

# Identifying Continence Options after Stroke

<b>Submission date</b> 07/07/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 07/07/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/12/2017	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Lois Thomas

**Contact details**  
Room 434, Brook Building  
University of Central Lancashire  
Preston  
United Kingdom  
PR1 2HE  
-  
lhthomas@uclan.ac.uk

## Additional identifiers

**Protocol serial number**  
6659

## Study information

**Scientific Title**  
Management of urinary incontinence for patients recovering from stroke: a multicentre randomised interventional trial

**Acronym**  
ICONS

## **Study objectives**

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.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Bradford Research Ethics Committee pending approval as of 20th July 2010 (ref: 10/H1302/60)

## **Study design**

Multicentre randomised interventional diagnosis, process of care and treatment trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Topic: Stroke Research Network; Subtopic: Rehabilitation; Disease: Therapy type, In hospital study

## **Interventions**

1. Systematic voiding programme (intervention group I):

This group will receive the individualised systematic voiding programme tailored to the physical and cognitive capabilities of each patient. The programme has two routes:

- 1.1. A combined package including bladder training and pelvic floor muscle training for those patients who are cognitively able
- 1.2. Prompted voiding for those with cognitive impairment

2. Systematic voiding programme PLUS supported implementation (intervention group II):

This group will receive the intervention outlined above, together with supported implementation. This will comprise:

- 2.1. Identification of barriers and facilitators to the intervention
- 2.2. Targeted organisational development activities
- 2.3. Use of facilitation as a means of supporting change

3. Usual care (control group):

Participants in this group will receive usual care provided by the stroke service. This may comprise:

- 3.1. Checking for urinary tract infection
- 3.2. Checking for overflow incontinence (bladder scanners will be provided)
- 3.3. Containment using a variety of devices (for example absorbent products) with regular changes and some form of toileting schedule

Total duration of treatment: participants will receive the interventions for the duration of their stay in the acute/rehabilitation stroke units. The intervention phase of the trial will last for nine months.

Total duration of follow up: 12 months post-stroke

### **Intervention Type**

Other

### **Phase**

Phase I/II

### **Primary outcome(s)**

Presence/absence of incontinence at six weeks post-stroke

### **Key secondary outcome(s)**

Quality of life: Incontinence Quality of Life Instrument (I-QOL), measured at 6 weeks, 3 months and (for participants recruited in the first three months only) 12 months.

### **Completion date**

30/06/2011

## **Eligibility**

### **Key inclusion criteria**

1. Aged 18 or over, either sex
2. Diagnosis of stroke based on the World Health Organization (WHO) criteria
3. Urinary incontinence (UI) as defined by the International Continence Society as "involuntary loss of urine"
4. Incontinence classified as stress UI, urge UI, mixed UI or 'functional' UI OR to be catheterised in the acute phase
5. Conscious (defined as either 'alert' or 'drowsy' on the Clinical Status on Admission Item of the European Stroke Database)
6. Medically stable as judged by the clinical team

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

Patients who refuse consent

**Date of first enrolment**

01/01/2010

**Date of final enrolment**

30/06/2011

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Room 434, Brook Building**

Preston

United Kingdom

PR1 2HE

## **Sponsor information**

**Organisation**

Lancashire Teaching Hospitals NHS Trust (UK)

**ROR**

<https://ror.org/02j7n9748>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Institute for Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR)

## **Results and Publications**

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	feasibility trial results	23/12/2014		Yes	No
<a href="#">Results article</a>	results	21/08/2015		Yes	No
<a href="#">Protocol article</a>	protocol	20/05/2011		Yes	No