Reviewer’s report

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

Version: 0 Date: 19 Jan 2018

Reviewer: Jeremy Segrott

Reviewer's report:

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.

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?

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?

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?). 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. Can more be said about how the trial has been designed in relation to specific effect sizes for these outcomes? Reference is also made to data being collected which are additional to the primary and secondary outcomes - can these be briefly summarised so that the reader has a full picture of all the data which will be collected?
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?; what are the ethical and governance arrangements for accessing employment registries and social networks to locate participants?; can participants agree to provide self report data but refuse to allow researchers access to administrative data?. 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.

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?

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)?

Some specific points and queries:

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

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

- Which are the European trials where implementation was not high quality (referred to in the Discussion)?

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

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I am a member of a research team which has received funding to evaluate the Family Nurse Partnership intervention (the intervention evaluated in this paper) in England.
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