Local Letterhead to be added

**Participant Information Sheet (re-consent)**

**(Final version 3.1 date: 07/05/24)**

**IRAS Project ID. 277021**

**Title of Study: Remote Conditioning After Stroke Trial-3 (RECAST-3)**

Name of Chief Investigator: Professor Tim England

Local Researcher(s):

**Introduction**

As part of routine clinical care, research staff check if patients are eligible for research studies. You were eligible to take part in the RECAST-3 study which aims to assess whether Remote Ischaemic Conditioning improves disability at 90 days following your stroke.

You have been taking part in a research study assessing new treatments for stroke. Your relative or consultee advised us that in their opinion you would have wanted to take part when you were unwell, soon after your stroke started. Before you decide if you want to continue, it is important for you to understand why the research is being done and what it involves. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear to you, or if you would like more information. Take time to decide whether or not you wish to continue to take part.

# What is the purpose of the study?

# There are very few effective treatments for stroke, and we are looking for new ways to treat and help prevent strokes from getting worse or new ones happening. ‘Remote Ischaemic Conditioning’ (RIC) may be one way of doing this. Evidence from experiments and other conditions suggests that interrupting the blood supply to the arms (for example, by inflating blood pressure cuffs) for brief episodes may help protect the brain from further damage. It is not clear exactly how this may work but it has been suggested that RIC may lead to the body releasing substances into the blood stream (such as ‘anti-oxidants’) that help protect the brain.

We would like to see if this intervention is effective in people immediately after they have had a stroke. We want to involve people like you in this multi-centre trial and investigate reasons how RIC might work.

# Why have I been invited?

You have been chosen because you have had a stroke, and we feel that you fit the requirements for this research project. It is up to you to decide whether or not to continue to take part. If you do decide to continue to take part, you will be given this information sheet to keep and be asked to sign a consent form. We are inviting 1300 participants like you to take part.

You cannot take part in the trial if any of the following apply to you:

* Age less than 18
* Dementia
* Participation in another study that involves taking a trial drug, unless co-enrolment in the two trials has been approved
* Known pregnancy - If you are a woman of childbearing potential (WOCBP), i.e. fertile, following menarche and until becoming post-menopausal unless permanently sterile (permanent sterilisation methods include hysterectomy, bilateral salpingectomy and bilateral oophorectomy), you will be offered a pregnancy test.

# Do I have to take part?

It is up to you to decide whether or not to continue to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

**What will happen to me if I take part?**

**Day 1** (the day you were enrolled):

* We will have asked questions about your stroke, medical history and performed a medical examination
* Your information will have been entered into a computer, which decided whether you received one of 2 possibilities: either ‘Remote Ischaemic Conditioning’ or a non-experimental (dummy) procedure i.e. you had a 50:50 chance as to whether the blood pressure cuffs were inflated to a high or low pressure depending on which treatment group you were assigned to.
* You will then have had a blood pressure cuff attached to both arms, which will have been inflated for 5 minutes then deflated for 5 minutes. This was repeated 3 more times. There was a 50:50 chance as to whether the blood pressure cuffs were inflated to a high or low (a sham procedure) pressure.
* A second dose of 4 cycles will be applied >4 hours after the end of the first dose if time allows it that day
* Prolonged inflation of the cuffs may cause feelings of numbness or tingling, which is not due to another stroke, and resolves when the cuffs are deflated

**Day 1** Thrombectomy sub-study (**optional** and selected hospitals only)

* If you needed a procedure called a Mechanical Thrombectomy as part of your standard care and your hospital is taking part (your researcher will let you know) you will have had an extra CT scan of the brain as soon as you entered the trial. This is called a CT Perfusion scan and some centres perform this as a matter of routine care. We will compare this to an MRI brain scan performed later in the week which is performed as part of your standard care. The CT Perfusion scan will enable us to make more accurate measurements of the size of the stroke in relation to the blood supply. It requires being able to lie flat in the CT scanner for an extra 5-10 minutes. This does mean additional X-rays involved with this scan (please see possible risks on the next page) and an injection of a fluid called a contrast agent. You can opt out of this if you like and still take part in the rest of the trial.

**RIC/Sham treatment period**

* On day 2 the team will check on you and make a clinical assessment.
* The team will treat you with 4 cycles of RIC or sham twice per day (am and pm) for a total of 28 doses over 14 days. Some centres cannot provide the treatment over a weekend hence the treatment period may extend to 18 days, making up for missed days over the weekend.

End of RIC/Sham treatment period (or on the day of discharge if earlier)

* At the end of the treatment period we will ask if you are managing in the trial, that you have not had any other problems and perform a regular neurological examination
* This will all take about 1 hour
* If you are due to be discharged before the treatment period ends, you will not continue RIC or sham outside of the hospital (i.e. the trial treatment stops)

**Day 90±7**

* We ask your permission to contact your GP or check with the NHS Information Centre to check on your condition three months after your stroke and to confirm your contact details. You will then be contacted for a telephone consultation with a member of the research team. This is to check your condition at that time. It will involve asking how you are able to move around, about how you feel your life has been affected by the stroke and some brief memory tests. In order to make the final evaluation of the study as objective as possible, the person who telephones you will not know if you received the active treatment or not
* This will be the end of your involvement in the trial

You will otherwise have the normal standard treatment for stroke. All medications will be continued as normal. We will need to see you at the times as explained above.

# Expenses and payments

Participants will not be paid to participate in the study. There will be no additional travel as a result of taking part in this study.

# What are the possible disadvantages and risks of taking part?

You may have experienced some discomfort when the blood pressure cuffs were inflated. There is a small risk that prolonged cuff inflation could cause bruising or bleeding under the skin of your arms, and this will be monitored closely.

*If you are participating in this trial, you will undergo brain imaging on several occasions. This imaging might be extra through trial participation. Typically, you might have a CT scan of your head which may be standard care. If you participate in the trial sub-study, you will also have additional brain perfusion imaging, to visualise the extent of your condition. This imaging uses x-rays to make the images.*

*Exposure to x-rays brings a small risk of causing cancer years in the future. During this trial you will receive the equivalent of around 6 years of the background radiation we encounter each day. This would increase your risk of cancer by 0.075% - for comparison, the lifetime risk of cancer across our population is 50%.*

If you take part in the optional thrombectomy sub-study, the CT Perfusion brain scan includes injection of a fluid called a contrast agent (iodinated contrast). Potential side effects of this include an allergic reaction – severe allergic reactions occur in <1% of people. Milder and uncommon (<1%) reactions include headache, sickness, rash, itching. Injection of contrast can also affect the kidney and is also uncommon (<1%) but this risk can be increased if you have, for example, pre-existing kidney disease or dehydration. The medical and research team will help you decide if it appropriate to offer this sub-study.

**What are the possible benefits of taking part?**

We cannot promise the study will help you but the information we get from this study may help reduce how badly your current stroke affects you or it might reduce the chances of you having another stroke. The information we get from this study will help in deciding the best treatments for stroke.

# What happens when the research study stops?

We would like to follow your progress over three months (90 days). When all participants have been followed up, the trial results will be analysed and published in a medical journal.

# 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. The researchers’ contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting NHS Complaints. Details can be obtained from your hospital. [please provide the contact details of PALS for the hospital]

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 the University of Nottingham, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

# Will my taking part in the study be kept confidential?

You should tell the participant how their confidentiality will be safeguarded during and after the study. We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you [and your medical records] during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws, the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Where possible, information about you which leaves the [site] will have your name and address removed and a unique code will be used so that you cannot be recognised from it, however sometimes we need to ensure that we can recognise you to link the research data with your medical records so in these instances we will need to know your name and date of birth. We will also need this information as we will need to follow up your medical records as part of the research, where we will need to ask the Government services that hold medical information about you (such as NHS Digital, the Office for National Statistics, among others) to provide this information to us. By signing the consent form, you agree to the above.

Your personal data (address, telephone number) will be kept for 12 months after the end of the study. All research data will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham’s, the Government’s and our funders’ policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information, we will seek your consent for this and ensure it is secure.

# What will happen if I don’t want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw, we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

If you were to lose capacity during the trial and were unable to decide whether you would like to continue in the trial, and an objection to your continuation was raised by your consultee (relative, friend); then you would be withdrawn from the study. If you were to be withdrawn, we will no longer collect any information about you or from you, but we will keep the information about you that we have already obtained. This is because we should not tamper with study records, the information may have already been used in some analyses and may still be used in the final study analyses.

# Involvement of the General Practitioner/Family doctor (GP)

A letter to your GP will have been sent informing them of your participation in the trial. We also ask your permission to contact your GP or check with the NHS Information Centre to check on your condition three months after your stroke and to confirm your contact details.

# What will happen to any samples I give?

We will not be collecting samples as part of this trial.

# Will any genetic tests be done?

No

# What will happen to the results of the research study?

The results of the study will be published in medical journals. However, any personal details will be kept strictly confidential, and no information will be given through which your relative can be identified. At the end of the trial, the research team will send your relative a summary of the results either via post or email.

**Who is organising and funding the research?**

This research is being organised by the University of Nottingham and is being funded by the NIHR Efficacy and Mechanism Evaluation (EME) Programme.

# Who has reviewed the study?

All research in healthcare 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 Greater Manchester South Research Ethics Committee.

# Further information and contact details

We are happy to answer any questions you may have relating to this study. Please ask the doctors or nurses on the ward, or the local principal investigator for further information.

**The member of the research team who gave you this information:**

Name:

Tel: (\_\_\_\_\_) \_\_\_\_\_\_ [insert detail]

**Local principal Investigator:**

Name:

Address:

Tel: (\_\_\_\_\_) \_\_\_\_\_\_ [insert detail]

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**Thank you for reading this information sheet**