Reviewer's report

Title: Effectiveness of functional splinting and the Cognitive Orientation to Occupational Performance (CO-OP) approach in children with Cerebral Palsy and Brain Injury: Two randomised controlled trial protocols

Version: 2
Date: 13 May 2014

Reviewer: Michal Katz-Leurer

Reviewer's report:

The manuscript is clear and well organized.

Please reconsider the following points:

The assumptions which sample size calculation was based on need some clarifications:

1. The sample size calculation is based on the study by Iona Novak "Occupational Therapy Home Programs for Cerebral Palsy: Double-Blind, Randomized, Controlled Trial", why should this type of intervention be the reference for sample size calculation? Why assuming an effect size of 0.9? It is not clear.

- In addition, the study by Novak et al. focused only among children with CP. Children post TBI probably will increase sample variability. This has to have an effect on sample size.

2. Can you please clarify the calculations "...effect size of 0.9, power analysis for the three groups...", Performing simple calculations reveal different numbers.

3. Assuming that MACS levels associate with outcomes means that this component need to be addressed during sample size calculation.

A Block randomization method seems to useful method for creating comparable groups based on for example participants' pathology, CP or TBI.

Statistical methods:

- Please clarify, what will be the method for "treating" drop outs: intention to treat method or per protocol?

- It is not clear, which statistical test will be used for each study aim. Please add the specific potential tests.

Study hypothesis:

What is the supportive evidence for this study assumption? I am sorry but this is not clear.

Some other points:

1. The CO-OP approach implementation among children post TBI seems to be problematic.
2. The motor performance and functional abilities of children post TBI are differ from the more typical appearance of children with CP and in addition is quite variable with this group of children.

3. Dose the COPM is an appropriate tool for assessing children post TBI? The MACS?

4. The age span seems to be quite large.

5. Severity of the injury, uni or bilateral involvement, cognitive and behavioral skills description, all need to be assessed.

Would not it be better to include only children with CP?

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

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.