###   *(Form to be printed on local headed paper)*

**Participant Information Sheet – CONSULTEE**

**(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. Your relative is 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.

**Invitation**

Your relative (it could also be a friend or someone you care for, but for brevity this document will use the term ‘relative’) is being invited to take part in a research study. Before you decide whether you agree to their participation, it is important for you to understand why the research is being done and what it will involve. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

**What is the role of the consultee?**

The consultee advises the researcher on what the participant’s wishes and feelings would be if they were able to consent for themselves, and on whether they should take part. The consultee does not give consent, only advice. The responsibility to decide whether the participant should be entered into the research lies ultimately with the researcher. Consultees will be provided with information about the research project and will be given the opportunity to discuss it and their role as consultee. All consultees must be able to understand their role and be willing to undertake it.

**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 from injury caused by a stroke.

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 your relative in this multi-centre trial and investigate reasons how RIC might work.

**Why has my relative been chosen?**

Your relative is being invited to take part because they have just had a stroke and we feel that they fit the requirements for this research project. We are inviting 1300 participants like your relative to take part.

Your relative cannot take part in the trial if any of the following apply:

* 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 your relative is 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), they will be offered a pregnancy test.

**Does my relative have to take part?**

We would like you to think very carefully about whether or not this person would have wanted to join the study. If your opinion is that he/she would have decided to take part, you would be given this information sheet to keep and be asked to sign a declaration form indicating your view allowing your relative to participate in the study. If you later decide that he/she no longer wishes to take part, please inform us and he/she will be withdrawn from the study. You do not need to give a reason and it will not affect the standard of care your relative receives.

**What will happen to my relative if they take part?**

**Day 1** (the day of enrolment):

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

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

* If your relative needs a procedure called a Mechanical Thrombectomy as part of their standard care and the hospital is taking part (your researcher will let you know), your relative will have an extra CT scan of the brain as soon as you enter 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 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 your relative from this sub-study and they can still take part in the rest of the trial.

**RIC/Sham treatment period**

* On day 2 the team will check on your relative and make a clinical assessment.
* The team will treat your relative 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 your relative is managing in the trial, that they have not had any other problems and perform a regular neurological examination.
* This will all take about 1 hour
* If your relative is due to be discharged before the treatment period ends, they 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 relative’s GP or check with the NHS Information Centre to check on their condition three months after their stroke and to confirm their contact details. Your relative will then be contacted for a telephone consultation with a member of the research team. This is to check your relative’s condition at that time. It will involve asking how your relative is able to move around, about how they feel their life has been affected by the stroke and some brief memory tests. If your relative is unable to answer the questions for any reason, we will contact you to give us information about your relative. In order to make the final evaluation of the study as objective as possible, the person who telephones you will not know if your relative received the active treatment or the sham procedure.
* This will be the end of their involvement in the trial

Your relative will otherwise have the normal standard treatment for stroke. All medications will be continued as normal. We will need to see them at the times shown 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 or risks of taking part?**

The main disadvantage is that your relative may experience some discomfort when the blood pressure cuffs are kept inflated. There is a small risk that prolonged cuff inflation could cause bruising or bleeding under the skin of your relative’s arms and this will be monitored closely.

*If your relative participates in this trial, they will undergo brain imaging on several occasions. This imaging might be extra through trial participation. Typically, they might have a CT scan of their head which may be standard care. If they participate in the trial sub-study, they will also have additional brain perfusion imaging, to visualise the extent of their 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 your relative will receive the equivalent of around 6 years of the background radiation we encounter each day. This would increase their risk of cancer by 0.075% - for comparison, the lifetime risk of cancer across our population is 50%.*

If your relative takes 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 decide if it is appropriate to offer this sub-study.

**What are the advantages of taking part?**

There may be none. We cannot promise the study will help your relative but the information we get from this study may help reduce how badly their current stroke affects them or it might reduce the chances of them 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 relative’s 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]

**Will their taking part in this study be kept confidential?**

We will follow ethical and legal practice and all information about your relative will be handled in confidence.

If your relative joins the study, we will use information collected about them and their 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 the information and using it properly. Rights to access, change or move your information are limited as we need to manage the information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your relative‘s rights, we will use the minimum personally – identifiable information possible.

You can find out more about how we use your relative’s 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 your relative as a research participant and we will do our best to meet this duty.

All information which is collected about your relative during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about your relative which leaves the hospital will have your relative’s name and

address removed (anonymised) and a unique code will be used so that they cannot be recognised from it.

Where possible, information about your relative which leaves the [site] will have their name and address removed and a unique code will be used so that they cannot be recognised from it, however sometimes we need to ensure that we can recognise them to link the research data with their medical records so in these instances we will need to know their name and date of birth. We will also need this information as we will need to follow up their medical records as part of the research, where we will need to ask the Government services that hold medical information about them (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 relative’s personal data (address, telephone number) will be kept for 12 months after the end of the study. All other data (research data) will be kept securely for 7 years. After this time your relative’s data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your relative’s confidentiality, only members of the research team will have access to their 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 your relative 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 do not want my relative to carry on with the study?**

Your relative’s participation is voluntary, and you are free to withdraw them at any time, without giving any reason, and without their legal rights being affected. If you withdraw your relative, then the information collected so far cannot be erased and this information may still be used in the project analysis.

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

If you agree, we will send a letter to your relative’s GP informing them of their participation in the trial. We also ask your permission to contact their GP or check with the NHS Information Centre to check on their condition three months after their stroke and to confirm their contact details.

**What will happen to any samples my relative provides?**

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 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 this study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participant’s 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**