STEPS II Study

Detailed Participant Information Sheet

V1.5

You are being invited to take part in the STEPS II study. Before you decide, it is important for you to understand why the 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. Please ask us if there is anything that is not clear or if you would like more information. Take as much time as you need to decide whether or not you wish to take part.

Thank you for reading this information sheet.

Project scientific title: EME Project: NIHR131791 - The Efficacy of Peroneal Nerve Functional Electrical Stimulation (FES) for the Reduction of Bradykinesia in Parkinson's Disease: An Assessor Blinded Randomised Controlled Trial (STEPS II).

A short title for the project is: Assessment of electrical stimulation to improve movement for people who have Parkinson's disease.

What is the purpose of the project?

People with Parkinson's Disease (pwPD) often have difficulty with walking, which can cause them to move slowly (called bradykinesia) and fall, leading to a reduced quality of life and possible injury. To try and address this, this study will see if a new device (called the ODFS Pace) can improve walking for pwPD. The small battery-operated device is worn on the leg and applies small electrical impulses to the nerves to help encourage movement in muscles that are not working properly. This is called Functional Electrical Stimulation (FES) and it is a non-invasive treatment.

The ODFS Pace is a FES device developed by researchers at Salisbury District Hospital. It consists of a small battery powered control box, sticky patches (called electrodes), a leg strap, and a pressure switch, which is placed in any style of shoe. It works by stimulating the nerve on the side of the leg (called the common peroneal nerve), which then causes the

muscles that lift the foot to contract. The stimulation is turned on and off using the pressure sensitive footswitch, which helps to lift the foot at the correct time when walking. The electrical stimulation can feel like pins and needles, and most people quickly become used to the sensation.

We have already carried out a small version of this project (known as a feasibility study) with 64 participants to check that people with PD are happy to take part and find the assessments and FES acceptable to them. This small study also showed us that some people who have PD are able to walk faster after using FES. We now want to carry out a larger study to show if FES is a useful treatment for PD, find out more about how FES can improve walking and learn more about participants experience using FES.

In this study, 234 people who have PD will be randomly allocated to one of two groups, usual care (Group 1) or FES with usual care (Group 2). Over 22 weeks, we will measure the changes in walking speed, number of falls, quality of life and PD symptoms. We will also do assessments to find out how the changes we see are happening and we will interview some study participants to find out about their experience of using FES.

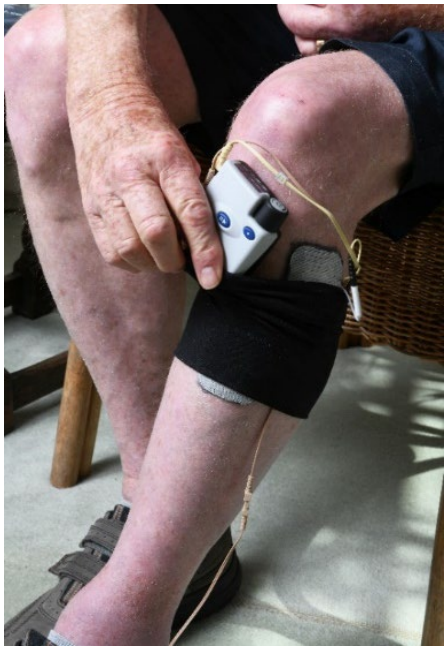


Figure 1a. The FES device.

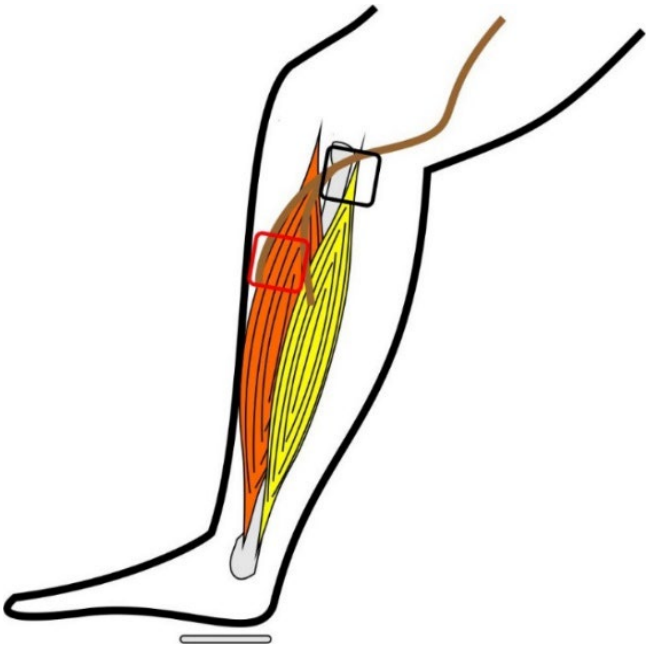


Figure 1b. The sticky patches are placed over the nerve, leg bone (fibula) and muscles.

Is FES safe?

The ODFS Pace FES device is CE-marked, meaning it meets EU safety, health and environmental requirements. FES was first introduced in 1996 and since then it has been widely used in the United Kingdom by over 20,000 people who have Multiple Sclerosis, had a stroke or spinal cord injuries to assist with walking. Research has demonstrated that FES is a safe treatment and it is recommended by National Institute for Health and Care Excellence (NICE).

Why have I been chosen?

You have been identified as someone who has some difficulty with walking due to PD. However, before you can be offered a place on the study, your suitability will be assessed against the following criteria:

Inclusion criteria summary:

- Able to walk 50 metres with appropriate walking aids, but without assistance from another person.
- Difficulty with one or more of the below:
    - Reduced movement of the foot and ankle while walking
    - Slow walking
    - Short, rapid strides
    - Stopping while walking (freezing)
    - Short stride length

Exclusion criteria summary:

- Treatment other than standard medicines
- Uncontrolled epilepsy, or a seizure within the last 3 months.
- Pregnancy or planned pregnancy
- Cardiac pacemaker, or other active medical implanted devices
- Other medical conditions that affect walking
- Cancer or skin conditions in the lower leg area
- Dementia, or other conditions that affect memory

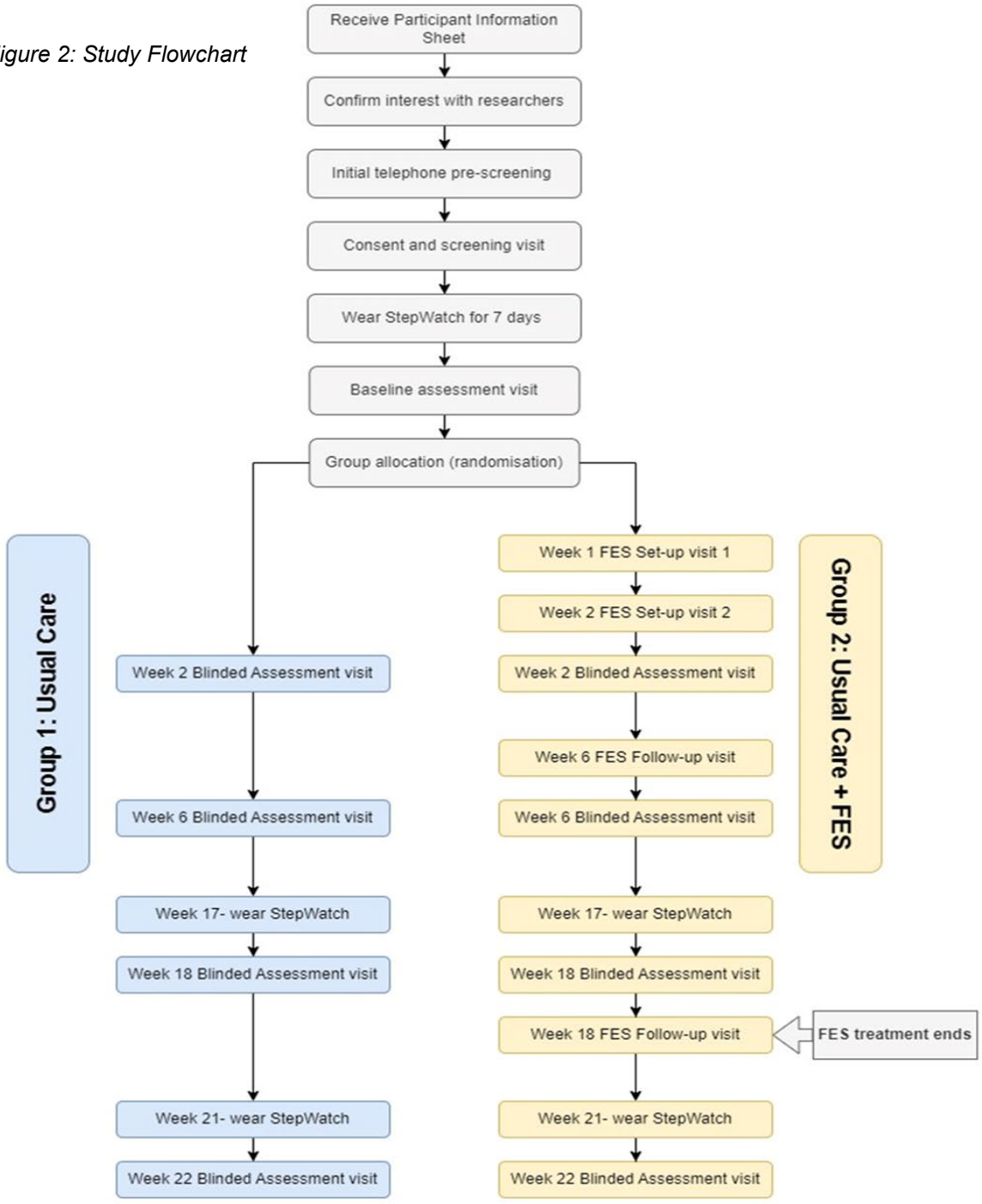
Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be asked to sign a consent form. During the study, you are free to withdraw at any time without giving a reason. If you decide to withdraw or decide that you don't want to take part, the usual care you receive will not be affected.

What will happen to me if I take part?

The flow chart below summarises the pathway participants will take during the 22 week study period and the appointments that each group will attend.

Figure 2: Study Flowchart



If you decide you would like to take part, you can contact the research team by telephone, e-mail or post using the details found at the end of this information sheet. Alternatively, you may inform your clinician that you are happy for a member of the research team to call you. You may also complete a self-referral form on the STEPS II website (www.plymouth.ac.uk/steps2). Information provided on the self-referral form will be submitted to your chosen site and the University of Plymouth Peninsula Clinical Trials Unit for monitoring purposes.

After receiving confirmation of your interest, a researcher will contact you by telephone to carry out initial eligibility **pre-screening call**. They will discuss the study in more detail with you, answer any questions you may have and ask you some questions to see if you may be suitable to take part. This telephone call will take about 15 minutes.

If the pre-screening shows that you may be eligible, and you still wish to take part, you will be invited to attend a face-to-face **screening appointment** at [localised clinic], where your suitability for the study will be assessed further. This appointment will take around 90 minutes and will consist of:

- Signing a consent form. You will have an opportunity to ask any questions, and if you need it, you can ask for more time to decide whether you would like to take part. You may choose whether you consent to optional points, including being contacted for further research and being video recorded for teaching purposes.
- Questions about your medical history. Please bring a repeat prescription showing any medication you take.
- Questions about your life, such as living circumstances and employment status, if you've experienced any falls, and how you find your walking.
- A 10-metre walk test. This will be timed, and you can use walking aids if needed.

Once the above has been completed, the researcher will inform you whether you meet the criteria to begin the study. If you are eligible, you will be given a device to count how many footsteps you take, called a StepWatch pedometer. This small device is worn on a strap around your ankle. You will be asked to wear it for 7 days to record how active you are in your daily life. You will be asked to return it at your next appointment, which will take place in 7 days. Your GP will also be informed of your participation in the study.

The next appointment, known as the **baseline assessment**, will take up to 2 hours. You will be able to take breaks during this visit, if required. The assessments will consist of:

- Checking whether there have been any changes to your medical history since your last appointment.
- Attaching small sensors (called Inertial Measurement Units) to your feet and lower back to record your body movements and the speed and pattern of your walking.
- A 10-metre walk test. The time taken and the number of steps taken will be recorded. You can use walking aids, such as a walking sick or frame, if needed.
- Dynamometry test. A device will be held against your leg by the researcher to measure the strength of your foot and hip muscles.
- Anticipatory postural adjustments test. You will be asked to step in targets on the floor, allowing us to measure your posture and movement.
- Mini-BESTest. This consists of a series of physical tests to assess your balance. You will be asked to stand from seated, stand on tiptoes, stand on 1 leg, lean forwards, backwards and sideways (with support), stand with eyes closed, stand on a sloped surface, walk at different speeds, walk while moving your head, walk and turn, step over an obstacle, walk while counting backwards out loud, and a timed up and go (TUG) test (stand up, walk a short distance, turn around, walk back, and sit down).
- Physical assessment. This will involve a series of small tasks to assess the motor symptoms caused by PD, such as tremor (shaking when not moving), rigidity (stiffness or tightening of the muscles) and bradykinesia (slow movement). It will be very similar to the physical assessments that your PD consultant completes with you at routine appointments.
- Questionnaires. These contain questions about your condition, how it affects your mood, behaviour, walking, quality of life, and daily activities and living. Some will be completed by yourself, or your partner or carer, and some will be completed with the researcher. You will not complete them one after another, but rather in-between physical tests to give you an opportunity to rest, should you need to.
- Falls and exercise diary. We will ask you to record daily if you have had any falls and whether you required any medical care as a result of a fall. At the end of the week, will also ask you to record any physiotherapy or exercise classes you have participated in during that week. This can be completed online or using pen and paper and will be recorded throughout your time in the study.

After the baseline assessment has been completed, the next step is to be assigned to either Group 1 (usual care) or Group 2 (FES with usual care). This is done using a computer system that chooses a group at random and is completely out of the control of the researchers. You will be informed later that day which group you are in.

If you are allocated to **Group 1** (usual care):
You will attend 4 blinded assessment visits. At these visits, all the measurements will be performed by a clinician who does not know which group you are in; this is called **blinding**. This is so they will not be influenced or make changes to the way they make the assessments. It is **very important** that you do not tell the clinician which group you are in. These will take place at weeks 2, 6, 18 and 22 and will take up to 2 hours long. You will have the opportunity to take breaks, if required.

The **weeks 2 and 6 blinded assessment** visits will be a repeat of the tests carried out at the **baseline assessment appointment,** detailed above.

The **week 18 and 22 assessment** appointment will mostly be the same as the **baseline** assessment appointment. The only differences are:

- You will not need to have the small sensors (called Inertial Measurement Units) attached to your feet and lower back.
- You will not need to complete the anticipatory postural adjustment test.

In addition to these assessment appointments, we will ask that you wear the Step-Watch pedometer around your ankle for 7 days during weeks 17 and week 21. This will be posted to your home address. You will be asked to return it to us at your week 18 and 22 blinded assessment visit.

If you are allocated to **Group 2** (FES with usual care):
You will attend the same 4 blinded assessment appointments and wear the Step-Watch pedometer as detailed in **Group 1**. You will also attend an additional 4 appointments for the setting up and checking the FES device at weeks 1, 2, 6, and 18. Each of these appointments will last about 60 minutes.

At the **week 1 FES Set-up 1** visit, you will be asked to complete two 10 metre walk tests and a timed up and go (TUG) test, where you will stand up, walk a short distance, turn around, walk back, and sit down. The FES clinician will then set up the device and show you, and if appropriate, your partner or carer, how to use it.

At the **week 2 FES Set-up 2** visit, the FES device will be checked to make sure it is set up correctly and you are comfortable using the device. The same tests as those in the **week 1 FES Set-up 1** appointment will also be repeated, with and without the FES device.

While you're waiting to attend the **week 6 FES Follow-up** visit, you will be asked to use the FES device each day. At first you will be asked to use it for short walks only. The amount you use the FES device will be increased daily over a 3-week period. After 3 weeks, you will be able to use it whenever you walk.

When you return for the **week 6 FES Follow-up** visit, the FES device will be checked and adjusted, if needed. The FES clinician will also see how much you've used the device and if you have experienced any problems with it. You will also be asked to complete the same tests as those in the **week 2 FES Set-up 2** appointment, with and without the FES device.

The **week 18 FES** appointment will mostly be the same as the **week 6 FES** appointment. In addition, you will be asked to return the FES device and complete two questionnaires about how you found the FES treatment.

The FES appointments will take place on different days to the blinded assessment appointments. This is due to the clinician completing the blinded assessment appointments not knowing which group you are in. It is **very important** that you do not tell the clinician at the blinded assessments what group you are in. If you are assigned to Group 2 (FES with usual care), you will be asked not to use FES device before the blinded assessment appointments and to **not** bring it with you. You **must** only bring the device to FES appointments; we will make sure that you are provided a list of all your appointments showing when you should and should not bring the FES device with you.

What clothes should I wear to appointments?

Wear what you feel comfortable in. We will need to have access to your lower legs for the physical examinations, and if you are allocated to Group 2 (FES with usual care), we will need to put sticky patches (electrodes) on one of your legs. Loose trousers, a skirt or shorts would be ideal. Tights or stockings should not be worn if you are in Group 2 (FES with usual care).

Telephone or Online Interviews

A researcher from the University of Southampton will also carry out interviews over the telephone or via online video call to find out what people think about FES treatment. If you are allocated to Group 2 (FES with usual care), you may be approached and invited to take part if you have successfully completed FES treatment or decided to stop using the FES device early. We'd also like to interview some partners and carers to find out what they think about FES treatment. There will be a separate information sheet relating to these interviews. You will be able to decide if you want to be contacted about this when completing your consent form.

What facilities does your department have?

There are disabled parking facilities outside the department. Within the department there are toilets suitable for wheelchair users and we have facilities to enable privacy when changing, placing electrodes or measuring equipment. Chaperones will be provided as necessary. [to be localised]

What are the possible disadvantages and risks of taking part?

If you are allocated to Group 1 (usual care), other than your time, we do not believe that there are any disadvantages or risks to taking part in this study. Although those in Group 1 will not receive the FES device, their role in the study is equally important as Group 2. This is because we need an accurate record of usual care and the way people respond to it, to compare with the new treatment.

If you are allocated to Group 2 (FES with usual care), there are no known serious risks from using FES, but there are some minor ones:

- The stimulation feels a bit like pins and needles. Most people become used to it quickly, but it is possible that you may find the sensation too uncomfortable and may decide not to use the device. Similarly, turning the stimulation up too high may be

uncomfortable, but not dangerous. During your FES set-up visit, the clinician will determine which setting is the best for you.

- In some cases, skin irritation from the sticky patches may occur. If this happens, you will be asked to contact your FES clinician. They will provide advice on how to solve the problem.
- Some people who have epilepsy can have an increase in symptoms in response to electrical stimulation. If you have had a seizure in the last 3 months you will not be eligible for the study.

The ODFS Pace, the FES device used in this study, has been extensively used by people who have other neurological conditions such as Multiple Sclerosis and stroke. No serious adverse effects from using the device have been recorded. If the device is damaged or broken, participants will not be liable and a replacement will be provided.

What are the possible benefits of taking part?

Although it has not yet been proven, information from our previous small study showed that FES can improve walking speed, reduce falls, and may reduce the overall impact of PD. If we produce good evidence for these effects, the study may lead to a new treatment being available within the NHS.

What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, we will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, we will make arrangements for your usual care to continue. If you decide to continue in the study, you will be asked to sign an updated consent form.

With your permission, we will contact your doctor and, where appropriate, your consultant before you start on the study. If you do start the study and there is any new information from your doctor, consultant or one of the researchers that could affect you continuing, we may ask you to withdraw from the study. If this happens, we will discuss it fully with you, and always consider your best interests, before making a decision.

Will I have my expenses reimbursed?

You are entitled to claim travel expenses for car journeys, which will be reimbursed at 24 pence a mile up to a maximum of 100 miles for each return trip. Public transport fares, and, in some circumstances, taxi fares, will also be reimbursed. A claim form will be provided at start of your time in the study to fill in for each study visit, at the end of your participation in the study you should give the claim form to the research team who will reimburse your travel expenses. In addition to being able to claim travel expenses, you will also receive a £20 Love to Shop voucher for each assessment visit you attend and complete. This applies to the baseline and weeks 2, 6, 18, and 22 blinded assessment visits detailed under 'What will happen to me if I take part?' section. You will receive your voucher in the post at the end of your time in the study, with a maximum value of £100 if all 5 blinded assessments are attended.

What happens when the research project stops?

Your usual care will continue as normal. If you are allocated to Group 2 (FES with usual care) you will be asked to return the FES device to the hospital. If you have found the FES treatment of benefit and wish to continue to use it after week 22, there may be some options that allow you to continue the treatment. Please discuss this with your FES clinician. Please note that this is not guaranteed, as FES is not currently part of standard care for pwPD.

What if something goes wrong?

If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this project, the normal National Health Service complaints mechanisms will be available to you. For information about how to complain please contact:

The Patient Advice and Liaison Service (PALS)
Salisbury NHS Foundation Trust
Salisbury District Hospital
Salisbury
Wiltshire
SP2 8BJ

Tel: 01722 429044

Email: sft.pals@nhs.net

Will my taking part in this project be kept confidential?

All information collected about you during the course of this research study will be kept strictly confidential. Each participant in the project will be given a unique code that does not contain any personal details. The study information will be stored on computers at Plymouth University for a period of one year following completion of the project. Only members of the research team and the Peninsula Clinical Trials Unit (PenCTU) at the University of Plymouth will have direct access to the study information. Non-identifiable participant records will be securely stored by Salisbury District Hospital for a minimum of 5 years following the completion of the study.

What will happen to the results of the research project?

We aim to complete this research by the end of 2027 and a report will be submitted to the National Institute of Health Research (NIHR), which is funding this work. Findings may also be published in scientific and medical journals, at conferences and research interest groups and at training days for clinicians. Confidentiality and patient anonymity will always be maintained. A summary will be available to read on the Peninsula Clinical Trials Unit website (www.plymouth.ac.uk/penctu), you will receive a notification via email (if provided) or post when the results are published.

Who is organising and funding the research?

The study is organised by the Department of Clinical Science and Engineering at Salisbury District Hospital and is funded by the NIHR as part of their Efficacy and Mechanism Evaluation (EME) funding stream. The money is to cover research expenses associated with the project, including part of the salaries of the research staff. No payment is made to your referring doctor.

Who has reviewed the project?

This project and information sheet were prepared in consultation with the STEPS II Patient Advisory Group. All research in the NHS is looked at by an independent Research Ethics Committee to protect your safety, rights, wellbeing, and dignity. This study has been reviewed and given favourable opinion by Yorkshire & The Humber- Sheffield Research Ethics Committee.

How will you use information about me?

We will use information from you and your medical records for this research project. This information will include your initials, name, date of birth and contact details. People will use this information to carry out 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 are will not be able to see your name or contact details. Your data will have a code number instead; this will be used instead of your name with the research data.

Salisbury NHS Trust is the sponsor for this study, based in the United Kingdom. We will be using information from you and your medical records to undertake this study and will act as the data controller for this study. This means that 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 for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

All information about you will be kept safe and secure. When the study is finished, the research data will be archived securely for a minimum of five years, after which it will be destroyed in a confidential manner. If we share the research data with others, and when we write our reports, this will be done in a way that no-one can work out that you took part in the study.

We may wish to contact you about participating in future research studies. If you agree to this, there will be an option for you to tell us on the consent form. This is optional and will not affect your ability to participate in this study.

All data will be collected, processed and stored in accordance with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.

Your data will not be shared outside of the UK.

What are my choices about how my information is used?

You can stop being part of the study at any time, without giving a reason, and we will not collect any further data, but we will keep information about you that we already have.

You can find out more about how we use your information by:

- asking one of the research team

- The Sponsor Data Protection Officer can be contacted at:
  IG/RA and Data Protection/Privacy Officer, Informatics Department, Salisbury NHS Foundation Trust, SDH Central, Odstock Road, Odstock, Salisbury, SP2 8BJ
  Tel: 01722 336262
  E-mail: Information.Governance@salisbury.nhs.uk
- reading the patient Privacy Notice at https://www.salisbury.nhs.uk/about-us/your-patient-information-privacy-notice
- visiting www.hra.nhs.uk/information-about-patients/

If you are concerned and believe we are processing your personal data in a way that is not lawful, you can complain to the Information Commissioner's Office (ICO) https://ico.org.uk/make-a-complaint/.

Contact for further information

If you need further information about the project, please contact:
[Local researcher's name, email and phone number]

If you wish to participate in this project, please complete the reply slip at the end of this information sheet and return it in the enclosed pre-paid envelope. Alternatively, you can contact the researchers using the above telephone number or e-mail address. If you have already informed your clinician that you would like to be contacted by one of the researchers, you will not need to complete the reply slip.

Thank you for reading this information sheet.

STEPS II Study Reply Slip

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If you have made a decision about taking part in the study, please read the statements below and tick the box that applies to you and return in the pre-paid envelope enclosed in this pack. Alternatively, you can contact the research team by telephone or email using the contact details provided in the Participant Information Sheet.

You do not need to complete this form or contact the research team if you have asked for a follow up telephone call with a researcher to be made.

- I am interested in taking part in the study and I am happy for you to contact me to talk about it. ☐
- I do not want to take part in this study, please remove me from the contact list. ☐

Please provide your details:

Name: ……

Address: ……..……..

…….....

Telephone Number: ……

Email: ……..….

Preferred day and/or time to call: ……....

……..

Please send to:
STEPS II STUDY
[Local NHS research team address]