Participant Information Sheet

A feasibility study to assess rectal sensitivity using elastic balloon versus a rapid rectal barostat bag: is there an agreement in London Classification diagnoses?

We invite you to take part in a research study

- This participant information sheet is to help you decide if you would like to participate in our research study
- It is important that you read through this information carefully and discuss this with friends and family before deciding if you would like to participate
- Please note that your care **will not** be affected whether you decide to participate or not in this study, and you may drop out of the study **at any point**
- If you have any further questions or concerns that you would like to discuss, please get in touch with the research team using the contact details below

What is this study about?

- Bowel symptoms include symptoms such as stool incontinence (unable to get to the toilet in time) and constipation (difficulty in emptying stool out of the body). These symptoms are very common. For example, 10% of the UK adult population are thought to suffer with faecal incontinence, and 20% are thought to suffer with constipation

- The rectum is where stool is stored before leaving the body. When the rectum becomes full people usually get the urge to go to the toilet and empty the bowel

- Some bowel symptoms can be related to how well the body senses stool in the rectum. For example, some people may be unable to sense when the rectum is full leaving them little time to get to the toilet on time

- To assess how well the body senses rectal filling (rectal sensitivity) a small balloon is gently positioned in the rectum and slowly inflated with air. This provides a similar sensation to that of the urge to go to the toilet and empty the bowel. By understanding how well rectal filling is sensed we hope to determine whether the cause of symptoms is related to changes in rectal sensitivity

- The most commonly used test of rectal sensitivity in clinical practice uses an elastic balloon. However, an alternative test uses a different type of rectal balloon which is non-elastic. This is called a rectal barostat. The rectal barostat test also provides additional information which can indicate the size of the rectum and how well the rectum is able to accommodate stool (stretchiness of the rectum)

- In this study, we are asking 30 patients who are referred for the elastic balloon distension test, to have the test repeated using the rectal barostat
- This study is taking place as part of a Masters research project
- We will compare the results from the elastic balloon test with the rectal barostat and see if the diagnosis changes. If there are changes in diagnosis when the barostat is used we may consider doing a further research study which will look at whether receiving a better diagnosis can lead to better treatment of symptoms
- In order to help us prepare for a definitive study on the rectal barostat we need to understand several things to help us design the next study. This includes: people willingness to participate, how comfortable the rectal barostat is (tolerability), how long the additional test takes and whether in some people a diagnosis changes between rectal barostat and other test

Why have I been asked to participate?

- You have been referred for anorectal physiology tests by your consultant, which means you are suffering with symptoms of constipation, leakage of stool, bowel urgency, or anal pain
- Part of these tests involves the elastic balloon distension test, to assess the sensitivity of your rectum, and see if this is contributing to your symptoms
- As you would be having this test as part of your standard care, you are also suitable to have the rectal barostat test. We would provide the additional results to your consultant

What would be required of me?

- You would arrive at the hospital for your standard anorectal physiology appointment

- A member of the research team will go through the research study and the standard tests with you. We will give you the opportunity to ask any questions. If you are willing to participate in the study you will be asked to sign a consent form for the study

- In addition to your standard anorectal physiology tests (please read through our Patient Information Leaflet for further details), you will undergo one additional test. This is called the Rectal Barostat Test

- During this test a catheter (tube) with a deflated non-elastic bag will be inserted into the back passage and gradually inflated. We will then ask you when you start to feel the bag filling, when it feels like your normal urge to use the toilet, and when this urge becomes desperate. As soon as you feel this the bag will be deflated and that feeling will go away

- This will be repeated a few times to check we get the same measurement. This could take up to 30 minutes in addition to your standard appointment

- The order in which you receive the tests is randomised. This means that half the study participants will undergo the standard elastic balloon distension test first whilst the other half the participants will undergo the rectal barostat test first. The order is determined after the consent process and depends upon the randomisation number that is provided after consent

- You would then be asked to fill out a questionnaire in reception after your appointment. This questionnaire will ask you questions about your participation in the study. This will help us plan a future study

based on your feedback. Completion of the questionnaire will take approximately 5 minutes

- This is all that will be required from you for the research study. The results of the rectal barostat test will then be reviewed by our team of healthcare scientists, and made available to you by your consultant

What are the benefits of taking part?

- The test will provide a more detailed assessment of the properties of the rectal wall, which could help to guide your consultant's advice on a treatment for your symptoms

- There will be no financial compensation or reward for taking part in this study

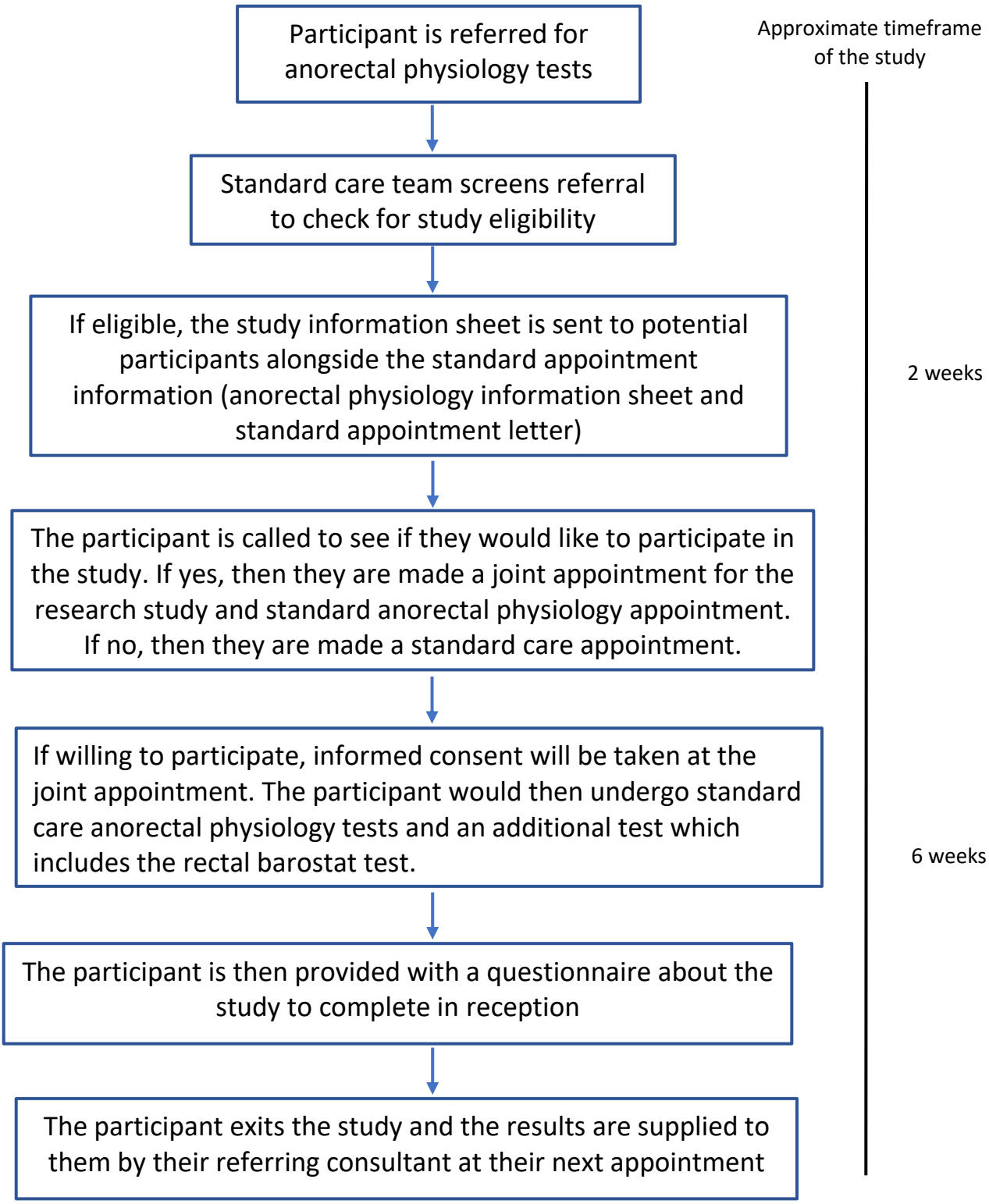
Are there any risks associated with this study?

- The rectal barostat is a very safe test, but you may experience some pain, discomfort, or bleeding when we insert the catheter into your rectum. To minimise this, we use lubricating gel when inserting the catheter

- There is a small risk of perforation (small tear) to the rectum (<1 in 1000). However, the risk associated with the rectal barostat test is less than standard rectal sensitivity using the elastic bag as the rectal barostat bag deflates once it reaches a certain pressure

- If you have any questions about these risks, please feel free to get in touch with a member of the research team

Study Pathway



Who is sponsoring this study?

- This study is being sponsored by Newcastle Upon Tyne Hospitals NHS Foundation Trust

How will you use information about me?

- We will need to use information from you and your medical records for this research project
- This information will include your name, initials, NHS number, medical record number, address, phone number, and email address. People will use this information to do the research or to check the 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
- 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

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, 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 have about you

Where can I find out more information about how my data 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
- by sending an email to the Newcastle upon Tyne NHS Foundation Trust data protection officer: nuth.dpo@nhs.net.
- by ringing us on 0191 282 3839

Who has reviewed the study & What will happen to the results of the study

- All research in the NHS 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 Dulwich Research Ethics Committee
- The results of your study will be made available to your referring consultant which may help guide further treatment
- Anonymised results (results which contain no personal information such as name or date of birth) may be published in peer reviewed scientific/medical journals

What if I don't want to take part?

- Taking part in this study is entirely optional, and your care will not change if you decide you do not want to be involved

- Instead, you will not have the barostat test, and you will attend for your standard anorectal physiology appointment
- If you do consent to taking part in this study, but change your mind, **you can withdraw at any point**

I do want to take part, what are the next steps?

- If you are interested in taking part, please let us know when a member of our team calls to confirm your standard appointment, and please bring this leaflet to your anorectal physiology appointment
- At the appointment you will have the opportunity to ask any questions about the study.
- After discussing the study at your appointment and if you would still like to participate we will ask you to sign the consent form
- Following this you will have the standard anorectal physiology tests done at the same appointment, with the additional barostat test

What if I have any concerns?

If you have any concerns you can contact the study chief investigator.
Dr Helen Parker
Email: nuth.nmpcegiphys@nhs.net
Telephone: 0191 2824493
Address: NMPCE
Medical Physics
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Royal Victoria Infirmary
Newcastle upon Tyne
NE1 4LP

However, if you prefer to raise your concerns with someone not involved in your care, you can contact the Patient Advice and Liaison Service (PALS). This service is confidential and can be contacted on Freephone: 0800 032 0202

Alternatively, if you wish to make a formal complaint you can contact the Patient Relations Department through any of the details below:

Telephone: 0191 223 1382 or 0191 223 1454
Email: nuth.patient.relations@nhs.net
Address: Patient Relations Department
The Newcastle upon Tyne Hospitals NHS Foundation Trust
The Freeman Hospital
Newcastle upon Tyne
NE7 7DN

Further information

- For more information about anorectal physiology tests and what they involve, please visit https://www.newcastle-hospitals.nhs.uk/services/medical-physics/gastrointestinal-physiology/
- For any support regarding your bowel symptoms, please consider visiting the Bladder and Bowel UK website to read through further information and advice: https://www.bbuk.org.uk/ .

Thank you for taking time to read through this participant information sheet.

If you have any queries, questions, or concerns please feel free to contact the study's Chief Investigator

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nuth.NMPCEGIPHYS@nhs.net