



Participant Information Sheet
People living with MND

Project title: Patterns of Behaviour and Personality in People with Neurodegenerative Disease and their Family Members

You are being invited to take part in a research study examining patterns of behaviour and personality in people living with motor neurone disease (MND) and their family members.

Before you decide whether or not you wish to take part, you may wish to read the information provided below carefully. It is important you clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Some people living with motor neurone disease (MND) experience changes in their behaviour and/or personality. There has been recent research that suggests that there is also a higher rate of neurological, psychological and psychiatric conditions within the family members of people living with MND than in the general population. However, the relationship of these to the behaviour and personality changes in people living with MND is unclear.

The main aims of this study are to:

1. Determine whether there are higher rates of symptoms of neuropsychiatric disorders in people living with MND and their family members compared to the general population.
2. Examine whether similar patterns of symptoms are present in people living with MND and their family members.

Findings from this study would indicate whether or not there is an overlap between certain neurodegenerative and psychiatric diseases.

Why have I been asked to take part?

You have been invited because of your diagnosis of MND.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you decide to take part, you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I agree to participate?

In this study, you'll be asked to do the following:

1. Answer questions about yourself and questions regarding health conditions in your family.
2. Complete a series of questionnaires measuring different behaviours and personality traits. This will take approximately an hour.
3. Complete a brief assessment of your memory, language and thinking skills. This will take approximately 20 minutes.
4. Pass information to any first or second degree relatives (including siblings and children, but also parents, aunts, uncles and cousins where possible) you think would be interested in participating in this study. We will give you a letter of invitation and participant information sheet for you to pass onto family members you feel may be interested. They will be able to contact the research team directly if they wish to participate.

This will be completed at the Anne Rowling Regenerative Neurology Clinic, Little France campus. If it is more convenient for you, we can arrange for a member of the research team to visit you at your home. In total, your participation will last approximately 1.5-2.5 hours. You will be offered frequent breaks and you may complete the assessments in up to three visits if you prefer. If you are unable to write or have any difficulties, we will assist you completing the questionnaires.

We will also ask for permission to speak to your spouse, partner or carer about changes in your behaviour.

You will not have to stop any medication or treatment that you are currently receiving and you will not undergo any invasive procedures as part of this study.

If you agree to participate, we will send a letter to your General Practitioner (GP) to let them know that you have agreed to participate in this study. We will ask you for permission to contact your GP.

It is possible that the results from this study may lead to further research. We will ask for your permission to contact you regarding participation in a future related study.

What are my rights?

You may decide to stop being part of the research study at any time without explanation. You have the right to ask that any data you have supplied to that point be withdrawn/destroyed. Withdrawal from the study will not affect your current or future treatment.

You have the right to have your questions about the procedures answered (unless answering these questions would interfere with the study's outcome). If you have any questions as a result of reading this information sheet, you should ask the researcher before the study begins.

What are the possible benefits of taking part?

There is no immediate benefit to you or your family in participating in this study. However, the information that will be obtained from this study will increase our knowledge of MND and symptoms of psychiatric disorders in people with neurodegenerative disease and their family members. The result will indicate whether there is an overlap between neuropsychiatric and neurodegenerative disorders. This may be of benefit to future patients.

What are the possible disadvantages and risks of taking part?

We do not anticipate that anything will go wrong. However, some of the questions may cause some people distress. If at any time you feel that your participation in the study is unduly stressful, you are free to discontinue. If you feel distressed at all by participating in the study, we encourage you to contact your General Practitioner (GP), MND nurse or one of the organisations listed at the end of this information sheet. You may also contact Professor Sharon Abrahams on 0131 650 3339 (Clinical Neuropsychologist on the research team).

Participation in this study involves completion of some standardised tests which are used in research to screen for clinical conditions involving symptoms of psychiatric disorders of which you may not be aware. Scores from these tests are for research purposes only and are not used for diagnostic purposes in this study.

It is not possible to provide feedback of individual scores to participants but we will ask for your permission to feedback any clinically relevant information to your MND health care team and GP. If you have any concerns, please contact Professor Sharon Abrahams on 0131 650 3339 (Clinical Neuropsychologist on the research team).

What if there is a problem?

If you have a concern about any aspect of this study, please contact Caroline McHutchison (Chief Investigator) who will do their best to answer your questions.

In the unlikely event that something goes 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 NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Expenses

If you decide to participate in person at the Anne Rowling Regenerative Clinic, we will reimburse you £7 an hour for your time.

Will my taking part in the study be kept confidential?

All information collected from participants will be kept strictly confidential and there are strict laws which safeguard your privacy at every stage.

Study researchers may need access to your medical records to carry out this research.

Data will be stored on a password-protected encrypted computer at the University of Edinburgh. Access to individual data will only be available to members of the research team.

You will be assigned a unique code so that your responses are anonymised and those analysing the data will not have access to your personal information.

Data generated during this study will be retained indefinitely to allow further analysis. It may be used in related studies in the future, subject to approval from NHS ethics. Any data used in future studies will not include identifying information such as your name or personal details.

In the unlikely event that you have given informed consent, but lose the ability to give consent during the study, the information we have already collected about you will be retained and used in the research. As previously stated, all personal information will be kept strictly confidential.

To ensure that the study is being run correctly, we will ask your consent for responsible representatives from the Sponsor and NHS Institution to access your medical records and data collected during the study, where it is relevant to you taking part in this research. The Sponsor is responsible for overall management of the study and providing insurance and indemnity.

What will happen to the results of the study?

The results of this study will be written up in a thesis as part of a PhD. Findings will also be published in relevant peer-reviewed scientific journals for distribution to other healthcare professionals and may also be presented at meetings and conferences. In all cases, your name and personal details will not be identified.

Who is organising the research?

This study has been organised and sponsored by University of Edinburgh and NHS Lothian

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. A favourable ethical opinion has been obtained from West of Scotland REC4. NHS management approval has also been obtained.

Where can I get further information?

Caroline McHutchison or Professor Sharon Abrahams will be glad to answer your questions about this study at any time. You may contact for further information using the following details:

Name: Caroline McHutchison

Doctoral Researcher

Address: School of Philosophy, Psychology and Language Sciences

7 George Square

Edinburgh EH8 9JZ

Phone: 0131 650 2927

Email: C.A.Mchutchison-2@sms.ed.ac.uk

Name: Professor Sharon Abrahams

Professor of Neuropsychology/Clinical Neuropsychologist
Address: School of Philosophy, Psychology and Language Sciences
7 George Square
Edinburgh EH8 9JZ
Phone: 0131 650 3339
Email: s.abrahams@ed.ac.uk

If you would like to talk to someone who is not directly involved with the study, please contact Dr Thomas Bak.

Name: Dr Thomas Bak
Address: School of Philosophy, Psychology and Language Sciences
7 George Square
Edinburgh EH8 9JZ
Phone: 0131 650 3441
Email: thomas.bak@ed.ac.uk

If you wish to make a complaint about the study, please contact NHS Lothian:

NHS Lothian Complaints Team
2nd Floor
Waverley Gate
2 - 4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 536 3370
feedback@nhslothian.scot.nhs.uk.

If you need to discuss any concerns you may have as a result of questions asked in this study, we encourage you to contact one of the following support organisations or see your GP to discuss further:

MND Connect – MND Scotland

Offers support and advice to people living with MND, their family members and carers.
Phone: 0808 802 6262
Email: mndconnect@msnassociation.org
Website: <http://www.mndassociation.org/getting-support/mnd-connect/>

MND Scotland Counselling Services

Emotional and psychological support for people living with MND, their family members, carer and friends.
Phone: 0141 332 3903
Email: info@mndscotland.org.uk
Website: <http://www.mndscotland.org.uk/services/counselling/>

The Samaritans

24/7 helpline for anyone wishing to talk to someone confidentially.

Phone: 116 123

Email: jo@samaritans.org

Website: <http://www.samaritans.org>

The MIND Infoline

Provides advice and guidance for those seeking help on mental health issues.

Phone: 0300 123 3393

Email: info@mind.org.uk

Website: <http://www.mind.org.uk/information-support/helplines/>

Thank you for taking the time to read this information sheet.