

# Baby sleep field test

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON40752

### Source

ToetsingOnline

### Brief title

Baby Sleep field test

### Condition

- Other condition

### Synonym

niet van toepassing

### Health condition

geen aandoening, onderzoek met gezonde deelnemers

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Philips Research

**Source(s) of monetary or material Support:** Philips financiert dit onderzoek

## Intervention

**Keyword:** Infant sleep

## Outcome measures

### Primary outcome

The main study parameters are physiological and biomechanical signals and the baby's sleeping behaviour.

### Secondary outcome

The qualitative information coming from the interviews at the end of the recording period will be used for development of the embodiment of a consumer product that will give feedback to the parents about the sleeping behaviour of their child.

## Study description

### Background summary

We are aiming to support parents with developing healthy sleeping patterns for their babies. In order to do so it is essential to give the parent more insight into the sleeping behaviour of their little one. Hence, we need to measure this sleeping behaviour in a home setting in a way that is acceptable for parents.

### Study objective

The primary aim of this test is to gather real-life data for development of a proposition to give feedback to parents on their baby's sleep. In addition, we will also evaluate the proposition together with the parents that are participating in the study.

### Study design

Babies will be monitored during bedtime for 7 consecutive days/nights, in their own baby bedroom to measure physiological and biomechanical signals. No obligatory interventions will take place, and as such this can be regarded as

observational study.

### **Study burden and risks**

The study needs to be carried out with baby\*s aged between 1 and 12 months, because we are aiming to develop a proposition that is specified for this target group, and their sleep behavior and body characteristics are clearly distinct from other age groups.

The risks involved in this study are minimized as well as the burden for the baby and their parents. Parents will be asked to switch on the measurements before the baby goes to sleep and switch them off when they take the baby out of bed. In addition, we will ask for their feedback and suggestions for improvement. This requires active involvement from their side, which takes time from the busy parent and can be seen as a potential burden. However, this active participation may also be very rewarding since they contribute to development of products that they, or other parents, might profit from in the future.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Children (2-11 years)

### Inclusion criteria

Healthy term babies aged between 1-12 months who are mild problem sleepers defined based on the Brief Infant Sleep Questionnaire (BISQ) as follows: baby's that display at least 3 days during the week the following behavior: >2 wake-up times per night, or >half an hour in wakefulness during the night. Only babies who are used to sleeping in their own bed and bedroom will be included in the study.

### Exclusion criteria

Infants will be excluded from participation in case they suffer from any medical complaint.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 10-09-2015

Enrollment: 16

Type: Actual

## Ethics review

Approved WMO

Date:	16-12-2014
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	15-04-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL50539.028.14