Author's response to reviews

Title: The effectiveness of VIPP-V parenting training for parents of young children with a visual or visual-and-intellectual disability: Study protocol of a multicenter randomized controlled trial

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Author's response to reviews:

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Doug Altman, Curt Furberg, Jeremy Grimshaw
Editors-in-chief Trials

Dear Doug Altman, Curt Furberg, Jeremy Grimshaw,

Thank you for the opportunity to revise and resubmit our study protocol named 'The effectiveness of VIPP-V parenting training for parents of young children with a visual or visual-and-intellectual disability: Study protocol for a multicenter randomized controlled trial' for a second round to your journal. We were glad to learn that both reviewers found our revised paper to be responsive to reviews and much improved. The first reviewer has pointed out that we should have been more clear in explaining the choice of our outcome measures. In this letter, we will outline how we addressed this issue, and outline our response to the editorial requests.

Reviewer #1
The authors have clarified this protocol a lot. In this version, the primary outcome is described in a very satisfactory way. However, I believe it is mandatory that the authors "un-exclude" the outcomes excluded, especially as this is the study protocol.

The authors state that they excluded two outcomes from the manuscript (emotional availability and early social communication). This is not possible as these outcomes have been collected (knowing that data collection is ongoing/finished). Excluding them “simply” would lead to outcome reporting bias in the study protocol (and probably in final publication)! These outcomes should now be secondary outcomes. The authors should also notify about how outcomes were changed from primary to secondary during the course of the
study.

We thank the reviewer for the compliment on the improvement of the manuscript. The reviewer suggests that the two previously excluded outcome measures (‘Emotional Availability Scales’ (EAS) and ‘Early Social Communication Scales’ (ESCS)) should be added as secondary outcome measures to prevent reporting bias. The overlap between the EAS, ESCS and the NICHD scales, which we propose to use in the study, is quite large; they all assess parental sensitivity and quality of parent-child interactions. We therefore decided a priori to choose one system, to reduce the risk of type I error. We do not believe excluding the EAS and ESCS would lead to outcome reporting bias in the protocol or in final publications. In addition, we planned to use the EAS coding system on data collected for the Three Boxes procedure (which will also be coded with the NICHD scales) and the ESCS coding system on the VIPP-V intervention videos. Therefore, no additional data has been collected for the EAS and ESCS. Another argument for choosing the NICHD scales was that at this moment, nobody in our research team is able to use the EAS and ESCS coding systems. Because the project ends in eight months we have decided to focus thoroughly on the NICHD scales and disregard the EAS and ESCS for now.

In response to the earlier suggestions of the reviewers we reassessed the planned outcome measures of the study critically. The reviewers were right to state there were (too) many primary outcome measures, and we therefore relabeled some of the primary outcome measures as secondary outcome measures. The video-feedback intervention focuses on improving parental sensitivity and in turn the quality of parent-child interaction (primary outcomes). In addition we are interested in whether participation in the intervention also lowers parenting stress and improves parental self-efficacy. These constructs however are not the focus of the intervention and are therefore better seen as secondary outcomes.

Reviewer #2

We would like to thank the reviewer for the attention given to the manuscript and the positive feedback. We are happy to see the reviewer was satisfied with the previous changes and approves of its current status.

Editorial requests

1. Please ensure the title conforms to journal style for study protocol articles. The title should follow the format ?_________: study protocol for a randomized controlled trial.? Please note that the title in the submission system should match that of your manuscript.

The title of the manuscript conforms to the journal style for study protocol articles.

2. Please move the list of abbreviations to immediately below the Trial Status.

The list of abbreviations has been moved to page18, directly below the ‘Status of the trial’.

3. Please include a figure title and legend section after the reference list.
A legend section has been added to Figure 1 (page 26).

We thank you and the two reviewers for the careful attention paid to this manuscript and the many helpful suggestions during the process. We believe the suggested alterations improved the informational value of the manuscript, and we hope you will reconsider this resubmission as a possible contribution to 'Trials'.