Reviewer's report

**Title:** Group versus individual sessions delivered by a physiotherapist for female urinary incontinence: an interview study with women attending group sessions nested within a randomised controlled trial

**Version:** 1  **Date:** 9 July 2008

**Reviewer:** Charis Glazener

**Reviewer's report:**

Major compulsory revisions or concerns

These papers concern a randomised controlled trial of two methods of delivery of a physiotherapy intervention for female urinary incontinence, a group held on three occasions versus three one-to-one sessions with a physiotherapist. The benefit is that the group sessions are considerably cheaper for the service provider (£7.73 per participant in the group and £53.73 for the individual treatments). They usefully use a mixed methods approach, including quantitative, qualitative and economic approaches. Women were selected from referrals to Physiotherapy departments. As far as I can tell, the conclusion appears to be that although there were no statistically significant differences in symptom severity or quality of life between the two groups, women preferred the individual treatment option, but it cost considerably more and was less cost-effective. It is not clear how much baseline differences between the groups (which should not occur in a randomised trial) were responsible (see point 6 below).

1. The outcomes are analysed using multiple imputations to replace missing data. I feel it would be more accurate to report the data as complete case analysis in the first instance and use the imputation approach as a sensitivity analysis.

2. It would be very helpful if data could be presented as simple numbers of women cured, improved, unchanged and worse in the two groups. This will make the paper much more useful and generalisable, as the data can be combined with those from other physiotherapy trials for meta-analysis in the appropriate Cochrane review.

3. There is a discrepancy between the two linked papers. In the Interview paper, it is stated that 28 women allocated to group treatment instead changed to individual sessions, whereas in the RCT paper this is given as 11 women in Figure 1 (Flow Diagram). The data need to be checked to ensure that the 28 or 11 women are analysed in the Group Arm to which they were originally allocated.

4. In the Background and elsewhere in the text, the authors refer to individual randomised controlled trials to support their assertion that physiotherapy is effective. They should instead refer to the appropriate Cochrane reviews (as they do for Bladder Training).
5. Regarding costs, while Table 3 shows the overall costs adding up the cost of the interventions and the subsequent resource use, it would be helpful to regard resource use as a separate outcome of treatment, to demonstrate whether (or not) there is also a significant difference in subsequent costs. My calculation is that not only is individual treatment more expensive, the subsequent costs are £7.27 greater as well, suggesting that there is increased resource use. This is counter-intuitive as one would expect that the individual treatments would be more effective – if not, why not? Why are the hospitalisation costs so much greater (£11.98 versus £3.40)?

6. Although it is often not necessary to provide a formal statistical comparison of baseline characteristics (as in Table 1) I do wonder whether the discrepancy in age (the average age of the Individual Rx women is 56, versus 49 in the Group Arm) is important. Similarly, fewer are in employment, and more have a degree or equivalent. This casts doubt on the randomisation process, which would be expected to distribute these characteristics evenly between the groups. The use of brown sealed envelopes has recently been called into question, as it is possible to tamper with them. However, the authors seem to have tried to ensure that this did not happen by quality control check s on sequential entry.

7. It would be helpful to describe the case mix of types of urinary incontinence at baseline (stress, urge and mixed) to increase the generalisability of the papers, especially since 350/551 women who were potentially eligible were not eventually recruited, plus another 24 who were unsure about participating.

8. A Consort Statement should be enclosed to demonstrate that all the aspects of RCTs that should be reported, have been.

9. The Interview Study (second paper) is based on a sample of 22 women, who would have preferred individual treatment but were allocated to the group arm but nevertheless turned up to at least one appointment. Therefore the views of those who got their chosen allocation are not represented, nor those who were so put off (the 28 or 11, see point 3 above) who did not go to the Group sessions at all. While the women made some relevant and helpful remarks (eg about embarrassment and needing to have information about what to expect) these could not be taken to represent the views of all the women who need physiotherapy treatment. I wonder particularly about the 350+24 women who were not in the study at all (see Point 7 above).

10. On the other hand, the Interview Study did not provide data on whether there was ‘increased peer support, mutual self help, giving and sharing of information, reduction in depression and isolation, increased motivation and compliance with treatment’, all of which were proposed in the Background section as theoretical benefits.

11. There does not seem to be a statement about overall response rates although some information can be gleaned from Table 2. This could usefully be added.
Minor essential revisions

1. Do not use the acronym FUI, refer to it by its full name.

2. In the description of economic appraisal, alternative therapies are complementary, not complimentary.

3. In Participants and Eligibility, surely (v) should be Grade III ‘or IV’ prolapse?

4. In the Interview Paper, Page 7, line 8-9, ‘several’ is not two women (E1, A13). Is it necessary to identify the women by these codes?

5. It would be helpful to know about the direction of the Symptom Severity Index and the IQOL – are higher scores better or worse? This is mentioned in the Methods but should be repeated at the bottom of Table 2. It is unfortunate that they go in opposite directions.

Discretionary revisions

1. It would be helpful to have an appendix detailing the content of the individual physiotherapy sessions. There is no agreement about what constitutes an acceptable minimum amount of exercise, repetitions, long or short contractions, or length of supervised treatment. The most important factor is likely to be finding a way of ensuring that women continue to adhere to an exercise programme after active supervision has finished. Anecdotal opinion is that pelvic floor muscles continue to improve for the first 4-6 months. It would be helpful to know what the interval was between the three appointments, whether for individual or group sessions. The data could also be interpreted to mean that neither group got sufficient physiotherapy input to make a measurable difference.

Level of interest: An article of limited interest

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interests