ICONS: IDENTIFYING CONTINENCE OPTIONS AFTER STROKE: FINDINGS FROM A CLUSTER RANDOMISED FEASIBILITY TRIAL.

Hypothesis / aims of study
Urinary incontinence (UI) following stroke affects half of hospitalised patients. It is often not managed in line with clinical guidelines. Cochrane systematic reviews have found some positive evidence of the effect of conservative interventions, such as bladder training and prompted voiding, but the effectiveness of these has not been specifically demonstrated with stroke patients. A feasibility cluster randomised controlled trial of the introduction of a systematic voiding programme (SVP) for the management of UI following stroke was undertaken in order to inform a full trial.

Study design, materials and methods
The SVP comprised a comprehensive continence assessment followed by bladder training for cognitively able or prompted voiding for cognitively impaired patients. Stroke services were randomised to receive the SVP (n=4), the SVP plus Supported Implementation (SVP+, n=4), or Usual Care (UC, n=4). Outcome was presence or absence of incontinence measured at 12 weeks post-stroke. The effects of the intervention on different types of incontinence were also explored. An integrated multiple component evaluation, underpinned by Normalization Process Theory [1], was conducted to describe how clinical staff embedded the programme into routine practice.

Results
Recruitment and retention: It was possible to recruit patients (413 in total; 164 SVP, 125 SVP+ and 124 UC), and retention was acceptable (response rate 88% at 12 weeks post-stroke).

Patient outcome: There was no suggestion of a beneficial effect of the intervention on outcome (SVP versus UC: OR 1.02, 95% CI 0.54-1.93; SVP+ versus UC: OR 1.06, 95% CI 0.54-2.09). However, both intervention arms had higher estimated odds of continence for patients with urge incontinence than UC (SVP: OR 1.58, 95% CI 0.83-2.99; SVP+: OR 1.73, 95% CI 0.88-3.43). There was a similar increase in the estimated odds of continence for patients with stress incontinence in SVP+ (OR 1.82, 95% CI 0.82-4.01) but this was not as marked in SVP (OR 1.04, 95% CI 0.45-1.82).

Process evaluation: 32 interviews were conducted with 38 staff from intervention sites. Findings describing embedding are:
- Thinking – taking part in ICONS and introducing the SVP led to changed perceptions of continence as a legitimate focus for rehabilitative practice.
- Planning – the logical structure provided by the SVP enabled a route to improved planning of care.
- Doing – the SVP helped staff make the shift to practice “routinised” around two hourly toileting. Individualising voiding intervals were difficult to achieve.

Evaluating – the SVP increased the visibility of continence management through greater evaluation of patients’ trajectories and outcomes and closer attention to workload.

Interpretation of results
The feasibility trial demonstrated clinical staff were able to implement the intervention, it was possible to recruit and retain patients and findings suggest a potential reduction in the odds of specific types of incontinence.

Concluding message
A phase three randomised controlled trial to test the effectiveness of the SVP for managing UI after stroke is now planned.

References

Disclosures
Funding: The research was funded by the UK National Institute for Health Research (NIHR) under its Programme Grants for Applied Research scheme (RP-PG-0707-10059). Clinical Trial: Yes Registration Number: ISRCTN08609907 RCT: Yes Subjects: HUMAN Ethics Committee: The trial was approved by: Bradford Research Ethics Committee (Reference number 10/H1302/60), which has a lead responsibility for studies with Mental Capacity issues, on 10th August 2010; site Research and Development departments and by the University of Central Lancashire Faculty of Health & Social Care Ethics Committee (FHEC) on 11th August 2010 (CA168). Helsinki: Yes Informed Consent: Yes