Plan Overview

A Data Management Plan created using DMPTuuli

Title: Headache and sleep disturbances after traumatic brain injury - a sham controlled repetitive transcranial magnetic stimulation study

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Project abstract:

Headache and sleep disturbances are major problems after traumatic brain injury. In 2018, 2200 brain injury patients were treated in Helsinki University Hospital (HUH). In this group of patients, incidence for severe drug-resistant and persistant headache is about 20 patients per year. Our main question is how to best harness the neuroplastic capacity of the human brain to treat this patient group. Our aim is to determine how medication-free neuromodulatory therapies such as repetitive transcranial magnetic stimulation (rTMS), which has shown promising results in decreasing pain and headache intensity, could be tailored for each individual patient. We also plan to explore the neural mechanisms behind the treatment effect. In other types of drug-resistant neuropathic pain, about 40-50% of the patients benefit from rTMS and similar effectiveness could be expected for patients with persistent headache. We will also study the treatment effect of rTMS on sleep disturbances and on glymphatic flow, which is a newly recognized brain-wide network that allows cerebrospinal fluid to clean brain parenchyma from harmful metabolic waste. To study the mechanisms of neuromodulatory treatment, close collaboration is needed between physicians, sleep researchers, and experts in brain imaging, signal analysis, and network modeling. Collaboration between HUH, University of Helsinki, and Aalto University (Department of Neuroscience and Biomedical Engineering, NBE) will offer the needed expertise. Department of Clinical Neurophysiology in HUH will offer expertise in conducting neuromodulatory treatments; together with Department of Radiology (HUH) and NBE of Aalto University the treatment effect will be studied using brain imaging, signal analysis and neuronal network modeling. Treatment-related functional neuroplasticity will be measured with TMS-EEG, with which cortico-cortical signal propagation and neuronal activation levels can be measured. The newest MRI methods will be used to quantify treatment-related structural plasticity in white matter. The newly built MREG technology in HUH will be used in studies of glymphatic flow. Neurological outpatient clinic together with pain clinic in HUH offers the expertise in treating and studying headache and pain. Aalto University with its most advanced TMS technology in the world and cutting-edge expertise in diffusion imaging and signal analysis will guarantee the adequacy of the technical quality of the studies.

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Headache and sleep disturbances after traumatic brain injury - a sham controlled repetitive transcranial magnetic stimulation study

1. General description of data

1.1 What kinds of data is your research based on? What data will be collected, produced or reused? What file formats will the data be in? Also give a rough estimate of the size of the data produced or collected?

A) data collected for this project: clinical data (.sav)
B) data produced as an outcome of the process: MRI images including magnetic resonance encephalography (MREG) (.jpeg)
C) previously collected existing data which is reused in this project: none
D) managerial documents and project deliverables (.doc)

1.2 How will the consistency and quality of data be controlled?

- Analog material will be digitised in as high resolution as possible for accuracy.
- In all conversions, maintaining the original information content is ensured.

2. Ethical and legal compliance

2.1 What ethical issues are related to your data management, for example, in handling sensitive data, protecting the identity of participants, or gaining consent for data sharing?

Personal data will be processed fairly and lawfully. It will be obtained only for the specified and lawful purpose which is our research question, and it will not be further processed in any manner incompatible with this purpose. Personal data will be adequate, relevant and not excessive in relation to this purpose. Personal and sensitive information will be removed from the data before sharing it in order to ensure privacy protection. Personal data processed for our purpose shall not be kept longer than is necessary.

2.2 How will data ownership, copyright and IPR issues be managed? Are there any copyrights, licences or other restrictions that prevent you from using or sharing the data?

Data is owned by HUS Hospital area. IPR issue concerning copyright is managed according to HUS data policy and Academy of Finland data policy. Issues concerning patent are not relevant in our project.

3. Documentation and metadata

3.1 How will you document your data to make them findable, accessible, interoperable and reusable for you and others? What kinds of metadata standards, README files or other documentation will you use to help others understand and use your data?

We will use descriptive metadata to enableidentification, location and retrieval of information resources by users

4. Storage and backup during the research project

4.1 Where will your data be stored, and how will they be backed up?

We will store and back up our data in external hard drives. The PI is responsible for backup and recovery.

4.2 Who will be responsible for controlling access to your data, and how will secured access be controlled?

The researchers of our research group have access to pseudonymised data, and they are authorised to analyse it. Secured access is controlled by use of password.

5. Opening, publishing and archiving the data after the research project

5.1 What part of the data can be made openly available or published? Where and when will the data, or their metadata, be made available?

At this point we are planning to make only part of our data openly available. This concerns demographic and clinical data. Advanced imaging data and other registrations require special analysing techniques and thus, open access would not be of benefit.

5.2 Where will data with long-term value be archived, and for how long?

Data with long-term value will be archived in a locked space accessible by the research group only. It will be stored for 15 years after finishing the project.

6. Data management responsibilities and resources

6.1. Who will be responsible for specific tasks of data management during the research project life cycle? Estimate also the resources (e.g. financial, time and effort) required for data management.

- Data collector: all researchers
- Metadata generator: PI
- Data analyzer: all researchers
- Project director: PI
- Data model and/or database designer: hired expert help
- Computing staff responsible for backup and/or storage: hired expert help