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ICONS II: Identifying Continence OptioNs after Stroke

Submission date
15/02/2018

Recruitment status
No longer recruiting

Registration date
19/02/2018

Overall study status
Completed

Last Edited
27/07/2022

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Half of patients admitted to hospital with a stroke suffer from urinary incontinence (UI). As well as involuntary loss of urine, symptoms include an urgent desire to pass urine (urge incontinence) or leaking urine when laughing or sneezing (stress incontinence). These symptoms are more severe in stroke survivors than in other people with UI and affect patients' ability to take part in rehabilitation and whether patients are able to return home. Many patients with stroke have urinary catheters inserted into the bladder to help with passing water. These are often not necessary and can lead to life-threatening infections.We have developed a programme for assessing and treating UI. It includes:
bladder training, which encourages people to extend the time between voids and helps them regain bladder control; prompted voiding, which aims to reduce incontinent episodes through verbal prompts to use the toilet and positive reinforcement from staff; a plan to remove urinary catheters if they are not necessary. The aim of this study is to assess whether the programme works in reducing the severity of UI and whether it should be recommended for use in routine clinical practice. There are four objectives. The first aim is to see if it is possible to recruit enough patients and if we can make sure patients in the "usual continence care" group do not receive the intervention. The second aim is to find out whether the programme reduces the severity of UI at 3 and 6 months after patients have been allocated to receive the intervention or care as usual. The third aim is to find out how the cost of providing the programme compares with providing care in the usual way, and whether it is economical to provide it given the benefits to patients and their families. Finally this study will assess how the programme is delivered, for example how well the programme instructions are followed.

Who can participate?
Adults aged 18 or over who have been admitted to hospital with stroke and have urinary incontinence or an indwelling urethral catheter.

What does the study involve?
Participants will receive either the programme for assessing and treating UI (described above) as well as usual continence care provided on the stroke unit, or usual continence care only.

What are the possible benefits and risks of participating?
We cannot guarantee any specific benefits for participants. Participants who receive the programme may find they have less sudden urges to go to the toilet, do not leak as often, or leak less urine. There are no serious side-effects associated with any part of this research.

Where is the study run from?
The study is being run by the University of Central Lancashire. There are 18 centres taking part.

When is the study starting and how long is it expected to run for?
November 2017 to October 2019

Who is funding the study?
National Institute for Health Research Health Technology Assessment Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NIHR HTA Programme trial reference: 16/111/31.

Study information

Scientific Title
ICONS II: Identifying Continence OptioNs after Stroke randomised controlled trial

Acronym
ICONS II

Study objectives

Is a systematic voiding programme a clinically effective and cost effective treatment for urinary incontinence (UI) in patients with urinary incontinence after stroke in secondary care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pragmatic multicentre randomised parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adults with stroke and urinary incontinence

Interventions
Participants who fulfil the eligibility criteria and have consented and completed their baseline questionnaire are randomised to either the intervention group or usual care group. Randomisation (1:1 ratio) is stratified by site and baseline continence category (none/slight: ICIQ-UI-SF score 0-5; moderate: 6-12; severe or very severe: 13-21; catheterised) using blocks of random length. The random allocation procedure is delivered using the secure remote web-based system provided by the Lancashire Clinical Trials Unit.

INTERVENTION:
The systematic voiding programme comprises assessment, behavioural interventions (bladder training or prompted voiding) and review. Assessment includes evaluation of the need for an IUC (to minimise inappropriate catheterisation), a protocol for IUC removal (if clinically justifiable), a 3 day bladder diary (to assess the pattern of UI) and an evidence-based continence assessment (to classify type of UI). The continence assessment includes: history taking, urine dipstick examination and (if indicated) a mid-stream urine specimen tested by microscopic examination, culture and sensitivities; a bladder scan to estimate post-void residual urine volume; and identification of the type of incontinence (stress UI: any response other than ‘never’ to the Leicester Urinary Symptom Questionnaire (LUSQ) question “Do you ever leak when you do any of the following?”; urge UI: the response ‘most of the time’, ‘sometimes’ or ‘occasionally’ to the LUSQ question “When you get the urge to pass urine, does any leak before you get to the toilet?”; mixed UI: both stress and urge UI; ‘functional’ UI, defined as mobility or balance restrictions stopping patients reaching the toilet on time).

The intervention begins within 24 hours of recruitment and continue until the patient is discharged from the stroke unit.

Participants who are catheterised are assessed for a trial without catheter. Participants who are not catheterised and are cognitively able receive bladder training; those with cognitive impairment OR patients with no control over their bladder receive prompted voiding. ICONS II staff make this decision (supported by the research nurse) based on the following criteria:

Prompted voiding: participants with cognitive impairment at baseline, defined as a score of 8 or more on the Six Item Cognitive Impairment Test (6-CIT (49)); or patients who have no control over their bladder, defined as answering 'all the time' to the ICIQ-UI-SF question 'how often do you leak urine?'

Bladder training: participantss with no cognitive impairment at baseline, defined as a score of 0-7 on the 6-CIT, and some control over their bladder, defined as answering 'several times a day', 'about once a day', 'two or three times a week' or 'about once a week or less often' to the ICIQ-UI-SF question 'how often do you leak urine?'

For participants catheterised in the acute stage, staff are asked to conduct a trial without catheter as early as possible unless there is a valid clinical reason not to do so, for example urinary retention, using a modified version of the HOUDINI protocol. Once the catheter is removed, participants begin assessment as described above.

USUAL CARE:
The standard patient care pathway often includes inserting an indwelling urethral catheter in the acute phase (139/289, 48% in the ICONS feasibility trial); there is typically no systematic approach to checking the need for continuing catheterisation or conducting a trial without catheter. The pathway may also include checking for urinary tract infection, containment using absorbent products and some form of toileting schedule for a small number of selected patients; this is unlikely to be based on a continence assessment or tailored to the patients' continence pattern.

Referral for specialist assessment is recommended for persistent incontinence, but this is rarely done for stroke patients.

Intervention Type
Behavioural

Primary outcome(s)
Severity of incontinence is measured using the International Consultation on Incontinence Questionnaire–Urinary Incontinence-Short Form (ICIQ-UI-SF) total score at baseline, discharge from the stroke unit, 3 months (primary endpoint) and 6 months post-randomisation.

Key secondary outcome(s))
1. Number of days with indwelling urethral catheter in situ measured using patient notes at discharge from the stroke unit, and patient/consultee report at 3 and 6 months post-randomisation
2. Number of urinary tract infections measured using patient notes at discharge from the stroke unit, and patient/consultee report at 3 and 6 months
3. Urinary symptoms measured using the Leicester Urinary Symptom Questionnaire (LUSQ), questions "Do you ever leak when you do any of the following?" and "When you get the urge to pass urine, does any leak before you get to the toilet?" only) at baseline, 3 and 6 months
4. Functional ability measured using the Barthel Index at baseline, 3 and 6 months
5. Quality of life measured using the EuroQol (EQ-5D-5L) at baseline, 3 and 6 months

6. Incontinence-specific quality of life measured using the Incontinence Quality of Life Instrument (IQoL) at 3 and 6 months
7. Falls measured using adverse event reports at discharge from the stroke unit, and patient /consultee report at 3 and 6 months
8. Death measured using adverse event reports at discharge from the stroke unit, and by General Practitioner notification at 3 and 6 months

Completion date
30/11/2020

Eligibility

Key inclusion criteria
1. Adult patients aged 18 and older with:
1.1. Acute stroke
1.2. UI (at least one episode within a 24 hour period) OR an indwelling urethral catheter
1.3. NIH Stroke Scale level of consciousness 0-2

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Long-term indwelling urethral catheter pre-stroke
2. Subdural or subarachnoid haemorrhage

Date of first enrolment
01/05/2018

Date of final enrolment
30/10/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Royal Bournmouth Hospital
Castle Lane East
Bournmouth
United Kingdom
BH7 7DW

Sponsor information

Organisation
University of Central Lancashire

ROR
https://ror.org/010jbqd54

Funder(s)

Funder type
Not defined

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results article containing primary endpoint	26/07/2022	27/07/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes