

# Effects of VIPP-V training in early intervention with parents of (very) young children with visual impairments or visual-and-intellectual disabilities.

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The project aims to adapt Video-feedback Intervention to promote Positive Parenting (VIPP) for parents of children with visual and visual-intellectual disabilities (VIPP-V), to test the resulting program on its effectiveness, and to prepare the...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON40402

### Source

ToetsingOnline

### Brief title

Effects of VIPP-V training with parents of children with disabilities.

### Condition

- Other condition

### Synonym

Increase sensitive responsiveness caregiving parent; improve parent-child relationship

### Health condition

vergroten sensitieve responsiviteit ouder en verbeteren gehechtheidsrelatie ouder en kind

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit

**Source(s) of monetary or material Support:** ZonMW-Inzicht

## Intervention

**Keyword:** attachment, parent-child interaction, sensitivity, visual impairment and visual-and-intellectual disability

## Outcome measures

### Primary outcome

\* Sensitivity of parents for the behaviours of their child with a visual impairment or visual-and-intellectual disability, quality of parent-child interaction

Instruments: Emotional Availability Scale (EAS), National Institute of Child

Health and Human Development (NICHD) scales, Early Social Communication Scales (ESCS)

\* Self-efficacy of the parent with regard to parenting

Instrument: Parental Efficacy Scale (SENR)

\* Parenting stress

Instrument: Parental Stress Index (PSI)

### Secondary outcome

\* The experiences of the early intervention workers with regard to using VIPP-V during early intervention

Instruments: Social Validity Scale, with added open-ended questions

Moderator variables:

- \* The development of the child on cognitive, social and emotional aspects

Instrument: Vineland Adaptive Behavior Scale (VABS)

- \* Working alliance between parent and intervention worker

Instrument: Working Alliance Inventory (WAI)

- \* Empathy of the intervention worker

Instrument: Empathy Quotient (EQ-short)

## Study description

### Background summary

Each year in the Netherlands, there are approximately 880 (very) young children with a visual or visual-intellectual disability receiving care from Bartiméus and Royal Dutch Visio. For parents of infants diagnosed with a visual or visual-intellectual disability such diagnoses may come after a period of worry and uncertainty because infants with these disabilities respond differently to their caregivers (Howe, 2006). The period around the diagnosis is often highly emotional and can be characterized as a period of crisis, giving way, later on, to a gradual process of adaptation (Glidden & Jobe, 2009; Schuengel et al., 2009). It is, however, important to acknowledge that the period of diagnosis and the surrounding emotional and practical upheaval coincides with a very important period in children's lives, in which they lay the foundations for their development within close relationships with their parents. The development of secure attachment relationships with parents is fundamentally important for healthy and resilient development (Sroufe et al., 2005), especially so for children with disabilities (Baker et al., 2007; Schuengel & Janssen, 2006). Early intervention services have been developed that offer support in adapting to the disability and promoting optimal development. These interventions are not evidence-based and transferable through written protocols. Current early interventions for children with a visual impairment or with multiple disabilities are said to focus mainly on social, physical and cognitive development. Interventions take place in the home and use video for

focusing on interactions, but there is no protocol. It is therefore unclear to what extent the interventions include the components that have been proven effective for improving the quality of parent-infant interaction. Preisler (1991, 1997) suggested that too little systematic attention is given to the parent-child relationship in early intervention for parents of children with a visual impairment.

Scientific insights on the importance of sensitive parenting and secure attachments for social-emotional development increased enormously, for children with (Schuengel et al., 2013) and without disabilities (Juffer et al., 2008). For children without disabilities, this has led to considerable progress in evidence-based intervention. A meta-analysis on interventions (Bakermans-Kranenburg et al., 2003) indicated that interventions focusing on sensitive parenting showed significant positive results and were more effective than interventions with a broad focus, for example on social support. Based on these findings, Video-feedback Intervention to promote Positive Parenting (VIPP; Juffer et al., 2008) was developed, with a variant focusing on Sensitive Discipline (VIPP-SD; Van Zeijl et al., 2006). Randomized clinical trials have shown effects on maternal sensitivity, through sensitivity on attachment, and on behavior problems and stress regulation (Velderman et al., 2006; Van Zeijl et al., 2006; Bakermans-Kranenburg et al., 2008; Moss et al., 2011). VIPP-SD has been certified in the Dutch registry of evidence based youth interventions.

For parents with children with a visual impairment the focus on the parent-child relationship is very important as the child's behavior and interaction, their attempts to communicate with their parents, are so different and difficult to understand (Howe, 2006). Also, the parent may experience the child to be unresponsive due to absence of emotional expressions, e.g. the child having a blank face (Tröster & Brambring, 1992). For parents with a child with a visual and an intellectual disability this may also be the case due to the relatively slow speed at which the child processes social information and therefore the delayed reaction given by the child, or even the absence of a reaction (Anderson, 2001).

Howe (2006) noted that due to the difficulty to understand and interpret the child's needs and behaviors, parental stress may increase, reducing the emotional availability of the parent, and therefore the parent may be a less responsive caregiver. Through early intervention programs parents can learn to relate with their blind children in a sensorily appropriate and attuned ways (Affleck et al., 1997). The problem chosen to study is therefore to address the gap in evidence-based early intervention with infants with visual and visual-intellectual disabilities, building on the model of proven effective interventions in other populations.

The need for evidence-based interaction support was identified recently in a \*best practice on video feedback\* working group of professionals at Bartiméus (Braams et al., Bartiméus, 2011) and affirmed by a survey we did among parents using the current early intervention programs at Royal Dutch Visio and at

## **Study objective**

The project aims to adapt Video-feedback Intervention to promote Positive Parenting (VIPP) for parents of children with visual and visual-intellectual disabilities (VIPP-V), to test the resulting program on its effectiveness, and to prepare the field for broad scale implementation if the program is effective. By doing so, the quality of attachment relationships between parents and children will improve, which contributes to development of good mental health and resilience against stressors. This is achieved by giving parents the opportunity to notice specific behaviour of their child, to adequately interpret the specific behaviour and to respond accordingly. Within the attachment theory the combination of these skills is defined as 'sensitivity'. VIPP with adjustments was also found to be effective intervention for various difficult parenting situations, for example for parents with a child with autism (VIPP-AUTI), with a child with challenging behaviour (VIPP-SD; Juffer et al., 2008), and for parents with learning disabilities (VIPP-LD). Researchers of the VU University and the University of Leiden will collaborate when adapting VIPP to VIPP-V, as has been done before in the development of VIPP-LD (Hodes et al., 2012). VIPP is deemed more suitable for intervention with parents of young children with a visual or visual-intellectual disability than the CONTACT program, which has been shown to be effective in intervention for carers of adolescents and adults with visual and visual-intellectual disabilities (Damen, Kef, Worm, Janssen & Schuengel, 2011). However, the experience and knowledge gained in the project CONTACT will be used in the current project.

The scientific research questions that will be answered are:

1. Based on literature, which adjustments of the VIPP should be made for the VIPP-V?
2. Do families receiving VIPP-V show higher parenting self-efficacy, parental sensitivity, a higher quality of parent-child relationships and lower levels of parenting stress compared to families only receiving the early intervention as provided by Bartiméus and Royal Dutch Visio at the moment (care-as-usual)?
3. How do professionals working with VIPP-V rate the social validity (usefulness, difficulty, feasibility) as a potential component of early intervention?

## **Study design**

To answer the first research question regarding which adjustments of the VIPP-program should be made for VIPP-V a literature search will be done. To answer the second and third research question regarding the effectiveness and social validity of VIPP-V a randomized controlled trial (RCT) with two groups will be conducted. 50 parents will receive Video-feedback Intervention

to Promote Positive Parenting Visual impairments: VIPP-V + care-as-usual and 50 parents will receive care-as-usual only.

A cohort will be recruited from the population of parents receiving early intervention services from Royal Dutch Visio and Bartiméus. Parents of children older than 9 months and younger than 5 years, with a visual impairment or visual-and-intellectual disability will be asked to participate in the study. Using stratified randomization, equal representation of families from both Royal Dutch Visio and Bartiméus will be achieved, as well as equal representation of children with varying developmental ages. Pretest (before the start of the intervention), posttest (after the end of intervention) and follow-up (three months after finishing intervention) data of both groups will be gathered. Changes in the experimental group with VIPP-V will be compared with changes in the control group with care-as-usual. If changes in the experimental group are more positive, then this constitutes evidence that implementation of VIPP-V will improve early intervention.

Parents of a child with a visual impairment as well as parents of a child with a visual-and-intellectual disability can participate in this study. As the sensitivity of the parent, parent-child interaction, parental efficacy and parental stress are the primary outcome variables, higher scores on sensitivity and efficacy are expected for parents with a child with a visual impairment as well as for a parent with a child with a visual-and-intellectual disability. However, to be sure about this exploratory analysis on the effect size will be done concerning the included two sub-groups (children with a visual impairment and children with a visual-and-intellectual disability). The CONSORT Statement Guidelines for RCTs will be used for publication (Schulz, Altman, Moher, 2010).

VIPP-V consists of 7 home-visits. Five regular home-visits which are scheduled every other week, and two boostersessions in the next two months. Trained intervention workers will provide VIPP-V to the families, according to a manual with the goals and activities for each home visit.

Through video-feedback the parent-child interaction of each individual parent-child dyad will be analysed and discussed. This way families of different cultural backgrounds can participate in the intervention and in the study. If necessary interpreters will be used to translate the video-feedback. Parents in the control condition will receive care as usual: early intervention as ordinarily offered by Bartiméus and Koninklijke Visio.

Early intervention is generally offered every two weeks to about every three months, depending on the needs of the parent. Although the frequency of care in the care-as-usual group is lower than the frequency of care in the group of parents who receive VIPP-V, it is important that the frequency of the care-as-usual remains as it normally is offered. If parents would generally receive no intervention, another design such as a waiting-list control group would have been appropriate. Since parents already receive early intervention it

would be ethically unacceptable to deny them this care, therefore a care-as-usual design has been chosen.

Before pretest parents will be asked to fill out a questionnaire regarding demographic information: age, cultural and social-economic background, health of parents, severity of disability of the child, medical background of the child, use of medication of the child, age and possible disabilities of siblings. At pretest parents will be asked to fill in two questionnaires about parenting stress and parental self-efficacy. Also, parent and child will be asked to participate in a play task (Three Boxes, NICHD, 1999). Video-tapes of this play task and answers on the questionnaires will be used to determine the primary outcome measures. The total duration of each measurement is approximately 1 hour for parents and half an hour for intervention workers.

Parents who meet the inclusion criteria will be informed about the study. They will receive a letter approved by the medical ethical committee of the VU medical center. This letter will be sent by the organisations with an accompanying letter of the organisation. Parents will be asked to consent to participate in the study. If parents have questions about participation or the study in general they can phone or mail to one of the eight VIPP-V coaches working at Royal Dutch Visio and Bartiméus. If they wish to mail the researchers this is also possible. Independent professionals will also answer questions if necessary. After each assessment parents will receive a small gift (a ball, puzzle, etc.) for their child.

Not participating in the study will have no effect on the regular early intervention program parents receive. It will have no consequences for the parents if they decide to withdraw during the intervention, the care-as-usual will then continue. When the study is finished, all parents will receive a report on the general effect of VIPP-V. If parents would like to receive information on their individual results, they will receive the information via the early intervention worker.

Employees in early intervention for parents of children with visual or visual-intellectual disabilities of Bartiméus and Koninklijke Visio have been closely involved in this project from the start. They will remain closely involved during and after completion of this project. The parents' association FOVIG is also closely involved in this study from the start and supports this project wholeheartedly, as can be seen in the composition of the project group. Viziris is a network-organisation of and for people with a visual impairment. After consultation with mr. Hulsen, mrs. Haaijer, mother of a daughter with multiple (also visual) disabilities, has been asked to participate as a client representative on behalf of Viziris.

## **Intervention**

The 'Video-feedback Intervention to Promote Positive Parenting (VIPP)' training

will be adapted into the VIPP-V, which will focus on the specific behavioural repertoire of children with a visual impairment or visual-and-intellectual disability. The VIPP-V will consist of 7 home visits. Five regular home visits every other week, and two booster sessions in the next two months. The VIPP-V sessions will be conducted by specially trained early intervention workers. VU University Amsterdam and Leiden University have extensive experience in training professionals in VIPP and maintaining treatment fidelity through regular supervision.

The early intervention workers use a protocol in which the goals and activities of each home visit are described. The first part of every home visit will be used to video-tape parent-child interaction. The second part of each home visit is used to discuss the behaviour of the parent and child through video-feedback. Parents will learn how they can interpret and understand the behaviour of their child with a visual impairment or visual-and-intellectual disability. Furthermore, sensitive and responsive ways of responding to the child's behaviour will be discussed. VIPP-V is based on the attachment theory, focusing on increasing parental sensitivity and the parent-child interaction. In order to answer the question whether VIPP-V is effective, changes in the experimental group with VIPP-V will be compared to changes in the control group with care-as-usual (CAU). If changes in the experimental group are more positive, then this constitutes evidence that implementation of VIPP-V will improve early intervention. Given sample size and time restrictions, no attempt will be made to dismantle the effective components of VIPP-V using a more complex design.

## **Study burden and risks**

In this study parents will be asked to fill out several questionnaires, the approximate time consumption for this is estimated at 3 hours. None of these questionnaires will pose a risk to the parents.

In addition, parents randomized into the experimental condition will participate in VIPP-V (7 home visits of 1.5 hours each = 10.5 hours in total). Even though participating in VIPP-V will ask a time investment of parents, we expect parents who participated in VIPP-V will learn to better interpret signals of the child, which may improve the parent-child relationship.

Experiences as learned from the study "What Works" (VU FPP), will be used to minimize potential risks and burden.

## **Contacts**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

- Parents of children with a visual impairment or visual-and-intellectual disability
- Children older than 9 months and younger than 5 years
- Visual impairment as defined according to the WHO standards, intellectual or learning disability as assessed by the clinical psychologist (gz-psycholoog) or pedagogue
- Written consent given by the parents for participation in the study
- Parents with a visual or auditory impairment will be included as participants
- Parents who are blind and/or deaf will be included as extra case studies, as it is not yet known how these parents can use video-feedback

### **Exclusion criteria**

- Children who do not live at home, for example due to hospitalization for serious medical problems
- Parents with an intellectual disability. For these parents an adapted training (VIPP-LD) is developed and currently tested by researchers of the VU University Amsterdam

- Siblings of participating children (only one child per family can participate in the study)

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	05-05-2014
Enrollment:	100
Type:	Actual

## Ethics review

Approved WMO	
Date:	11-02-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

### Register

CCMO

### ID

NL47334.029.13