DASH

Digital App for Speech and Health Monitoring Study

1. Introduction

You are being invited to take part in a research study. Before you decide if you would like to take part, it is important for you to understand what taking part will involve. Please read the following information carefully and discuss it with others if you wish. Please ask a member of staff if there is anything that is not clear or if you would like more information. **Thank you for reading this and considering taking part!**

2. What is the purpose of this study?

Many people living with neurodegenerative conditions such as motor neurone disease, dementia, multiple sclerosis, and Parkinson's disease experience speech problems. Using common digital technologies such as smartphone apps, we can record and analyse speech in detail to provide new information for people living with these conditions, researchers, and healthcare professionals. This may help improve both care for these conditions and efforts to find new treatments. This study will investigate the use of these digital speech recordings to help diagnose and monitor these conditions.

3. Why have I been invited to take part?

This study is available to people who are at least 16 years old and meet the following criterion:

- A diagnosis of (or under investigation for), a neurodegenerative condition such as motor neurone disease, multiple sclerosis, Parkinson's disease, or dementia.

4. Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to complete a consent form. 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.

5. What will happen if I take part?

If you agree to take part in this study, at your first appointment, we will collect some background information and you will be guided through the App by a researcher. If you have your own device such as a smartphone, tablet or laptop, we will help you access the App and show you how to use it. We ask that you try to use the same device to access the App throughout the study.

The App submission includes:

- Speech recordings (reading out paragraphs, responding to questions, describing pictures, and other verbal tasks),
- Short health questionnaires (mood, sleep, quality of life, and disease-specific questions),
- An optional feedback survey, so you can tell us about your experience using the App.

We may ask that you attend your first appointment with someone who knows you (a relative, friend, or carer). This is so we can ask them questions about your health and provide guidance on participating in the study. We anticipate your first appointment will take no longer than 2.5 hours. This depends on your condition, as it will include clinical and cognitive assessments specific to your condition in addition to completing the App. If you already had some of assessments completed recently by your doctor, nurse or researcher, we may not need to repeat them. You can also choose to provide an optional blood sample (9mls) which we will use to compare disease markers in the blood against changes in your speech. Thereafter, there are two assessment types over 24 months, a 'short assessment' and a 'full assessment'. These include the below:

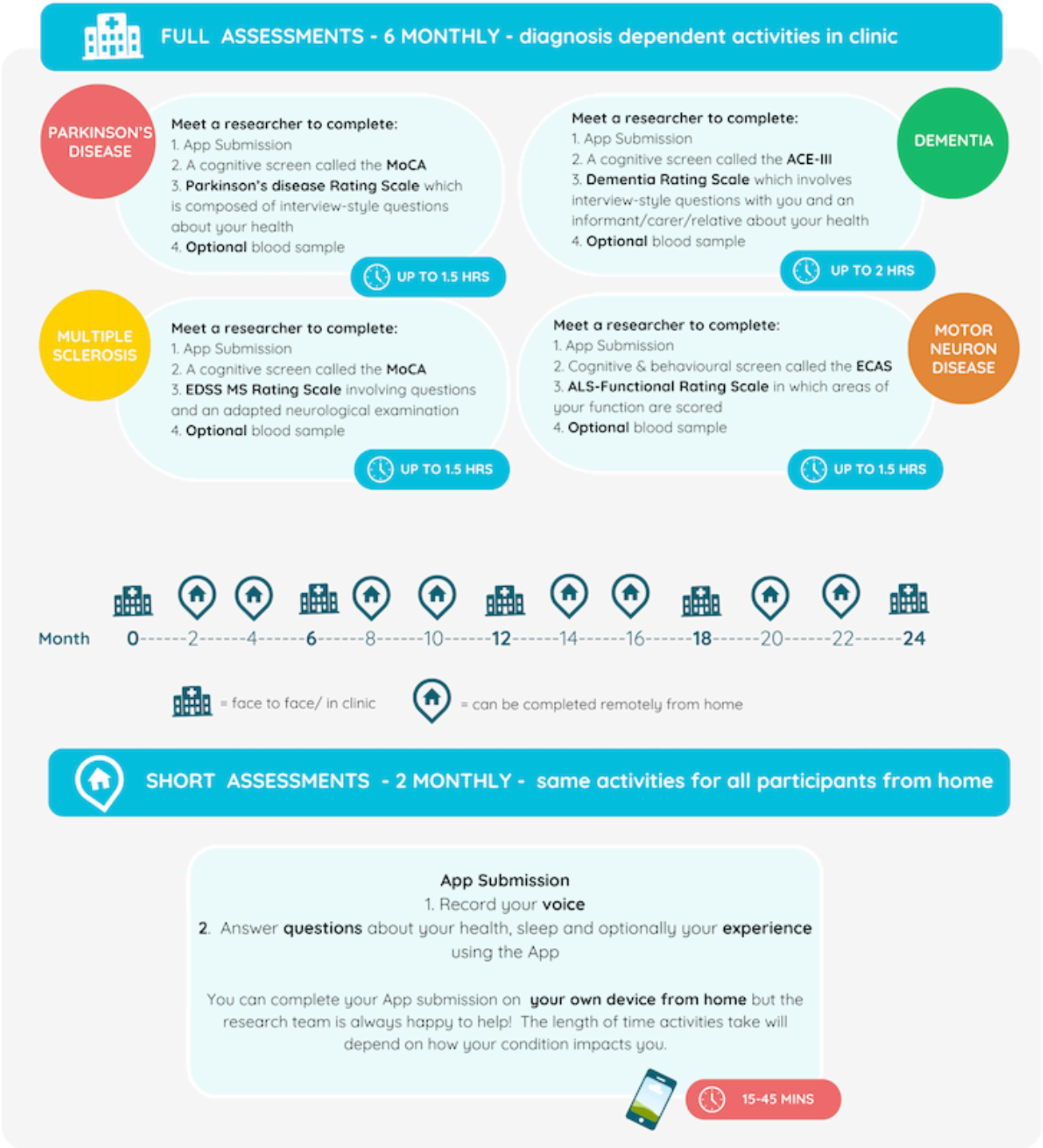
- **8 x Short Assessments** (at months 2, 4, 8, 10, 14, 16, 20 and 22):
  The short assessments are the same for all participants. The short assessments will involve completing the App submission only. We anticipate this will take between 15-45 minutes depending on how your condition impacts you. These can be conducted in-person at the clinic, or remotely from your home on your own device.

- **4 x Full Assessments** (at months 6,12, 18 and 24):
  The full assessments are tailored to your condition and are completed in the clinic if possible. In addition to completing the App submission, the full assessments will involve completing specific clinical and cognitive assessments and an optional blood sample. We anticipate this assessment will take approximately 2 hours depending on how your condition impacts you. With your permission and in exceptional circumstances a researcher may complete this by teleconference or visit you at your home to complete this.

With your permission, we will make up to two attempts to remind you about your upcoming assessment by email or telephone.

If you are involved in other studies that are completing the same disease rating scales or cognitive screening tests, with your permission, we may request access to the relevant information to reduce the amount of time it takes for you to participate in this study.

Figure 1. Study Assessments
This provides information on what will happen at each assessment.



6. What are the possible benefits of taking part?

You are unlikely to personally benefit directly from the results of this study, but the results may be of benefit to people with a neurological condition in the future. We anticipate that our research will lead to a better understanding of these conditions and could help in producing new and better treatments, tests, and ultimately, preventing neurological conditions. You may also enjoy using the App as a tool to check in with how you are feeling.

We will offer refreshments and reimbursement of your travel expenses up to £30. We understand that individual circumstances vary, and we are committed to considering expense reimbursement requests on a case-by-case basis. Please ask one of the research team who will advise on this.

7. What are the possible disadvantages and risks of taking part?

The only disadvantage to taking part in the study is the need to allocate the time to participate and donate samples. Risks may include the following;

- Some questions may ask about general and mental health, which some people may find distressing.
- You may feel tired during assessments. If you feel fatigued, please take breaks as you need.
- The optional blood sample collection can be a bit uncomfortable and/or leave some bruising.

The App assessments are in an experimental stage and the results are not validated, so we cannot guarantee direct access to results. However, we may offer an optional result report at the end of your participation.

8. What will happen to the samples, data and speech recordings I provide?

All samples, data and speech recordings you contribute will be used to research new ways to improve the diagnosis and monitoring of neurological conditions. The analysis of your speech recordings and research data will be conducted by researchers at the University of Edinburgh and SpeakUnique, a speech technology company based in the University. The blood samples you donate and their derivatives will be used for the project, and any remaining samples will be safely stored in the University of Edinburgh's NeuroCARE Biological Samples Research Tissue Bank, so that future ethically approved research projects can study them as well. This may involve extracting plasma, serum, DNA and/or RNA from the samples you provide for use in carefully controlled laboratory research into neurological conditions. These components of blood help us understand specific conditions better. DNA holds the instructions for building and maintaining our bodies.RNA is like a messenger that takes the instructions from DNA and helps carry them out. Extracting DNA can help identify genetic mutations or differences that are associated with specific conditions. RNA provides insight into how genes are turned on or off in different conditions. This can help us predict risk and understand and treat disease.

Our future studies may involve working with high-quality international research centres, including third party organisations in the United States, and sharing non-identifiable data with organisations within and outside the UK and European Economic Area (EEA). Not all countries have the same level of data protection regulation. We will only share your data and samples for future research studies following an approval process. Where data is being shared with a third party, there will be an appropriate data-sharing agreement between organisations to ensure your information is safe. This will maximise the value of your contribution. Anonymous research data and samples will be shared. We will **never share or publish** personally identifiable information without explicit consent. **However, please note it is not possible to completely anonymise speech recordings and recordings of your speech may be shared with our collaborators.** The data and samples you provide may also be used to develop and evaluate new commercial treatments, tests, biomarkers or products for people with neurological conditions. Your participation will not entitle you to benefit financially from these potential commercial products.

9. Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

10. How will we use information about you?

We will need to use information from you for this research project. We may also use data from other research studies you are participating in. We collect personal identifiable information including your name, date of birth, address, post code, GP details, telephone number, and e-mail. 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 will not be able to see your name or contact details. Your data will have a code number assigned instead. We will keep all information about you safe and secure in the University of Edinburgh.

As mentioned in section 8, some of your information such as your age, diagnosis, disease-related information, information, **recordings of your speech** and other non-identifiable data you contribute to the study will be shared with other researchers conducting ethically approved studies. Where data is being shared with a third party, there will be an appropriate data-sharing agreement between organisations to ensure your information is safe. 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.

Please note that if we discover significant information about your health during the course of this study, we will inform you. With your permission, we may write to your GP and/or specialist care team so that they can follow up on any issues.

11. 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.

12. 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 **www.hra.nhs.uk/patientdataandresearch**
- by asking one of the research team
- by sending an email to anne.rowling.clinic@ed.ac.uk
- by ringing us on 0131 465 9517

13. What if there is a problem?

Your health and wellbeing is a priority in this study. If we identify a significant issue with your health during the course of this study, we may contact your GP and/or specialist team in order to arrange the appropriate follow-up.

Please contact the research team if you have any questions about the study. If you wish to raise a concern regarding your participation, you can contact Dawn Lyle (see below) who is independent of the study. 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 legal action for compensation against NHS but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

14. If you wish to make a complaint please contact NHS Lothian:

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

15. What if I want to stop taking part?

You are free to withdraw at any time without providing a reason. We will stop collecting any new information about you, but any data you have already provided, including speech recordings, will remain in the study.
If you lose the ability to make decisions about this study in the future, you will also be withdrawn from participation and any data you have already provided will also remain in the study.

16. What happens when the study is finished?

The data, speech recordings and samples collected for this study will be archived in a

research database and tissue bank at the University of Edinburgh, so that researchers can access this valuable resource for studies in the future. These resources will be retained indefinitely, and maybe sent to other Universities, NHS organisations or companies for future ethically approved research studies.

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

Results from this research will be written up as scientific papers, published in peer-reviewed journals and presented at specialist conferences and meetings. We will also provide updates on research facilitated through the Anne Rowling Clinic and other University of Edinburgh websites, social media, press releases, newsletters and events. You may also opt to receive updates on study progress and results by email or post. **You will not be identifiable in any published results or website/newsletter updates.**

18. Who is organising and funding this study?

This study has been organised by the Anne Rowling Regenerative Neurology Clinic at the University of Edinburgh, and SpeakUnique, a University of Edinburgh based speech technology company. The study is being Sponsored by the University of Edinburgh and NHS Lothian. This study is partially funded via a collaboration between Eisai, Gates Ventures and LifeArc.

19. Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC). This study has been designed with input from patient representatives. A favourable ethical opinion has been obtained from Hampshire B REC. NHS management approval has also been obtained.

20. If you have any further questions, please contact:

The Research Team
The Anne Rowling Regenerative Neurology Clinic, University of Edinburgh, 49 Little France Crescent, Edinburgh, EH16 4SB. Tel: 0131 465 9517. Email: loth.dash@nhs.scot

If you would like to discuss this study with someone independent please contact:
Dr Peter Foley, Consultant Neurologist
The Anne Rowling Regenerative Neurology Clinic, University of Edinburgh, 49 Little France Crescent, Edinburgh, EH16 4SB; Tel: 0131 465 9517, Email: anne.rowling.clinic@ed.ac.uk.

If you require this document in an alternative format, such as large print or a coloured background, please contact the Anne Rowling Clinic via email anne.rowling.clinic@ed.ac.uk or telephone 0131 465 9517.