Abstract

VIPP-V is a parenting training program developed to train caregivers of young children with a visual or visual-and-intellectual disability. This training program was developed as part of the Family Support System (FSS) which is a comprehensive service that caters to children and their families to support the inclusion of children with disability in mainstream society. The main aim of the FSS is to prevent or delay the use of educational support services and to support parents in preparing their children for a life in mainstream society. In the FSS, VIPP-V is one of the offered training programs. However, there is no published evidence of the effectiveness of VIPP-V in improving the participating caregivers' parenting skills. The current study aims to evaluate the effectiveness of VIPP-V parenting training in improving the parenting skills of parents of young children with a visual or visual-and-intellectual disability. The study protocol is described in this article. The study is a multicenter randomized controlled trial with participants from five different centers in the Netherlands. The intervention group will receive the VIPP-V training, while the control group will receive usual care. The primary outcome measure is the change in the caregivers' parenting skills, as assessed by the Parenting Competence Questionnaire. The secondary outcome measures include the change in the children's behavior, as assessed by the Child Behavior Checklist, and the change in the parents' satisfaction with the training, as assessed by the Parenting Training Satisfaction Questionnaire. The study will be conducted over a period of 12 months, with a follow-up period of 6 months. The study is expected to be completed in December 2016.
Dear Doug Altman, Curt Furberg & Jeremy Grimshaw,

Thank you for the opportunity to revise and resubmit our study protocol entitled ‘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’ to your journal. The reviewers have given us many thoughtful suggestions to improve this paper. We would like to thank both reviewers and the editor for their time and effort put into providing useful feedback for improving our manuscript. In this letter, we will outline how we addressed each of the comments made by both reviewers and the editor.

Reviewer #1

Compulsory revisions
1. Outcomes: it is not clear what the primary outcome of the study is. I would recommend the authors to state a single primary outcome, on which sample size was calculated (I believe it would be parental sensitivity, but it is unclear).

We thank the reviewer for this helpful suggestion and have changed the paragraph on measures accordingly. As primary outcome measures we indeed focus on parental sensitivity and parent-child interaction; these variables are further described under ‘Primary outcome measures’. To increase the feasibility of the study we have chosen to focus on one observation-measure to assess parental sensitivity and quality of parent-child interaction. We have therefore excluded the ‘Emotional Availability Scales’ and the ‘Early Social Communication Scales’ from the manuscript. To gather as much information as possible with only one instrument for assessing parental sensitivity and quality of parent-child interaction, we have decided to now use all scales of the NICHD coding system instead of the previously mentioned three scales. Parental self-efficacy and parenting stress are labeled as secondary outcome measures and the experiences of early intervention workers with VIPP-V during early intervention are described under a new heading ‘Outcomes regarding feasibility of implementation’ (see also comment #8) (page 8-10).

2. It is unclear what authors will compare. Measures are adequately described, but not what comparisons are planned and using which measurements (Change from pretest to post-test between arms? Comparison of values after each assessment? Will results be described as proportions?) and using which assessments?

We thank the reviewer for directing us to this unclarity. In the design of the study we will compare the scores on primary outcome measures (parental sensitivity, parent-child interaction) and secondary outcome measures (parental self-efficacy and parenting stress) of families in the experimental condition with their own scores on a previous assessment, as well as with scores of families in the control condition at the same assessment. Change over time in parental sensitivity, quality of parent-child interaction, parental self-efficacy and parenting stress from pretest to post-test and from pre-test to follow-up will be assessed in the experimental group, and compared with the control group. Results will be described as rates of change. This plan for analyses has been described more clearly in the paragraph on ‘Data analysis’ (page 15).

Minor revisions
3. Study population = the sentence relating to coaches and VIPP-V intervention workers relate more to procedures to standardization of the intervention.

This sentence regarding coaches and VIPP-V intervention workers has been deleted from the paragraph on ‘Study population’ and this issue is addressed in the paragraph ‘Video-feedback Intervention to promote Positive Parenting in parents of children with Visual or visual-and-intellectual disabilities (VIPP-V).’
4. I'm not sure about the sentence regarding participation of parents with auditory or visual disability themselves: are their children excluded from the study (which should be clearly stated) or are they included (but what is an “extra case”)? 

Parents with a visual or auditory disability themselves will be included in the study. However, data from these families will be analysed as extra case studies, because it is not yet known whether these parents can benefit from the use of video-feedback. In other words, these families will be assessed in addition to the 100 planned to be included families. This has been stated more clearly on page 6.

Discretionary revisions
5. It would be easier for readers if intervention & outcomes were described earlier (maybe before procedure): indeed, in the procedure paragraph, there are references to the intervention or measures which are described afterwards.

In accordance with this helpful suggestion we have changed the order of the method-section. Now, first the study design and study population are described, then the intervention and measures, and finally the procedure, randomization, blinding and data analyses (page 5-15).

6. Procedure = Should the sentences related to randomization be in the randomization section?

In the procedure-section the way randomization is performed in three blocks and how this relates to the followed procedure for enrolled families and early intervention workers is described. We decided to include this information briefly in the procedure-section, because it describes the effect for enrolled families. Further details regarding randomization are described more extensively in the randomization-section (page 12-13).

7. Interventions are well described in the protocol. Assessment of fidelity to what was planned should be described in the intervention section, rather than in a separate paragraph (treatment integrity) at the end of the protocol.

We thank the reviewer for the compliment on the description of the interventions. We plan to assess whether the intervention is carried out according to the manual (treatment integrity) by coding 10% of randomly selected video-tapes of home visits. This procedure is part of the study and not standardized practice in clinical care. We therefore deem it more appropriate to describe treatment integrity as part of the control variables of the study instead of as part of the intervention (page 12).

8. Secondary outcome = I feel that the secondary outcome presented is more of an “additional results concerning feasibility”.

We thank the reviewer for pointing out this inconsistency to us. We have changed the structure of the paragraph on measures (see also comment #1) and have added an extra paragraph on outcomes regarding feasibility of implementation under which the experiences of early intervention workers with VIPP-V are now described (page 10).

Reviewer #2
Compulsory revisions:
1. Trial Registration: With respect to parents with a disability- this is listed as an exclusion criteria when the trial was registered but not in the protocol, one or the other should be amended to reflect this change. 

In the Trial Registration is described that parents with a visual or auditory disability will be included as extra case studies, as it is not yet known how these parents can benefit from video-feedback. Parents with an intellectual disability will be excluded for participation in the study. They can benefit more from participation in another adaptation of VIPP (VIPP-LD; Hodes et al., 2014). In the inclusion and exclusion criteria of the study is also described that parents with a visual or auditory disability will be included as extra case studies, and parents with an intellectual disability will be excluded from participation (page 6; see also comment #4 of reviewer #1).

2. Page 5, study population: 8 coaches and 15 workers training to use VIPP-V seems a lot for a population of 50 patients receiving the intervention, further description of the training received
should be provided so that readers can assess the homogeneity of the intervention received across those administering.

Researchers of Leiden University have trained eight special education- and behavioral- experts from Royal Dutch Visio and Bartiméus as coaches in VIPP in a 5-day training. During this training period all eight coaches practiced their newly acquired skills in a pilot family, and received five intervention sessions of 3 hours each with fellow coaches and three supervision session of 3½ hours each. At the end of the training period trainers from Leiden University checked the video-recordings and scripts of one of the seven home visits of all coaches. Then, two of these coaches (one of each organisation), in alternating collaboration with the second author, have trained fifteen early intervention workers (8 from Bartiméus and 7 from Royal Dutch Visio) in conducting VIPP-V. Early intervention workers received five days of training in VIPP-V over a period of 2 months. During this same period the intervention workers completed a VIPP-V intervention with one family who, due to age, could not be included as a participant in the study. Each of the five training days was dedicated to one home visit (the last two of the seven sessions are booster sessions in which previous topics are repeated), and during the training all intervention workers participated in intervision sessions on each VIPP-V home visit. Two of the trainers provided feedback on one of the scripts and on a video-recording of the feedback moment with the parent of each intervention worker. The VIPP-V training materials, video-recordings, scripts and provided feedback of the trainers of all intervention workers were finally sent to researchers of Leiden University for a check (page 7-8).

Homogeneity of the intervention is ensured, because for all participating families for each home visit a standardized protocol is used in which the goals and activities of the home visit are described. In addition, each intervention worker receives three supervision meetings with a VIPP-V coach to ensure the intervention in each family is carried out in a similar way (page 7-8).

We trained so many VIPP-V intervention workers, because the intervention process in each family is quite time consuming, making it preferable for intervention workers to treat only one family at the time. In addition, we hypothesize that the video-feedback intervention will prove to be effective. In that case it is convenient many intervention workers have already been trained in providing this intervention, making broad scale implementation more feasible.

3. Page 7, blinding: “researcher coding and analyzing the data will be blinded…” this is unclear, do the authors mean that the outcome assessor will be blinded to the intervention?

Researchers who will code parental sensitivity and the quality of parent-child interaction with the NICHD-scales will not know whether the observed family participated in the intervention or not, and will also remain blind to the assessment moment (pretest, post-test, follow-up).

Research assistants conducting the assessments are not blinded to the intervention, because different questionnaires are used for families participating in the intervention condition and in the control condition (families in the control condition are not asked about working alliance of the VIPP-V intervention worker). This has been stated more clearly on page 14.

4. Page 5, Inclusion and Exclusion Criteria: Minor comment: The WHO standards for defining visual impairment should be referenced.

We thank the reviewer for her careful reading of our manuscript, and have corrected this omission (page 6).

5. Page 9, Care-as-usual: It may be due to reporting, but it’s my understanding that the authors are not clear on what usual care is at the sites. If they do know what usual care looks like, it should be described as clearly as the intervention is. If they do not, the authors need to address more fully how they intend to compare the intervention and usual care groups more thoroughly, especially when usual care and the intervention are not dissimilar. I feel the need for reassurance in the text that the usual care group and the intervention group are distinct.

We thank the reviewer to pointing out this unclarity to us. At Royal Dutch Visio and Bartiméus families receive care for a wide range of issues and topics, such as mobility training and magnifier training for the child, and guidance for parents on parenting issues, play behavior and choice of schools. Care-as-usual can be quite diverse. Therefore all parents are asked at pretest, post-test and follow-up what kind of care they are currently receiving, and how many contact moments and how many hours of care they have received in the last month. We will use these variables as control variables in further analyses.
It is important to stress that families randomized into the experimental condition will receive both VIPP-V and care-as-usual, while families randomized into the control condition will receive only care-as-usual. VIPP-V is a new intervention and is currently only offered within the context of the study. Even though families in the control condition may receive guidance on parenting issues, they will not participate in a video-feedback intervention, because it is not currently being offered. We believe that through randomization, kind and amount of care-as-usual will be equally represented in both conditions. In addition, families in the experimental condition will also receive VIPP-V. Extra information on kind and amount of care-as-usual has been added to the paragraph on care-as-usual on page 8.

6. Page 14, data analysis: No mention of how the analysis will be adjusted for if there is baseline imbalance. There is no mention of stopping rules or interim analyses, even if not applicable this should be explicitly stated.

To reduce the risk for baseline imbalance a stratified randomization procedure is used (Roberts & Torgerson, 1999) in which equal representation of families from both Royal Dutch Visio and Bartiméus is pursued, as well as equal representation of children with varying chronological ages. A random allocation list will be generated in three blocks, based on three periods in which the intervention will be offered. After the second block a check will be done for baseline imbalances between conditions, so, if necessary, these imbalances can be corrected in the final block. This information has been added to the paragraph on Randomization (page 13). Baseline characteristics will be described in descriptive analyses. Before analysing, differences in baseline characteristics between the experimental and control condition will be checked. If differences are found, they will be reported and controlled for in further analyses (page 15).

Minor comments:
7. Page 13, measure of control variables: first sentence is grammatically incorrect
   This sentence has been changed to 'Potential stressful experiences during intervention and treatment integrity will be measured and used as control variables' (page 12).

8. Page 13, sample size calculation: The last sentence of this section could be in the section below.
   We have moved this sentence on the use of intention-to-treat analyses to account for drop-out to the section on drop-out (page 14).

9. I am surprised that I was not sent a completed SPIRIT checklist with this protocol.
   At the request of reviewer #2 we have added the SPIRIT checklist to the revised version of our manuscript. According to these guidelines we have added some requested information to the manuscript: we have added information on the allocation ratio (1:1; page 5, 13), added a figure on the data collection procedure (page 13, 25), added information on how families are informed on study progress and receive a general report at the end of the study (page 13), added a remark that intervention workers are, necessarily, not blinded to condition (page 14), added information about a check for outliers and winsorizing these outliers if necessary (page 15), added a paragraph on data management and monitoring (page 15), added information on publication policy, stating that all authors will have access to the full dataset, will have equal opportunity to publish on the dataset and the use of professional writers is not planned (page 16), and finally elaborated on the role of study sponsor (page 19).

Editor
1. The authors should clarify their primary outcome. Currently too many outcomes are listed as primary outcomes. The authors should clearly report the overall time frame indicating pre-specified time point(s) (e.g. difference from baseline to 3 months; average over 1 year (at baseline, 6, and 12 months); final values at 1 month; etc). The primary outcome should be consistent with the sample size calculation.
   As primary outcome measures this study focuses on parental sensitivity and parent-child interaction; these variables are described under ‘Primary outcome measures’ (page 8-9). Parental self-efficacy and parenting stress are studied as secondary outcome measures and the experiences of early intervention workers with VIPP-V during early intervention are studied as ‘Outcomes regarding feasibility of implementation’ (see also comment #1 of reviewer #1) (page 10). We have calculated the necessary sample size based on the effect size reported in a meta-analysis on randomized controlled trials of interventions focusing on maternal sensitivity (Bakermans-Kranenburg et al., 2003). To clarify the overall time frame of the study, we have included a figure (Figure 1) about the research procedure. In addition, in
the Data Analysis section (page 15) we have described how we plan to carry out analyses and how scores on primary and secondary outcome measures of families in the experimental condition will be compared with their own scores on a previous assessment, as well as with scores of families in the control condition at the same assessment. Change over time in outcomes from pretest to post-test and from pretest to follow-up will be assessed in the experimental group, and compared with the control group. Results will be described as rates of change (see also comment #2 of reviewer #1).

2. **Statistical analysis:** The authors should not plan within group comparisons as the aim of the trial is to compare both groups. They should clarify how they will take into account clustering, who will be responsible for the analysis (independent statistician). They should clarify why they use LOCF instead of multiple imputation.

The aim of this study is to study the effect of the video-feedback intervention VIPP-V. For this aim we will study an interaction effect between the between-subject factor (experimental vs. control condition) and the within-subject factor (assessment: pretest, post-test, follow-up) (page 14). In this study-design repeated measures are nested in families, families are nested in intervention workers, and intervention workers are nested in organisations. Before studying the intervention effect, we will therefore assess how much variation is present at higher levels to determine whether multilevel analyses are needed. If these analyses show a minimal level of clustering (design effect < 2.0; Peugh, 2010), ANOVA repeated measures will be carried out, otherwise multilevel modelling will be done (page 15). In multilevel modeling missing values are estimated on the variance and covariance of all participants on all assessments (Snijders & Bosker, 1999), and no additional analyses technique (such as LOCF or multiple imputation) is necessary. If ANOVA repeated measures are conducted we choose to use the principle of last observation carried forward (LOCF) instead of multiple imputation, because LOCF provides a more conservative estimate of the intervention-effect than multiple imputation which resembles our hypothesis of effectiveness more closely. We hypothesize the video-feedback intervention will improve parental sensitivity and the quality of parent-child interaction over time. Families will experience the most benefit of intervention if they participate in all sessions, and families who drop-out may not improve as much as families who finish the intervention.

Data are collected by research assistants who are not blinded to condition or assessment, because of practical feasibility. Every family participating in the study has been assigned an ID-number independent of condition. Researchers coding the observation data will be blinded to the condition of families as well as to the assessment (page 14). The authors of this manuscript will perform the analyses. They have not carried out any observation assessments, and will be blinded to condition of families because of the independent ID-numbers.

3. **Intervention:** to facilitate implementation in practice, authors should provide more details on how the care providers will be trained.

Researchers of Leiden University have trained eight special education- and behavioral- experts from Royal Dutch Visio and Bartiméus as coaches in a 5-day training. During this training period all eight coaches practiced VIPP in a pilot family, and received five intervention and three supervision sessions. At the end of the training period trainers from Leiden University checked the video-recordings and scripts of one of the seven home visits of all coaches. Then, two of these coaches (one of each organisation), in alternating collaboration with the second author, have trained fifteen early intervention workers in conducting VIPP-V. Early intervention workers received five days of training in VIPP-V and intervention sessions over a period of 2 months. During this same period the intervention workers also completed a VIPP-V intervention with a pilot family. Two of the trainers provided feedback for each intervention worker. After the training the VIPP-V training materials, video-recordings, scripts and provided feedback of the trainers of all intervention workers were sent to researchers of Leiden University for a final check. Homogeneity of the intervention is ensured, because for all participating families for each home visit a standardized protocol is used. In addition, each intervention worker receives supervision (see also comment #2 of reviewer #2; page 7-8).

4. **The authors should use the CONSORT guidelines for Nonpharmacologic treatments (Annals internal medicine 2008) to report their manuscript.**

We thank the reviewer for this suggestion, and provide with this revised manuscript, in addition to the SPIRIT checklist, the CONSORT guidelines for Nonpharmacologic treatment.
Editorial requests:
5. Please include the date your study was registered with your trial registration number at the end of the Abstract.
The trial was registered in the ‘Nederlands Trial Register’ on December 5th 2013. This date has been added to the trial registration number at the end of the abstract (page 2).

6. Please remove the tables from the main body of your manuscript.
Table 1 has been removed from page 7, and been added at the end of the manuscript (page 24). In the text is written where about the table should be placed.

7. Please include a list of abbreviations used in the manuscript and their meanings.
A list of used abbreviations has been added to the manuscript on the last page (page 26).

We thank you and the two reviewers for the careful attention paid to this manuscript and the many helpful suggestions. 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’.