Reviewer’s report

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.

Version: 1 Date: 9 June 2011

Reviewer: Charlie Goldsmith

Reviewer’s report:

The following are suggestions to improve this protocol.

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.

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.

3. P 3, p 1, l 1. Replace [significantly] by [dramatically] or some similar term.


5. P 3, p 1, l 4. Replace [range] by [interval]. A range is the length of an interval.

6. P 3, p 1, l 8. Suggest replacing [significant] by [important] or a similar term.

7. P 3, p 2, l 4. Provide a reference for this justification.


9. P 4, p 1, l 1. Replace [significantly] by [dramatically] or some similar term.

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

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 Recent goes out of date with time.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.


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

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

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

16. P 7, p 1. What is the proposed allocation ratio?

17. P 7, p 3. Will they be restricted from using IUT?

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.

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

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

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

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.

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.

A random sample of 10 R(eferences) was checked for citation accuracy. This reviewer also likes to see the issue number as it makes it easier to find a R when it is needed.

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

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.


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].


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 [49]{920):i-iv,1-119].

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.].