Reviewer’s report

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

Version: 2 Date: 15 December 2012

Reviewer: William Whitehead

Reviewer’s report:

This is a very important study assessing whether physiotherapy (including biofeedback) provides added benefit when combined with standard medical care for constipation in children; it is important because this has been a controversial issue and inconsistent results have been reported. A major strength is that the authors have surveyed physiotherapists to develop a consensus protocol for treating constipation. Other strengths are that the study is multicenter and is adequately powered.

Major Compulsory Revisions:

1) The primary outcome is whether the child ceases to qualify for the diagnosis of FC by the Rome III criteria. It is critical to know how sensitive and responsive this measure is to an intervention. An examination of the criteria raise some concerns about this: 3 of 6 symptom criteria include the phrase “History of…” There needs to be some operationalization of how this criterion will be assessed at follow-up, and what is the period of time over which the other criteria will be evaluated at follow up points.

2) It is stated that some aspects of the physiotherapy protocol including EMG biofeedback and rectal balloon training will be included in treatment only when indicated by the presence of functional deficits in these areas, but there is no discussion of how this will be taken into account in the analysis of the data.

3) In any behavioral intervention, and especially in those done in children, the non-specific effects of attention and therapist contact time are potential confounders. The contact time in these two treatment arms are quite different. There should be some discussion of this. A related point is that the protocol leaves the number of treatment sessions in each arm up to the interventionists, specifying only that the standard care group will receive at least 3 sessions and the physiotherapy group will receive no more than 6. The number of sessions completed should be taken into account in the data analysis.

Minor Essential Revisions:

1) There are too many abbreviations, and these make the manuscript difficult to read.

2) On page 4 there are two ambiguous terms – “dysfunction of the colon, rectum or pelvic floor muscles”, “withdrawal of stool”. Please explain or clarify these expressions.
3) On page 4, it would be helpful to give an estimate of the proportion of constipated children who exhibit dyssynergic defecation.

Discretionary Revisions

1) In behavioral trials such as this, neither the subjects nor the therapists can be blinded to which is the active intervention. There are concerns about bias at two levels: the collection and interpretation of the outcome data and the unconscious bias of the interventionists. The authors have done a good job of eliminating the first source of bias by collecting the primary outcome measure through web assessments which are standardized. They might consider measuring the level of expectancy of the interventionists for each arm of the study before the intervention and testing to see if this accounts for any between-therapist effects.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

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

Declaration of competing interests:

I declare that I have no competing interests.