Author's response to reviews

Title: ICONS: Identifying Continence OptioNs after Stroke: findings from a cluster randomised controlled feasibility trial

Authors:

Lois H Thomas (lhthomas@uclan.ac.uk)
Caroline L Watkins (clwatkins@uclan.ac.uk)
Christopher J Sutton (cisutton@uclan.ac.uk)
Denise Forshaw (dforshaw@uclan.ac.uk)
Michael J Leathley (mjleathley@uclan.ac.uk)
Beverley French (bfrench1@uclan.ac.uk)
Christopher R Burton (c.burton@bangor.ac.uk)
Francine Cheater (f.cheater@uea.ac.uk)
Brenda Roe (bhoe@aol.com)
David Britt (david.britt@freeuk.com)
Joanne Booth (jo.booth@gcu.ac.uk)
Elaine McColl (elaine.mccoll@newcastle.ac.uk)

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Author's response to reviews: see over
Dear Editors

We would like to thank Professor Adrian Wagg and Professor Sandy Middleton for their very constructive comments and suggestions. We outline below how we have addressed their concerns.

Professor Adrian Wagg

Abstract: This is a concise and accurate extract of the study with a sound digest of results.

Background: This is well written and encapsulates the current state of knowledge in this area. The purpose of the study is well articulated. There is a misspelling of focused.

Thank you very much for your positive comments. We have corrected the spelling of ‘focussed’ throughout.

Methods: Whilst “facilitation” and the interventions are well described, the study may well benefit from some measurement of facilitation, for instance according to the model described by Carroll (Carroll C, Patterson M, Wood S, Booth A, rick J Balain S. A conceptual framework for implementation fidelity, Implementation Science 2007; 2: 40) may well be a useful addition. There appears to be no accounting of fidelity to the intervention intended included in the trial plan. Was there a planned recording for a non-responder analysis? Otherwise this is well thought out.

We conducted a comprehensive assessment of implementation fidelity as part of our process evaluation, and used Hasson’s adaptation of Carroll’s conceptual framework. Given the complexity of this part of the study, we have reported it in two separate papers, one methodological and the other describing the process evaluation. These are not yet published.

The authors might plan for an assessment of PFM function by nursing staff, rather than physiotherapists, given the difficulty – certainly basic PFMT does not need specialist physiotherapy for delivery

This was our original intention, however nursing staff were reluctant to do this without physiotherapist involvement in assessing if patients were able to exercise their pelvic floor muscles and also in teaching nursing staff and patients what to do. Physiotherapists felt they did not have the necessary expertise – in their opinion this fell within the remit of physiotherapists specialising in women’s health. Given all the problems experienced in the feasibility trial, we have decided to leave pelvic floor muscle training out of the intervention in the proposed ICONS II trial, but we do hope to conduct research in this area in the future.

Results: The proportion of “non-stroke” patients is high – this will certainly need to be taken into account for future planning.

The “usual care” throughput is significantly lower than the two intervention arms – whilst this may be simply due to chance, given the randomisation - was there something else to account for the disparity?

We have added further explanation of these findings on page 12.

The high proportion of stroke patients ineligible for inclusion is of concern – the exclusion criteria did not seem overtly strict and the approach appears more pragmatic. Perhaps the authors might discuss the implications of this for a future planned trial which may have limited external validity.

The feasibility trial highlighted that potentially eligible patients with mild incontinence may have been missed, particularly in intervention units. Our revised recruitment strategies for the full trial, discussed on page 13, should increase the number of eligible participants.

Otherwise the results are well reported in the light of this feasibility trial. The results are consistently and faithfully reported – there appears to be no manipulation of the results.
Discussion

This is a well considered discussion which systematically assesses the study from the perspective of feasibility and methodological refinement. The authors might consider the pragmatic provision of PFMT, which has utility for SUI, MUI and UUI; a standardised definition of “medically stable” and pharmacological management for UUI in addition to their conservative interventions.

We have decided not to include PFMT in the full trial (please see above) and also to remove the inclusion criterion ‘medically stable’. The protocol focused on conservative interventions and we did not seek to influence prescribing of drugs for urinary symptoms. However, the continence assessment included a review of patients’ medication: staff were encouraged to identify any medications patients were taking that may worsen urinary symptoms and to discuss these with medical staff.

Action on the catheterisation of stroke patients remains a target – this will not only have an impact on active continence management but on CAUTI and urethral trauma, all of which may either delay rehab or render continence less likely.

We agree this is a very important issue. In the full trial we plan to address catheterisation more explicitly in the protocol, as outlined on page 15.

Some consideration should be given to the absence of fidelity to intervention and facilitation measures.

Please see response above.

Professor Sandy Middleton

Major Revisions

• Please clarify in abstract and main document that feasibility outcomes about retention (referred to retention of participants in trial) as opposed to urinary retention.

We have changed the wording to ‘participant retention’ in the abstract (page 2) and in the main document (page 14).

• Is quality of life and death the one outcome? If not please add a comma after “quality of life”.

These are two separate outcomes; a comma has been added after ‘quality of life’ on page 2.

• Page 6: As the randomisation is done by Newcastle Clinical Trial Unit, it would be helpful to say that they were independent of the research team.

One of the research team, Elaine McColl, is Director of the Newcastle Clinical Trials Unit, so it would not be strictly true to say the CTU was independent of the research team.

• Page 7: Please clarify if senior research fellow and consultant nurse (external facilitators) went together or individually to sites.

We have added a sentence explaining that the senior research fellow and consultant nurse were responsible for two sites each on page 7.

Does “ward manager” mean ward nursing manager? Would you please clarify and given an indication of the seniority of this role (ie. nursing unit manager or nurse manager) to make it more clearly translatable to international roles.

‘Ward manager’ has been changed to ‘stroke unit nursing manager’.

• Page 10: Statistical analysis – for the 12 weeks outcome, will you please indicate the length of time as you did for the 6 weeks.
We have clarified this by stating that all data received were included with no restriction on when questionnaires were received (page 9).

- Page 12 (paragraph 2 and 4): Please delete “real” - ie. “there was no real suggestion....”

‘Real’ has been deleted in both paragraphs.

Minor Essential Revisions

- Page 13 – discussion: Might the large numbers of non-strokes who ended up on the stroke units also be due to individual hospital policy which compels staff to admit ‘possible’ strokes or non-strokes?

We have added further explanation of this on page 12.


This is now written in full.

- Figure 1: Please clarify that the “6 and 12” refer to weeks at the end.

We have added ‘weeks’ after ‘6’ and ‘12’ in Figure 1.

Discretionary Revisions

- In background or discussion, the authors might like to add an additional reference supporting the need for their trial:


Thank you for suggesting this reference – we have added it in the ‘background’ section (page 3 second paragraph).