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RESTORE - PARTICIPANT INFORMATION SHEET FOR THE OBSERVATIONAL STUDY AND RANDOMISED TRIAL

Study Title:	A randomised trial of surgery versus no treatment to RESTORE cardiopulmonary function in severe pectus excavatum – The RESTORE TRIAL
IRAS ID:	331910
Study Doctor:	If you have any questions about this study, please talk to your study team. *<Full name of principal investigator, title, institutional affiliation, address, phone number>*
Study Sponsor & Data Controller:	*South Tees Hospitals NHS Foundation Trust*
Participant ID:	*<INSERT, IF AVAILABLE>*

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SUMMARY

You are being asked for your consent to take part in a research study. This section provides an overview of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide more detail.

WHY IS THIS RESEARCH BEING DONE?	Pectus Excavatum (PE), also known as funnel chest, is a condition where the ribs and breastbone (sternum) grow inwards forming a dent in the chest. People with severe PE, can have symptoms such as breathlessness, dizziness, fainting and pain with exercising. This can be very restrictive in daily life. Treatment for PE includes surgery, which lifts the sternum up, which relieves these symptoms. High-quality data showing that the surgery improves physical health and heart-lung function is limited. The purpose of this study is to see how surgery to treat PE affects a participant's ability to be physically active. We will also look at how much this costs the National Health Service (NHS) overall.
WHAT HAPPENS TO ME IF I AGREE TO TAKE PART IN THIS RESEARCH?	You have already been diagnosed with severe PE and you have been told that you are eligible for surgery. In this research study there are two different parts and you can choose to take part in one or the other: Option (1), AN OBSERVATIONAL GROUP: You will go ahead as normal with your scheduled surgery. We will collect some data from your medical notes and ask you to complete some questionnaires. After your surgery, we will follow-up with you about your health for a period of about 3-4 years. During this time, you will be asked about your health, to do exercise tests and to complete questionnaires. Option (2), A TRIAL: The other part of the study is where you would be allocated to undergo surgery as soon as possible (within 3 months) or with a year's delay. This delay provides us with data to compare how effective surgery is in improving physical health. The group you are allocated to will be chosen randomly by a computer (like tossing a coin). There is equal chance of being allocated to each group. Your health will then be followed up for a period of about 3-4 years. During this time, you will be asked about your health, to do exercise tests and to complete questionnaires.
COULD BEING IN THIS RESEARCH HARM ME?	The research involves standard surgical procedures for treating PE. The health risks for you are the same whether you have these procedures as a participant in this research study or outside of the research study. The most common surgical complications are pain and minor wound infections. More rarely you may require repeat chest drains, suffer deeper wound infections or movement of the bars placed in your chest during surgery (Nuss operation only) needing hospital treatment. Very rare complications include more major damage to the heart or lungs, blood clots and extremely rarely the possibility of life-threatening complications. As a follow-up to your surgery you may have a follow-up CT scan and chest X-rays which exposes you to a small amount of radiation.
YOUR PERSONAL DATA	In this research study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy laws. At the end of the study, we will save the data for 5 years in case we need to check it and for future research, after which it will be destroyed.

	We will make sure no-one can work out who you are from the reports we write. The information pack tells you more about this.

1. WHY AM I RECEIVING THIS INFORMATION SHEET?

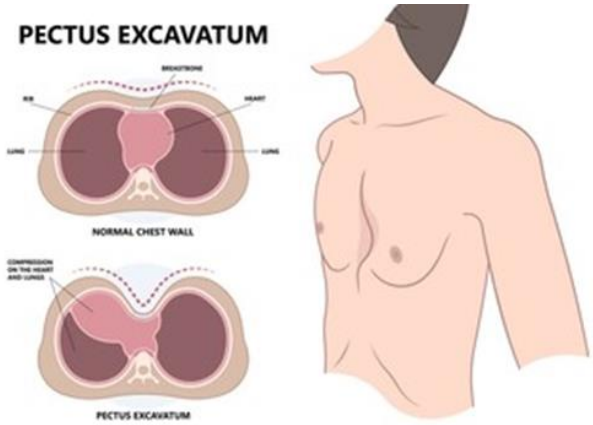
You are being asked to take part in this clinical research study because you have very severe Pectus Excavatum (PE), you experience significant symptoms as a result and you have already been assessed by a national team of pectus experts as being eligible for surgery.

Joining the study is entirely up to you. Before you decide if you want to join, you should understand why the study is being done and what it would mean for you.

This information sheet tells you about the study. Please take your time to read it carefully, and a member of the research team will also go through this with you. Then ask your doctor or nurse if anything is not clear or if you would like more information. If you decide to join the study and later change your mind, you will be able to stop at any time without giving a reason.

If you decide not to take part in this study, you will still get your standard medical care.

2. WHY IS THE STUDY BEING DONE?



Pectus Excavatum (PE), also known as funnel chest, is a condition where the ribs and breastbone (sternum) grow inwards forming a dent in the chest. It is a condition which can occur at or soon after birth, although for most it occurs during a growth spurt (at around 11-14 years). For most people with PE there is no significant impact on health; however, people with severe PE, the narrowing of the chest cavity can affect how the heart and lungs work, causing symptoms such as breathlessness, dizziness, fainting and pain with exercising. This can be very restrictive in daily life. Surgery for PE lifts the sternum away from the heart, which relieves these symptoms. There are two types of surgery. One is called Nuss and one is called Ravitch. Both types are going to be included in this study. Your surgeon will discuss these with you to help you decide which is the best type for you.

In England, funding for surgery for PE is very limited because there is not enough high-quality data showing that the surgery improves physical health and heart-lung function. The purpose of this study is to see how surgery to treat PE affects a participant's physical ability and heart function. We will also look at how much this costs the health service overall.

There will be 300 participants across up to about 12-15 hospitals in the United Kingdom taking part.

We will ask 100 participants to take part as an observational group for the study; these are people like yourself, with very severe PE, who have been assessed by a team of pectus experts and who are eligible for NHS-funded surgery.

We will also compare 200 other people with severe PE in a trial with two treatment groups: the first group of 100 people will have early surgery (within 3 months) and the second group of 100 will have surgery after being followed-up for a year first (this part of the study is a randomised-controlled trial). All three groups will be followed-up for 3-4 years after surgery.

It is entirely up to you to decide whether you want to take part in this study or not. Your choice will not affect your ongoing care or any future medical care. You can decide whether or not to take part in the observational arm of the study any time prior to your surgery, as long as the study team have an opportunity to collect some data from you. If you want to take part in the randomised part of the study then the study team would need to know prior to any standard care surgical slot being allocated to you.

3. WHAT HAPPENS TO ME IF I TAKE PART IN THE STUDY?

If you choose to take part, we will need to collect a set of baseline data from you or your medical records, including your exercise tests, and you will be asked to complete a set of questionnaires, to document your severe PE. The questionnaires will cover aspects of your physical fitness, quality of life, physical and mental wellbeing and use of healthcare resources. Where available, we will take existing data from your ongoing care; however, where, for example, your exercise tests are more than a year old (or more than 6 months' old, if you are under 16), we might ask you to repeat them.

OPTION 1 - OBSERVATIONAL GROUP

If you choose to take part in the observational group, your surgery and after care (which should include a low-radiation dose CT scan) will take place as planned and we will collect data from your medical records.

You will then be followed up at 6 and 12 months, and then at approximately 3 years after surgery. If you undergo the Nuss procedure, then we expect bar removal to be at approximately 2.5-3 years after surgery. The final follow-up at approximately 3 years, will be timed to be at least 6 months after bar removal. All post-surgery visits will collect data from you about your health and you will be asked to complete the same set of questionnaires as at baseline. At 12 months and 3 years you will be asked to perform an exercise test too.

OPTION 2 - TRIAL OF EARLY OR LATE SURGERY

If you choose to take part in the randomised-controlled trial, you will be asked if you are willing to travel to another hospital(s) for treatment and which one(s). This is because capacity for treating pectus and surgery is limited across England, so you might also prefer to see a team at another hospital to be included in the trial sooner. You will also be asked if you have a preference for the type of surgery to have (Nuss or Ravitch). The treatment group you will be allocated to, will be decided by chance (like tossing a coin), the chance that you are allocated to the early or late surgery group will be 50% or 1 in 2. You will be told as soon as possible which group you have been allocated to:

Early-surgery group

If you are allocated to this group, your surgery will take place within 3 months of allocation.

You will follow routine after care which should include a low-radiation dose CT scan and we will collect data from your medical records. You will then be followed up at 6 and 12 months, and then at approximately 3 years after surgery. If you undergo the Nuss procedure, then we expect bar removal to be at approximately 2.5-3 years after surgery. The final follow-up at approximately 3 years, will be timed to be at least 6 months after bar removal.

All post-surgery visits will collect data from you about your health and you will be asked to complete the same set of questionnaires as at baseline.

At 12-months and 3-years you will be asked to perform an exercise test too.

Late surgery group

If you are allocated to the late-surgery group, you will be contacted at 6 and 12 months after the date of allocation and asked to complete some questionnaires.

At 12 months, you will also be asked to perform an exercise test.

Your surgery will then take place within 3 months of this date and you will follow routine after care which should include a low-radiation dose CT scan and we will collect data from your medical records.

You will then be followed up at 6 and 12 months after surgery, you may also be contacted at approximately 3 years after surgery. The 3-year follow-up will depend on when you enter the trial and we will be able to let you know well in advance whether this will take place or not. Also, if you undergo the Nuss procedure, then we expect bar removal to be at approximately 2.5-3 years after surgery. The final follow-up at approximately 3 years, must also be timed to be at least 6 months after bar removal.

As for the other groups, all post-surgery visits will collect data from you about your health and you will be asked to complete the same set of questionnaires as at baseline.

At 12-months and 3-years (if this goes ahead) you will be asked to perform an exercise test too.

The team is also interested in understanding your surgery preferences and you will be invited to take part in a survey at 16 months after allocation.

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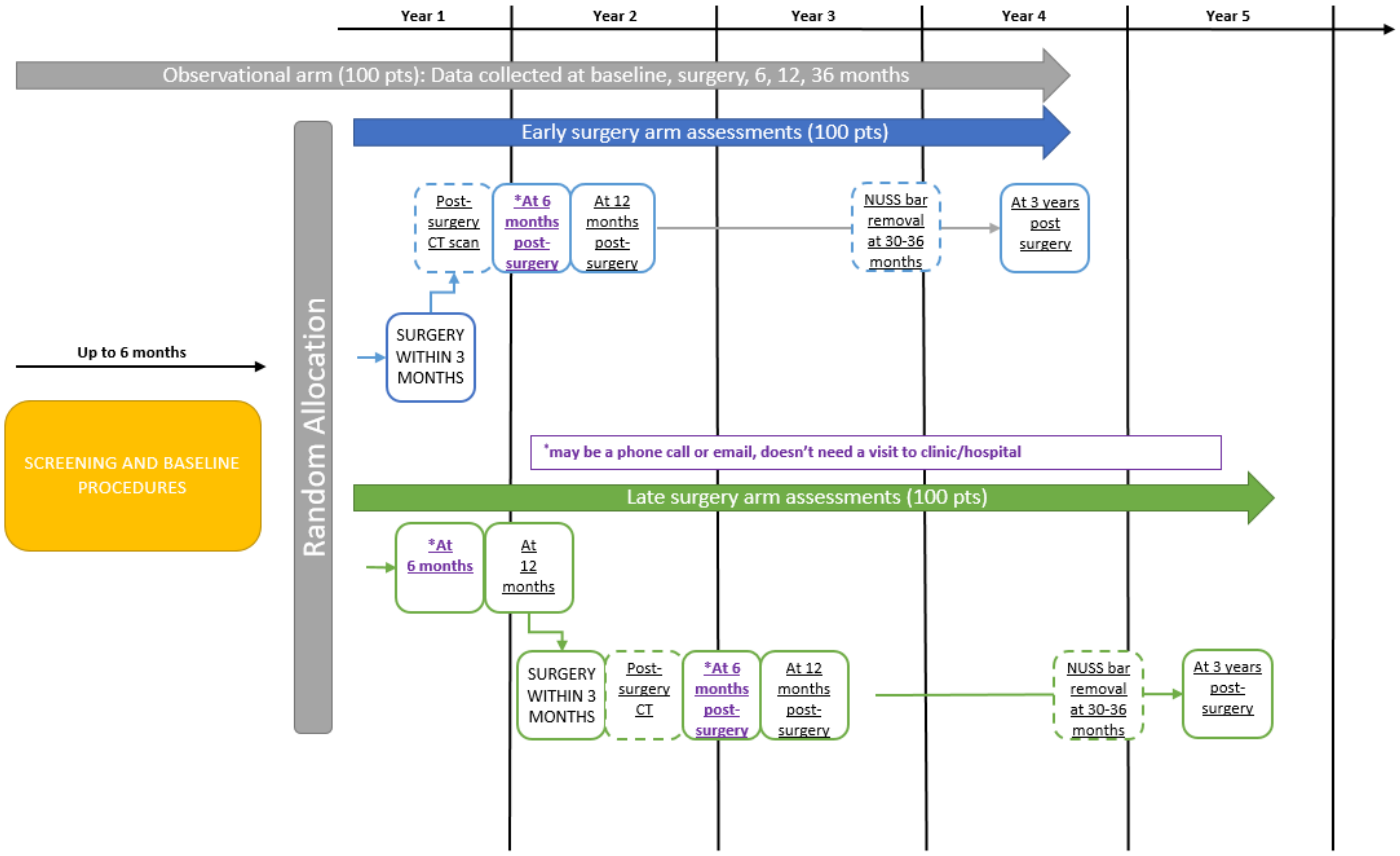
YOUR JOURNEY THROUGH THE STUDY



Highlighted in purple text with a * in the scheme above, are those times where you don't need to visit the hospital if you are happy to enter your own data online or have a phone call instead. We estimate this will take between 40 to 60 minutes to complete questionnaires and provide medication usage information. Some of the questionnaires ask similar questions and there may appear to be overlap, but it is important for our study that all of the questionnaires and all the questions within them are completed for all patients. If you want to complete the questionnaires online, we will need your email address. We will send links to the questionnaires.You can take a rest between completing them, similar to if you complete them on paper, the link can be accessed as many times as needed.

Some follow-ups will need you to go to your hospital site/clinic, which could take a couple of hours to complete. If you are in the observational group, or allocated to the early surgery group you will need to attend hospital/clinics between 4 and 6 times, of which, 2 times would be purely for the study. Your involvement could last around 3.5 years.

If you are allocated to the late surgery group you will need to attend hospital/clinics between 5 and 7 times, of which, 3 times would be purely for the study. Your involvement could last around 4.5 years.

If you need to repeat any of the baseline assessments, it may need another visit or two at the start.

You are responsible for attending all study visits scheduled by the study team. If you need to reschedule any visits, please contact your study team.

At each visit and between visits, you should let your study team know if you have any new symptoms, or your health or condition changes. Please also let your study team know as soon as possible if you are

admitted to hospital. If you see another doctor, please tell this doctor you are taking part in this study and that they can contact the study team for information.

We may also need access to your scans (CT scan, echo, etc) to confirm clinical details and we are asking for your consent for this. We would also like to keep these scans for future research, if you agree.

Please speak to your study team right away if you have any concerns or questions.

4. ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

As you are eligible for surgical treatment whether or not you take part in the study, there is no additional benefit to you in taking part in this study.

However, we know that the information collected in this study will help doctors and the NHS learn more about the impact of surgery on people with PE, and this in turn may help future patients.

5. WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART? WILL THERE BE ANY COMPLICATIONS?

As with any surgery, there are risks of complications, including bleeding, infection and problems with the anaesthetic, you might also need chest X-rays to check the placement of the bars (if you have the Nuss procedure) and X-rays use small amounts of ionising radiation. Your surgeon will talk through specific pectus surgery risks with you.

If you take part in the randomised-controlled trial, there is a potential of delay to your surgery. This might have an impact on your health.

We will be collecting your personal data, with this is a risk your confidentiality might be breached, despite us keeping it as safe and secure as we can. In Section 7 of this information leaflet we tell you more about how we handle information we collect about you.

Important information about pregnancy

Women of childbearing age will be asked to perform a pregnancy test as part of standard care prior to surgery and CT scans. If you become pregnant during the study, please inform your study doctor immediately. Surgery, CT scans and the exercise test would pose a significant risk to any pregnancy so these would not be carried out while you are pregnant. Information about your pregnancy and the outcome will be collected.

6. WHAT PROCEDURES WILL BE DONE IN THIS STUDY AND WHAT ARE THE RISKS?

Study Procedures(s) Glossary	Description text	Risks
Surgery 	You will undergo either the Nuss or Ravitch operations. Your surgeon and care team will discuss this with you in detail.	As described above
Cardio-Pulmonary Exercise Test (CPET) 	A Cardiopulmonary Exercise Test (CPET) is used to assess your exercise capacity and investigate the response of the heart and lungs. You should wear clothing and shoes comfortable for exercising in. You will be asked to exercise, on an indoor static bike. You will be encouraged to exercise for as long as you can whilst your body's response is recorded. To track your heart during exercise, sticky patches called electrodes will be put on your chest. Your chest will be cleaned with alcohol and shaved in some areas (if necessary) for this. An inflatable cuff will be placed on your upper arm to measure blood pressure and a facemask to check your lungs. A pulse oximeter (probe) will be placed on your finger to assess blood oxygen levels. These will not hurt. All your CPET assessments will be done at the same hospital/clinic.	The risk for CPET is the same as for mild-moderate exercise, the number of patients who develop symptoms is low (1:1000). From our experience, due to the nature of the test occasionally patients may feel lightheaded We will be monitoring you closely during the test, with continuous ECG, blood pressure and oxygen measurements. If you develop significant symptoms, we will stop the testing.
Questionnaires 	You will be asked to complete 11 questionnaires up to 6 times during the course of the study. The questionnaires will be about: - Your medical history and medications - Your health and level of activity - Your quality of life – including how well you get about doing daily activities - How you're feeling, how you feel about your condition and how you look - What health services you have recently used and how much time and money you have spent using them As well as directly with a study team member, you will be able to complete these questionnaires online or over the phone, if you prefer.	You may feel uncomfortable with completing some of the questionnaires. Should any of your answers be of concern to the study team, your GP will be contacted to assess your needs and help provide psychological support.
General health interview 	You'll be asked at each follow-up generally about your health, medications you are taking and any complications or additional hospital visits that you might have had since the last time the team contacted you. If you prefer, you will also be able to answer these questions online.	No risks
Low-radiation CT scan 	If you take part in this study you will have low-dose CT scans of your chest after surgery (there may also be the need for a scan before surgery if no recent scans are available). A CT scan is part of routine care after pectus surgery, but a pre-surgery scan would be extra to those that you would have if you did not take part. . There may also be a need for standard chest x-rays to check the placement of the bars (Nuss procedure), or assess for possible complications. These procedures	Ionising radiation may cause cancer many years or decades after the exposure. We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study will increase the chances of this happening

	use ionising radiation to form images of your body and provide your doctor with other clinical information.	to you to about 0.03% (0.06% if you also require a pre-surgery scan).

7. WHAT ARE MY RIGHTS AS A STUDY PARTICIPANT?

What if something goes wrong?

If you think there has been damage to your health as a direct result of participating in this study, you must tell your study team as soon as possible. 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 South Tees Hospitals NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

You will be told if any new information becomes available that may affect your decision to continue to take part in the study. You will be asked to sign a form if you agree to continue with your participation. Some new information may also mean that you will no longer be able to continue in this study. If this happens, your study doctor will discuss this with you.

If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer. The research team can give you details of the right Data Protection Officer. If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

What happens if I don't want to carry on with the study?

You can completely stop study participation at any time, without giving a reason, but we will keep information about you that we already have.

You can also choose to only partly withdraw, for example, where you might not want direct contact with the study team, but are happy with completing questionnaires online.

How will we use information about you and how will it be kept confidential?

We will need to use information from you and your medical records for this research project, this will include your personal data.

The following types of personal data collected in the study, will include:

- Information to arrange your participation in the study such as your name, address, telephone number, email address.
- Information such as your date of birth, sex at birth, postcode, ethnicity.
- Health information such as medical history, medical conditions, results of your exercise tests, results of imaging (like CT scans).

Data collected for the study is "coded". This means any information that could directly identify you, like your name, is removed by your hospital study team and replaced by a code. This code is usually a number. A separate list that matches the code to who you are is kept by your hospital study team (separate from coded data). If you choose to use the electronic system to answer the questionnaires, then we will need to keep your email address with the study data.

Your records at your hospital will remain "un-coded" and contain data that can directly identify you. If you prefer to have your surgery at another hospital, your name and contact details will be shared with a national coordinator who will make the arrangements for transfer and your uncoded data will also be passed on to

the new hospital teams. The national coordinator will be based at South Tees Hospitals NHS Foundation Trust.

Apart from the hospital study teams and national coordinator, only a small group of people from the sponsor can see your un-coded data to make sure the study is done properly. These people must keep your data private. People who do not need to know who you are will not be able to see your name, NHS number or contact details.

Your data are protected by UK data privacy laws (UK GDPR and the Data Protection Act 2018). As the Sponsor of this study, South Tees Hospitals NHS Foundation Trust is the data controller for this study. This means that we, as South Tees Hospitals NHS Foundation Trust researchers, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible. We will keep identifiable information about you for 5 years after the study has finished, unless you provide your additional consent to a longer-term follow-up after the end of the study. If you do agree to the longer-term follow-up, then we will keep your information for another 5 years after the end of the follow-up period.

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.

We will keep all information about you safe and secure.

Who receives my coded data?

The coded data will be provided to the research team, who include people at other NHS institutions and UK universities.

Anyone your data is shared with must protect it in the same way as described in this Information Sheet.

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.

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

Will I receive any financial reimbursement, expenses or compensation?

You will not be paid for taking part in this study and your surgery and medical care will not cost you anything.

We are able to help with travel costs (up to £40 for each visit) when you return to hospital/clinic for the repeat exercise test (at 12 months after allocation for the late-surgery group and at 12 months and 3 years after surgery).

If you choose to have surgery at another hospital, we are also able to help support some travel and accommodation costs for yourself and a carer, please discuss this with your study team.

Who is organising and funding the study?

Funding has been provided by the National Institute for Health and Care Research Health Technology Assessment (HTA) Programme. South Tees Hospitals NHS Foundation Trust is organising this study and known as the 'Sponsor'.

Who has approved the study?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee which is there to protect your safety, rights, wellbeing and dignity. This project has been reviewed and was given a favourable review by the East of Scotland Research Ethics Committee.

What happens with the study results?

A description of this study will be available on www.isrctn.com

No information will be published that can identify you.

After the whole study is finished and the data have been analysed, we will report our findings to the funder, to the National Institute for Health and Care Excellence (NICE) and to a number of professional surgical societies and present at surgical conferences. We will also work with our Patient Advisory Group (PAG) and the patient representatives on the research team to decide on the best way to let patients and the public know about the results.

How have patients and the public been involved in this study?

There are two patient representatives on the funding application team and they will continue to remain involved with the study. They have helped to develop the question and how we might answer it in the design of the study, with the two treatment groups, the assessments and the follow-up periods.

The patient representatives have also been involved with reviewing this Participant Information Sheet.

Will my General Practitioner (GP) be informed of my participation?

Your GP will be notified that you are taking part in this study. Your GP may be approached to provide further information about your health during the course of this study, this might be in asking for results of blood tests or the results of other tests.

8. FURTHER INFORMATION AND CONTACT DETAILS:

Please contact <ENTER STUDY TEAM DETAILS>

Thank you for reading this information and considering taking part in this study.