

Effects of a soft baby carrier on fathering

Submission date 29/06/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/07/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/10/2021	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The aim of this study is to test whether the use of either a soft baby carrier or an infant seat 2 months after the birth of their first baby is associated with more sensitive and involved fathering, different hormonal levels, and different brain responses to infant signals.

Who can participate?

Men who recently had their first baby

What does the study involve?

Participants are randomly allocated to receive either a soft baby carrier or an infant seat, to be used 6 hours per week for 3 weeks. The quality of their interaction with their infant is measured using scales at the start of the study, after the intervention (3.5 months) and at follow-up (7 months). Involvement in infant care is measured using a questionnaire and a mobile phone application, hormone levels are measured using saliva and hair samples, and brain activity is measured using MRI scans at the same timepoints.

What are the possible benefits and risks of participating?

Participants can enjoy interacting with their infant in the infant seat, or carrying their baby around in the soft baby carrier. No risks are known.

Where is the study run from?

Vrije Universiteit Amsterdam and Leiden University (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?

Marian Bakermans-Kranenburg, PhD
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Study website

<http://www.vadersinbeeld.nl/>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CCMO NL62692.058.17

Study information

Scientific Title

Effects of a soft baby carrier on fathers' hormonal levels, neural processing of infant signals, and parenting behaviour

Study objectives

1. An intervention with a baby carrier (versus an infant seat) for fathers in the early postnatal phase results in different hormonal, neural and behavioral responses to infant stimuli
2. The baby carrier intervention promotes fathers' parenting in terms of quantity (involvement) and quality (sensitivity)
3. The baby carrier intervention affects fathers' basal hormonal levels that may mediate neural and behavioral effects

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 21/02/2018, Ethics Committee of the Leiden University Medical Centre on behalf of the Central Committee on Research Involving Human Subjects (CCMO) (Albinusdreef 2, 2300 RC Leiden, Netherlands; +31 (0)715263241; cme@lumc.nl), ref: P17.215, NL 62692.058.17

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Sensitive and involved parenting in fathers

Interventions

Participants are randomised using a random number generator, odd vs even numbers decided on assignment.

This intervention manipulates the amount of physical contact between father and child. Fathers in the intervention group (half of the sample, randomly selected) will receive an ergonomic soft baby carrier. Infants in the carrier are chest to chest with their father, supported by the adult's upper torso. Fathers are requested to use the baby carrier for at least 6 hours per week, spread over a minimum of 4 days, for 3 weeks. Fidelity will be measured using a motion logger and a temperature data logger fixed to the baby carrier.

In parallel with the intervention sessions, the fathers in the control group are invited to have their baby close by in a baby seat, a Doomoo seat (Doomoo, 2004), inducing proximity between the father and baby without physical contact. Fathers are requested to use the baby seat for at least 6 hours per week, spread over a minimum of 4 days, for 3 weeks. Fathers receiving the control intervention who use a baby carrier will not be discouraged from doing so. The researchers will use intent-to-treat analyses, keeping them in the control group.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Kodaki Flip or Ergobaby Adapt infant carrier, Doomoo infant seat

Primary outcome measure

Quality of interaction with infant measured using the Ainsworth (1974) observation scales and Challenging Play Behavior scales at baseline (2 months), after the intervention (3.5 months) and at follow-up (7 months)

Secondary outcome measures

1. Involvement in infant care measured using a questionnaire and a mobile phone application at baseline (2 months), after the intervention (3.5 months) and at follow-up (7 months)
2. Oxytocin levels and cortisol levels (baseline and reactivity to interaction with infant) measured using saliva and hair samples at baseline (2 months), after the intervention (3.5 months) and at follow-up (7 months)
3. Differential activity and connectivity in parental brain areas, resting state and reactivity to infant stimuli, measured using (f)MRI at baseline (2 months), after the intervention (3.5 months) and at follow-up (7 months)

Overall study start date

17/10/2014

Completion date

01/09/2020

Eligibility

Key inclusion criteria

1. Male adults who recently had their first baby
2. The infant is healthy and full-term (i.e., born after 37 weeks of gestation)

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Male

Target number of participants

140

Total final enrolment

80

Key exclusion criteria

1. Not cohabitating with the biological mother of the child
2. No mastery of the Dutch language

3. A current endocrine disorder, or the use of medication potentially interfering with the endocrine system
4. A cardiovascular disease
5. A psychiatric disorder
6. Current heavy drinking, regular use of soft drugs, use of hard drugs within the past 3 months
7. MRI contraindications (e.g., metallic foreign objects, a neurological disorder)
8. Using a baby carrier for over 5 hours per week at the time of inclusion
9. Having an upper torso injury that could hinder the use of a baby carrier

Date of first enrolment

02/03/2018

Date of final enrolment

21/02/2020

Locations

Countries of recruitment

Netherlands

Study participating centre

Vrije Universiteit Amsterdam

Van der Boechorststraat 7

Amsterdam

Netherlands

1085BT

Study participating centre

Leiden University

Wassenaarseweg 5

Leiden

Netherlands

2300RB

Sponsor information

Organisation

European Research Council

Sponsor details

Covent Garden

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Sponsor type

Research council

Website

<https://erc.europa.eu>

ROR

<https://ror.org/0472cxd90>

Funder(s)

Funder type

Research council

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

1. Protocol (Open Science Framework (OSF) preregistration) at <https://osf.io/6q3t5/>
2. Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/11/2021

Individual participant data (IPD) sharing plan

The Principal Investigator should be contacted for access to the datasets: 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 interaction can be shared. The data will become available 1.5 years after the end of the project, i.e. 1 July 2023; they 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?
Other publications	Pretest results	30/06/2021	05/08/2021	Yes	No
Results article		01/10/2021	12/10/2021	Yes	No