Author’s response to reviews

Title: Follow-Up Study Regarding the Medium-Term Effectiveness of the Home Visiting Program "Pro Kind" at age seven: study protocol for a randomized controlled trial

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Author’s response to reviews:

Dear Dr. Moore,

Thank you for the chance to revise our manuscript “Follow-Up Study Regarding the Medium-Term Effectiveness of the Home Visiting Program “Pro Kind,” Based on a Randomized Controlled Research Design among children at age 7 years” for publication in BMC Trials.

You will find that we have addressed all of the reviewer’s concerns. Our responses to the reviewer comments can be found right under the respective issue.

We would also like to thank Dr. Segrott for taking the time to thoroughly assess our study protocol. We appreciate his valuable input and believe his expertise has helped us in improving the manuscript. We sincerely hope that the revised version now meets the high standards of BMC Trials.

We are looking forward to hearing from you regarding the progress of our submission.

Sincerely,

Sören Kliem
Reviewer reports:

Reviewer #1: Thank you for asking me to review this paper which is a protocol for a follow-on study of the Nurse Family Partnership intervention in Germany, and which extends an existing RCT.

Overall I thought this was a well written paper which explains the need and rationale for the study, sets out its aims clearly, and provides considerable details on the measures to be used and how they will be employed.

There are some areas of the study design where I felt it might be helpful to provide greater detail or additional information. I have listed these below and hope they are helpful to the authors.

1. On pages 7-8 it might useful to have slightly more information about the findings from the original RCT, and for terms such as 'small positive effects' to be briefly quantified. There are three references provided for the original study, but two of these are working papers which I was not able to locate online. Are there peer-reviewed and publicly papers which can be cited here?

- We now provide more information about the findings from the original RCT and quantify the effects in more detail. Since in the meantime more publications have become available we are now able to cite four of them. Two of the four referenced papers are already published, meanwhile one is forthcoming in the Journal of Health Economics, while one is still under review and only available as a Human Capital and Economic Opportunity Global Working Group (HCEO) working paper. The HCEO working paper series is listed e.g. in the Social Science Research Network (SSRN). Therefore, the working paper can be cited regularly (p. 9).

2. More generally I would find it helpful to have a greater sense of how the follow-on study presented in the protocol extends and builds upon the original RCT, and how the measures being collected map on to the intervention's logic model and its hypothesized causal mechanisms and outcomes. For instance, to what extent are outcomes measured in the original trial hypothesized mediators of longer term outcomes being collected in the follow-up study?
- We now provide a figure illustrating both the original trial as well as the follow-up and the way the follow-up builds upon the original study (p. 20). Furthermore, we added information about the domains addressed in the ProKind intervention (p. 5-6).

3. Can more be said about how the trial has been designed in relation to specific effect sizes for these outcomes?

- We now added additional information regarding power calculations from the original trial as well as varying attrition rates and following power assumptions for the follow-up (p. 7). Furthermore, we performed a sensitivity analysis to estimate minimum detectable effect sizes in the follow-up study (p. 35).

4. The research questions for the follow-on study are presented very clearly but I wasn't sure if I fully understand the framing of primary and secondary outcomes (with the latter being less likely to be affected by the intervention?).

- We now extended our explanation of what constitutes a primary vs. a secondary outcome in more detail (p. 23).

5. There appear to be 10 primary outcomes for the study - can more be said about whether each of these is equal and how the findings will be brought together and interpreted if there is a mixed pattern of results.

- We have added a section about dealing with multiple testing (p. 35).

6. In the main body of the paper I would find it helpful to have more detail on the strategies being used to recruit participants, the procedures used for data collection and some of the practical and ethical aspects of these dimensions of the study. For example: what challenges are anticipated in relation to following up large numbers of participants over the long term follow up and how will these be managed?

- We have added information about panel maintenance in the discussion section (p. 37).
7. What are the ethical and governance arrangements for accessing employment registries and social networks to locate participants?

- We apologize for the apparently misleading wording. Participants were not located via social media. Employment registries were accessed with the participants’ consent to gain outcome information regarding employment. Social media was used to contact the individuals via the project’s Facebook page, which they could follow. All procedures have been approved by an ethics committee and supervised by a data protection officer. Due to the misleading wording we have removed the paragraph from the manuscript.

8. Can participants agree to provide self-report data but refuse to allow researchers access to administrative data?

- Yes, this was/is of course possible. We have now added the respective information (p. 19).

9. Data collection from both mothers and children covers a number of sensitive issues and although the steps being taken to deal with support needs and prevent distress are covered this could be discussed in more detail.

- We added a long passage detailing training of staff regarding communication and de-escalation techniques. We have furthermore outlined procedures for dealing with the discovery of problematic information and potential legal obligations. Additionally, we detailed how to avoid any unnecessary strain on mother and child due to the interview and testing situation (p. 15-19).

10. On page 14 it is stated that where participants who do not wish to participate in the study they will be reminded of the importance of the study, and the financial incentives being provided. Is there a risk here that participants might feel pressure to participate, and can the authors describe steps taken to ensure that this is not the case? Similarly where participants are asked for their reason for non-participation or withdrawal from the study are they permitted to refuse participation or to withdraw without providing a reason? In relation to the incentives being provided can the amounts be specified?

- We again apologize for our unsensitive wording. Mothers have been very politely informed that this kind of research is very important especially due to the longitudinal nature of the study. However, they were not and will not be pressured in any way to participate. By no means was or will it be necessary to provide a reason for non-participation. However, often
they provide one (such as not having enough time, or not wanting to be visited at home). In these cases, we try providing solutions such as offering to do the testing at the research institute, splitting the long visit into multiple smaller ones or contacting them again a few month later in case that is more convenient. Due to the apparent irritation this passage has caused we have deleted it from the manuscript.

11. Sub group analyses: I was not entirely clear as to whether sub groups for analysis would be specified in advance. Also what exactly is meant by 'implementation factors' (am I right in thinking these relate to characteristics of the participants rather than the implementation of the intervention)?

- We specify those subgroups in advance for which the original trial showed stronger intervention effects. These are gender and number of mother related risk factors at pre-assessment. 'Implementation factors' was a misleading term in this relation as ‘Implementation factors' relate to characteristics of the participants rather than the implementation of the intervention as the reviewer correctly notes. We have changed the wording in this passage thereby hopefully clearing up matters. Additionally, we analyse subsequent births as a mediating factor in a sub analyses as more second births in the treatment group were one main effect in the original trial.

We have now rewritten the subgroup analysis section to make all discussed issues clearer.

12. Some specific points and queries:

For Hypothesis 4.4. can the direction of effect be specified?

- The intervention aimed to reduce unwanted pregnancies. The intervention made no statement concerning second births. However, the number of second births strongly increased in the treatment group in the original trial. Therefore, it is difficult to specify the direction of the effect in the follow-up trial. As mentioned above, we will do sub-analyses with further births as a mediating factor.

13. Is it possible to state the exact length of the main follow-up from original baseline?

- We changed the title as follows:” Follow-Up Study Regarding the Medium-Term Effectiveness of the Home Visiting Program “Pro Kind,” Based on a Randomized Controlled Research Design among children at age 7 years”
14. Which are the European trials where implementation was not high quality (referred to in the Discussion)?

- Again, our apologies for inelegant wording. We did not mean to imply that the studies we mentioned from France, the UK and the Netherlands were of inferior quality. We simply wanted to point out that is a general scarcity of high quality NFP program evaluations in Europe. We have hence changed the wording of the passage.

15. Pages 7-8 - a link is discussed between improvements in mental health and fewer pregnancy terminations- can this be explained in more detail?

- Life-Satisfaction is related to fertility. Mothers who are happier tend to decide for an abortion less frequently. However, convincing evidence is rather weak. Therefore, we changed the text on pages 7-8 and made the statement that “maternal well-being lead to fewer pregnancy terminations” less strong.