Video-feedback intervention to promote positive parenting and sensitive discipline in families with twins

Submission date	Recruitment status No longer recruiting	Prospectively registered		
28/07/2021		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
05/08/2021	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
28/01/2022	Other			

Plain English summary of protocol

Background and study aims

Interventions to help parents in their interaction with children have been not highly effective. The aim of this study is to test the VIPP-SD intervention, which is a video-feedback intervention that tries to improve the sensitivity of the parents and sensitive discipline. The study also tests whether the success of the intervention depends on the temperament of the parents.

Who can participate?

Parents with twins living in the western region of the Netherlands

What does the study involve?

The study involves six yearly visits, alternating home visits and lab visits. Families are randomly allocated to the intervention group or the control group. Families in the intervention group receive the VIPP-SD intervention, which includes five biweekly sessions during which the researcher films about 15 minutes of parent-child interactions and provides feedback on the child's or parent's behavior of the previous session based on the theme of the session. Families in the control group receive five phone calls parallel to the intervention sessions to assure that they had the same number of contacts. Families are interviewed about the general development of their twins.

What are the possible benefits and risks of participating?

No risks are anticipated. Benefits for the participants are that they receive reimbursements for each visit. Furthermore, they receive videos of their interactions with their children.

Where is the study run from? The University of Leiden (Netherlands)

When is the study starting and how long is it expected to run for? June 2012 to October 2021

Who is funding the study?

The Leiden Consortium on Individual Development (L-CID) is funded through the Gravitation program of the Dutch Ministry of Education, Culture, and Science and the Netherlands Organization for Scientific Research (NWO grant number 024.001.003). Additional funding was provided by the Netherlands Organization for Scientific Research (MJBK: VICI Grant no. 453-09-003; MHvIJ: NWO SPINOZA prize).

Who is the main contact?

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- 2. Eveline Crone
- 3. Marinus Van IJzendoorn

Contact information

Type(s)

Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

NTR5312

Study information

Scientific Title

The effect of the VIPP-SD on parental sensitivity and sensitive discipline in parents of schoolaged twins: a randomized controlled trial replication of the preschooler twin study

Acronym

VIPP-SD Twin MC

Study objectives

It is hypothesized that:

- 1. Sensitivity and sensitive limit-setting of parents in the intervention condition will significantly decrease less or increase more post-intervention, compared to sensitivity and sensitive limit-setting of parents in the control condition
- 2. VIPP-SD effects will be similar for both twins within a family, thus the addition of the child level in the model will not explain significant variation
- 3. Parents who are more temperamentally reactive will profit more from the VIPP-SD than parents with lower reactivity

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 19/05/2015, the Central Committee on Research Involving Human Subjects (CCMO, Postbus 16302, 2500BH Den Haag, The Netherlands; +31 (0)703406700; ccmo@ccmo.nl), ref: NL50277.058.14

Study design

Single-center longitudinal randomized controlled trial intervention study

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Parental sensitivity and sensitive discipline

Interventions

Method of randomization

The researchers randomized the study sample at the family level in a ratio of 2:3 using a computer-generated blocked randomization sequence (block size = 19 families, stratified by timing of the intervention and twin sex). 91 (37%) families were allocated to the intervention group and 152 (63%) families were allocated to the control group. Due to limited resources, it was not possible to have a 50-50 split for intervention and control group, however, the power of the study was only marginally affected by this ratio. The researchers randomized the sample

after the second wave (T2) before the intervention to avoid selective attrition. An independent researcher who was not involved in data collection or data coding assigned the families to either condition using a random numbers generator.

Methodology

The VIPP-SD (Juffer, Bakermans-Kranenburg, & Van IJzendoorn, 2008) includes five biweekly sessions during which the intervener filmed approximately 15 minutes of standardized parentchild interactions and provided feedback on the child's or parent's behavior of the previous session based on the theme of the session. Families in the control condition received five phone calls parallel to the intervention sessions to assure that they had the same number of contacts. Following a standard protocol, families were asked about the general development of their twins using a semi-structured interview.

Total duration

The total duration of the intervention is 10 weeks, whereas the time from the first assessment until the third assessment (including the intervention) is 2 years (T1: pretest, T2: pretest, T3: posttest, with intervening periods of 1 year and the intervention taking place between T2 and T3).

Intervention Type

Behavioural

Primary outcome(s)

- 1. Parental sensitivity measured using observation of the computerized version of the Etch-A-Sketch task coded using the revised Erickson 7-point rating scale at baseline (T1), 12 months later (T2) and 24 months later (T3)
- 2. Parental sensitive discipline measured using observation of the adapted version of the Do-Don't task coded using the revised Erickson 7-point rating scale at baseline (T1), 12 months (T2) later and 24 months later (T3)

Key secondary outcome(s))

1. Social competence of the children measured using a parent-report questionnaire at baseline (T1) (Strength and Difficulties Questionnaire), 12 months later (T2) and 24 months later (T3) 2. Inhibitory control of the children measured using a parent-report questionnaire (Temperament in Middle Childhood Questionnaire (TMCQ)) at baseline (T1) and 12 months later (T2) and the Early Adolescent Temperament Questionnaire (EATQ) 24 months later (T3)

Completion date

15/10/2021

Eligibility

Key inclusion criteria

- 1. Twin families from the western region of the Netherlands
- 2. Twins have the same gender
- 3. Parents are Dutch speaking
- 4. Parents and grandparents are European

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Total final enrolment

256

Key exclusion criteria

Being a parent of a twin child with a congenital disability, psychological disorder, chronic illness, hereditary disease, visual/hearing impairment, or an IQ of <70

Date of first enrolment

01/01/2015

Date of final enrolment

31/12/2015

Locations

Countries of recruitment

Netherlands

Study participating centre Leiden University Medical Center

Albinusdreef 2 Leiden Netherlands 2333 ZA

Sponsor information

Organisation

Dutch Research Council

ROR

https://ror.org/04jsz6e67

Funder(s)

Funder type

Research council

Funder Name

Nederlandse Organisatie voor Wetenschappelijk Onderzoek

Alternative Name(s)

Netherlands Organisation for Scientific Research, Dutch National Scientific Foundation, Dutch National Science Foundation, Dutch Research Council (Nederlandse Organisatie voor Wetenschappelijk Onderzoek), NWO:Nederlandse Organisatie voor Wetenschappelijk Onderzoek, Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO), Dutch Research Council, The Dutch Research Council (NWO), Dutch Research Council, Netherlands, NWO

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Netherlands

Funder Name

Ministerie van Onderwijs, Cultuur en Wetenschap

Alternative Name(s)

Ministry of Education, Culture and Science, Netherlands, OCW

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Marian Bakermans-Kranenburg (mjbakermans@gmail.com). Pseudonymized data will be shared upon request. Data sharing starts 1 year after the end of the project (01/10/2024). The data will be shared after approval of the request for data sharing and when a Data Transfer Agreement (DTA) has been signed by both parties. The duration of sharing the data will

be agreed upon with the requesting party. Data will be shared with researchers interested in collaborating and using the data for research purposes, in line with the FAIR principles. A Data Transfer Agreement (DTA), specifying the aim and type of data sharing, will be signed by both parties. This ensures a legal basis for data sharing and prevents overlap of research projects. Data will be shared via a secured drive or digital research environment in accordance with data security guidelines as is common practice with the University of Leiden and the Vrije University of Amsterdam. Participant consent was obtained to use the data for research purposes.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/01/2022	28/01/2022	Yes	No
Protocol article			05/08/2021	Yes	No
Protocol article			05/08/2021		No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes