

HEALTH PROFESSIONAL INFORMATION SHEET

ICONS: Identifying Continence OptioNs after Stroke

Invitation to participate

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

(Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detail about the conduct of the study).

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1

What is the purpose of the study?

Urinary incontinence is common after stroke and can be very unpleasant and a cause of distress and embarrassment for patients and their carers. Urinary incontinence may hamper rehabilitation and may affect whether or not patients are able to return to their own home, as well as return to leisure activities, work or an active social life. It is also costly for families and for the Health Service. We would like to try out a package of assessment and treatment of urinary incontinence while people are in hospital, which is designed to help them become continent again.

In this phase, we would like to assess how acceptable the package is for patients and those looking after them. We will modify and develop the package based on what patients and health professionals tell us.

Our study is, to our knowledge, the first to rigorously test a package designed to assess and treat urinary incontinence after stroke in a hospital setting.

We would like to invite you to take part in Phase I of the study.

Why have I been invited?

We would like to invite you to take part because you are part of the health care team who have been using our package to look after patients who have urinary incontinence after their stroke. We would like you to take part so we can find out your experiences of using the package.

Your views will be very valuable to the research team, who will use your experiences and suggestions to improve the package before introducing it in a larger number of stroke services.

Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason.

What will happen to me if I take part?

Interviews

You will be invited to take part in six focus group interviews (one per month) with other health professionals from your stroke service. These will be arranged at a date and time convenient for you. We anticipate that each interview will last around one hour.

The interviews will take place in a quiet and private location on the unit. They will be facilitated by a member of the research team. The researcher will ask you if you are happy to have the interview audio taped.

What are the possible disadvantages of taking part?

We do not anticipate any disadvantages of taking part.

What are the possible benefits of taking part?

Taking part will give you the opportunity to share and discuss your views of the package of care with other health professionals, who have also been using the package, at regular time points throughout the six month intervention period.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be treated in confidence. The details are included in Part 2.

This completes Part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

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

You are free to withdraw from the study at any time, without giving a reason. It may not be possible to separate out your contributions to focus group interviews, so if you decide to withdraw we will ask your permission to use the data you have provided up to the point of withdrawal.

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 (01772 893643). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

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 Lancashire Teaching 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 (if appropriate).

Will my taking part in the study be kept confidential?

All research data will be treated and stored according to the Data Protection Act (1998) and the Caldicott Principles. All data will be treated as confidential according to the Medical Research Council definition: "any information obtained by a person on the understanding that they will not disclose it to others" (MRC, *Personal Information in Medical Research.* 2000). All health professionals who consent to take part will be allocated a code number and all data recorded about them will be identified by their code number.

All quotations from respondents used in reports and publications will be anonymised and individual respondents will not be identifiable from them.

Computers used in the study will be password protected. All paper data will be stored in locked filing cabinets in a locked office. Access to all data will only be available to research staff from the study.

Your personal details will be destroyed at the end of the study. Data forms and interview transcripts will be stored for 10 years in line with the recommendations of the Medical Research Council document *Good Research Practice* (2000). Data will be stored in a locked cabinet in the programme coordinator's office (also locked). Access will be given only to the research team via the programme coordinator.

What will happen to the results of the research study?

Findings will be shared widely using a range of methods following advice from the Programme Patient, Public and Carer Involvement Group. These will include:

- a) Written feedback will be provided to all study participants who would like it.
- b) Presentations at a range of stroke and incontinence related conferences, for example the Society for Research in Rehabilitation, UK Stroke Forum and Royal College of Nursing Continence Forum.
- c) Presentations to appropriate forums within the participating Trust.
- d) Findings will be disseminated via the North West Stroke Task Force information sharing channels, for example clinical practice sharing meetings, newsletters, patient and carer information documents (produced with Cumbria Social Services and Help the Aged), attendance at Service User Groups and local conferences. Findings will also be shared via the Stroke Research Networks.
- e) We will submit findings to peer-reviewed academic (e.g. Stroke) and popular (e.g. Nursing Times) journals to maximise readership.

Who is organising and funding the research?

The research is sponsored by the Lancashire Teaching Hospitals Foundation NHS Trust. It is funded by the National Institute for Health Research under the Programme Grants scheme.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by Bolton Research Ethics Committee.

You may keep this information sheet and you will also be given a signed consent form for you to keep.

Further information Specific information about this research project

Please contact the Programme Coordinator:

Dr Lois Thomas School of Nursing and Caring Sciences University of Central Lancashire Preston PR1 2HE

Email address: lhthomas@uclan.ac.uk 01772 893643

Who you should approach if unhappy with the study Please contact Dr Lois Thomas, details as above.

For any concerns during the study

Please contact <add details of research nurse>