

# Effects of a soft baby carrier on fathering

<b>Submission date</b> 29/06/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/07/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/10/2021	<b>Condition category</b> 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  
m.j.bakermans@vu.nl

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Marian Bakermans-Kranenburg

**ORCID ID**

<https://orcid.org/0000-0001-7763-0711>

**Contact details**

Paulus Buysstraat 13

Leiden

Netherlands

2334 CH

+31 (0)642565426

[m.j.bakermans@vu.nl](mailto:m.j.bakermans@vu.nl)

## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

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](mailto: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.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?
<a href="#">Results article</a>		01/10/2021	12/10/2021	Yes	No
<a href="#">Other publications</a>	Pretest results	30/06/2021	05/08/2021	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes