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: 23 Oct 2019

Reviewer: Reviewer 2

Reviewers report:

PEER REVIEWER ASSESSMENTS:

OBJECTIVE - Full research articles: is there a clear objective that addresses a testable research question(s) (brief or other article types: is there a clear objective)?
Yes - there is a clear objective

DESIGN - Is the current approach (including controls and analysis protocols) appropriate for the objective?
Yes - the approach is appropriate

EXECUTION - Are the experiments and analyses performed with technical rigor to allow confidence in the results?
No - there are minor issues

STATISTICS - Is the use of statistics in the manuscript appropriate?
No - there are issues with the statistics in the study

INTERPRETATION - Is the current interpretation/discussion of the results reasonable and not overstated?
N/A - no results to interpret

OVERALL MANUSCRIPT POTENTIAL - Is the current version of this work technically sound? If not, can revisions be made to make the work technically sound?
Yes - current version is technically sound

PEER REVIEWER COMMENTS:

GENERAL COMMENTS:
this paper describes the study protocol of an (?) already ongoing) study. the topic is very valuable, and aims to assess the impact of a post discharge intervention study in former extreme preterm neonates with focus both on these preterm neonates, as well as their parents. In contrast, a pharmaco-economic assessment based on the main outcome variables (parents and child) may be a valuable add on. Another issue relates to the power calculation: i miss the number in the abstract, and i suggest that the authors should also consider subgroup randomization, since this reviewer assumes that the % outcome will display a gestational age-dependent variability. Since the overall power calculation is already not very stringent, i highly recommend to stick to the 130 to be recruited, since otherwise, we will end up again with a practice that is not supported by any evidence (since as reflected in the ethical parts of the paper, also these intervention may generate side effects, besides the need for resources ?
REQUESTED REVISIONS:
as mentioned earlier, more focus on power calculation and subgroup randomisation should be considered.

ADDITIONAL REQUESTS/SUGGESTIONS:
cfr higher mentioned

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

No

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

No

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Unable to assess

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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