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

Submission date	Recruitment status	[_] Prospectively registered
28/07/2021	No longer recruiting	[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?
1. Marian Bakermans-Kranenburg, m.j.bakermans@vu.nl
2. Eveline Crone
3. Marinus Van IJzendoorn

Study website
https://www.samen-uniek.com/

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NTR5312

Study information

Scientific Title
The effect of the VIPP-SD on parental sensitivity and sensitive discipline in parents of school-aged 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

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
See additional files

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 parent-child 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 measure
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)

Secondary outcome measures
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)

Overall study start date
01/06/2012

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

Age group
Mixed

Sex
Both

Target number of participants
250

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

Sponsor details
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Sponsor type
Research council

Website
https://www.nwo.nl/

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, 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

Publication and dissemination plan
1. A pre-registration is available online: https://doi.org/10.17605/OSF.IO/AMR5P
2. Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/12/2021

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?
Protocol article			05/08/2021	Yes	No
Protocol article			05/08/2021	Yes	No
Results article		27/01/2022	28/01/2022	Yes	No