

Telehealth in MND-Research (TiM-R)

Participant Information Sheet and Informed Consent Form

We would like to invite you to contribute to a database to help research into Motor Neuron Disease (MND). Before you decide if you would like to take part, it is important that you understand why this is being done and what it would involve for you. We would encourage you to read this information sheet in your own time and consider whether you would like to participate. Thank you for reading this.

What is the purpose of this database?

This database aims to collect information about people with MND, which can then be made available to support research that looks at causes, progression, and treatments.

We would also like to use the database to invite you to research studies, and keep you updated with research news such as recruitment updates and results.

Why have I been invited?

You have been invited to this database because you are someone with MND living in the UK.

What would my participation involve?

We will ask you to register on Telehealth in MND-Research (or TiM-R for short). TiM-R is an online system developed with people with MND and researchers, and can be accessed through any internet browser or downloadable app on your phone, tablet or laptop.

Once you have registered, you'll be asked to complete regular questionnaires relating to a range of MND symptoms, mood, and wellbeing. Most of these questionnaires are sent once every two months and take a maximum of 45 minutes to complete at a time convenient to you. We will continue to send you questionnaires regularly for as long as you are willing to complete them. Each questionnaire is voluntary.

You'll also receive research news through your TiM-R account and be invited to further studies that you may be eligible for. You can take part in TiM-R and these additional studies regardless of where you live. It is your choice whether to participate in these other studies.

Do I have to take part?

No. It is entirely up to you to decide whether or not to take part. You are free to end your participation at any time, without needing to give a reason. You can do this by unregistering from TiM-R or by using the study contact details provided below. You can also choose not to answer some questions if you do not want to or return to TiM-R after a break. Deciding not to participate will not affect your clinical care.

What information will be recorded and how will this be used?

The TiM-R questionnaires will ask you about you, your health and how MND affects you. These will include things such as your weight, breathing, and mobility. The answers you provide will be anonymised and stored in a database. Approved researchers can then apply to use this information to do research on MND. This may include researchers from universities or commercial companies, both inside and outside of the UK. We may charge a small fee to researchers for the use of this information to support the upkeep of TiM research.

Approved MND researchers can also apply to invite you to future research studies. For approved studies, we will send the invitations to you directly using TiM-R. We will never send any information that can identify you to people outside of the TiM-R research team.

What will happen to the information collected about and from me during the project?

The information you provide will be stored on the Dementia Platform UK (DPUK) Secure eResearch Platform, hosted by Swansea University. All information will immediately be anonymised, meaning that no one outside of our team can connect your answers to you. If we allow researchers to use your questionnaire answers for MND research, we will never give them anything that can identify you.

We would also like to combine your TiM-R questionnaire answers with information that is collected routinely by the NHS during your care. This will allow us to conduct more in-depth research into MND. This will include information collected as part of the UK MND Register, NHS databases, other research studies, or the Telehealth in MND-Care platform, if you use this as part of your clinical care.

What are the possible benefits and disadvantages of taking part?

We hope that you will find this study beneficial and as an opportunity to be involved in contributing to future MND research. You may also be able to use TiM-R to be invited to studies that you would normally not be able to participate in and hear updates about MND research.

The only disadvantage to you is the time taken to complete the questionnaires.

Expenses and payments

You will not receive any payment for taking part in this research study.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Contact details are provided at the end of this information sheet.

Alternatively, you can contact the Chief Investigator of the study, Professor Chris McDermott:

Professor Chris McDermott
Sheffield Institute for Translational Neuroscience
385a Glossop Road
Sheffield
S10 2HQ

If you remain unhappy and wish to complain formally, you can do this by contacting: Luke Thompson, Head of Data Protection & Legal Services. Email: Luke.Thompson@sheffield.ac.uk

Will my taking part in the study be kept confidential?

This research database may lead to studies being published externally in a journal, on a website, or via a conference presentation. Your personal details will be kept strictly confidential, and your name will be removed in any work published as a result of this research. We will not use your name in any publications that result from this research. After registering, you can decide whether we tell your healthcare team about your involvement in TiM-R by providing this information.

How will we use information about you?

We will need to use information from you for this research database. This information will include your initials, a name, an email address, NHS number, date of birth, and information that you enter

into TiM-R. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results, but we will destroy your personal, identifiable data. We will write our reports in a way that no-one can work out that you took part in the study.

What are my choices about how my information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have, unless you specifically ask us to remove this. If you would like this removed, we will discuss with you which information we are able to remove (i.e. any information that has not been included in databases shared with research teams already, which we cannot identify your individual information within).

We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.

Where can I find out more about how my information is used?

You can find out more about how we use your information by contacting the study team at The University of Sheffield, on Tim-r@sheffield.ac.uk or 0114 222 2291.

You can find out more about how we use your information at <https://www.sheffieldclinicalresearch.org/> or by contacting the study team.

Alternatively, the Health Research Authority has useful guidance available on their website at <http://www.hra.nhs.uk/information-about-patients/>

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). Our Head of Data Protection & Legal Services is Luke Thompson and you can contact them by email (Luke.Thompson@sheffield.ac.uk).

Who is organising and funding the study?

This research is funded by LifeArc (<https://www.lifearc.org/>) who are a medical research charity specialising in bridging the gap between research and patients. The funding forms part of the research aiming to bring together MND researchers and find a cure for MND faster.

Who has reviewed this project?

This study has been reviewed and approved by the Health Research Authority and an NHS research ethics committee. If there is any aspect of the project, or your participation that you would like to discuss further, or feel you may need support with, please do not hesitate to get in touch with us using the contact details listed below.

Further information

For further information about the research study, please contact Dr Liam Knox who is a member of the central study team at The University of Sheffield using the email address or phone number here: Tim-r@sheffield.ac.uk or 0114 222 2291.

INFORMED CONSENT FORM		
Name of project: Telehealth in MND-Research (TiM-R)		
IRAS ID: 340577		
		Please initial box
1. I confirm that I have read and understand this Participant Information Sheet and Informed Consent Form explaining the research project and I have had the opportunity to ask questions.		
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without there being negative consequences. In addition, should I not wish to answer any particular question or questions, I am free to decline.		
3. I understand that information I provide will be collected and kept strictly confidential. I give permission for members of the research team to have access to this information. I understand that my name will not be linked with the research materials, and I will not be identified or identifiable in the report or reports that result from the research.		
4. I agree to anonymised information being provided to researchers outside of the central team for the purposes of MND research and that these researchers may be charged a small fee to access this information.		
5. I agree to routinely collected data about me to be linked to the information I provide on the TiM-R system.		
6. I understand that data collected during the study may be looked at by individuals from Sheffield Teaching Hospitals NHS Foundation Trust and the University of Sheffield, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.		
7. I agree to be contacted about future research studies via the TiM-R system.		
8. I would like to participate with TiM-R.		
PARTICIPANT		
Print Name:		
Date:		