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Identifying Continence OptioNs after Stroke

Submission date	Recruitment status	[_] Prospectively registered
07/07/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/07/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/12/2017	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Presence/absence of incontinence at six weeks post-stroke

Secondary outcome measures
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.

Overall study start date
01/01/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 796; UK sample size: 796

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
England

United Kingdom

Study participating centre
Room 434, Brook Building
Preston
United Kingdom
PR1 2HE

Sponsor information

Organisation

Lancashire Teaching Hospitals NHS Trust (UK)

Sponsor details
Royal Preston Hospital
Sharoe Green Lane
Fulwood
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England
United Kingdom
PR2 9HT
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douglas.mitchell@lthtr.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.lancsteachinghospitals.nhs.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	20/05/2011		Yes	No
Results article	feasibility trial results	23/12/2014		Yes	No
Results article	results	21/08/2015		Yes	No