Author's response to reviews

Title: INVESTIGATE-I (INVasive Evaluation before Surgical Treatment of Incontinence Gives Added Therapeutic Effect?): the protocol for a mixed methods study to assess the feasibility of a future randomised controlled trial of the clinical utility of invasive urodynamic testing.

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Author's response to reviews: see over
Dear sirs

Re: MS: 1652332992550025

INVESTIGATE-I (INVasive Evaluation before Surgical Treatment of Incontinence Gives Added Therapeutic Effect?): the protocol for a mixed methods study to assess the feasibility of a future randomised controlled trial of the clinical utility of invasive urodynamic testing.

Megan Murdoch, Elaine McColl, Denise Howel, Mark Deverill, Brian S Buckley, Malcolm Lucas, Christopher R Chapple, Douglas G Tincello, Natalie Armstrong, Cath Brennand, Jing Shen, Luke Vale and Paul Hilton

We are grateful to the editors and reviewers for their thorough evaluation of our protocol. We have reviewed their suggestions in detail and summarise our responses below:

**Referee 1.**

1. P(age) 2, p(aragraph) 1, l(ine) 1. Suggest replacing [a significant] by [an important] or some similar term. Save significant for a statistical context. 
   **Accepted, and modified**
2. P 2, last l. Include the date of registration and the date that first patient was randomised if that has been done. See 41 also.
   **Date of registration included**
3. P 3, p 1, l 1. Replace [significantly] by [dramatically] or some similar term.
   **Accepted, and modified**
   **Accepted, and modified**
5. P 3, p 1, l 4. Replace [range] by [interval]. A range is the length of an interval.
   **Accepted, and modified**
6. P 3, p 1, l 8. Suggest replacing [significant] by [important] or a similar term.
   **Accepted, and modified**
7. P 3, p 2, l 4. Provide a reference for this justification.
Reference included

This is a simple list of tests; however, at the referee's suggestion we have included a reference

9. P 4, p 1, l 2. Replace [This] by [These] since data is a plural word.
Accepted, and modified

10. P 4, p 1, l 4. Suggest dropping [significantly].
Accepted, and modified

11. P 4, p 4, l 3. Replace [Two recent] by [Trials reported in 2000 and 2001 randomizing ...]. Recent goes out of date with time. And some might quibble as to whether these dates are recent.
Accepted, and modified

Reference included

13. P 5, p 5, Item 3, l 1. Do you have sampling frames for these clinicians?
Specification included

14. P 5, p 6, l 1. What are the names of the six units?
Detail added as requested

15. P 5, p 6, l 3. Since [or] logically includes [and], suggest dropping [and/]. Also P 6, p 1, bullet 3, l 1.

Whilst in binary logic, 'or' might mean 'and/or', it this does not apply in the present context; some of these Trusts provide both secondary and tertiary care, others only secondary. So in this situation, we feel that and/or is correct; we have changed to +/- as an alternative.

16. P 7, p 1. What is the proposed allocation ratio?
1:1 – added to text

17. P 7, p 3. Will they be restricted from using IUT?
Yes; we had thought this clear, but have added more explicitly

18. P 7, p 8, l 2. Drop [in order] in front of [to] as the words are redundant in English. Also P 9, p 3, l 3. Also P 10, p 1, l 3. Also P 13, p 2, l 3.
Accepted and modified

19. P 8, p 4 and 5. The measurement properties of the outcome tools should be specified, possibly in an appendix.

With respect, we feel this level of detail is unnecessary; the references included allow the reader to obtain more information about the individual outcome tools should they wish this

20. P 9, p 1, l 1. Replace [little] by [few]; and [parameters] by [variables]. A parameter is a characteristic of a distribution of a variable in a population and not another name for a variable in a sample. Also P 9, p 2, l 3 and P 9, p 3, l 3. Also P 13, p 2, l 2.
Modified

21. P 9, p 1, l 4. Replace [significant] by [important] or some similar word.
Accepted and modified

22. P 9, p 2, l 5. Delete [average].
Deleted

23. P 9, p 2, l 8. If you indeed expect to have a 50% attrition rate, then it would be wise to find ways to retain the sample as such a high attrition would make any trial less than credible.

As indicated, we have taken the most pessimistic forecast for each stage in the study; we would hope that overall attrition would not be as high as 50%, but this is of course another reason for undertaking a feasibility study

24. P 10, p 2, l 6 and 7. Is there a reference to this strategy?
25. P 10, p 2, l 8. Is there a reference for this sample size?

26. P 10, p 5, l 2. Provide a reference to the source of this software.

27. P 10, p 6. Is there support that the contact details will be available from these societies for this work?

28. P 10, p 7, l 5. Suggest adding [s] to [show] to read [shows] as the noun of this sentence [experience].

29. P 11, p 2, l 5 and 6. Was consideration given to pilot the questionnaire on a sample of the clinicians who will be in the survey? They may have different views on the quality of the questionnaire than others might.

30. P 11, p 3. This data analysis plan is inadequate. Specify exactly what you plan to do.

31. P 11, p 5, l 3. Is there a reference that 12 is adequate?

32. P 11, p 10. What are the types of persons who will be members of this committee and the numbers?

33. P 12, p 1, l 3. Provide reference to the GCP guidelines that will be used.

34. P 12, p 2. Provide a reference to this system or describe what it hopes to accomplish.


36. P 13, p 1, l 10. Insert [UK] between [A] and [national].


38. P 14, p 2. Make the list of abbreviations more complete. For example, from the same page, NICE, NIHR, EUA, GDG are not included. It should be all the forms used in the protocol.

39. P 15, R 1, 11 and 12 were not able to be found and should be checked for
accuracy.

All correct

40. P 15, R 7 and 8. Since Trials likes to publish ALL authors, replace [et al] by the rest of the authors. Also P 16, R 13, 17, 26 and 27 and P 17, R 29, 30 and 31.

Modified


Modified

42. P 15, R 13, L 1. Replace [et al] by Mayne C, Jones DR, Taylor D; and on l 3, insert [(1)] after [30].

Modified


Modified

P 15, R 15 has the author order incorrect; it is: [Kerry S, Hilton S, Patel S, Dundas D, Rink EP, Lord J]; and insert on l 3 the complete citations as [4920]:i-iv,1-119.]

Corrected

P 15, R 25 The names and title are inaccurate, they are: [Glaser BG, Strauss AL: The Discovery of Grounded Theory: Strategies for Qualitative Research.].

Corrected

Referee 2:

1) Abstract: Background
a) Replace “significant” with “serious”. It is often best to use “significant” only in reference to statistical significance.

Accepted and modified

2) Outcomes
a) Consider stating the criteria for success of feasibility. Ie the criteria that will be used to decide whether or not feasibility has been established. These need to be based on the feasibility outcomes.

We have not defined specific criteria for success in the approved protocol; hence we did not feel it appropriate to include such criteria in our publication. We have however added a paragraph of text to the manuscript to describe our thoughts on this issue.

We hope that you feel that we have adequately addressed these points in our manuscript, and look forward to your editorial decision on our submission in the near future.

Yours sincerely

Yours sincerely,

Paul Hilton
Consultant Gynaecologist and Urogynaecologist