Reviewer’s report

Title: Stockholm Preterm Interaction-Based Intervention (SPIBI) - Study protocol for an RCT of a 12-month parallel-group post-discharge program for extremely preterm infants and their parents

Version: 0 Date: 09 Aug 2019

Reviewer: Marian Jongmans

Reviewer's report:

Main points
- The trial endpoint is marked at 12 months CA and the EAS is the primary outcome measure. It is nice that the EAS is repeated at 24 months CA; why not again at 36 months CA?
- I guess that, given the 2 follow-up moments (24 and 36 months CA), the data analyses approach described (page 21) needs to be elaborated in the sense that the design changes to a more longitudinal approach (with at least 3 measurement points) using, for example, more sophisticated methods like linear mixed models. I can see no such description (yet)? it would be good if hypothetical models can be defined at this moment already in order to avoid later 'fishing expeditions'?
- As the authors point out themselves (page 12, first paragraph), the children / parents participating in the 'control' group are not 'true' controls in the sense that they ONLY receive the TAU but additional measurements as well. I agree with their worry. In fact, one of the suggestions to tackle this Hawthorne effect (i.e. participation in research in itself causes change in the behavior of the research participants) could be to introduce a THIRD group in the design: a post-test only group. This is a control group in which measurements are only performed at the time-point of the primary outcome, this avoiding as much interference from study participation with the results of the study as possible.
- Measurements: I appreciate the use of a logbook and wonder: will any of the data reported in the logbooks be of help / use as variables to include in a (prediction)model?
- I find the description of the TAU (for example on page 13) not clear enough. How many times are children / parents seen by a paediatrician, physiotherapist, psychologist in the 'regular' follow-up program in Sweden and what aspects of their development are screened?
- The authors are realistic in their expectations of the number of children able to include during the recruitment period (until 2020) (page 14). But, if the targeted number of 130 is NOT reached: what will happen? Extend the recruitment period? Is there a bottom limit which the authors at least want to achieve? Moreover, the possibility of applying subgroup data analyses is mentioned (page 21): this might be jeopardized if not enough children can be recruited.
- (page 27): Availability of data and materials. The authors mark this as 'not applicable'. However, in this (new) day and age of Open Science I would strongly suggest to look at the possibilities for sharing data and materials (in the Swedish context of course).

Minor points
- Abstract: penultimate sentence it is stated that the trial will give valuable information for all children in Sweden. I suggest to change this to all children born in de Stockholm region since I can imagine that the possibilities to provide an intensive type of care like SPIBI is (more) difficult to realize in all regions of Sweden (?)
- English needs some language corrections. For example, in the abstract (background section) it should be run (instead of runs) and (discussion section) the word parental is misspelled (= parnetal). Likewise, on page 6 it should be "Since parental sensitivity seems to be ... (instead of seem to be). And so there are many more examples throughout the text. Please check carefully.
- I suggest to add the words 'emotional availability' to the keywords for this paper (as it is the main outcome measure)
- The text describing the measurements and the information in Table 2 do not match. For example, the BRIEF is also administered at 3 years CA (and missing from the Table). And so are the PSE, RES, HADS and STAI at term age?

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

Yes

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

Yes

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Yes

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I am able to assess the statistics

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