Systematic voiding programme in adults with urinary incontinence following acute stroke: the ICONS-II RCT

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†In memoriam

Disclosure of interests

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Primary conflicts of interest: Kina Bennett is a co-applicant on the National Institute for Health and Care Research (NIHR)-funded i4i MyPad and the NIHR Programme Development for the imPRoving End of life care Practice in stroke cARE (PREPARE) study. Joanne Booth reports another research grant from the NIHR Health Technology Assessment (HTA) programme on urinary incontinence and is a member of the Trial Steering Committee (TSC) of the CATHETER (RCT: CompAring THE clinical

and cosT-Effectiveness of vaRious washout policies versus no washout policy in preventing catheter associated complications in adults living with long-term catheters) study, funded by the HTA programme. Bruce Hollingsworth is a member of the NIHR Professorial Fellowship Committee and reports NIHR funding as co-investigator for the following: the NIHR health and health inequalities impact of a place-based community wealth initiative, Research Design Service North West, School for Public Health Research LiLaC (LIverpool and Lancaster universities Collaboration for public health research), NIHR Collaboration for Leadership in Applied Health Research and Care (CLAHRC) North West Coast and the NIHR Applied Research Collaboration North West Coast. Gordon Prescott reports receiving other grants from NIHR as co-applicant, not related to urinary incontinence research, and is a member of the Data Monitoring Committee (DMC) of the CATHETER trial of preventing catheter-associated complications. Christine Roffe is chairperson of the TSC for the Imaging cerebral Neuro-inflammation in acute and chronic CerebroVascular Disease: a predictor of outcome and biomarker for guiding treatment (IN-CVD) study, funded by the NIHR Efficacy and Mechanism Evaluation (EME) programme; is a member of the DMC for the CAARBS (RCT of: a Calcium channel or Angiotensin converting enzyme inhibitor or Angiotensin Receptor Blocker regime to reduce blood pressure variability following ischaemic Stroke) feasibility study comparing a calcium-channel blocker versus angiotensin-converting enzyme inhibitors/angiotensin receptor blockers-based regime to target blood pressure variability following transient ischaemic attack and minor ischaemic stroke funded by a British Heart Foundation (BHF; London, UK)/The Stroke Association (TSA; London, UK) programme grant (2016–present); is a member of the DMC for the Penumbral Rescue by Normobaric O = O Administration in Patients With Ischaemic Stroke and Target Mismatch ProFile (PROOF) study, examining high-dose oxygen treatment in patients with large vessel occlusion and acute ischaemic stroke, funded by a European Union Horizon 2020 grant (2016–present); is an independent member of the TSC for the LACunar Intervention (LACI-2) Trial–2, funded by a BHF grant; is an independent member of the TSC for the Paramedic Acute Stroke Treatment Assessment (PASTA) study; is a co-applicant member of the TSC for the Right-2 study of pre-hospital treatment with glyceryl trinitrate patches in acute stroke; is a co-applicant member of the TSC for the Tranexamic acid for hyperacute primary IntraCerebral Haemorrhage (TICH-2) study; is a member of the James Lind Alliance Stroke Research Priority Setting Group (2020–present), UK Biotechnology and Biological Sciences Research Council Future Leaders Funding board (2020–present), TSA Research Awards Panel (2019–present), the UK Swallowing Research Group (2019–present) and the UK Stroke Forum Steering Group (2015–present); was a member of the NIHR HTA General Board (2017–21) and the NIHR Stroke National Specialty Group (2015–18); is chairperson of the NIHR Hyperacute Stroke Research Centre Oversight Group (2015–present); and is the Stroke NIHR National Specialty Group Portfolio Lead for Acute Clinical Studies (2015–present). Chris Sutton is a member of the NIHR HTA Commissioning Funding Committee (January 2020–present) and reports receiving institutional funding from NIHR for his role as co-investigator on several projects [not related to stroke or incontinence research, except for funding for the NIHR Global Health Research Group Improving Stroke Care in India (IMPROVISE) to July 2020], was an independent member of the TSC for the ELECtric Tibial nerve stimulation to Reduce Incontinence in Care homes trial and is an independent member of the Programme Steering Committee for the OPTimising Implementation of Ischaemic Stroke Thrombectomy (OPtimIST) programme grant. Lois Thomas was a Health and Social Care Delivery Research (HSDR)-commissioned panel member (2015–19). Caroline Watkins reports several current and recent NIHR-funded projects; is a member of the NIHR advanced fellowship panel, NIHR PARADISE (Predicting af AfteR cArDIac SurgEry - the PARADISE Score: A Clinical Prediction Rule for Post-operative Atrial Fibrillation in Patients Undergoing Cardiac Surgery) oversight panel, international advisory committee of NIHR Global Health Research Group on Atrial Fibrillation and the TSC/DMC for the NIHR Metoclopramide for Avoiding Pneumonia after Stroke (MAPS-2) study; is chairperson of the TSC/DMC for NIHR COVID-NURSE and the DMC for NIHR HomeHealth; is a co-applicant on the NIHR CLAHRC North West Coast Confirming the Mechanism of Motivational Interviewing Therapy after Stroke (COMMITS) project, NIHR Symptoms, Trajectory, Inequalities and Management: Understanding Long COVID to Address and Transform Existing Integrated Care Pathways (STIMULATE-ICP) grant, NIHR PREPARE programme development grant, NIHR Risk rEduction interVEntion for Raised blood preSsurE (REVERSE)

Research for Patient Benefit (RfPB) project grant, NIHR Global Health Research Group Stroke In Sierra Leone (SISLE); has two NIHR-funded doctoral fellowships; is chief investigator of the NIHR Global Health Research Group IMPROVISE and IMPROVIng Stroke care in India – Advancing The INSTRUCT Operations and Network (IMPROVISATION); was a deputy director of NIHR CLAHRC North West Coast; and is currently implementation lead of NIHR Applied Research Collaboration North West Coast.

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Plain English summary

The ICONS-II RCT

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Plain English summary

Urinary incontinence affects around half of stroke survivors. It causes embarrassment and distress, affecting patients' ability to take part in rehabilitation. It also has a major impact on families and may determine whether or not patients are able to return home. Finding the underlying cause and addressing it can prevent, cure or reduce problems. Doing this in a systematic way for everyone with incontinence problems as early as possible after the stroke, while they are still in hospital, may work best. We also wanted to avoid using catheters in the bladder to drain the urine away, as these are often unnecessary and can cause urinary tract infections.

This study aimed to test whether or not continence problems and the use of urinary catheters could be reduced if everyone with incontinence was fully assessed and given the right management and support early after hospital admission. We also wanted to find out if the benefits outweighed the costs.

We planned to involve 1024 men and women with incontinence from 18 stroke units in the study, with 512 people receiving the intervention and 512 receiving usual care. However, the trial was paused because of COVID-19, at which time only 157 participants had been recruited. When we were thinking about restarting the study and looked at its progress, we found that not enough people had agreed to take part and, of those who had agreed, many had not returned their outcome questionnaires. This indicated that the trial was not feasible and should not restart.

We could not make any firm conclusions about whether or not the intervention worked, as not enough people were involved. We found that stays in hospital after stroke are shorter than they were in the past. This suggests that future studies investigating ways of treating incontinence should consider interventions with management and support for incontinence that continue after patients leave the hospital.

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This report

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