uclan
University of Central Lancashire

icons
Identifying Continence OptioNs after Stroke

PARTICIPANT INFORMATION SHEET

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 (difficulty in controlling emptying of the bladder) is common after stroke and can be very unpleasant and a cause of distress for patients and their carers. Urinary incontinence may hamper rehabilitation and delay patients from returning home and resuming leisure activities, work or an active social life. There are also financial costs for families and for the Health Service. We would like to try out a treatment plan for urinary incontinence with hospital inpatients aimed at helping them become continent again. We will assess whether the plan seems to work and how acceptable it is for patients and those looking after them.

Why have I been invited?

The health care team will be using our plan to look after you. We would like you to take part so we can find out how you have progressed and your experiences of being looked after using the plan.

Do I have to take part?

It is up to you to decide; taking part is entirely optional. We will describe the study and go through this information sheet with 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. This would not affect the standard of care you receive.

What will happen to me if I take part?

You will be invited to:

a) **allow nursing and research staff to check your progress** OR
b) **allow nursing and research staff to check your progress AND take part in interviews with researchers**

A) Checking your progress

We would like to note some details about how you are progressing with your treatment. The nursing staff will keep a diary of what treatment you have had for continence and how you are progressing. This information and information from your case notes relevant to this study will be used by the research staff to monitor your progress.

We would also like to ask you some questions about your condition and progress before you start the plan and at six weeks, three months and, for some participants, at twelve months after the date you had your stroke.
We will write to your GP to tell them you are in the study and also to check you are still at the same address before we post questionnaires to you at home.

B) Interviews

You will be invited to take part in an interview about the hospital management of your continence. This will take place during your stay and will be arranged at a time convenient for you and to fit in with your care and treatment. We anticipate that the interview will last between half an hour and one hour.

The interview will take place in a quiet and private location on the unit. It will be carried out by a member of the research team who is experienced at interviewing patients. The researcher will ask you if you are happy to have the interview tape-recorded; you may refuse if you prefer not to have your comments recorded but still continue in the project. Names will not be recorded and all tapes will be destroyed within three months of project completion.

You may find talking about continence upsetting. You will be able to stop the interview at any time and nursing and medical staff will be there to support you if you are upset during or after the interview. If you would like support, please contact:

Ward: Sister
☎

Ward: Sister
☎

If you would like a relative or friend to come along to the interview with you, they would be very welcome.

What are the possible disadvantages of taking part?

We will ask you to talk about how your continence has been assessed and managed, and we realise this is a sensitive subject. We will do all we can to minimise embarrassment for you and any relative or friend you have with you. The interview has been developed very carefully to focus on assessment and

treatment received rather than focussing on the details of your continence problems.

What are the possible benefits of taking part?

You may welcome the opportunity to discuss the care you have received and to suggest ways this could be improved.

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. If you withdraw from the study, we will destroy all the information you have provided.

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 patients who consent to take part will be allocated a code number and all data recorded about that patient will be identified by their code number.

All quotations from participants used in reports and publications will exclude personal details. No individuals will be identifiable from them.

Computers used in the study will be password protected. All paper records will be stored in locked filing cabinets in a locked office. Only research staff from the study will have access to the records.

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 International Continence Society, Society for Research in Rehabilitation, UK Stroke Forum and Royal College of Nursing Continence Forum.
c) Presentations to appropriate forums within the participating Trusts.
d) Findings will be disseminated via the Clinical Practice Research Unit information sharing channels, for example clinical practice sharing meetings, 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 Bradford Research Ethics Committee.

You may keep this information sheet and you will also be given a copy of the signed consent form 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 you are unhappy with the study?

Please contact Dr Lois Thomas, details as above.

For any concerns during the study

Please contact the Research Nurse add name or Denise Forshaw, the Trial Manager, either on site or as below;

Denise Forshaw
Trial Manager
University of Central Lancashire
Preston PR1 2HE
Email address: dforshaw@uclan.ac.uk
☎ 01772 893713

Research Nurse
email address
☎