will be doing research involving human subjects, and I am aware of and compliant with laws and regulations concerning privacy sensitive data.

- The Wet Medisch-Wetenschappelijk Onderzoek met Mensen (WMO, or Medical Research (Human Subjects) Act) applies to my project; I will have it reviewed by a Medical Research Ethics Committee. In addition I will comply with the Kwaliteitsborging Mensgebonden Onderzoek (Quality Assurance for Research Involving Human Subjects)
- Wet op de Geneeskundige Behandelingsovereenkomst (Medical Treatments Contracts Act)
- Yes, I will involve human subjects in my research. I will comply with the Algemene Verordening Gegevensbescherming (AVG)

The Medical Device Regulation (MDR) is also applicable.
The departement "Medische Technology& klinische Fysica"of the Radboudumc is involved.
contact details: Roland Loeffen: roland.loeffen@radboudumc.nl

2.2 I will be doing research involving human subjects, and I have (a form of) informed consent from the participants for collecting their data.

- Yes, and this informed consent allows for the reuse of data (note that in the Code of Conduct for Medical Research, ‘reuse’ is also referred to as ‘further use’)

All subjects will be asked specifically consent for the re-use of data and according to the AGV law subjects have to give new consent if their data are used for other research purposes.
According to this principle data access is not open but restricted

2.3 I will be doing research involving human subjects, and I will protect my data against misuse.

- Yes, the data will be pseudonymised. (please explain how this will be done, and by which organisation) and

We will use PIMS (participant identify Management System; see http://pims.radboudumc.nl) for deidentification of patient (traceable) personel information. Storage of the deintification list is apart from the data and restricted.
For quantative data, tape recorded video interviews it is not feasible

2.4 I will stick to the privacy regulations of my organisation

- Yes

3. Making data findable

3.1 The data collection of my project will be findable for subsequent research. E.g., on a catalogue, a web portal, or through the search enginge of the repository (note: this is key item 3, which you should report to ZonMw at the end of your project).

- Yes, it can be found through an online (metadata) catalogue or web portal (please specify)

With help of Radboud university Libabry (https://www.ru.nl/research-information-services/) the project and data can be found at the DANS EASY archive after teh study is terminated.(https://easy.dans.knaw.nl/ui/homeOpens in a new window).
In addition, metadata of published collections can be found through Narcis (https://www.narcis.nl/).

3.2 I will use a metadata scheme for the description of my data collection (note: this is key item 7, which you should report to ZonMw at the end of your project).

- Yes, I will use a generic metadata scheme (please specify)

Data collection metadata follows Dublin Core standards

3.3 I will be using a persistent identifier as a permanent link to my data collection (note: this is key item 1, which you should report to ZonMw at the end of your project).

- Yes, in addition to the DOI code I will be using another persistent identifier (please specify)

DANS EASY uses Digital Object Indentifiers.
Each dataset will automatically receive a DOI and URN

4. Making data accessible

4.1 Once the project has ended, my data will be accessible for further research and verification.

- No (please explain)

Data will be accessible once the data collection has been published (e.g. at paper publication)

4.2 Once the project has ended, my data collection will be publicly accessible, without any restrictions (open access).

- No, there will be access restrictions to my data collection (please explain)

In line with privacy legislation, The Radboud University Medical Center and local ethical committee require that users of these data publications can be identified (e.g in case of violation of Data Use Agreement). Therefore, potentially identifiable data are shared under a specific Data Use Agreement that requires authentication to download these data sets.

4.3 I have a set of terms of use available to me, which I will use to define the requirements of access to my data collection once the project has ended (please provide a link or persistent identifier; also note that this is a key item 4, which you should report to ZonMw at the conclusion of your project).

- Yes, my institution has drafted a set of terms of use with the help of a legal advisor

With help of the valorisation department a data transfer agreement is conducted for future data sharing.

4.4 In the terms of use restricting access to my data, I have included at least the following:

- Collaboration in using the data set, including agreements on publication and authorship
- Whether or not the data set may be linked with another data set (for reasons of privacy)
- The manner in which the data set can be accessed
- Conditions related to data security
- The approval of the participants allows for further research using this data set

5. Making data interoperable

5.1 I will select a data format, which will allow other researchers and their computers (machine actionable) to read my data collection (note: this is key item 5, which you should report to ZonMw at the end of your project).

- Yes (please specify)

Preferred formats according to DANS EASY regulations are used:
https://dans.knaw.nl/nl/over/diensten/easy/toelichting-data-deponeren/voor-het-deponeren/bestandsformaten

5.2 I will select a terminology for recording my data (e.g., code, classification, ontology) that allows my dataset to be linked or integrated with other datasets (note: this is key item 6, which you should report to ZonMw at the conclusion of your project).

- Yes, metadata standard (please specify)

CASTOR EDC is used to store data. Castor supports the storage of metadata, so datafields can be enriched with the available metadata standards below:

MedDRA - Medical clinical observations (healthcare) - https://biosharing.org/bsgs002647.
SNOMEDCT - Medical clinical observations (healthcare) - https://biosharing.org/bsgs000098
LOINC - Clinical and laboratory observations - https://biosharing.org/bsg-s000106Data Documentation Initiative (DDI) - survey and kwalitative data - https://biosharing.org/bsg-s000605 CASTOR EDC https://helpdesk.castoredc.com/article/55-metadata-settings

5.3 I will be doing research involving human subjects, and I have taken into account the reuse of data and the potential combination with other data sets when taking privacy protection measurements.

- Yes, the participants have given their permission for reuse of the data, and the data have been pseudonymised

6. Making data reusable

6.1 I will ensure that the data and their documentation will be of sufficient quality to allow other researchers to interpret and reuse them (in a replication package).

- I will document the software used in the course of the project (please specify)
- I will perform quality checks on the data to ensure that they are complete, correct and consistent (please explain)
- I will document the research process (please explain)

CASTOR EDC will be used for capturing research data, which includes quality checks on the data and monitoring.
The monitor will verify data of the eCRF to source data with the help of certified data capturing systems --> CASTOR EDC
Steps in data cleaning will be documented, SPSS analyses will be documented with the help of syntaxes
I will add readme files in the data repository to each subfolder for interpretation of the folder content.
I will add comments to software scripts to enhance interpretation.

6.2 I have a number of selection criteria, which will allow me to determine which part of the data should be preserved once the project has ended. (see also question 1.9 and 6.1)

- Yes

structured castor files

6.3 Once the project has ended and the data have been selected, I can make an estimate of the size of the data collection (in GB/TB) to be preserved for long-term storage or archival.

- Yes (please specify)

< 5 GB

6.4 I will select an archive or repository for (certified) long-term archiving of my data collection once the project has ended. (note: this is a key item, which you should report to ZonMw at the conclusion of your project)

- Yes, and this archive has a different form of certification (please specify the archive and certification)
- Yes, and this archive has a data seal of approval (please specify the archive)

DANS EASY has a Data Seal of Approval (part of CoreTrustSeal) and NESTOR certificate.

6.5 Once the project has ended, I will ensure that all data, software codes and research materials, published or unpublished, are managed and securely stored. Please specify the period of storage.

- Yes, in accordance with other guidelines (please explain, and specify the guidelines and the number of years)

In accordance to the Radboudumc guidelines all datam software codes and research materials published or unpublished will be stored at least 15 years.

6.6 Data management costs during the project and preparations for archival can be included in the project budget. These costs are:

- Unknown (please explain)

There are no project-specific costs for long-term archiving and for sharing of published data, these are included in the project overhead costs.

6.7 The costs of archiving the data set once the project has ended are covered.

- Yes (please elaborate)

DANS-easy is free of use