Author's response to reviews

Title: Effectiveness of Primary Care Triple P on Child Psychosocial Problems in Preventive Child Healthcare: a Randomized Controlled Trial

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Author's response to reviews:

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Reviewer's report - REVIEWER 1

Title: Effectiveness of Primary Care Triple P on Child Psychosocial Problems in Preventive Child Healthcare: a Randomized Controlled Trial

Version: 3 Date: 28 June 2013

Reviewer: Marian Bakermans-Kranenburg

Reviewer's report:

BMC Medicine: Effectiveness of Primary Care Triple P on Child Psychosocial Problems in Preventive Child Healthcare: a Randomized Controlled Trial.

The current paper describes the results of an RCT testing the effects of Primary Care Triple P in an at-risk sample in the Netherlands. PCPT was found to show no better effects than Care As Usual, neither on the primary outcome (SDQ), not on the secondary outcomes. The authors conclude that “Evidence on the effectiveness of PCTP is still inconclusive, so it requires additional study.”

This is an important study, as it comprises the first RCT investigating the effects of PCPT in the Preventive Child Healthcare system. The RCT design outperforms the waiting list design in testing intervention effectiveness. Moreover, this one of the very few studies testing Triple P not authored by Triple-P affiliated personnel. In a recent review and
meta-analysis (Wilson et al., 2012), it was noted that that was the case for only 1 out of 33 studies examining the effectiveness of Triple P. Independent effect studies are of course of crucial importance to the field.

With the aforementioned meta-analysis in mind, I was not too surprised to see the effects of the current trial; they support the absence of an effect as documented in the meta-analysis.

From this perspective I consider the authors conclusion that “Evidence on the effectiveness of PCTP is still inconclusive, so it requires additional study” as incorrect - or at least too mildly put.

[RESPONSE]
Thank you for these positive comments. We agree with the reviewer that our conclusion needs rewording. We did so, taking into consideration that our study is underpowered due to a lower inclusion than we aimed at.

Therefore, we adjusted the conclusion at the end of the abstract as follows (page 3):

“Based on this study, we cannot conclude that PTCP is more effective than the usual care in Preventive Child Healthcare.”

[The original sentence was: “Evidence on the effectiveness of PCTP is still inconclusive, so it requires additional study.”]

The study has a sound design, the analyses are clear, the results unambiguous, and the limitations are acknowledged and discussed in a convincing way. I like the additional intent-to-treat analyses. The paper could be further improved by taking the following issues into account:

1. Include the alphas for the internal consistencies of the questionnaires

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[RESPONSE]
Thank you very for your interest in and appreciation for our work.
We calculated the Cronbach’s alphas of our questionnaires and included them in
Table 2. The alphas are:
SDQ: # = .60; ECBI #: = .87; PS: # = .84; PSBC: # = .97; PSI: # = .88; DASS: # = .94

2. I do not understand the sentence “The highest mean improvement scores were also found for the SDQ and the ECBI. “ (p11) Is perhaps part of the sentence (e.g., “at the six-month followup”) missing?

[RESPONSE]
Thank you for noting this error, a part of the sentence was missing by accident. We adjusted the text as follows (page 11):
“The highest mean improvement scores were also found for the SDQ and the ECBI at the six-month follow-up.”

3. Conclusion: “Implementation of PCTP may still be justified, although it does not necessarily surpass CAU in effectiveness”. (p14) I wonder whether the results warrant that conclusion when cost-effectiveness is taken into account

[RESPONSE]
We agree with the reviewer that this is an interesting issue. However, assessment of cost-effectiveness was not the aim of our study. We do not know whether implementation of PTCP will contribute to care at a lower costs regarding treatment of child psychosocial problems.
Therefore, we adjusted the final sentence of the Conclusion section as follows (page 14):
“Furthermore, research is needed to determine whether the costs of the large-scale implementation in PCH counterbalance its benefits.”

4. Figure 2: Please include the baseline assessment in the figure, and add confidence intervals (SD or SE) around the point estimates; from the current figure without confidence intervals not conclusion can be drawn.

[RESPONSE]
We added the confidence intervals around the point estimates (see adjusted Figure 2).
The baseline assessment is not included in the figure because the analysis was corrected for baseline values. For the observed mean baseline scores we refer to Table 1 ‘Demographic and outcome measures at baseline of participants by treatment group (n=67).’

5. I checked the authors’ 2010 paper presenting the design. Indeed, they aimed at including a sample that was twice the size of the current sample. It seems that already on the level of the eligible sample the intended group size (2010) was much larger than that in the current flow chart, so the actual flow of inclusion, exclusion, and attrition was not different from what was expected. It would be important that the Discussion includes some reflection on the deviation from the original design. What were the reasons for the smaller-than-intended sample? Were PCHs reluctant to participate? Was the inclusion period reduced? Were financial constraints decisive and put an early end to the study?

[RESPONSE]
Thank you for noting this issue. We did not stop our study prematurely. The smaller-than-intended sample size had a few reasons:
[1] The intended group size was based on the number of children to be screened in one year by the three participating PCH organizations [Spijkers, 2010]. However, after we started the study, the participating organization implemented Primary Care Triple P (PCTP) as routine in some parts of their regions, because of severe pressure from local policy makers to do so. To prevent contamination of the care-as-usual with PCTP, we had to exclude these parts from further inclusion, which led to a decrease in the flow of inclusion.

[2] The process of inclusion was incorporated in the routine daily practice of Preventive Child Healthcare. As a consequence, not all parents were invited to participate, due to
either a too high workload or reluctance of either the CHP or the parent. This may have contributed to a lower inclusion as well.

We added the following text to the Strengths and limitations section (page 14) “During the trial, PCTP was implemented as routine care in some of the participating regions.

To prevent contamination, we had to exclude these regions. Moreover, in the remaining regions the inflow of eligible parents of children with mild psychosocial problems was lower than expected because some parents were not invited to participate, due to a too high workload or reluctance of either the professional or the parent to participate in an RCT. This led to a lower than intended sample size.”

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests

Reviewer’s report – Reviewer 2
Title: Effectiveness of Primary Care Triple P on Child Psychosocial Problems in Preventive Child Healthcare: a Randomized Controlled Trial
Version: 3 Date: 3 July 2013
Reviewer: Sarah Stewart-Brown

Reviewer’s report:
Thank you for asking me to review this paper which reports a trial of one aspect of a wellknown parenting programme. The need for this trial is well justified.

Methods
The research methods can be criticised on the basis that the approach to calculation of the sample size may have resulted in underpowering the study. The calculation is based on an effect size of 0.5. This is within the average effect size for all trials of Triple P. However many of the latter are with clinically indicated participants where the possibility for
improvement is much greater. Meta-analysis of trials of targeted and indicated parenting programmes together give an average effect size of 0.4 (see for example Kendrick D, Barlow J, Hampshire A, Stewart-Brown S, Polnay L. Parenting interventions and the prevention of unintentional injuries in childhood: systematic review and meta-analysis. Child: care health and development. 2008:34(5);682 - 695 ). Trials of programme in subclinical populations like this where outcomes are measured with clinical indicators are likely to show smaller effect sizes still, but these may still be important in the event the authors recruited just over half of the intended sample size. It is important that small RCTs are reported so their results can be included in meta-analyses but it is also important that the fact they are underpowered is acknowledged. It is not entirely clear what the eligible population constituted. It is said that children with conduct disorders were excluded but those with a clinical and subclinical level of problems were eligible. Does this mean only those children who had seen a psychiatrist and had a diagnosis of conduct disorder were excluded and those who had similar levels of problems but had not been diagnosed were included?

[RESPONSE]
Thank you for raising this point. Indeed children sufficing the inclusion criteria were excluded if they had a formal diagnosis. We have clarified this issue in the Methods section. The modified text is (page 5):

“In short, prior to a routine PCH health examination, parents completed a screening questionnaire concerning child psychosocial problems. Parents of children with an elevated score on psychosocial problems were assigned at random to the experimental group (PCTP) or care as usual except if the child had a formal psychiatric diagnosis or currently
received
treatment for these problems.”

Results
I am not clear about the results reported on page 11. It would seem there was one positive
finding (SDQ Conduct), but this disappeared in the intention to treat analysis. If this is the case
on what basis were the analyses reported previously undertaken.

[RESPONSE]
Thank you for this observation. The results described in our manuscript were based on the
analyses including all participants with at least one post-measurement (n=67). In this analysis,
conduct problems decreased significantly more in the PCTP group than in the CAU group.
However, in the intention-to-treat analyses, based on all 81 participants with at least a baseline
measurement, this effect disappeared. For the intention-to-treat analysis, the last observation
carried forward was used. This was accurately described in the Methods section (see: Statistical
methods) and the Results section (1st paragraph).
Whilst is it only one of many outcomes and therefore should not be over interpreted the SDQconduct
score finding is important since conduct or behaviour problems is the primary goal of
Triple P.

[RESPONSE]
Thank you for this comment. We agree with the reviewer that the effectiveness of PCTP
regarding conduct problems is of importance, but cannot make strong inferences on that as the
other 19 outcomes that we assessed did not support superiority of PCTP compared to CAU. We
already mentioned this observation already in the Results section as well as in the Discussion
section. To further clarify the issue of the importance of decreasing conduct problems, we have
adapted the sentence concerned in the Conclusion section.
The adjusted sentence in the Conclusion section is (page 14):
“Since PCTP seems to reduce child psychosocial problems, particularly conduct problems, and
to have no serious adverse effects, implementation of PCTP may still be justified, although it
does not necessarily surpass CAU in effectiveness.”

Discussion
Only a small proportion of eligible parents consented to take part. It is important that this is
discussed and addressed in the discussion. It implies potential for bias in external validity issues
relating to recruitment by screening in contrast to recruitment by open invitation need
addressing. Open invitation is much more likely to recruit parents who are ready to change and
this is important in behaviour change interventions. This trial (was it adequately powered)
could just be showing that screening is an inappropriate method of recruiting to the Triple P
programme.

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[RESPONSE]
Thank you for raising this point. Indeed only a small part of parents participated. In general,
relatively low participation rates seem to occur in most randomized trials; we are not sure
whether the preventive setting adds to that.

We added the following text to the Strengths and limitations section (page 14)
“During the trial, PCTP was implemented as routine care in some of the participating regions.
To prevent contamination, we had to exclude these regions. Moreover, in the remaining
regions the inflow of eligible parents of children with mild psychosocial problems was lower
than expected because some parents were not invited to participate, due to a too high
workload or reluctance of either the professional or the parent to participate in an RCT. This led
to a lower than intended sample size.”

The power calculation is discussed and said to be based on a clinically relevant difference of 3 points on the SDQ. A clinically important difference is only relevant in clinical populations.

[RESPONSE]
Thank you for this comment. However, the notion of clinically relevant difference refers to the practical importance of any treatment offered in a health care setting. In this context, clinically relevant implies: the effect of the intervention or treatment is sizeable enough to adopt the intervention in the interest of prevention of a public health problem. We did not make changes regarding this issue.

In subclinical populations such as this particularly with highly skewed measures such as the SDQ and Eyberg, smaller differences are to be expected and given the larger size of the population smaller differences may be very important in terms of population attributable risk. The conclusions should mention the fact that the trial was underpowered and that the differences found could be important viewed from a public health perspective.

[RESPONSE]
We added the following sentence in the Conclusion section (page 14):
“Since this study is underpowered, conclusions need to be interpreted carefully.”

The abstract needs amending accordingly. Major compulsory revisions

1. Address issues related to sample size described above including reporting that this trial was underpowered

[RESPONSE]
We agree that the underpowering of the study should be accommodated in the wording of the conclusion.

Therefore, we adjusted the conclusion at the end of the Abstract as follows (page 3):
“Based on this study, we cannot conclude that PTCP is more effective than the usual care in Preventive Child Healthcare.”

Moreover, we added the following sentence in the Conclusion section (page 14):

“Since this study is underpowered, conclusions need to be interpreted carefully.”

2. Address relevance of 'clinically important differences' in context of prevention

We aimed at a 0.5 effect size, i.e. a three-point-decrease in SDQ total score that we considered to be a relevant difference as it implies a change from a subclinical to a normal total score on the SDQ. The population share of children with mild psychosocial problems is large, however, which implies that smaller effect size may still have relatively large effects at population level.

We doubt, however, whether in case of smaller effect sizes, the effects outweigh the efforts may per child, of parents, child, and professional.

We have added a short discussion of this issue to the Discussion section (page 13):

“Smaller effects may still have a relatively large impact on population health, given the large share of children with mild psychosocial problems.[ref Rose] However, it can be doubted whether such small effects outweigh the effort made per child by parents, child and professionals as involved”

3. Discuss recruitment method and influence on outcomes

Thank you for raising this issue. We added a comment on this as indicated before. The added text is (page 14):

“During the trial, PCTP was implemented as routine care in some of the participating regions. To prevent contamination, we had to exclude these regions. Moreover, in the remaining regions the inflow of eligible parents of children with mild psychosocial problems was lower than expected because some parents were not invited to participate, due to a too
workload or reluctance of either the professional or the parent to participate in an RCT. This led to a lower than intended sample size.”

Quality of written English: Acceptable
Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:
Professor Stewart-Brown undertakes primary and secondary research on parenting programmes. She is a trustee of the UK Charity Family Lives