Reviewer's report

Title: A Randomized Controlled Trial comparing Parent Child Interaction Therapy - Toddler, Circle of Security– ParentingTM and Waitlist controls in the treatment of disruptive behaviors for children aged 14-24 months: Study Protocol

Version: 0 Date: 21 Jun 2020

Reviewer: Carlo Schuengel

Reviewer's report:

Thank you for the opportunity to review this well-written study protocol. The author team is to be commended for undertaking this extensive and well-designed trial, situated within the well-known Karitane center, which has a record of contributions towards evidence-based child and family interventions. The invitation for review specifically contained the following questions, briefly addressed below.

1. Will the study design adequately test the hypothesis?
   The main hypothesis regards a gradient effect, specifically an ordinal relationship between the group-factor (0) waitlist, (1) Cos-P, (2) PCIT-T and parenting and child outcomes. The group-factor is under experimental control through restricted block randomization. Thus, any positive association between the group factor and outcomes may be interpreted as an effect if being randomized towards COS-P or PCIT-T. Implicit in the hypothesis is the expectation that randomization towards PCIT-T leads to better outcomes than randomization towards COS-P. In principle (but saying later point about a priori power), this is also a hypothesis that could be tested with this design.

   In general, the outcome measures chosen appear well-justified given the theoretical framework for both interventions as well as the theoretical framework of the study. The only exception may be Parental Emotion Regulation (p. 20). It is not clear from the theoretical framework for the study as well as the theoretical basis for the interventions how these interventions would directly affect parental emotion regulation. Therefore, should the efficacy of the interventions be assessed on the basis of this outcome? This is all the more important given the large ratio of outcome measures against sample size.

2. Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing?
   In general, the methods are well described and document. One detail that was missing on page 16 is the number of therapists involved in offering COS-P. This detail is important given the potential for therapist effects and the opportunity for assessing such effects.

3. Is the planned statistical analysis appropriate?
- Linear mixed model repeated measures analysis of variance for the three time conditions (p. 23) is generally appropriate for testing effects of interventions, but important details are missing to assess how the authors deal with some of the intricacies of their approach.
  – For example, The WLC-group is not included in T3. So are the authors planning a test of their hypotheses on the basis of T1-T2 and a test of the hypothesis of superiority of PCIT-T over COS-P on the basis of T1-T3?
  – Will a separate analysis be conducted for the outcomes that were not included in T2 (i.e., the SSP)?
  – What are the decision rules if the results from these different hypothesis tests are (partially) conflicting?
  – Furthermore, it is unclear how the hypothesis of a gradient effect would be tested in the T1-T2 analysis of WLC, COS-P, and PCIT-T. Are the authors using planned contrasts of just testing whether the within (time) x between (group) interaction factor is significant?

- The authors plan to use Cohen's criteria for interpreting the clinical significance of their findings. However, what are the arguments for using this benchmark? And how is the benchmark related to effect size expectations? Most research on psychosocial interventions suggests that effect sizes for differences between treatment and waitlist-controls might be inflated due to the nocebo effect for being on a waitlist. In contrast, the difference in effects between two active treatments is likely to be much smaller than for treatment versus no treatment. Therefore, it seems reasonable to use different benchmarks for both these types of effects.

- Related to the previous point, it is unclear what the basis is for the effect size expectation on p. 24 and it is also not clear whether this refers to the absolute efficacy (treatment versus WLC) or relative efficacy (PCIT-T versus COS-P).
- More details are needed on the power calculations, given the mixed linear models that will be employed and the Bonferroni adjustments for family-wise error rate. Also, it is unclear whether the power calculations refer to difference between any intervention and waitlist (which is limited to 2 measurement occasions) or difference between the two active interventions (which has 3 measurement occasions but would also have to be based on a much lower effect size).
- The sentence about the post-hoc testing is quite dense and needs fuller explanation, especially given that the alpha was divided by 4 to adjust for multiple comparisons, but the study includes 12 outcome variables.

The study plan and power analysis might benefit from a consideration of primary hypotheses and secondary hypotheses, with the primary hypotheses including the outcomes that would at least have to show significant effects for the intervention to be favored over alternatives. The tests for these outcomes would not need to be Bonferroni-corrected, because the whole 'family' of tests falls under the same error rate (.05) of the decision rule. For any secondary hypotheses with less strict decision rules, Bonferroni-style controls of error rate may still be applied. Structuring the hypotheses and outcomes like this would allow for clearer study outcomes while preserving statistical power.

4. Is the writing acceptable?
Yes, writing is straightforward, direct, and clear.
Regarding the Conflict of Interest statement, I wondered whether the authors have also considered their authorship of the adapted PCIT protocol (Kohlhoff and Morgan) as presenting a possible reason for at least intellectual interest that readers may be made aware of? This also regards the affiliation of several of the authors with the clinical center that is offering the intervention. Although this information is transparently within the manuscript itself, it may be important to review the journal policy on declaring information that has the potential for being perceived as presenting a possible conflict of interest.

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Yes

**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.

Yes

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