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Father trials: video feedback to promote positive parenting for expectant fathers

Submission date	Recruitment status	[_] Prospectively registered
26/06/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/06/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/10/2022	Other	

Plain English summary of protocol

Background and study aims
This study examines whether a brief video-feedback program using ultrasounds with fathers during the pregnancy of their first child leads to more sensitive and more involved fathering after the baby's birth, compared to phone calls on the development of their unborn child. The study also tests whether the father's hormone levels and brain activity are influenced by the video feedback.

Who can participate?
Fathers whose partners are 20 weeks pregnant from their first infant

What does the study involve?
Participants are randomly allocated to receive either three sessions of video feedback to stimulate father-unborn infant interaction, or three phone calls on the development of their unborn infant. Parental sensitivity is measured through observation before the intervention using a life-like baby doll, and after the intervention during 10 minutes of interaction with the own infant at age 2 months

What are the possible benefits and risks of participating?
There are no known risks. Benefits may be the pleasure of extra ultrasounds or knowledge about the development of the unborn baby

Where is the study run from?
Leiden University and Vrije Universiteit Amsterdam (Netherlands)

When is the study starting and how long is it expected to run for?
October 2014 to September 2020

Who is funding the study?
European Research Council (Belgium)

Who is the main contact?
Prof Dr Marian Bakermans-Kranenburg
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Study website
http://www.vadersinbeeld.nl/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CCMO NL62696.058.17

Study information

Scientific Title
Efficacy of a prenatal video-feedback intervention to promote positive parenting for expectant fathers (VIPP-PRE) using live ultrasound images

Acronym
VIPP-PRE

Study objectives
1. The Prenatal Video Feedback lntervention to promote Positive Parenting (VIPP-PRE) results in different hormonal, neural, and behavioral responses to infant stimuli and video clips designed to elicit protective parenting
2. VIPP-PRE promotes fathers' parenting in terms of quantity (involvement) and quality (sensitive interaction)
3. VIPP-PRE affects fathers' basal hormonal levels (i.e. oxytocin, vasopressin, cortisol, estradiol, and testosterone), which in turn may mediate neural and behavioral effects

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/03/2018, Ethics Committee Leids Universitair Medisch Centrum (Albinusdreef 2, 2300RC Leiden, Netherlands; +31 (0)715263241; cme@lumc.nl), ref: b. P17/216/SH/sh, NL62696. 058.17

Study design
Interventional blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Prenatal and postnatal parenting

Interventions
This is a randomized controlled trial (RCT) with a between-subject design in a critical phase of parenthood: the transition to having the first baby. It focuses on the 50% of parents who have been neglected in parenting research and - until recently - in family policies: fathers. ln most western countries fathers have increased their participation in parenting over the past decades. And even though in most families the participation of fathers in child-rearing is modest, the parental role of fathers is highly relevant for child development. This study will test the effects of a prenatal version of the Video Feedback lntervention to promote Positive Parenting (VlPP) on fathers' hormonal levels, on their processing of infant signals, and on their parenting behavior, including the quantity (involvement) and quality (sensitivity) of father-child interaction. The proposed study tests whether exposure to and interaction with the unborn

infant increase the father's involvement during pregnancy and after birth. A special focus is on a dimension of parenting that has received considerable attention in animal research but, despite its evolutionary importance, not in studies on humans: the role of the parent as protector.

The RCT includes an experimental group and a control group (randomised using a random number generator) and will be conducted during pregnancy (i.e. gestational age 20-30 weeks). The interventions start 1-2 weeks after the pretest. The first posttest is administered 1-2 weeks after the intervention, and a follow-up 5- 6 months later (i.e. infant is 8 weeks old).

A total of 140 (2 x 70) fathers having their first baby were planned to be included. Due to a number of factors (recruitment turned out to be difficult, and COVID-19), inclusion was ended when N = 73 fathers had been included.

Participants are randomly allocated to receive either three sessions of video feedback to stimulate father-unborn infant interaction (VIPP-PRE program), or three phone calls on the development of their unborn infant.

The VIPP-PRE program consists of three visits to the ultrasound centre between the 21st and 31st week of pregnancy. The visits take place every 1-2 weeks and last for approximately one hour. Fathers will be invited to interact with the fetus both verbally and by touching and softly massaging the infant through the mother's abdominal wall. The baby's behavior will be made visible through ultrasound.

The main study parameters are:
1. Parenting behavior, including physiological response to infant stimuli ("handgrip task"), sensitivity ("quality of care"), involvement ("quantity of care"), and protection ("Enthusiastic Stranger Paradigm"). The study will examine the effects of VIPP-PRE on these parenting behaviors.
2. Activity in brain areas associated with parenting. The study will examine the effects of VIPP-PRE on activity in these areas in fathers during the processing of infant signals and brief video vignettes designed to elicit protective parenting.
3. Oxytocin, vasopressin, and estradiol levels will be assessed in saliva. Cortisol and testosterone will be assessed in both saliva and hair samples. Saliva samples are used to measure current hormonal levels. Hair samples provide information on hormone levels in the recent past: as human scalp hair grows approximately 1 cm per month, hormone concentrations in 1 cm hair reflect the mean exposure of 1 month.

These assessments have all previously been approved by the METC and the CCMO (see N154702.058.15 and nr. NL49069.000.14) and tested in a pilot sample (see N154702.058.15 and P15.359).

ln line with the pilot study (see NL54702.058.15), participants will answer questions through a mobile app and online questionnaires at home. Similarly, the partners of the participants will complete online questionnaires. Participants will provide additional saliva samples in between visits

Intervention Type
Behavioural

Primary outcome measure
Parental sensitivity measured through observation before the intervention using a life-like baby doll, and after the intervention during 10 min of interaction with the own infant at age 2 months

Secondary outcome measures
1. Hormonal levels measured from saliva and hair samples at pretest, at prenatal posttest 1 week after the intervention, and at 2 months after the birth of the baby
2. Brain structure, connectivity, and reactivity measured using (f)MRI at pretest, at prenatal posttest 1 week after the intervention, and at 2 months after the birth of the baby

Overall study start date
17/10/2014

Completion date
01/09/2020

Eligibility

Key inclusion criteria
1. First-time expectant fathers
2. Sufficiently fluent in Dutch
3. Living with their partner who had an uncomplicated pregnancy of a singleton and was between 18 and 31 weeks pregnant at the time of inclusion

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
140

Total final enrolment
73

Key exclusion criteria
1. No endocrine or cardiovascular disease
2. No current drugs or alcohol abuse
3. No medication potentially interfering with the endocrine system of neural activity
4. No birth defects in the families of either parent
5. Not having partners that used alcohol, tobacco, or illicit drugs during the pregnancy or had a body mass index (BMI) over 30 kg/m² before pregnancy

Date of first enrolment
01/05/2018

Date of final enrolment

31/01/2020

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University
Wassenaarseweg 5
Leiden
Netherlands
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Study participating centre
Vrije Universiteit Amsterdam
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Sponsor information

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University/education

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Sponsor type
Government

Website
https://erc.europa.eu/about-erc/contact-us

ROR
https://ror.org/0472cxd90

Funder(s)

Funder type
Government

Funder Name
H2020 European Research Council

Alternative Name(s)
H2020 Excellent Science - European Research Council, European Research Council, H2020 Wissenschaftsexzellenz - Für das Einzelziel 'Europäischer Forschungsrat (ERC)', H2020 Ciencia Excelente - Consejo Europeo de Investigación (CEI), H2020 Excellence Scientifique - Conseil européen de la recherche (CER), H2020 Eccellenza Scientifica - Consiglio europeo della ricerca (CER), H2020 Doskonała Baza Naukowa - Europejska Rada ds. Badań Naukowych (ERBN), EXCELLENT SCIENCE - European Research Council, WISSENSCHAFTSEXZELLENZ - Für das Einzelziel 'Europäischer Forschungsrat, CIENCIA EXCELENTE - Consejo Europeo de Investigación, EXCELLENCE SCIENTIFIQUE - Conseil européen de la recherche, ECCELLENZA SCIENTIFICA - Consiglio europeo della ricerca, DOSKONAŁA BAZA NAUKOWA - Europejska Rada ds. Badań Naukowych, ERC, CEI, CER, ERBN

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan

The protocol for the data analysis has been registered on the OSF: https://osf.io/2qw3m/

Planned publication in a high-impact peer-reviewed journal of the effectiveness of the intervention on fathers' behavior, hormones, and neural reactivity

Intention to publish date

01/11/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Dr Marian Bakermans-Kranenburg (m.j.bakermans@vu.nl or mjbakermans@gmail.com). Pseudonymized data will be shared, and in some cases (dependent on the participants' specific permission) videotaped parent-infant interactions can be shared. The data will become available 1.5 years after the end of the project, i.e. 1 July 2023; data will be available for a period of 10 years. A data and material license agreement, 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 have been pseudonymized when possible.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/07/2022	06/10/2022	Yes	No
Results article		01/08/2022	06/10/2022	Yes	No
Protocol file	version 1	18/07/2017	13/10/2022	No	No