

Identifying Continence Options after Stroke (ICONS): an evidence synthesis, case study and exploratory cluster randomised controlled trial of the introduction of a systematic voiding programme for patients with urinary incontinence after stroke in secondary care

Lois H Thomas,^{1*} Beverley French,¹
Christopher J Sutton,¹ Denise Forshaw,¹
Michael J Leathley,¹ Christopher R Burton,²
Brenda Roe,³ Francine M Cheater,⁴ Jo Booth,⁵
Elaine McColl,⁶ Bernadette Carter,¹ Andrew Walker,⁷
Katie Brittain,⁸ Gemma Whiteley,⁹ Helen Rodgers,¹⁰
James Barrett¹¹ and Caroline L Watkins¹ on behalf of
the ICONS project team and the ICONS patient, public
and carer involvement groups

¹School of Health, University of Central Lancashire, Preston, UK

²School of Healthcare and Medical Science, Bangor University, Gwynedd, UK

³Evidence-Based Practice Research Centre, Edge Hill University, Ormskirk, UK

⁴School of Health Science, University of East Anglia, Norwich Research Park, Norwich, UK

⁵Department of Nursing and Community Health, Glasgow Caledonian University, Glasgow, UK

⁶Newcastle Clinical Trials Unit, Newcastle University, Newcastle upon Tyne, UK

⁷Robertson Centre for Biostatistics, Glasgow University, Glasgow, UK

⁸Institute of Health and Society and Institute for Ageing and Health, Newcastle University, Newcastle upon Tyne, UK

⁹Lancashire Teaching Hospitals NHS Foundation Trust, Royal Preston Hospital, Preston, UK

¹⁰Institute of Neuroscience, Newcastle University, Newcastle upon Tyne, UK

¹¹Wirral University Teaching Hospitals NHS Foundation Trust, Arrowe Park Hospital, Wirral, Merseyside, UK

*Corresponding author

Declared competing interests of authors: Elaine McColl is a member of the National Institute for Health Research (NIHR) Programme Grants for Applied Research subpanel and also a member of the NIHR Journals Editorial Board.

Published March 2015

DOI: 10.3310/pgfar03010

Scientific summary

Identifying Continence Options after Stroke (ICONS)

Programme Grants for Applied Research 2015; Vol. 3: No. 1

DOI: 10.3310/pgfar03010

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

Urinary incontinence (UI) following acute stroke is common, affecting between 40% and 60% of people in hospital. National audit data suggest incontinence is often poorly managed. In Cochrane systematic reviews, conservative interventions (e.g. bladder training and prompted voiding) have been shown to have some effect; however, their effectiveness has not been demonstrated with stroke patients.

Programme aim

To develop, implement and evaluate the potential clinical effectiveness and cost-effectiveness of a systematic voiding programme, with or without supported implementation, for the management of UI after stroke in secondary care.

Design

A two phase programme.

Phase I (development):

- evidence synthesis of combined approaches to manage UI post stroke
- case study of the introduction of a systematic voiding programme (SVP) in one stroke service.

Phase II (feasibility):

- cluster randomised controlled exploratory trial, incorporating a process and health economic evaluation.

Two dedicated patient, public and carer groups, one comprising members with aphasia, collaborated on the design and conduct of the programme.

Phase I: evidence synthesis

Objectives

- Determine whether or not combined behavioural interventions (CBIs) improve UI in adults (*effectiveness*).
- Identify the barriers and enablers to successful implementation (*acceptability*).
- Describe and define the potential components/mechanisms of action of the intervention (*predictors*).

Methods

Data sources were searched from inception to October 2008:

- Databases of published material, including Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health Literature, PsycINFO and Allied and Complementary Medicine Database.
- Databases of unpublished trials and theses, including *metaRegister* of Current Controlled Trials, National Institutes of Health RePORTER (formerly CRISP), CentreWatch, National Institute for Health Research, Index to Theses and Dissertation Abstracts International.
- Conference proceedings for the International Continence Society (ICS) (2006–8).

Study inclusion

Effectiveness review

Randomised and quasi-randomised controlled trials (RCTs) of CBIs in adults. CBIs were defined as interventions that include more than one behavioural technique directly targeted at improving the management of incontinence.

Acceptability and feasibility review

Studies collecting qualitative or quantitative data from service users or staff about their perceptions of experiences of behavioural interventions.

Predictors of adherence or treatment outcome review

Observational studies or clinical trials that included multivariate analysis on the association between a predictor variable and treatment adherence to a behavioural UI intervention of any kind, or treatment outcome for a CBI.

Results

Effectiveness

Ten studies with 13 intervention–comparison pairs and 1163 participants. For the primary outcome of *number of people remaining incontinent at post treatment*, results for comparisons with another treatment were marginally non-significant [relative risk (RR) 0.87, 95% confidence interval (CI) 0.75 to 1.01]. Results for non-treatment comparisons were significant, favouring the CBI (RR 0.81, 95% CI 0.70 to 0.94).

Acceptability and feasibility

Six studies involving 184 participants identified service users' views. Barriers to continence promotion included increased fear of being wet, attitude to exercises and fitting them into daily life. For elderly people in residential care, influencing factors included a tolerance for UI symptoms and a preference for interventions that facilitated independence from staff. Enablers to participation included having realistic goals and expectations, and gaining a sense of mastery and control.

Six studies involving 427 participants identified staff views. Barriers to continence promotion included aims of treatment, staff motivation, education and conflicting work priorities. Enablers to the promotion of continence included staff education, adequate staffing and experience of success.

Predictors of adherence or treatment outcome

Seven studies with 882 participants identified independent predictors using multivariate analysis. The only variable confirmed as a predictor of improvement in more than one study was treatment adherence.

Phase I: case study

Objectives

- Identify the organisational context for embedding a SVP.
- Explore health professionals' views around embedding the SVP into practice.
- Measure presence/absence of UI and frequency of UI.

Design

Mixed-methods single case study including diagnostic analysis of context using interviews with clinical leaders analysed with soft systems methodology; a process evaluation using interviews with staff delivering the intervention and analysed with normalisation process theory (NPT); and outcome evaluation using data collected from patients receiving the SVP and analysed using descriptive statistics.

Setting

An 18-bedded acute stroke unit in a large trust serving a population of 370,000.

Participants

Health professionals and clinical leaders with a role in either delivering the SVP or linking with it in any capacity were recruited. Patients were aged ≥ 18 years with a diagnosis of stroke and UI as defined by the ICS.

Intervention

A SVP comprising assessment (including a comprehensive continence assessment), individualised conservative interventions tailored to the physical and cognitive capabilities of each patient and weekly review.

Results

Organisational context

Eighteen health professionals took part in four group interviews. Findings suggest an environment not conducive to therapeutic continence management and a focus on containment.

Embedding the systematic voiding programme into practice

Twenty-one unit staff took part in six group interviews. After initial confusion there was an embedding of processes facilitated by new routines and procedures.

Outcome evaluation

Forty-three patients were recruited, 28 commencing the SVP. Of these, six out of 28 (21%) were continent at 6 weeks post-stroke or discharge.

Conclusion

It was possible to embed the SVP into practice despite an organisational context not conducive to therapeutic continence care.

Phase II: exploratory cluster randomised controlled trial with integrated process and health economic evaluation

Objectives

- Assess feasibility in terms of rates of participant recruitment and retention.
- Assess fidelity to the intervention.
- Conduct a qualitative assessment of feasibility from the perspective of multiple stakeholders.

- Conduct a preliminary evaluation of supported implementation (using *facilitation* as an implementation strategy to support and enable people to change their practice) compared with implementation alone.
- Investigate patient-related factors affecting patient outcome.
- Investigate stroke service-level factors potentially affecting stroke service outcomes to estimate the amount of unexplained variability in outcomes between trusts and between patients.
- Confirm the choice of primary and secondary outcome measures for a full-scale cluster randomised trial to evaluate effectiveness.
- Develop and test data collection tools for an economic evaluation within a full-scale cluster randomised trial.

Design

A three-arm, parallel, open, exploratory, pragmatic, cluster RCT of a SVP, with or without supported implementation, for the management of UI after stroke in secondary care.

Setting

Twelve NHS stroke services in England and Wales.

Participants

Four hundred and thirteen patients with UI were recruited between 1 January 2011 and 31 July 2012; 124 usual care, 164 intervention and 125 supported implementation.

Baseline data were collected for all patients. The overall response rate at 6 weeks was 85% (306/362), excluding patients recruited at 6 weeks and those who had died. At 12 weeks, the overall response rate was 88% (330/374), excluding one patient recruited at 12 weeks and those who had died. At 52 weeks, data were collected for 176 out of 315 (56%) participants excluding those who had died.

Intervention

Systematic voiding programme.

Main outcome measures

Primary outcome was presence/absence of incontinence measured by the International Consultation on Incontinence Modular Questionnaire (ICIQ). Secondary outcomes were quality of life (QoL), frequency and severity of incontinence, urinary symptoms and activities of daily living.

Results

There was no suggestion of a beneficial effect of the intervention on outcome at 6 weeks post stroke. Findings were similar at 12 weeks post stroke [intervention vs. usual care: odds ratio (OR) 1.02, 95% CI 0.54 to 1.93; supported implementation vs. usual care: OR 1.06, 95% CI 0.54 to 2.09].

There was no evidence of better outcomes on the ICIQ or Incontinence Severity Index at 6 weeks post stroke. At 12 weeks, there was weak evidence of better outcomes on the ICIQ in supported implementation (OR 1.22, 95% CI 0.72 to 2.08), but the CI is wide and includes both clinically relevant benefit and harm. Both intervention arms had higher estimated odds of continence for patients with urge incontinence than usual care (intervention: OR 1.58, 95% CI 0.83 to 2.99; supported implementation: OR 1.73, 95% CI 0.88 to 3.43). There was a similar increase in the estimated odds of continence for patients with stress incontinence in supported implementation (OR 1.82, 95% CI 0.82 to 4.01), but this was not as marked in intervention (OR 1.04, 95% CI 0.45 to 1.82). Findings are suggestive of a potential reduction in the odds of specific types of incontinence.

Per-protocol analysis suggested that those who received the intervention according to protocol had better outcomes than usual care, although this did not appear to hold for supported implementation (OR relative to usual care intervention: 1.52, 95% CI 0.67 to 3.41; supported implementation 1.02, 95% CI 0.38 to 2.76).

Process evaluation

Methods

An integrated multiple component evaluation, underpinned by a logic model, was conducted in order to describe implementation and assist in explaining why the intervention and its components were or were not successful.

Delivery of the intervention to individuals: assessed through an analysis of adherence to the protocol in terms of management of catheterisation and intervention documentation.

Response of individuals: assessed through semistructured interviews with patients at discharge.

Response of clusters, recruitment and reach in individuals, delivery to and response of individuals and maintenance of processes over time: assessed using NPT. Qualitative, semistructured interviews with health professionals involved in the intervention to explore experiences of implementation.

Context in which the trial was conducted: assessed using soft systems methodology.

Results

Delivering the intervention

Some aspects of catheterisation appeared closer to protocol recommendations in supported implementation in terms of catheter removal [median 13 days, interquartile range (IQR) 5–35 days vs. median 20 days, IQR 8.75–35.25] and patients still catheterised at discharge (19, 15.2% vs. 35, 21.3%).

Documentation of the regime interval and the schedule of proposed voiding times in the clinical logs was done on less than half of occasions (38.9% in intervention; 31.9% in supported implementation).

Response of individuals

Twelve interviews with participants from six sites, eight from intervention and four from supported implementation.

Findings categorised according to the logic model are:

- Thinking: educational element of the intervention helped participants understand that post-stroke UI was a common and treatable problem.
- Planning: knowledge of ward systems was important, for example in timing toileting requests to allow for delays at 'busy' times.
- Doing: perseverance and adaptation of the programme were identified as important.
- Evaluating: setting and achieving realistic outcomes was important.

Response of clusters

Thirty-two interviews, conducted with 38 staff from intervention sites. Findings describing embedding are:

- Thinking: taking part in Identifying Continence Options after Stroke 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 2-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.

Context

Fifty interviews, conducted with 59 staff from all 12 sites. Findings describing pre-intervention context are:

- Thinking: nursing was ascribed with expertise in continence, but in reality no evidence was being used and practice revolved around containment.
- Planning: the default position regarding services was a lack of clinical leadership and a mismatch between skills, knowledge and practice.
- Doing: there were strong contextual barriers to individualised continence management, including insurmountable routine systems.
- Evaluating: services within the trial demonstrated little, if any, attention to systematic evaluation of clinical practice or patient outcomes around UI.

Health economic evaluation

Objective

The development and evaluation of data collection methods to inform an economic evaluation within a full-scale cluster randomised trial. This included description of the costs associated with the SVP and a preliminary exploration of potential cost-effectiveness.

Methods

Data were recorded on the cost of the training, the programme and post-hospital resources. Resource use and trial data were combined to assess evidence of potential cost-effectiveness.

Results

The cost of the SVP had to be calculated using staff estimates. These were provided by 8 out of 12 (66.7%) of the sites, which translated into an average per patient cost for the SVP of £1482 (intervention) and £1830 (supported implementation). The total cost of training was £12,185 per trial arm with an additional cost of £9642 for supporting implementation. The postal questionnaire response rate for eligible patients was approximately 73% and 56% at 12 and 52 weeks, respectively; response rates were similar across groups. When questionnaires were returned, the response rates across items varied but there was little difference between groups regarding the number of items completed. The programme draws on resources in the short term but we did not measure the opportunity cost (fewer patients being incontinent and its associated reduction in input). The mean 52-week costs in the trial arms were £9563 (usual care), £12,423 (intervention) and £10,913 (supported implementation). All trial arms showed a reduction in quality-adjusted life-years from baseline: -0.45 (usual care), -0.36 (intervention) and -0.41 (supported implementation). It is unclear if this loss of quality-adjusted life-years is due to the SVP not working, the European Quality of Life-5 Dimensions (on which the quality-adjusted life-year was based) failing to pick up a meaningful difference, or a combination of factors.

Conclusions

The exploratory trial has demonstrated it is feasible to conduct a full cluster RCT.

Recommendations for research

The future trial will adopt this design with the following modifications.

Trial arms

- Include two trial arms only, intervention and usual care.

Recruitment

- Obtain consent as soon as possible after admission, regardless of whether or not participants are medically stable.

Data collection

- Use 12 weeks post consent as the main outcome point.
- Include reduction in incontinence episodes as a secondary outcome.
- Consider approaches to increasing response rate at long-term follow-up.
- Introduce more rigorous procedures for monitoring catheterisation (including 'trial without catheter').

Health economic component:

- Record in-hospital episodes of incontinence and the resources required to respond to such episodes.
- Identify resources required to perform the programme through direct observation.
- Consider obtaining post-hospital resource use data by asking patients to maintain diaries or going directly to providers of services.
- Identify resource use items more directly related to the effects of incontinence.
- Include a range of QoL measures.

Study registration

This study is registered as ISRCTN08609907.

Funding

The National Institute for Health Research Programme Grants for Applied Research programme. Excess treatment costs and research support costs were funded by participating NHS trusts and health boards, Lancashire and Cumbria and East Anglia Comprehensive Local Research Networks and the Welsh National Institute for Social Care and Health Research.

Programme Grants for Applied Research

ISSN 2050-4322 (Print)

ISSN 2050-4330 (Online)

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

The full PGfAR archive is freely available to view online at www.journalslibrary.nihr.ac.uk/pgfar. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Programme Grants for Applied Research* journal

Reports are published in *Programme Grants for Applied Research* (PGfAR) if (1) they have resulted from work for the PGfAR programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Programme Grants for Applied Research programme

The Programme Grants for Applied Research (PGfAR) programme, part of the National Institute for Health Research (NIHR), was set up in 2006 to produce independent research findings that will have practical application for the benefit of patients and the NHS in the relatively near future. The Programme is managed by the NIHR Central Commissioning Facility (CCF) with strategic input from the Programme Director.

The programme is a national response mode funding scheme that aims to provide evidence to improve health outcomes in England through promotion of health, prevention of ill health, and optimal disease management (including safety and quality), with particular emphasis on conditions causing significant disease burden.

For more information about the PGfAR programme please visit the website: <http://www.nihr.ac.uk/funding/programme-grants-for-applied-research.htm>

This report

The research reported in this issue of the journal was funded by PGfAR as project number RP-PG-0707-10059. The contractual start date was in October 2008. The final report began editorial review in September 2013 and was accepted for publication in July 2014. As the funder, the PGfAR programme agreed the research questions and study designs in advance with the investigators. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PGfAR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, CCF, NETSCC, PGfAR or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the PGfAR programme or the Department of Health.

© Queen's Printer and Controller of HMSO 2015. This work was produced by Thomas *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).

Programme Grants for Applied Research Editor-in-Chief

Professor Paul Little Professor of Primary Care Research, University of Southampton, UK

NIHR Journals Library Editor-in-Chief

Professor Tom Walley Director, NIHR Evaluation, Trials and Studies and Director of the HTA Programme, UK

NIHR Journals Library Editors

Professor Ken Stein Chair of HTA Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

Professor Andree Le May Chair of NIHR Journals Library Editorial Group (EME, HS&DR, PGfAR, PHR journals)

Dr Martin Ashton-Key Consultant in Public Health Medicine/Consultant Advisor, NETSCC, UK

Professor Matthias Beck Chair in Public Sector Management and Subject Leader (Management Group), Queen's University Management School, Queen's University Belfast, UK

Professor Aileen Clarke Professor of Public Health and Health Services Research, Warwick Medical School, University of Warwick, UK

Dr Tessa Crilly Director, Crystal Blue Consulting Ltd, UK

Dr Peter Davidson Director of NETSCC, HTA, UK

Ms Tara Lamont Scientific Advisor, NETSCC, UK

Professor Elaine McColl Director, Newcastle Clinical Trials Unit, Institute of Health and Society, Newcastle University, UK

Professor William McGuire Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads Professor of Health Sciences Research, Faculty of Education, University of Winchester, UK

Professor John Powell Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK

Professor James Raftery Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts Professor of Child Health Research, UCL Institute of Child Health, UK

Professor Helen Snooks Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Please visit the website for a list of members of the NIHR Journals Library Board:
www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: nihredit@southampton.ac.uk