PARTICIPANT INFORMATION SHEET

HEALTHY VOLUNTEERS

Title of the project:

CognoMND: An automated cognitive assessment tool for people with Motor Neurone Disease (MND) based on language (utilising automated speech recognition and Machine Learning)

Study Reference: STH22599

Principle Investigator: Dr Leslie Ing

You are being invited to take part in a research study. Before deciding whether you wish to participate, it is important that you understand why this research is being done and what it will involve on your part. Please take time to read the following information carefully. Talk to others about the study if you wish.

- Part One tells you the purpose of the study and what will happen to you if you take part.
- Part Two gives you more detailed information about the conduct of the study.

Ask the research team using the numbers below if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part in the study.

Thank you for taking the time to read this.

Part One: About the study

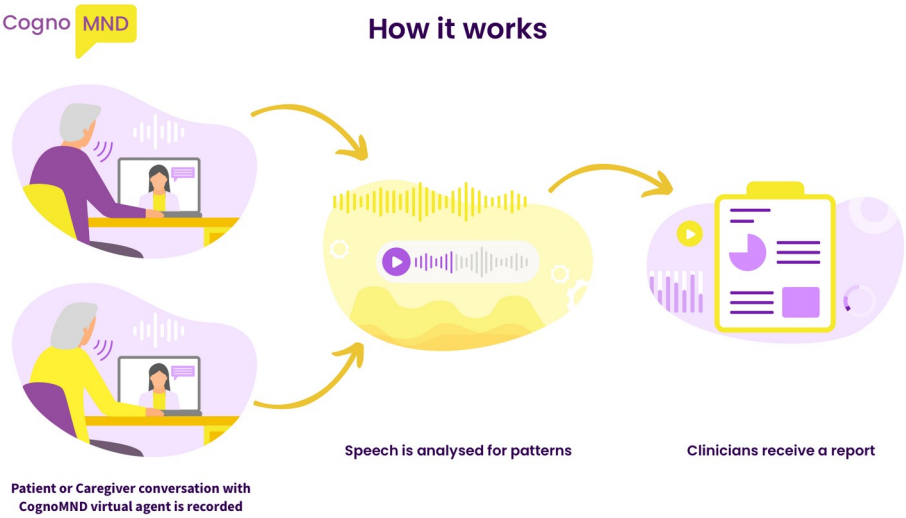
1. What is the purpose of this study?

The aim of this study is to understand whether patients with MND and their caregivers can talk to a digital doctor (CognoMND) regarding their neurological health.

CognoMND is a digital doctor i.e. a human looking image on a computer screen that will ask you questions regarding your health. CognoMND will not be able to respond to your answers.

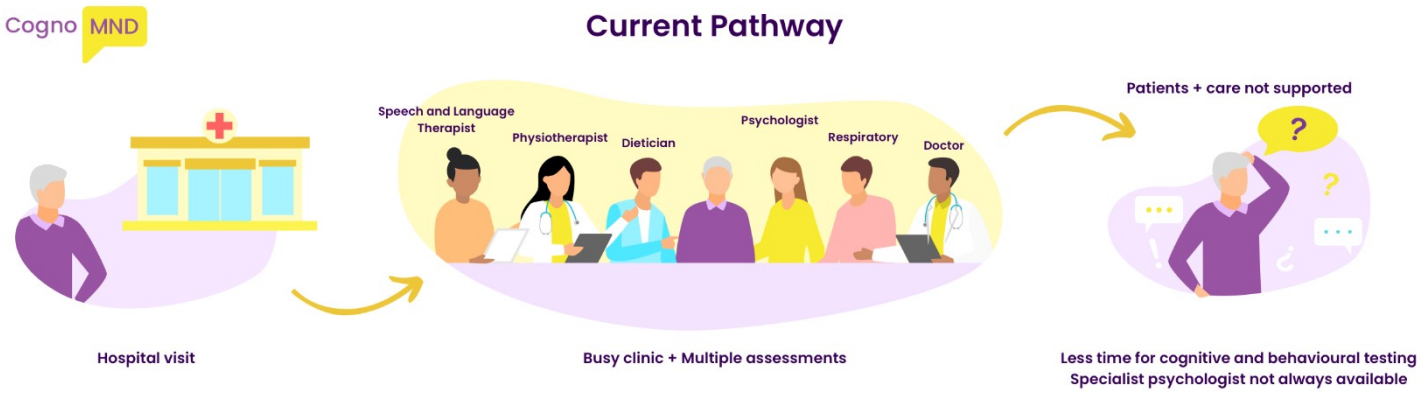
Healthy volunteers will speak with CognoMND and your answers will be analysed by a computer program to understand normal speech patterns and thinking abilities. This will help us compare your results with those of people living with MND to see how speech and thinking may be affected by the disease.

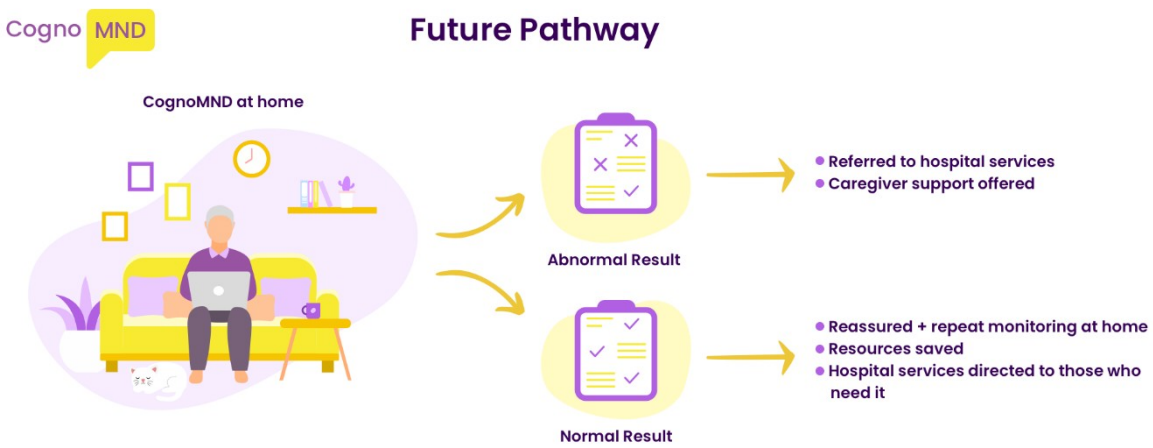
Cognо MND



This study looks at how people with cognitive and behaviour problems describe their difficulties in daily life. We are also interested to see how speech patterns may change over time.

At present it often takes a long time before cognitive and behaviour problems are diagnosed accurately. We hope that in the future we can use CognoMND, so no-one misses out on an early assessment and has access to support or treatment.





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2. Why have I been chosen to take part?

You have been asked to take part because you are a **healthy volunteer** who may have found out about this study through a public advertisement, or seen a poster at the hospital or University, or through word of mouth. You do not have a diagnosis of Motor Neuron Disease but will be asked to speak with CognoMND to help establish normal speech patterns and thinking abilities. Your participation will help us understand how healthy individuals respond, which will provide a comparison for those living with MND.

3. Do I have to take part?

No, it is entirely up to you. Taking part in the research is entirely voluntary and will not alter your usual medical care. It is important that you understand all the information about the study by reading this information leaflet and talking to a member of the study team. The study team will also discuss the study with you in detail. You can also discuss this study with your GP or your clinician.

You are free to stop taking part in this study at any time and without giving a reason. Your decision to not take part will not impact on your ability to participate in future studies or your current and future clinical care.

4. What will happen to me if I take part?

If you are interested in taking part in the study and have not already expressed your interest to the study team, you can:

- Email: If sent information and PIS via email, you may respond directly to the invitation or email: l.ing@sheffield.ac.uk
- Telephone: Contact a member of the study team via the contact numbers at the end of this information sheet

You will be given enough time to consider taking part and ask any questions that may arise. If you would like to take part, we will ask you to complete a paper or electronic consent form before we carry out any research activities. This may be sent via an email link or you may sign a paper copy if you have an in person visit.

We will ask if you would like to take part at the hospital or at your own home. You can be accompanied by family, a caregiver or a friend if you would like.

Your appointment will take about 1 hour. During your appointment you will be asked to carry out the following key tasks:

A) Talk to CognoMND

B) Complete a questionnaire about your mood and anxiety levels

C) For patients and healthy volunteers: Complete a cognitive assessment
For caregivers: Complete a behavioural questionnaire.

D) Complete a questionnaire about how you found speaking to CognoMND

E) Complete a Quality of Life questionnaire

You may also be invited to take part in an online or face-to-face interview to gather feedback on your experience talking to CognoMND.

After your first assessment

We may ask you to **repeat** your conversation with the digital doctor and complete another cognitive test **once every three-six months for up to two years** (4- 8 times in total). This is because cognitive and behavioural problems can get worse over time, so it is important that we monitor people using this new tool.

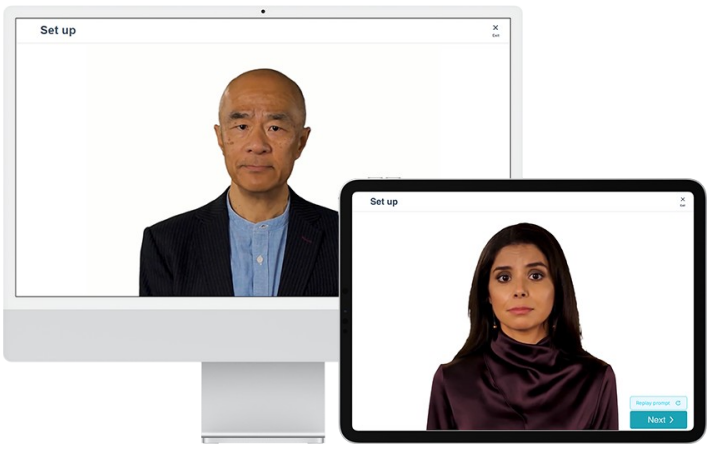
You are free to say 'no' to repeating the assessment.

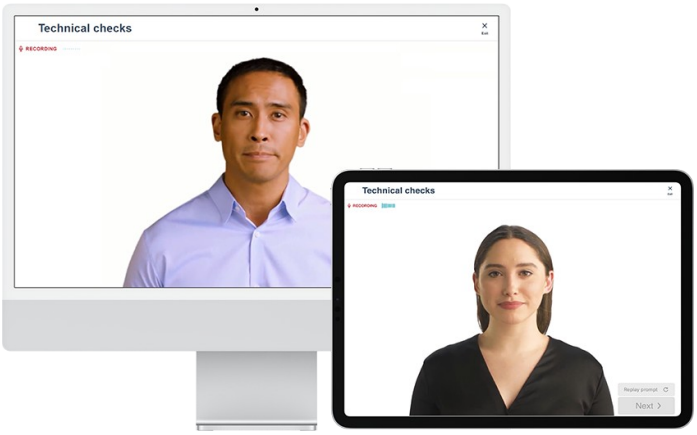
We plan for most repeat tests to be undertaken at home but if needed we will support you to come to a clinic.

Please read the information below for details about exactly what each task entails:

A) <u>Talking to CognoMND</u>

This will take about 15 minutes. You will access CognoMND using your own laptop/tablet where possible. The computerized human face of CognoMND will appear on the screen. It will ask you questions out loud which are similar to those that a doctor would ask patients in a memory clinic. You will be asked to answer the questions by speaking out loud as naturally as possible, before pressing a button to move onto the next question. Your interaction will be audio and video recorded. Consent for video and audio recording will be established in the consent form.





The picture above shows what CognoMND looks like on a computer.

This link shows a video of some volunteers using CognoMND:
https://www.youtube.com/watch?v=mVXzEsyD4BI

B) <u>Completing the mood and anxiety questionnaires</u> (within CognoMND)

This will take about 15 minutes. The questionnaire assesses for depression and anxiety and therefore contains some personal questions. You are completely free to stop at any point without reason. This questionnaire is included because mental health disorders can cause changes to the way people speak, which might impact the results. Some people may find these questions upsetting, therefore at the end of the assessment there will be signposting to an appropriate service if you feel that your mood or anxiety levels are too high. Also, the researcher will inform your GP if you score very highly on either of the screening tools. We will request your consent for this in the consent forms.

C) <u>Completing the CognoMND questionnaire</u> (within CognoMND)

This will take about 10 minutes. The questionnaire will be included at the end of your CognoMND session. It will ask you questions about how easy you found speaking to CognoMND, and also about how good or bad you think your cognition is. This part is not compulsory, and you can complete the other measures and not do this part.

D) <u>Completing the cognitive assessment (patient) / behavioural questionnaire (caregiver)</u>

This will take about 20- 40 minutes. This must be completed alongside a researcher, therefore a member of the research team will arrange a time for this with you. We will arrange this either face-to-face in clinic, your home or via a video link.

E) <u>Quality of Life (QoL) questionnaire</u> (in person, video or phone call)

We wish to assess the usefulness' of CognoMND in healthcare and collecting QoL will help us with this. These take approximately 5-10 minutes and can be undertaken in person or during video or telephone call.

All of these tasks, except QoL and standard validated cognitive tests have been adapted to allow you to do them at home if you are unable to visit the research site. It may be possible to have a researcher visit you in your own home with a laptop to guide you through the tasks, dependant on your location.

We will collect the first part of your postcode. This will be used be used as a measure of economic and social diversity to ensure we are collecting participants from all areas. You will be able to choose whether you consent to this in the consent form.

Each follow-up CognoMND session will be similar to the first. If you decide to participate, we will review your medical records because they may contain information which is relevant to the study results. The central research team consists of members of the Sheffield Teaching Hospitals NHS Trust, The University of Sheffield, and the regulatory authorities.

You may be accompanied by a family member/friend at your research appointments should you decide to have these in person, although they will be encouraged to let you answer questions independently. Consent will be taken to audio and video-record you and, where possible, your family member/friend's interaction with the CognoMND. If your family member/friend does not want to be seen or heard, but you do, the study team will proceed by only audio-recording your responses. It will be made clear that you can stop the assessments at any time.

The audio files recorded at each visit will be transcribed. This means that your audio files will be typed up. The transcription will remove any personal details that could identify you. The computer also produces a transcript of what you have said, but this is still not 100% accurate, so we also use a professional to type up what you have said to improve the system. The audio files and transcripts are stored on password protected servers within the University of Sheffield.

During your participation in this study, your standard of care will not be affected in any way.

5. Technical help with CognoMND

We have set up a dedicated email which you can contact if you have any technical issues with the CognoMND system or your device when setting this up. This email is: sth.help-cognospeak@nhs.net.

6. Expenses and payments

Shopping vouchers will be offered for your time.

7. What are the possible benefits of taking part?

We do not anticipate any immediate benefits to you for taking part in this study; however, the information from this research will be used to help improve future health services by understanding the ways in which people with memory or other cognitive problems talk about their problems. If people are able to talk to a computerised person, this may be used in primary care or even at a person's home to screen for dementia.

8. What are the possible inconveniences or disadvantages of taking part?

You can access CognoMND at home or in a hospital or community setting. It may take up to 60 minutes to complete all parts although speaking to CognoMND only takes 10-20 minutes. You will be asked to fill in a questionnaire on mood and anxiety and this can be upsetting for some people.

If you do not get used to the idea of speaking to CognoMND, you are free to stop at any point. You can also stop during the other assessments at any stage.

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you would like to know more and consider participating in the study, please continue to read the additional information in Part 2 before making a decision.

Part 2: Additional Information

1. What if I wish to complain about the way in which this study has been conducted or how I have been treated?

If you have a concern about any part of this study, you can speak to the study doctor or member of the study team who will do their best to answer your questions. You can contact Dr Daniel Blackburn on 0114 2222230 or Dr Leslie Ing on l.ing@sheffield.ac.uk in the first instance.

If you remain unhappy and wish to formally complain you can do this via the NHS complaints procedure or by contacting the Patient Services Team at 0114 271 2400 or sth.pals@nhs.net.

Sheffield Teaching Hospitals NHS Foundation Trust (STH NHS FT), has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this trial. This study is also covered by sponsor insurance via the University of Sheffield.

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 Data Protection Officer is Michael Maginnis and you can contact them by phone 0114 2265153 or email sth.infogov@nhs.net.

2. What if I am harmed?

If you are harmed by your participation in this study, there are no special compensation arrangements. In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against STH NHS Foundation Trust or the University of Sheffield, but you may have to pay your legal costs.

NHS bodies and Universities are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical trial as a result of negligence on the part of a member of the study team, liability cover would apply.

Non-negligent harm is not covered by the NHS indemnity scheme. Sheffield Teaching Hospitals NHS Foundation Trust therefore cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered.

3. Will my taking part in this study be kept confidential?

Yes, all the information about your participation in this study will be kept confidential. In the unlikely event that there is a need to disclose information, for example for medical reasons, this will be done with your consent (see Clause 7 below).

Please note that the central study team is made up of staff working for the STH NHS Foundation Trust and the University of Sheffield (all of whom may have access to your data). The central study team will need to analyse the video- and/or audio-recording of your consultation with CognoMND.

All material collected for this study will be made pseudo-anonymous (by using extracts of the written, video and sound material, without any additional information that could identify you). Data will be held on the Google Cloud Portal (GCP) for the automatic processing and training of the AI algorithms. This will be held confidentially and no data which will be personally identifiable will be shared. The University of Sheffield will manage the data for the purposes of the study. Material collected for this study (in anonymous form) may be included in academic publications, presentations and future ethically approved research studies. If you would not like us to use them in the future, they will be destroyed after 15 years. Data will then be erased from all computer storage facilities according to the standard university procedures in place at the time for deleting and handling confidential, digital data.

Data collected from caregivers will be stored in their care-partner's (person with MND) site file.

4. How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information may include your initials, NHS number, name and contact details. 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 study ID 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. We will write our reports in a way that no-one can work out that you took part in the study.

5. What are your choices about how your 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. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

6. Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from https://www.sheffieldclinicalresearch.org/for-patients-public/how-is-your-information-handled-in-research/
- by asking one of the research team
- by sending an email to Dr Leslie Ing (l.ing@sheffield.ac.uk)
- by ringing us on 0114 2159101
- by contacting our data protection officer Michael Maginnis by telephone 0114 2265153 or email sth.infogov@nhs.net

7. Will my General Practitioner (GP) / family doctor be involved?

We will not routinely inform your GP about your participation in the study, but we will ask your permission to contact your doctor if you wish them to be informed of your participation.

If we identify any incidental abnormalities of clinical significance during the study, for example if you score particularly highly on your anxiety, mood, or thinking ability questionnaires, then we will ask you for your consent to inform your GP so that we can ensure you get any support you may need.

8. What will happen to the results of the study?

The findings from this study will help show how patients with memory or other cognitive problems talk about their difficulties with their doctor.

The data will be analysed at Sheffield Teaching Hospitals NHS Foundation Trust and the University of Sheffield.

We plan to let other doctors and researchers know the results of this study by publishing the results in medical journals and presenting the results at medical conferences. It will not be possible to identify you from any of the data that will be presented. We also plan to write a summary of the results for everyone who has taken part in the study so you will know what results were found, however this will only be done once all patients have completed all assessments as part of the study. We may use direct quotes from your interaction with CognoMND in the papers to be published; however, these will be anonymous, and you will not be identified in any publication. It usually takes one or two years before the results of a study like this will be published.

We may share data with other researchers in the UK or worldwide. You will not be identified in any report or publication.

The results of this study may lead to the development of patents and/or to commercial benefits for sponsors and researchers. A patent is a right to the exclusive use of an invention, such as a new test or new drug, for a fixed period of time. You would not be entitled to receive any financial benefit from this.

9. Who is organising the research?

This study is sponsored by the University of Sheffield and will be managed through the Sheffield NIHR Biomedical Research Centre (BRC) in collaboration with Sheffield Teaching Hospitals NHS Foundation Trust.

10. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the **[*Pending Ethics Comittee*]**.

11. Who do I approach if I have further questions?

If you require more information about this study please contact the research team by the following options:

- Dr Leslie Ing: l.ing@sheffield.ac.uk or 0114 215 9112
- Dr Daniel Blackburn: d.blackburn@sheffield.ac.uk or 0114 2222262

If you would like to talk to somebody who is independent from this study, to discuss volunteering in research, please contact the NHS Patient Services Team (PST) on 0114 271 2400 or sth.pals@nhs.net

12. What do I do if wish to take part?

If you wish to take part in the study, please contact the research team to inform them by the following options:

- By Email: l.ing@sheffield.ac.uk
- By Telephone: 0114 215 9112

You will be given the opportunity to ask any further questions to the research team before agreeing to take part.

You will be asked to sign the consent form that accompanies this Information Sheet and present this at your research appointment. We will find a suitable date and time for your interview.

Thank you for reading this information sheet and considering taking part in this study.

If you decide to take part you will be given a copy of this information sheet and the signed consent form to take home with you and keep.