Geoffrey Jefferson Brain Research Centre

NHS Northern Care Alliance NHS Foundation Trust

ABRIMS Participant Information Sheet

Study Title: *Assessment of Brain-injury using Radio Frequency Induction and Microwave Spectroscopy*

Short Title: *ABRIMS*

Principal Investigators: *Dr Stuart Watson & Dr Adrian Parry-Jones*

1. Introduction

You are being invited to take part in a research study based at Salford Royal Hospital. Before you decide whether to participate, it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Please take time to decide whether you wish to take part, or not.

2. Why have I been invited to take part?

You have been invited to take part in the study as you have recently suffered a stroke. This may be an ischemic stroke, caused by blockage of an artery in the brain, or an intracerebral haemorrhage, caused by bleeding in the brain.

3. What is the purpose of the research?

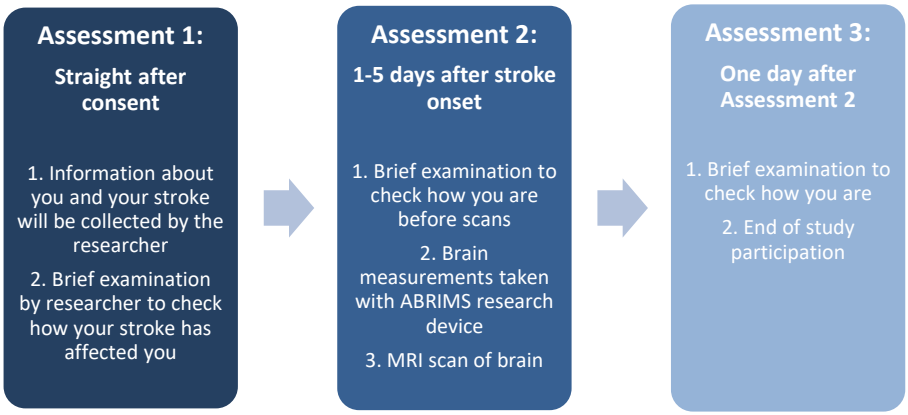
We know that treating strokes as quickly as possibly is vital to good recovery. Where a patient has a blocked brain artery, treatment involves using a clot-busting drug within four and a half hours of onset to ensure as much surrounding tissue can be saved as possible. Where a patient has had a brain bleed, treatment will involve reversal of blood thinning drugs and rapid blood pressure lowering to reduce the risk of further bleeding. Therefore, treatment of the two types of strokes is quite different and treatment of both types must happen very quickly to get the most benefit. The sooner clinicians identify the type of stroke, the sooner they can start treatment.

This study will help to determine whether using a portable device placed on your head can detect the presence of stroke and whether this is a bleed or a clot. This device uses radio waves and radar waves to quickly provide information about the brain. If the portable device we are testing can do this it could even be used in the ambulance. Diagnosis of the type of stroke in the ambulance would allow even quicker treatment, either immediately on arrival to hospital or even in the ambulance on the way to hospital. This speeding up of treatment would lead to improved outcomes for all stroke patients.

To begin to understand whether the device could work in this way, we are inviting patients who are in hospital with a recent stroke to help us. For those wishing to take part in the study, we will compare the readings from the new device with those taken from a standard MRI scanner.

4. What will happen if I take part?

If you decide you would like to take part in the study, we will first ask you to give informed consent. The research team will ensure you have had adequate time and information to decide. Once you have given consent you will undergo some assessments on three occasions. The first will be just after consent, the second will be 1-5 days after your symptoms began and the third will be either one day after your research scan, or at discharge from Salford Royal Hospital. These assessments are also shown in the diagram below.



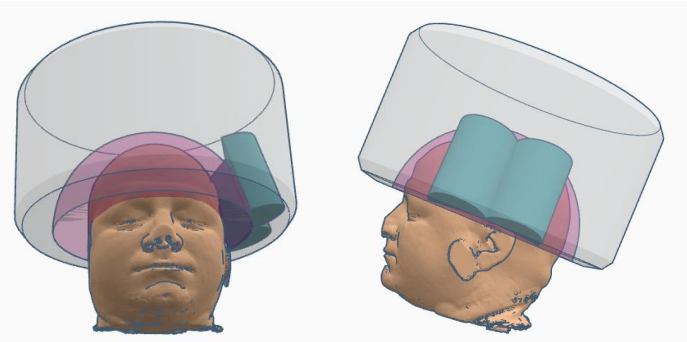
Assessment 1:

During this assessment, the researcher will collect some basic information from you and from your medical notes. They will perform a short examination to see how the stroke has affected you. This will take no more than 20 minutes.

Assessment 2:

Once assessment 1 is complete, the researcher will arrange a time for Assessment 2 to take place. This will depend on the availability of the MRI scanner. You will be informed when Assessment 2 is planned as soon as the date and time are booked. On the day of Assessment 2, a researcher will visit you on the ward. They will check that you are still happy and safe to proceed with the assessment and repeat the examinations performed during Assessment 1, which will take no more than 20 minutes. You will then be transferred to the MRI scanner suite by the research team. This is conveniently located nearby on the floor below the Hyper Acute Stroke Unit and in the same building. Before you have your MRI scan, the research team will use the ABRIMS device to collect readings in the rooms next to the MRI scanner. The device is placed gently over your head and is shown in the diagram below.

ABRIMS Device



The device works by transmitting radiofrequency and radar waves and collecting readings from the brain. The radio waves used are much less powerful than some other routinely used medical devices and the radar waves are a hundred times weaker than a typical mobile phone. The waves are not known to cause any side-effects and the device complies with all relevant safety requirements. The device will be placed over your head for no more than 15 minutes.

Following this, you will be moved into the MRI scanner for a standard MRI brain scan. This is expected to take no more than 40 minutes. As with any MRI scan, you will be provided with ear plugs and ear defenders to protect you from the noise in the scanner. You will be provided with a buzzer to press so you can get the attention of the radiographer and the research team, should you need them at any time. They will be able to hear you and talk to you through the standard communication system in the scanner. When the MRI scan is complete, you will be escorted back to the Hyper Acute Stroke Unit, and this will complete Assessment 2.

Assessment 3:

This will happen the day after Assessment 2, or on discharge from Salford Royal Hospital, if sooner. A researcher will visit you on the ward to check on how you are doing and collect information on any changes to your health. This will take no more than 15 minutes, and this will complete your participation in the study.

5. Do I have to take part?

No, taking part is voluntary and it is up to you to decide whether to take part. Any help you give is very much appreciated. If you decide to take part, you are free to withdraw at any time without giving a reason. A decision to withdraw at any time will not affect the standard of any care you receive. If you decide not to take part, you do not have to give a reason.

If you were to lose capacity during the study, we would check your preferences on the consent form as to whether you wish your data to be retained or if you would prefer it to be withdrawn. Capacity will be assessed at each time point within the study to ensure ongoing capacity and to ensure you are happy to continue in the study. If at any point you do not wish to continue, please let the research team know and no further assessments will take place.

6. What are the possible benefits of taking part?

Within this study you will undergo additional tests over and above routine care with the research team, however there will be no other direct benefits to taking part in this study. The results of this study could have benefits and impact on the stroke pathway, ensuring early diagnosis and improved outcomes for patients in the future.

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

There are no real increased risks to taking part in this research project, there is an extra scan within this project, however there would be no increased risks associated with this. The ABRIMS device uses radio waves and radar to take readings from the brain. The strength of these waves is much less than existing medical devices and mobile phones and no adverse effects are expected.

8. *a)* How will we use information about you?

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

This information will include your NHS number and name. The research team, or delegated auditor will use this information to do the research or to check your records to make sure that the research is being done properly.

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.

8. *b)* 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.

8. *c)* Where can you find out more about how your information is used?

You can find out more about how we use your information

a) at www.hra.nhs.uk/information-about-patients/
b) our leaflet available from https://www.ncaresearch.org.uk/patients-public/
c) by asking one of the research team (details below)
d) by contacting the Northern Care Alliance NHS Group Data Protection Officer DataProtection.Officer@nca.nhs.uk
e) by viewing the Sponsor's privacy link Patient Privacy Notice – How We Use, Share & Protect Your Personal Information

9. Expenses and payments?

We are unable to pay you for taking part in this study, however all study activity should take place during your inpatient stay, therefore no additional visits to the hospital would be required.

10. What will happen to the results of the research study?

The final outcomes from the study will be communicated via presentations in scientific meetings and by peer reviewed publications. This can be shared with participants if they wish. We will aim to publish the results approximately 12 months after completion of the study

11. Who is organising and funding the research?

The research is organised by the Research Team at Northern Care Alliance NHS Foundation Trust in partnership with the University of Manchester. The research is funded through public sources via the UK government's Engineering and Physical Sciences Research Council (EPSRC) and management oversight (Sponsorship) is provided by Northern Care Alliance NHS Foundation Trust.

Commented [AP1]: Worth saying there isn't a commercial motive?

12. Who has reviewed this study?

We can confirm that the study has been reviewed and approved by an appropriate NHS Research Ethics Committee, (Research Ethics Committees XXXXX).

13. What if there is a problem?

If taking part in the study harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action. Regardless of this, if you have a concern about any aspect of the way you have been approached or treated during this study, you should speak to the researchers who will do their best to answer your questions (see contact details below).

If you have any complaints about the treatment you have received as part of this study, you can contact the hospital PALS (Patient Advise and Liaison Services) team:

Patient Advice and Liaison Service
Northern Care Alliance NHS Foundation Trust
Stott Lane, Salford M6 8HD
Telephone: 0161 206 2003

Contact Names and Details for Further Information

If you have any questions about this research, please write to us or email us using the following contact details. Thank you for taking the time to read this information sheet.

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Geoffrey Jefferson Brain Research Centre

Northern Care Alliance NHS Foundation Trust

Study Coordinator XXXXX
Telephone:
Email:

Thank you for taking the time to read this participant information sheet. Please do not hesitate to contact the study team as above for any further information or if you have any questions