Author's response to reviews

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

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page 4 “In some patients, delayed colonic transit may be the result of dyssynergic defaecation. Approximately 50% of children show this abnormal defecation pattern. Withdrawal of stool, hard painful defecation or fear of stool, resulting in a vicious circle, is the most commonly proposed explanation of the aetiology of dyssynergic constipation in children”

page 6 Web-based measurements will be obtained before the first visit to the physiotherapist (M WB 1), three months after randomisation (M-WB 2) and before the final visit to the physiotherapist (M-WB-3) (Figure 1). Shortly before randomisation (M-PPT 1) and at six month, adjacent to M-WB 3, measurements at the physiotherapist will take place (M-PPT 2). After M-PPT2 a final visit at the paediatrician is scheduled.

Web-based measurements include a structured patient reported outcome, which assesses the presence of the Rome III criteria and laxative use, co morbidity (such as urinary problems and abdominal pain), the Strength and Difficulties Questionnaire (SDQ) and a two weeks diary. At follow-up (M-WB 2 and M-WB 3) the web-based measurements are supplemented with the global perceived effect (GPE).

At the last visit at the paediatrician, use of laxatives and the presence of Rome-III-criteria (primary outcome) are recorded.”

page 7 “Usual care laxative use in children with faecal impaction and older than two years is 1-1.5 g /kg per day for a maximum of seven days. The maintenance dose is 0.3 to 0.8 g/kg per day. The dose will be tailored to individual needs during the trial with guidance of the Bristol Stool Form Scale”.

page 12 “Adjusted group differences will be analysed using multivariable logistic regression with ordinal variables transformed into dummies, taking into account
possible differences in mean number of sessions. Finally, subgroup analyses will be done to establish normal values and observed differences in effectiveness for relevant clinical subgroups.

page 13 “Confounding in our trial may arise due to the Hawthorne-effect as a result of differences in number of the protocolised contacts. Although it is expected, based on experience, that the mean number of treatment sessions will be equal, adjusted group differences will be analysed.”