



***Packing of Perianal Abscess
Cavities; An observational
feasibility study***

North West Research Collaborative

Patient Information Sheet

Thank you for taking the time to think about being involved. Please read this information carefully. It explains why we are doing the study and what will happen to you if you take part. Please ask if anything is not clear (contact details are given at the end of this form). Taking part in this research is completely voluntary and your normal care services will not be affected if you decide not to be involved.

Background

A perianal abscess is a collection of pus at or near the back passage (anus) caused by an infection. This usually causes severe pain. The treatment is an urgent operation to cut the skin over the abscess and drain the pus, which relieves the pain. When the pus has been drained, a cavity remains. This is normally packed with an internal dressing. The pack is changed regularly until the cavity heals, which may take between two and eight weeks. Patients are usually discharged on the day after surgery and on-going dressing changes are performed by a treatment room nurse or district nurse.

What is the purpose of the study?

Although the use of an internal dressing (pack) is current treatment in the UK, there is little evidence that it is beneficial. The purpose of this study is to collect information about the current treatment of perianal abscesses across the North West region. This information will be essential to prepare for a larger study where we will compare the difference between packing and non-packing of the abscess cavity. We want to find out what is the best time to see patients and how best to record the results of the operation and how much it affects peoples' lives.

Who is doing the study and who has approved it?

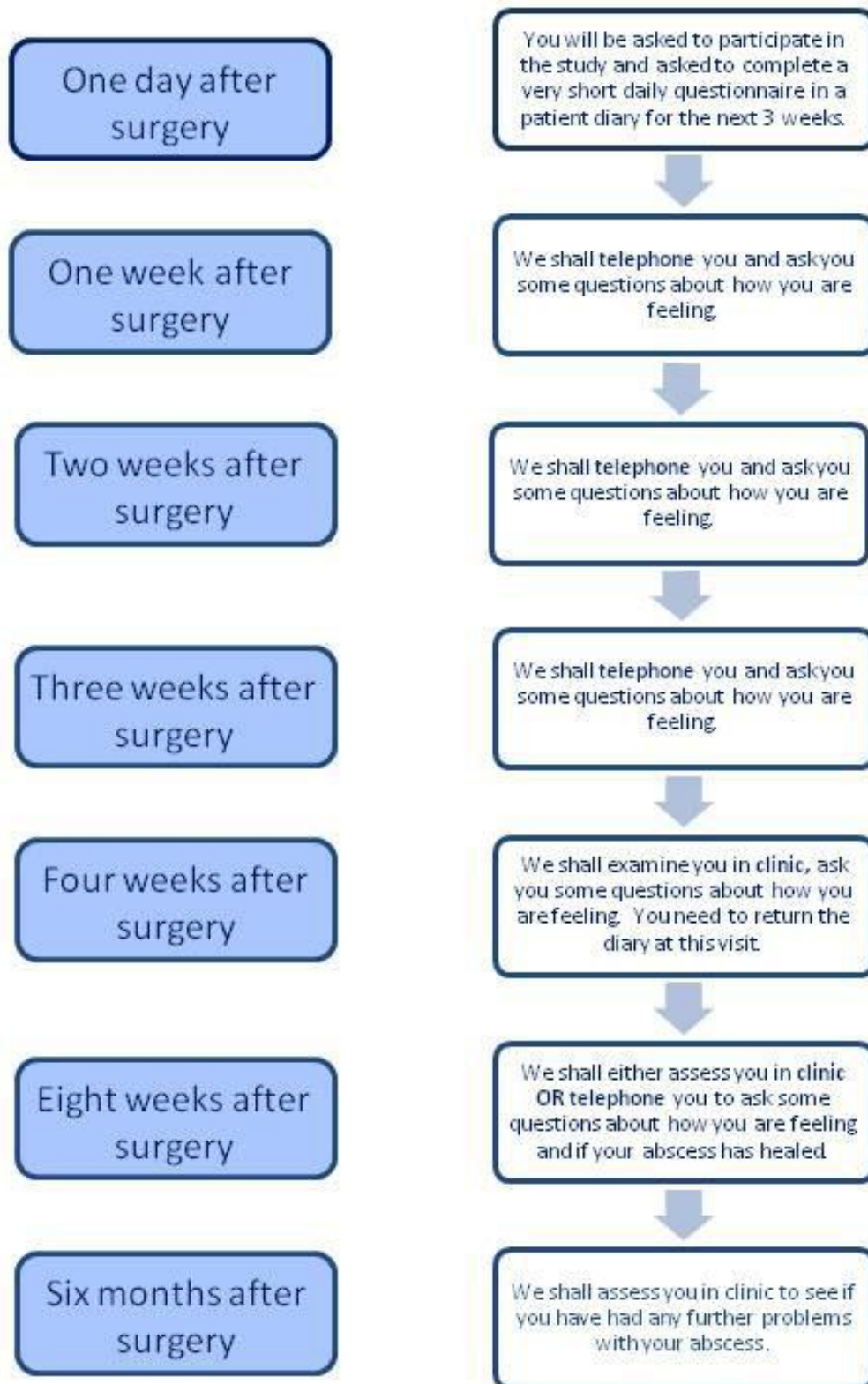
The project is being run by the North West Research Collaborative. This is a team of surgical registrars and consultants based in the North West Region. The study is being supported by the Liverpool Clinical Trials Unit, and has been approved by the Research Ethics Committee (REC Reference:).

Why have I been chosen?

You have been asked to take part because you have been diagnosed with a perianal abscess which requires an operation. As a profession, we know very little about the healing of perianal abscesses and how their current treatment impacts on our patient's lives.

What will taking part involve?

This study will only collect information. **There will not be any change to the treatment of your abscess.**



Do I have to take part in the study?

No. The study is completely voluntary. It is up to you to decide whether or not to take part. If you decide to take part, you can stop at any time without giving a reason. This will not affect the care you receive.

Are there any benefits in taking part?

You will not benefit in taking part but we hope that you will find it rewarding to be involved in research that may help us to develop and improve treatment for future patients. You will be provided with a contact number for the duration of the study, so you have access to expert advice.

Are there any disadvantages to taking part in this research?

Your surgical treatment will not be affected. The main disadvantage is the time it will take to complete the patient diary and participate in the consultations which are to see how you are getting on.

What about my expenses?

You will receive £10 at your first clinic appointment four weeks after your surgery. You will receive another £10 at the final clinic appointment at 6 months. This money is to cover travel expenses.

Will my taking part in the study be kept confidential?

Yes. This information will not be shown to anyone outside the research team, or individuals representing the Research Sponsor or Regulatory authorities (for the purpose of monitoring or auditing the study). The information will be presented at surgical conferences and the results may be published in medical journals. All personal details will be removed so that no one will be able to trace the information to you.

Will direct quotes from me be used?

Quotes that you give in the course of this study may be used in future reports, articles or presentations that relate to this research. These quotes will be anonymous.

How can I find out the results of the study?

The results will be published on the North West Research Collaborative website (nwresearch.org). They are also likely to be available in local publications produced by Manchester University, Central Manchester Foundation Trust and University Hospital South of Manchester.

What to do 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 will give you their contact details. If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Advice and Liaison Service at your site. Any complaint about the way you have been dealt with during the study will be addressed.

What do I need to do next?

If you would like to be involved in this research, please complete the attached consent form and return to the doctor who gave it to you.

For further information, please contact:

Thank you for taking the time to consider being involved.