Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Study Invitation Letter

Dear All Ireland Institute of Hospice and Palliative Care member,

Our research team is conducting a survey titled '*The current outcome measures and treatment practices used by Occupational Therapists, Physiotherapists and Speech and Language Therapists working with people living with ALS/MND*'.

Avril Mc Tague and Lesley Doyle are PhD students in the MIRANDA programme in the Academic Unit of Neurology, School of Medicine in Trinity College Dublin, the University of Dublin.

We would like to hear from qualified Occupational Therapists, Physiotherapists/Physical Therapists or Speech and Language Therapists/Pathologists who have experience of working with people living with ALS/MND. This research study has been approved by TCD's School of Medicine Research Ethics Committee. Approval was granted on 5th July 2023.

Participation in this survey is voluntary. This survey will take 10-15 minutes to complete, and the responses are anonymous.

Please see the attached participant information leaflet for more information on the study.

The link to the survey is below;

https://scsstcd.qualtrics.com/jfe/form/SV_a5eEUYlQbhHL6Xc

The survey will close on 10th December 2023.

Please share this survey with your Occupational Therapy, Physiotherapy/Physical Therapy or Speech and Language Therapy/Pathology colleagues. We are aiming to gather as many responses as possible from therapists working in different countries and from a range of clinical settings such as hospital, hospice, or community-based care.

If you have any question about taking part in the study, please feel free to contact us at mctaguam@tcd.ie or doylel17@tcd.ie.

Kind regards,

Avril Mc Tague Lesley Doyle

Trinity College Dublin
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Participant Information Leaflet

Name of Study: A survey of the current outcome measures and treatment practices used by Occupational Therapists, Physiotherapists and Speech and Language Therapists working with people living with ALS/MND

Site	Academic Unit of Neurology, School of Medicine, Trinity Biomedical Sciences Institute, Trinity College Dublin
Principal Investigator(s) and Co-Investigator(s) (insert names, titles and contact details)	Project Leads (MIRANDA programme PhD students): • Avril Mc Tague, mctaguam@tcd.ie • Lesley Doyle, doylel17@tcd.ie Principal Investigator for MIRANDA: • Miriam Galvin, primary investigator for the MIRANDA programme, galvinmi@tcd.ie Co-Investigators (MIRANDA programme student supervisors): • Dara Meldrum, Associate Professor in Clinical Measurement and Device Technology, meldrumd@tcd.ie • Deirdre Murray, McKeon Assistant Professor in Clinical Measurement, dmurray1@tcd.ie • Lucy Hederman, Assistant Professor in Computer Science, hederman@tcd.ie
Study Organiser/ Sponsor (if applicable)	Study funded by the Health Research Board (HRB) Collaborative Doctoral Awards
Data Controllers	Trinity College Dublin
Data Protection Officer	Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2 dataprotection@tcd.ie

You are being invited to take part in a research study that is being carried out as an online survey by Avril Mc Tague and Lesley Doyle, PhD students in School of Medicine, Trinity College Dublin (TCD).
Before you decide whether or not you wish to take part, please read this information sheet carefully. If you have any questions, ask Avril Mc Tague or Lesley Doyle (contact details are given the end of this information sheet). Don't feel rushed or under pressure to make a quick decision. You should understand the risks and benefits of taking part in this study so that you can make a decision that is right for you.

This leaflet has five main parts:
Part 1 – The Study
Part 2 – Data Protection
Part 3 – Costs, Funding and Approval

Part 4 – Future Research
Part 5 – Further Information

Part 1 – The Study

Why is this study being done?

We are doing this study to find out about the international clinical practices of Occupational Therapists, Physiotherapists/Physical Therapists and Speech and Language Therapists/Pathologists working with people living with Amyotrophic Lateral Sclerosis (ALS)/Motor Neurone Disease (MND).
ALS/MND is a rare neurodegenerative disease which results in progressive loss of muscle strength and function. Occupational Therapists, Physiotherapists/Physical Therapists and Speech and Language Therapists/Pathologists are a core part of the multidisciplinary team caring for people living with this disease.
One role of Speech and Language Therapists/Pathologists is to carry out assessment of speech and swallow but there have been no international surveys to determine if therapists think that the outcome measures used to describe symptoms are clinically useful for ALS/MND. Occupational Therapists and Physiotherapists/Physical Therapists aim to maximise function and quality of life for people living with ALS/MND, their family and/or caregivers. However, there have been no studies completed to investigate the current treatment practices among Occupational Therapist and Physiotherapist internationally.
This study will:

- Explore the current clinical practices among Occupational Therapists, Physiotherapists/Physical Therapists and Speech and Language Therapists internationally.
- Identify the most useful outcome measures used by Speech and Language Therapists/Pathologists for the assessment of speech and swallow function.

Why have I been invited to take part?

Qualified Occupational Therapists, Physiotherapists/Physical Therapists or Speech and Language Therapists/Pathologists who have experience of working with people living with ALS/MND are the target respondents we would like to hear from.
This is an international survey, and we want to gather responses from therapists working in a range of clinical settings such as hospital, hospice or community-based care.

Do I have to take part? Can I withdraw?

No, you do not have to take part in this study. Participation is completely voluntary. Your consent to take part will be assumed if you choose to answer the questions in this survey. If you start the survey, you can discontinue at any time.

What happens if I change my mind?

You can discontinue the survey at any time by closing the Qualtrics tab of your internet browser. If you choose to discontinue, any responses you have already provided will be saved in the online survey platform. You cannot withdraw responses that you have already given because the data is anonymous so it will not be possible for us to identify which survey responses are yours.

How will the study be carried out?

This an online survey that you can complete from any location. The survey link will remain open until 10th December 2023. The survey is hosted on the Qualtrics online platform. You will receive access to the survey link via email or a social media platform. The survey questions and answers are written in English.

What will happen to me if I decide to take part?

If you agree to take part, you will be asked to answer questions about your experience of working with people living with ALS/MND. You can complete the survey at a location and time of your preference between August and December. It will take about 10 to 15 minutes to complete.
We will ask you to tell us your profession because some sections of the survey are profession specific.
Speech and Language Therapists/Pathologists will be asked about:

- the outcome measures that you think are the most useful for remote monitoring of symptoms, and for reporting findings in research.
- the assessment devices that you use to measure communication or swallow symptoms.

Occupational Therapists and Physiotherapists/Physical Therapists will be asked about:

- current treatment practices in the symptom management of ALS/MND.
- the role of technology within your current practice in ALS/MND.

Everyone who completes the survey will be asked about demographic information including years of experience and the care setting where you work.

What will happen to my Data?

The results from this survey will be anonymous. You will not be identifiable at any stage. Your survey responses will initially be saved within the Qualtrics online survey platform. When the survey closes, the responses from all survey participants will be removed from Qualtrics and extracted to an Excel file. Two researchers on the team, Avril Mc Tague and Lesley Doyle, will be responsible for ensuring data security. The Excel file containing survey responses will be stored within a password protected TCD-approved electronic file storage

system with access restricted to only members of the research team. We will access the Excel file using TCD-provided encrypted laptops with up-to-date firewall software. The Excel file will be deleted after seven years, in line with best practice.

Are there any benefits to taking part in this research?

Taking part in this study may not directly benefit you. However, this study will help us to better understand the current clinical practices of Occupational Therapists, Physiotherapists/Physical Therapists and Speech and Language Therapists/Pathologists working with people living with ALS/MND. This study will inform future research into the development of digital outcome measures for tracking speech and swallowing symptoms in people living with ALS/MND which may be of benefit to Speech and Language Therapists/Pathologists. Responses will also be used to inform the development of a novel online digital exercise platform for people living with ALS/MND and their family/caregivers, which may also be of benefit to Occupational Therapists and Physiotherapists/Physical Therapists.

Are there any risks to me or others if I take part?

We do not anticipate any breach of confidentiality. The survey is anonymous and Qualtrics does not collect your IP address, ensuring that no identifiable information is captured about you.

Will I be told the outcome of the study? Will I be told the results of any tests or investigations performed as part of this study that relate to me?

The results of this study will be published in a peer-reviewed medical journal and presented at a medical conference.

Part 2 – Data Protection

What information about me (personal data) will be used as part of this study? Will my medical records be accessed?

As part of the questionnaire responses in connection with this study, we will collect and process your occupation, gender, years of experience and country of clinical practice. We will use the findings from the questionnaire to help us to understand the current assessment methods and treatment practices of Occupational Therapists, Physiotherapists/Physical Therapists and Speech and Language Therapists/Pathologists working with people living with ALS/MND.

What will happen to my personal data?

Your data will be processed only for the purpose of this study which is to understand the clinical practices of Occupational Therapists, Physiotherapists/Physical Therapist and Speech and Language Therapists/Pathologists. We will retain the anonymous data for the duration of the research study, for publication, The information will be retained for as long as is necessary and as short as is needed. It will be destroyed after seven years.
This survey will use the online survey platform, Qualtrics. The Qualtrics platform preferred provider is Amazon Web Services (AWS), which have data centres located in Ireland. When the anonymous data is exported from Qualtrics, it will be stored securely on the TCD network for the duration of the PhD; it will not be transferred outside of Ireland.

Who will access and use my personal data as part of this study?

The following people will have access to the anonymous survey data:

- Miriam Galvin who is the primary investigator for the MIRANDA PhD clinical programme and part of the supervisory team
- Avril Mc Tague and Lesley Doyle, PhD students who are the part of the research team
- Their supervisors, Dara Meldrum, Deirdre Murray and Lucy Hederman, who are co-investigators

The online platform Qualtrics will be used to collect responses. As soon as the survey closes, all responses will be extracted and removed from the Qualtrics platform and will then be stored within a secure electronic file storage system in TCD, Ireland. It will not be transferred to any other sites.

Will my personal data be kept confidential? How will my data be kept safe?

Your privacy is important to us. We take many steps to make sure that we protect your confidentiality and keep your data safe. Here are some examples of how we do this:

- When you complete the survey, your data will be stored anonymously on the Qualtrics online questionnaire platform. Qualtrics is compliant with GDPR, and further information can be found at https://www.qualtrics.com/uk/platform/gdpr/
- Once data is exported from Qualtrics by the researchers, this anonymous data will be stored electronically on a secure TCD Microsoft 365 platform. The information will be stored in line with TCD good practice guidelines and data protection legislation. Only the research team will have access to this data. They will access it using laptops provided by TCD that have up-to-date encryption and firewall software.

- A risk assessment of the data protection implications of the health research was carried out by the researchers in line with practice and identified as being a low level of risk.
- Survey responses are anonymous so no participants will be identified in presentations or publications relating to this study.
- The research team have all completed training in GDPR data protection law. If any member of the research team disclosed or facilitated unauthorised access to the research data, it would result in disciplinary action.

However, if something did go wrong, we would report it to the TCD Data Protection Commission within 72 hours after having become aware of it and follow the University Personal Data Breach Procedural Guidelines.

What is the lawful basis to use my personal data?

Your responses will only be used in this research study. The legal basis for collecting and processing your data is in accordance with Article 6(1)(f) of the GPDR for legitimate interest. You will also be asked for your consent to commence the survey. These study findings will not be used for future studies.

What are my rights?

This is an anonymous survey which means that you will be unable to access your data, receive a copy of it, restrict processing, delete or receive your data in a portable format because as we will be unable to identify which responses are yours. You will have the right to discontinue the survey at any time by closing the Qualtrics tab of your internet browser.

You can contact your study researchers, Avril Mc Tague at mctaguam@tcd.ie or Lesley Doyle at doylel17@tcd.ie, or the Trinity College Data Protection Officer, Secretary's Office, TCD, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.

Part 3 – Costs, Funding and Approval

Has this study been approved by a research ethics committee?

Yes, this study has been approved by TCD's School of Medicine Research Ethics Committee, email SOMREC@tcd.ie. Approval was granted on 5th July 2023. No members of the research team have a link to the research committee. A report will be provided to the research ethics committee annually and on completion of the study.

Who is organising and funding this study? Will the results be used for commercial purposes?

This study is being completed by Avril Mc Tague and Lesley Doyle as part of their PhD study and supervised by TCD staff members Dara Meldrum, Lucy Hederman and Deirdre Murray. These PhDs are funded by the Irish Health Research Board (HRB) Collaborative Doctoral Award (CDA) as part of the MIRANDA (Multidisciplinary Innovation and Research Advancing Neurological care in a Digital Age) programme. There is no pharmaceutical company involved, there is no payment for recruiting participants into the study and the results will not be disclosed for commercial purposes.

Is there any payment for taking part? Will it cost me anything if I agree to take part?

No, there is no payment for taking part. It will not cost you anything if you agree to take part.

Part 4 – Future Research

Will my personal data and/or biological material be used in future studies?

Your data will not be used for future studies.

Part 5 – Further Information

Who should I contact for information or complaints?

If you have any concerns or questions, you can contact:

- The researchers: Avril Mc Tague and Lesley Doyle, PhD students MIRANDA project, Academic Unit of Neurology, School of Medicine, Trinity Biomedical Sciences Institute (TBSI), TCD, 152 – 160 Pearse Street, Dublin. Email: mctaguam@tcd.ie and doylel17@tcd.ie
- Data Protection Officer, TCD: Data Protection Officer, Secretary's Office, TCD, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.

Under GDPR, if you are not satisfied with how your data is being processed, you have the right to lodge a complaint with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: www.dataprotection.ie.

Will I be contacted again?

No, you will not be contacted again, this study only involves completion of one survey.