Baby breathing monitoring @home

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON51291

Source
ToetsingOnline

Brief title
Baby breathing

Condition

- Other condition

Synonym
healthy physiology, movement

Health condition

Het onderzoek heeft geen betrekking op een aandoening. In de studie werken we alleen met gezonde baby□s. De beoogde uiteindelijke toepassing zal ook alleen voor gezonde kinderen gebruikt mogen worden.

Research involving
Human

Sponsors and support

Primary sponsor: Philips
Source(s) of monetary or material Support: bedrijven; Philips Research financiert het onderzoek

Intervention

Keyword: Home setting, Infants, Physiology, Unobtrusive monitoring

Outcome measures

Primary outcome

Can we measure baby behavior and physiology by camera and / or wearable?

- Video recordings will be made at the participants* home. These recordings

will be used afterwards to test if we are able to measure the behaviour and/or

of the baby.

Secondary outcome

Study 1:

- Can we measure breathing at all by camera when the baby is in bed?

- Can we measure when the baby is in and out of bed?

- Can we derive sleep stages from the data?

- Can we distinguish the baby (audio & movement) from other people near the bed

(i.e. parents and/or siblings)?

Study description

Background summary

Philips Research is investigating if it is possible to monitor the behavior and physiology of babies using a camera and/or wearable to reassure parents w.r.t. the behavior of their baby by using these devices. Monitoring algorithms can be developed by analyzing video recordings of healthy babies in the home situation.

In this study data will be collected with either on-the-market devices (Baumer camera, PC), modified devices (baby monitor, the only modification is making the data available for storage so that the video can be analysed retrospectively) and a prototype (Smartmattrass / Bender - DOC issued, the matrass measures movement). The system will only collect data.

The data will be analysed after data collection has ended to investigate whether it is possible to develop algorithms that can meet the requirements of the secondary goals.

Study objective

The aim of the study is to collect video recordings which will be used retrospectively internally at Philips to test whether an algorithm can be used to measure the behavior and physiology of babies by using a camera and/or wearable. Development of, and testing if the algorithm can perform, will be done afterwards at Philips and not while recording are performed at the participant*s home.

Study design

The study is an observational study. The collection of the recordings will be done at the parents* home. Two cameras will be placed next to the baby*s bed. Beneath the mattress of the bed, the smart mattress will be placed.

The two sessions per participant are as follows: During the first home visit a couple of questions will be asked about the sleep behavior of the baby. The baby-sleep-diary will be explained and the set-up will be installed next to the baby bed. During the second home visit, parents will be asked for their feedback and the set-up will be taken back to Philips. In between the two home visits, recordings will be made of the baby bed and the baby when it is in bed. The recordings will take 36-48 hours in total.

When a subject decides to stop the study participation, an extra subject will be recruited to complete the data set.

Study burden and risks

The total time needed for the two home visits and filling in the baby sleep diary will be two hours. Home visit 1 takes about 45 minutes, home visit 2 takes about 30 minutes. In between the 2 home visits, recordings will be made of the baby bed and the baby while it is in bed for 48 hours maximum.

A risk analysis has been done for the study. The expected risk is low. Interventions will not be done in this study. During the study video recordings will be made using 2 cameras: a baby video monitor and a Baumer camera. The

software of the baby video monitor has been adapted for this study to be able to store the recordings at the PC which is commercially available. The Baumer camera is also commercially available. The smart mattress measures the movement of the baby. The mattress is a prototype. A risk analysis has been done for this device (see Technical file) and a Declaration of Conformity is available.

The burden for the baby is low. We don*t ask for a change in the daily rhythm of the baby, we even want to keep the rhythm as it is. For the participation in the study, the baby doesn*t have to do any extra actions.

Recordings will be screened, and if it is the case that there are recordings of e.g. parents which are not dressed, the recordings with this information will be deleted before storage for the analysis.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Babies and toddlers (28 days-23 months)
Newborns

Inclusion criteria

Participation in the study is possible when parents :
• Have a baby aged >3 weeks to 10 months;
• Have a baby who sleeps in its own bed (i.e. different sleeping surface than parents; same room is allowed);
• Live in the Netherlands;.
• Are able to speak and read Dutch or English.

Exclusion criteria

Participation in the study is not possible when:
• the baby is under supervision of an Health Care professional because of health, feeding or developmental problems;
• the parents or caregivers are unwilling or unable to provide informed consent on behalf of you, your baby and other children.
• the parents or caregivers are unwilling or unable to comply with the study requirements
• the parents or caregivers do not give permission to use their audio-video image data recorded during the study as described in the information letter and privacy notice
• the parents or caregivers are not able to fill in the questionnaires and baby sleep diary

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):	07-02-2022
Enrollment:	20

Type:	Actual

Ethics review

Approved WMO Date:	22-12-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-03-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-08-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL79600.100.21
Other	nog niet bekend, onder review