# Plan Overview

*A Data Management Plan created using DMPonline*

**Title:** USING TELEHEALTH TO ENHANCE MANAGEMENT OF VULNERABLE GROUPS DURING THE COVID-19 PANDEMIC

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**Project abstract:**

Background: Amyotrophic Lateral Sclerosis (ALS) (MND) is a progressive neurodegenerative condition resulting in decline in mobility, arm function, respiratory function, speech, swallow and in 30-50% cognitive and behavioural impairment. ALS is recognized as a heterogeneous condition with different pathogenic mechanisms, clinical presentations and disease trajectories. Remote but accurate tracking of patient's clinical symptoms, early recognition of risk, and rapid transfer to an appropriate facility will be essential to prevent a crisis for people with Motor Neurone Disease (MND) and Frontotemporal Dementia (FTD). Telehealth in Motor Neurone Disease (TiM) is a system which allows people with MND and their carers to engage with their clinical team in real-time using a customized remote digital application. The implementation of TiM as a clinical tool has been approved by the Beaumont Hospital Data Protection Officer (DPO) through a Data Protection Impact Assessment (DPIA) and a Data Sharing Agreement with the hosting company ADI has been signed by the Beaumont Hospital Chief Operating Officer (COO). This study proposes to evaluate the TiM system to provide immediate support for those with MND and FTD. Approximately 400 adult patients in Ireland with MND could benefit from this immediate and innovative approach. Objectives: To evaluate the use of the TiM system by obtaining patient, carer and HCP perspectives on remote monitoring/telemedicine. To identify the key attributes required by the users of TiM, in order for TiM to be acceptable and useful. To evaluate the impact of COVID-19 on the use of technology for healthcare in patients with MND and their carers and their attitudes to this change. Methods: Participants will be recruited from the Irish tertiary multidisciplinary MND clinic. Purposive sampling will be used to recruit patients at all stages of MND using King’s Staging System. People with MND, their carers and healthcare professionals (HCPs) will be asked about their opinions on using TiM in a semi-structured way. Three methods will be used, firstly a questionnaire will be used to gather feedback from patients, carers and HCPs (n = approx. 300). This will primarily focus on the usability of the TiM service. Following this, a smaller number of patients and carers will be interviewed individually in more detail (n = 10-15). Participants’ opinions about using the TiM service for remote monitoring and communication, the experience of being a carer for a person with MND, and the impact of the

TiM system on the health services provided will be explored in these interviews. Finally, focus groups will be carried out with HCPs who are using TiM (n = 20). Interviews and focus groups will be recorded, transcribed and analysed by the researchers.

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# USING TELEHEALTH TO ENHANCE MANAGEMENT OF VULNERABLE GROUPS DURING THE COVID-19 PANDEMIC

## Data description and collection or re-use of existing data

### How will new data be collected or produced and/or how will existing data be re-used?

- New Data
  - New data will be collected through remote focus groups, interviews and online surveys using Qualtrics or paper-based surveys if preferred.
  - Interviews and focus groups with patients, carers and HCPs will take place via WebEx or Microsoft Teams. Both are considered secure and appropriate for use in patient care and research. Audio and video recordings of interviews and focus groups will be collected from which transcripts will be automatically created with the consent of all participants. Data will be pseudonymised when transcriptions are reviewed and coded during analysis by the research team. Interviews and focus groups will be used to explore the experiences of patients, carers and HCPs who have used the TiM system in the preceding months.
  - Surveys will collect data about ease of use of the TiM platform, time taken to upload, usefulness and suggested modifications. Surveys in multiple administration modes will be made available (Online via Qualtrics or paper-based).
- Existing Data
  - Data previously collected as part of the routine MND service will be used to inform the recruitment and stratification of interviews and focus groups. Participants have already consented to the use of this data from their clinical chart as part of the consent for this study and also having previously consented to the MND Register.
  - Anonymised operational data such as, the number of people who create a TiM account and the number of clinical questionnaires they complete, will be collected automatically by the TiM platform and used to identify a variety of users for recruitment.
- Personal data may be elicited and recorded as part of the process, but this is not a direct focus of this part of the study.
- Data provenance will be recorded in a single README text file that describes the data collection and processing methods used.

### What data (for example the kind, formats, and volumes), will be collected or produced?

- Qualitative data generated from remote interviews and focus groups will be in MP4 format. Transcriptions of these interviews and focus groups will be automatically generated by Microsoft Teams in a VTT caption file format. Transcriptions will be checked for errors and pseudonymised by the researchers.
- Data from approximately 10-15 interviews and 3-4 focus groups lasting approximately 30 minutes and one hour each will be collected, equating to approximately 20-60 Gigabytes (GB). The size of a 1-hour Microsoft Teams recording is 400 Megabytes (MB).
- Quantitative data generated from online surveys will be in CSV format. This format was chosen as it is human-readable and easy to edit manually. It is considered to be the standard format used by Qualtrics.
- Quantitative data generated from paper surveys will be in paper format.
- Interview/focus group recordings will not be made available to others, to protect the anonymity of

the participants.
- Anonymised aggregated data summaries and resulting themes may have value for other research users in the future and could be shared, following the appropriate data sharing protocol.

## Documentation and data quality

### What metadata and documentation (for example the methodology of data collection and way of organising data) will accompany data?

- A README text file will be made available that introduces and explains the project. Blank study information leaflets, consent forms, questionnaires and interview schedules will be made available to accompany the corresponding datasets.
- A qualitative data document for the interviews and focus groups will include relevant contextual information of participants.
- FAIR data management will be achieved through agreed data description, file naming conventions and metadata standards, DOI assignment and machine-actionable shared data (if possible), anonymised (where necessary) via trusted repositories with Creative Commons licencing.
- Files will be named by date (DDMMYY), description, and file type. For example, for interview/focus group files: 100321_interview2_video.mp4, 100321_interview2_trans.txt.
- The Dublin Core Metadata Initiative (DCMI) Standards will be used to guide the organisation of metadata.

### What data quality control measures will be used?

- The individual participant will have an opportunity to review and amend the transcript from their interview/focus group if they wish. During analysis, the recording transcripts will be pseudonymised.
- The data collected will be limited to what is required in order to answer the research question.
- Automatic data validation measures will be programmed into the Qualtrics surveys, to control the type of answers allowed and alert participants to missing responses.
- A data entry Standard Operating Procedure (SOP) will be developed and deployed for the paper-based surveys, to ensure consistency with the electronic surveys.
- Two members of the research team will review the transcripts / summarised data to monitor data quality and ensure anonymisation.

## Storage and backup during the research process

### How will data and metadata be stored and backed up during the research process?

- Data, both qualitative and quantitative (spreadsheets, transcripts/audio, text, databases), will be stored on encrypted computers, using a shared institutional drive (Microsoft SharePoint and

OneDrive) which is automatically backed up by IT support services at Trinity College Dublin (TCD).
- The key for the data will be held by members of Prof. Hardiman's team in the Academic Unit of Neurology (AUoN), TCD specifically overseen by the Research Manager.
- All evaluation data will be held for seven years as per standard practice.

**How will data security and protection of sensitive data be taken care of during the research?**

- The collected data will be held by and accessible to members of Prof. Hardiman's research team in the AUoN, TCD. Access to these data will be controlled by Prof Hardiman's Research Manager using relevant sharing permissions and protocols using approved, data protection compliant storage resources including SharePoint, OneDrive and a locked cabinet in the AUoN, TCD.

## Legal and ethical requirements, codes of conduct

**If personal data are processed, how will compliance with legislation on personal data and on security be ensured?**

- A consent form will be provided to potential participants at the initial approach. Following this, the research study will be outlined and discussed, and the patient information leaflet will be provided. Any questions will be answered. The written consent form will be signed at the start of the focus group/interview which will ensure that time for reflection will be available between initial contact and consent. It will be explained that focus groups and interviews will be conducted and recorded. The patient will be advised of which format is preferable to use but an option will be provided to them if possible. It will be outlined that audio recordings will be transcribed, and the participants will not be identified by name. The right to withdraw or discontinue the interview at any time will be emphasised.
- Data sharing agreement will be completed, researcher training in General Data Protection Regulation (GDPR) and national health regulations assured, and a DPIA Form completed and assessed by Beaumont Hospital’s DPO. The DPO has approved that the data be stored in TCD, as this is how our infrastructure works.
- The data subjects will be informed of their data protection rights initially by way of an information leaflet provided to them in the MND clinic. Later if they proceed with the study, they will be further informed of their data protection rights through the privacy notice they are initially consented with, which they can see on the TiM system app as well as through links to a webpage with further information in a letter of invitation. They will be informed that in order to exercise these rights, e.g., right of access, right to be forgotten, they can contact the DPO of the data controller in Beaumont Hospital who will process this request.
- The pseudonymised personal data collected as part of the evaluation study will be held in the AUoN in TCD and access to this will be controlled and recorded by the Research Manager.

**How will other legal issues, such as intellectual property rights and ownership, be managed? What legislation is applicable?**

- Issues related to intellectual property rights and ownership are dealt with in a signed contract between TCD and The University of Sheffield.
- Intellectual Property will be managed in accordance with the Prime Sponsor Requirements and the National IP Protocol.
- Article 6 (a) "Consent from the data subject" and Article 9 (j) "Archiving purposes in the public interest, scientific or historical research purposes or statistical purposes" are the legal basis and relevant condition for the proposed processing of personal data in this study.

**What ethical issues and codes of conduct are there, and how will they be taken into account?**

- Should any concerns regarding the participants' wellbeing emerge during the study the Consultant will be informed with the patient’s consent.
- ALS/MND patients are a vulnerable population due to the progressive nature of the disease. Additionally, as patients of the MND clinic, the participants could be considered vulnerable as they may be in an unequal relationship with healthcare professionals involved in the research. All researchers all have experience working with ALS/MND patients and are experienced in managing this vulnerability in a sensitive manner and will aim to empower patients through providing information.

## Data sharing and long-term preservation

**How and when will data be shared? Are there possible restrictions to data sharing or embargo reasons?**

- As the PI is the HSE National Clinical Lead for Neurology, the project also forms part of the engagement with HSE senior management in the context of the COVID-19 response. The PI has developed the HSE Guidelines for the care of vulnerable neurological patients within the community. Telehealth will form a major part of the solution in addressing the needs of non-COVID-19 patients in the short term and is likely to be incorporated in the management of scheduled care in the longer term. The innovation described in this project will form part of a detailed implementation plan for all forms of scheduled care in Neurology, over the coming 36 months.
- The evaluation of TiM will be used to showcase service improvement and will be rapidly modified to provide a similar programme for other vulnerable groups.
- Results of the study will be published on the HRB Open Research platform, as well as providing lay summaries for patients, carers and staff which will be available on HSE and TCD websites. The aggregated results will be available via a summary paper in lay language and provided to participants if they wish. Results will be disseminated through publications and presentations at national and international meetings.
- Evaluation data will be retained in electronic format on encrypted TCD machines for continued access by the research team to facilitate the analysis and dissemination process. If a data subject specifically withdraws consent and requests that their data on the system be destroyed, then their data will be permanently deleted from the system.
- Data sharing will be via access to a shared institutional drive with secure cross-institutional data-sharing provided via institutional computing services (backed up nightly to strict security

protocols).

**How will data for preservation be selected, and where data will be preserved long-term (for example a data repository or archive)?**

- Any resulting papers from this study will be deposited to TCD TARA, an open access repository.
- The electronic evaluation data containing personal identifying information will be permanently deleted at the end of the 7-year post-study retention period, in line with GDPR requirements. Anonymised data will be retained for future use, in line with what participants initially consented to.
- The paper-based data containing personal identifying information will be disposed of via the Beaumont Hospital Confidential waste system at the end of the 7-year post-study retention period, in line with GDPR requirements.
- Data that won't be made FAIR and shared, such as signed consent forms, will still be preserved and protected. These will be stored in a locked cabinet in the AUoN, TCD. Access to these data will be controlled by Prof Hardiman's Research Manager.

**What methods or software tools are needed to access and use data?**

- To access and re-use pseudonymised data from this study, potential users need to request access directly from the PI's Research Manager of this project. No additional equipment or software will be needed.

**How will the application of a unique and persistent identifier (such as a Digital Object Identifier (DOI)) to each data set be ensured?**

- All documents related to this project will be stored in our library of datasets on our secure SharePoint online storage.
- A clearly labelled index of folders containing the data/data sets will be set up using a consistent naming strategy unique to the TiM project. The data from this project will be catalogued in line with the rest of our datasets, where we document the name of the relevant files, their contents and their location, which will be maintained.

## Data management responsibilities and resources

**Who (for example role, position, and institution) will be responsible for data management (i.e. the data steward)?**

- A data steward (Mark Heverin, Research Manager, AUoN TCD) will ensure HRB DMP maintenance/reporting and FAIR research data management.

**What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR (Findable, Accessible, Interoperable, Re-usable)?**

- Funding dedicated to data management and ensuring that data will be FAIR for this project has been secured through a Research Grant Award from the HRB. The TiM budget awarded by the HRB includes a budget for a FAIR Data Research Manager 20% FTE for four months.
- FAIR data management principles will be followed, and resulting papers will be published as open access, in immediately accessible journals and will be added to TCD TARA where possible. TCD TARA is OpenAIRE- and FAIR-compliant.