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Effects of a soft baby carrier on fathering

Submission date
29/06/2021

Recruitment status
No longer recruiting

Registration date
22/07/2021

Overall study status
Completed

Last Edited
12/10/2021

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Quality of life

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(s)
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)

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

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

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, EXCELLENT SCIENCE - European Research Council, H2020 Ciencia Excelente - Consejo Europeo de Investigación (CEI), CIENCIA EXCELENTE - Consejo Europeo de Investigación, H2020 Wissenschaftsexzellenz - Für das Einzelziel 'Europäischer Forschungsrat (ERC)', WISSENSCHAFTSEXZELLENZ - Für das Einzelziel 'Europäischer Forschungsrat, H2020 Excellence Scientifique - Conseil européen de la recherche (CER), EXCELLENCE SCIENTIFIQUE - Conseil européen de la recherche, ECCELLENZA SCIENTIFICA - Consiglio europeo della ricerca, H2020 Eccellenza Scientifica - Consiglio europeo della ricerca (CER), ERC, CEI, CER

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

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.nlor, 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?
Results article		01/10/2021	12/10/2021	Yes	No
Other publications	Pretest results	30/06/2021	05/08/2021	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes