Author's response to reviews

Title: A mixed methods study to assess the feasibility of a randomized controlled trial of invasive urodynamic testing versus clinical assessment and non-invasive tests prior to surgery for stress urinary incontinence in women: the INVESTIGATE-I study

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Author's response to reviews: see over
Dear Editors

Re: A mixed methods study to assess the feasibility of a randomized controlled trial of invasive urodynamic testing versus clinical assessment and non-invasive tests prior to surgery for stress urinary incontinence in women: the INVESTIGATE-I study.

Thank you for your further email of 14/8/2015, regarding our manuscript reference above, submitted initially on 11/3/2015. My colleagues and I are most grateful to you and the reviewers for the efforts they have gone to in assessing our work, and for their constructive comments. We have been through these, and outline below our responses to the latest comments. A revised manuscript has been uploaded through www.trialsjournal.com.

We would be grateful for your further consideration of the revised manuscript for online publication.

Yours sincerely,

Paul Hilton
Retired Consultant Gynaecologist and Urogynaecologist
AUTHORS’ RESPONSE TO EDITOR’S AND REVIEWERS’ COMMENTS

Editorial requests:

1. For completed randomised controlled trials, Trials requires the submission of a populated CONSORT checklist and flow diagram. We appreciate that you have included the flow diagram as an additional file, but would be grateful if you could also include the checklist.

Sincere apologies for this omission; a CONSORT checklist was completed with our previous re-submission, but appears not to have uploaded; this is now added as an additional file

Reviewer/handling editor comment:

1. Reading the paper, I appreciate both the reviewer's point and also the stance taken by the authors. It appears that 36 eligible women agreed to be interviewed (p.27) (this is not the same as determining a pre-set number of participants), of which 29 were interviewed. However, as the reviewer notes, the proposed method also suggests that analysis is conducted alongside the interview process and that at some point sufficient evidence was accrued (saturation was reached): p.19 "Data collection continued until saturation of themes was reached and interviews no longer generated new concepts".

The question is: how many of the 29 agreed participants had actually been interviewed by that point? And did the purposive sampling approach ensure that the sample that ended-up being interviewed really represent fully the randomization, participation, allocation status and study site status of this group? Or, were all 29 interviewed and then at some point in the analysis - say, after analysing 20 of the 29 transcripts - saturation was deemed to be reached and the remaining 9 transcripts were ditched? I agree that this needs to be clarified - principally on p.19.

We are sorry that this issue still caused some confusion. We have now made further revisions to the Methods section covering this study element (p14-15) and to the relevant section of the Results (p19). In summary, these revisions now make clearer that: women were purposively selected for interview; analysis took place alongside data collection; all 29 completed interviews were included in the analysis; four women who had agreed to be interviewed ultimately were not as the data was considered saturated and they were from groups already well represented in the sample. We hope that this is now clear.