Data Management Plan

Investigating spinal cord stimulation using electroencephalography in chronic pain patients with a spinal cord stimulator implant

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Project end: Ongoing

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List of Abbreviations

ACH	Auckland City Hospital
ADHB	Auckland District Health Board
DSMC	Data safety monitoring committee
DSMP	Data safety monitoring plan
EEG	Electroencephalography/electroencephalogram
EMG	Electromyography/electromyogram
HDEC	Health and Disability Ethics Commission
SCS	Spinal cord stimulation/stimulator
TARPS	The Auckland Regional Pain Service
VM	Virtual Machine

Project

Title

Investigating spinal cord stimulation using electroencephalography

Abstract

Clinicians have used spinal cord stimulation (SCS) for decades to provide relief to patients with intractable chronic pain. The treatment involves implanting an electrical pulse generator (usually in the buttock) that delivers rhythmic pulses of electrical current to targeted parts of the spinal cord (SC). The mechanisms of SCS in treating chronic pain are currently poorly understood, it does not work for everyone, and the complication rate is high.

We plan to investigate the nature of the brain's electrical response to SCS. We will use electroencephalography (EEG) in up to 20 participants with SCS implanted to treat chronic pain. Participants will have their EEG recorded while therapeutic SCS is delivered.

A better understanding of brain activity during SCS could lead to improvements in SCS therapy and in the selection of patients likely to benefit from this treatment. This research could also offer new insights into SC physiology, more generally. This could have wide-ranging therapeutic applications. For instance, studies have recently demonstrated that SCS can help restore movement in patients paralysed by SC injury.

Field(s) of Research

110903 Central Nervous System

110301 Anaesthesiology

110399 Clinical Sciences not elsewhere classified (Pain Medicine)

Project Funding

Neurological Foundation of New Zealand Small Project Grant – 1916SPG

Data Organisation

Description of Digital Data

The following is an enumeration of data structures that will be generated during the course of this study. Using NodeJS, a web form implemented in AngularJS will be established to record data to a JSON-based password-protected MongooseJS/MongoDB database using an ExpressJS REST API with authorised access mediated by Auth0. The frontend and backend will run on separate VMs on the Nectar cloud. The backend will be inaccessible from outside the Nectar cloud. Data will be converted to tab-separated value or JSON files when required. Unique hexadecimal IDs will be assigned by MongoDB, and linked to a human-readable ID in a separate table.

- Screening data
    - Basic candidate information table
        - Candidate identifier (Hexadecimal string)
        - Date added (Date)
        - Added by user (String)
        - Screening status (Pending/Passed/Failed)
        - Contact status (Pending details/Pending contact/Pending follow up/Complete)
        - Participation status (Pending/Consented/Decline)
        - Participant identifier (Hexadecimal string)
        - Candidate index (integer)
        - Human-readable candidate identifier (String)
    - Reidentifiable information table
        - Candidate identifier (Hexadecimal string)
        - Candidate initials

        - Date of birth (Date)
        - Gender (M/F/Other)
    - Screening log table
        - Candidate identifier (Hexadecimal string)
        - Date last updated (Date)
        - Age 18+ (Yes/No)
        - Operational SCS implant (Yes/No)
        - SCS not constantly delivered for therapy (Yes/No)
        - Date of last surgery at implant site (Date)
        - Willing to be approached by research team (Yes/No)
        - Notes (String)
    - Contact details table
        - Candidate identifier (Hexadecimal string)
        - Given name (String)
        - Family name (String)
        - Contact phone number (String)
        - Contact email address (String)
        - Preferred contact route (Phone/email)
        - Notes (String)
    - Recruitment log table
        - Candidate identifier (Hexadecimal string)
        - Participant information received (Yes/No)
        - Participant information read (Yes/No)
        - Participant information questions answered (Yes/No)
    - Contact event table

        - Candidate identifier (Hexadecimal string)
        - Contacted by (String)
        - Follow up date (Date)
        - Notes (String)
        - Next follow up due (Date)

- *Consent forms*

  PDF files completed on a tablet, stored in an encrypted directory

- *Identifiable key table*

  A single tab-separated value format table stored in an encrypted directory including:

  - Participant ID
  - Patient first and last name
  - Contact phone number
  - Contact email address
  - NHI

- *Participant contact conditions table*

  A single table detailing the circumstances under which the participant (by ID) has indicated that he/she should be contacted, including:

  - Participant ID
  - Contact for future studies (Yes/No)
  - Contact with publications (Yes/No)

- *Participant data sharing consent table*

  A single table including details of how the participant requests data sharing requests be handled (see Data Publication, p. 18), including the following columns:

  - Participant ID

- Share with other studies led by a public research organisation based in Aotearoa NZ (Yes/No/HDEC Approved/Contact details of authority)
- Studies led by an overseas research organisation (Yes/No/HDEC Approved/Contact details of authority)
- Studies led by an overseas private research body (Yes/No/HDEC Approved/Contact details of authority)
- Data downloadable publicly (Yes/No)

- *Participant characteristics table*

  A single table including:

  - Participant ID
  - Date of birth
  - Gender
  - Date of recording session
  - Clinical indication for SCS (name)
  - Clinical indication for SCS (ICD-10 diagnosis code)
  - SCS trial implant date
  - SCS definitive implant date
  - Device specification identifier (ID)
  - Electrode vertebral location
  - Average pain severity before SCS (0-10)
  - Average pain severity after SCS (0-10)
  - Reported handedness (L/R/A)

- *Therapeutic stimulation parameters table*

  A table with details of the participant's therapeutic settings and usage patterns for each participant (by ID):

  - Participant ID
  - Frequency (Hz)
  - Pulse width (ms)
  - Amplitude (mA)
  - Stimulation on period (s)
  - Number of times SCS delivered per day (Integer)
  - Percentage of day program active (%)

- *Ethnicity table*

  Each participant may report multiple ethnicities, these will be held in a separate comma-separated value format table for each participant (by ID) containing reported Ministry of Health standard ethnicities.

- *Pain characteristics table*

  Each participant may have more than one distinct area of pain, a comma-separated value format table will be composed for each participant (by ID) containing:

  - Participant ID
  - Pain location
  - Pain severity (0-10)
  - Pain frequency (Times per day)

- *Device characteristics table*

  A table containing for each SCS device encountered:

  - Device specification identifier (ID)
  - IPG specifications (Make/Model/Version)
  - Electrode specifications (Make/Model/Version)
  - Notes on range of values for:
    - Frequency

        - Amplitude
        - Pulse-width
        - Electrodes
    - Notes on ease of changing parameters

- *Patient discomfort table*

  A table for each participant (by ID), containing visual analogue scale (VAS) reports of discomfort before each block undertaken, with the following columns:

    - Block number
    - VAS discomfort rating

- *Electrophysiological recordings*

  EEG and EMG will be stored in their original directory format, and also converted to the Brain Imaging Data Structure (BIDS-EEG) standard for analysis and dissemination.

Description of Non-Digital Data

Our goal is to conduct a completely paperless study.

Collection/Creation Methods

Identifiable patient data (Name, NHI) will be transferred to *Participant log table* in the case of successful recruitment.

All other non-physiological data will be entered password-protected secure web forms hosted on a research virtual machine (VM). Electrophysiological data will be recorded by our 64-channel EGI Philips GSN400 with Physio16 add-on for EMG recording, uploaded to the same VM as soon as practical, where they will be converted to BIDS-EEG standard format.

Data Organisation

- Encrypted shared drive folder

(U:/Anaesthesiology/RESEARCH/Matt/SCS_EEG_feasibility/identifiable_data)

  - License file (license.txt)
  - Unencrypted readme file (Readme.md)
  - Screening log table (SCS_EEG_feasibility_screening_log.tsv)
  - Identifiable key table (SCS_EEG_feasibility_id_table.tsv)
  - Readme files per table

- Nectar volumes (~/SCS_EEG_feasibility/)
  - Nectar volume for Raw data (mounted at data/raw/)
    - Readme file (Readme.md)
    - MongoDB collections
    - Electrophysiological recordings (EEG/<PPT ID>)
  - Nectar volume for Processed data (mounted at data/processed/)
    - License file (license.txt)
    - Readme file (Readme.md)
    - Participant contact conditions table (ppt_contact_conditions.tsv)
    - Participant data sharing consent table (ppt_data_sharing.tsv)
    - Participant characteristics table (ppt_demographics.tsv)
    - Therapeutic stimulation parameters table (ppt_scs_params.tsv)
    - Ethnicity table (ethnicity/<PPT ID>_ethnicity.tsv)
    - Pain characteristics table pain/<PPT ID>_pain.tsv)
    - Device characteristics table (device/<DEV ID>_device.tsv)
    - Patient discomfort table (discomfort/<PPT ID>_discomfort.tsv)
    - BIDS-EEG format recordings (BIDS-EEG)
  - Readme files per table

Data Storage and Backup

Identifiable data will be stored in a password-encrypted directory on the backed-up University of Auckland Department of Anaesthesiology shared drive. These data will not be duplicated or transmitted, except for auditing purposes approved by the HDEC.

Other data and documentation will be stored in a master location on a research VM on the Nectar cloud, a secure backed-up platform with storage located in Auckland. These data may be transferred to password-protected University and researcher machines for analysis.

Ethics and Privacy

Ethical Approval Details

Ethical approval is currently being sought from the Health and Disabilities Ethics Commission (HDEC). Approval to conduct the research at Auckland District Health Board (ADHB) will be sought thereafter.

Ethical Issues

The study involves manipulation of an active implantable medical device (i.e. a high-risk device). As such, we have appointed a Data Safety Monitoring Committee (DSMC), as outlined in our Data Safety Monitoring Plan (DSMP) document.

Data will include identifiable health data. Patient NHI will be requested, as we will retrieve contact details from the ADHB Patient Information Management System if the participant asks to be contacted (e.g. with results). As we are storing sensitive healthcare information, we will ensure that all data are stored in Aotearoa New Zealand (unless participant permission is granted otherwise).

We plan to test a data sharing protocol that recognises the value of the endowment of data by participants, and gives participants options as to how and where their data are used. The focus of this initiative is on enhancing Māori data sovereignty, but it will operate similarly

for all participants as individuals or collectives. This process is further described in Data Publication (p. 18).

Data Privacy and Security Issues

Data will be deidentified as soon as possible. The Screening log, Consent forms, and Identifiable key tables will be kept in a single password-encrypted directory on a secure backed-up University of Auckland server. Other master data will be stored securely on a research VM, and password-protected University and researcher machines as required. If a data breach is detected, it will be reported immediately to the chair of the DSMC, and the HDEC.

Relevant Policy

In keeping with the University of Auckland's Code of Conduct for Research (version reviewed June 2015), the University of Auckland will own the data generated by this project. (Section 5.4). Confidentiality of data will be observed (Section 5.4). We will share data in keeping with our participants' indicated wishes (Section 4.5), but provide data for auditing purposes when and as approved by the HDEC.

Responsibilities and Resources

Data Management Staff

MRM will be responsible for data management. The School of Medicine at the University of Auckland will be the long-term kaitiaki, and the University, including MRM and AFM, will be responsible for faithfully executing our participants' wishes with respect to data sharing.

Required Resources

We will require storage space on the Department of Anaesthesiology shared drive, which is allocated automatically. A volume on the Nectar cloud will be established on Auckland hardware for storage of the data. A VM on the Nectar cloud will serve web forms, and eventually be used for reporting and data processing.

Sharing and Access Control

Description of Sensitive Data

The Screening log, Consent forms, and Identifiable key tables will contain participant names and contact details. The Identifiable key table will include NHIs. Other tables contain sensitive health information to varying degrees.

Access Control and Security Measures

The Consent forms and Identifiable key tables will be kept in a single password-encrypted directory on the backed-up University of Auckland Department of Anaesthesiology shared drive. These data will be transferred to their secure location as soon as possible, and securely deleted (overwritten) from the machine on which they were collected after testing fidelity of the copy. They will not be duplicated or transmitted, except for auditing purposes approved by the HDEC.

The Screening log will be stored in our MongoDB database, with password-mediated web access to facilitate access by screening clinicians. This will necessarily include identifying data, which will be transferred to the encrypted Identifiable key table and overwritten when the patient either accepts or declines enrolment, or at the end of the study. We also plan to include reidentifiable data, such that clinicians can distinguish whether the patient has been screened before.

Other tables will be stored in a deidentified form on password-protected University or

researcher machines. Data will not be stored offshore. Encrypted file passwords, along with the latest version of this DMP, will be stored in a locked cabinet at the Department of Anaesthesiology.

Access to the components of our web portal will be restricted based using role-based access control (RBAC). Screening clinicians will have read and write access to the Screening log. DSMC members will have read access to automatically generated reports, and the Screening log without identifiable data. Researchers will have read and write access to the Screening log (minus reidentifiable data), Participant data, and reports. Access to the server will be restricted to the research team only. A dummy website with synthetic data will be created for test and audit purposes.

Metadata and Documentation

Description of Accompanying Metadata

Each table will have an associated Readme text file describing the meaning of each column and how the data were collected. Overall Readme files in each of the data storage locations will document the files that should be present, and our kaitiaki data sharing protocol. This DMP will be filed in a locked cabinet at the Department of Anaesthesiology.

Spatial Extent of Data

SCS is provided by ADHB for patients around the North Island. Most participants are likely to be from Auckland.

Temporal Extent of Data

2019.04.01 to [ongoing, to be determined]

Data Publication and Reporting

Data Ownership

The University of Auckland will own all data generated by this project.

Data Publication

Preparation Methods

We see research as a collaboration between researchers and participants, with the University being the kaitiaki of the data, a valuable taonga. We consider it part of our duty to ensure that the participant has the right to retain sovereignty over his/her data, and that it would be inappropriate to exclude participants who want to retain some say in how their data are used. Such exclusion may also constitute a breach of te Tiriti of Waitangi.

To this end, we will ask participants how they would like their deidentified data shared on their consent form, with the facility to delineate how data are shared depending on the location and purpose of the requesting party, the levels being:

- Data downloadable by general public
- Studies led by an Aotearoa New Zealand public research organisation
- Studies led by overseas research bodies
- Studies led by an overseas private research organisation

For each option (except publicly downloadable), the participant will be able to select whether data sharing should be:

- Unrestricted
- Restricted to projects approved by the HDEC
- Restricted to projects approved by another authority/individual, with contact details
- Not available

University, including MRM and AFM, will be responsible for faithfully executing our participants' wishes with respect to data sharing. Metadata for the study (Readme files) will be published on the University of Auckland's figshare data repository, including any conditions on access compiled over all participants. Deidentified data from participants who have requested no restrictions on sharing their data will be published to the data repository, linked to the metadata publication.

Licensing

Deidentified data from participants who have requested no restrictions will be published with a CC-BY license. Data that the participant has indicated can be shared with restrictions will be distributed as appropriate with a Kaitiakitanga license. Other data, including raw data, will be All Rights Reserved.

Retention and Disposal

Data Retention Period

The data will be retained for at least 10 years after publication of the last paper related to the data, as required by the HDEC.

Method of Disposal

If data do need to be destroyed, paper forms will be disposed of securely, and digital data will be deleted or otherwise made inaccessible.

Archiving and Preservation Plan

We do not consider that these data need special allowances for archiving and preservation.