Reviewer's report

Title: The effect of pelvic physiotherapy on reduction of functional constipation in children: design of a multicentre randomised controlled trial

Version: 3 Date: 24 February 2013

Reviewer: William Whitehead

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Major Compulsory Revisions:

The primary outcome measure continues to be listed as whether the child fulfills Rome III diagnostic criteria for functional constipation. As I noted previously, this is an inappropriate measure because 3 of 6 Rome criteria ask about the history of symptoms and will not be responsive to treatment. The authors should use one of the measures currently listed as secondary for the primary outcome. The best choice would be either the NRS or the GPE.

The protocol states that the intervention will be patient-tailored based on the child's age and motivation, and the parents' motivation. The relative lack of specificity in how these decisions will be made and how the "dose" of the intervention received by each child will be assessed, will make it difficult for others to replicate the trial. This level of ambiguity may also make it difficult to interpret a negative trial outcome. I believe what is needed is a set of decision rules for the interventionists and a checklist that will make it possible to characterize the intervention received by each child.

Concerns were raised that differences in outcome could be attributed to differences in the number of clinic visits between treatment arms (up to 8 for PTT vs. up to 3 for standard medical care). If it is not feasible to match the number and length of visits, the authors should include a measure of expectation of benefit and a measure of satisfaction with treatment (completed after initial exposure to the intervention in each arm of the study).

Level of interest: An article of limited interest

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.