Changes in sleep and arousal patterns of infants during and after the transition from home to day-care: an observational pilot study

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Primary Objective: To describe the sleep and arousal patterns of firstborn infants between two and six months of age in day-care compared to home settings during and after the transition from home to day-care. Secondary Objective: To identify…

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

Summary

ID

NL-OMON52944

Source
ToetsingOnline

Brief title
Sleep of infants during transition from home to day-care

Condition

- Other condition

Synonym
nvt

Health condition

nvt

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: DUS-I fonds

Intervention

Keyword: arousal, daycare, infants, sleep

Outcome measures

Primary outcome

1. infant*s moment of falling asleep

2. infant*s number of times waking up and arousals during sleep

3. infant*s total hours of daytime sleep

4. infant*s moment of waking up

5. parental and day-care staff member*s perception of sleep quality of the

infant

Secondary outcome

1. light intensity during sleep

2. amount of ambient noise during sleep

3. ambient temperature

4. CO2 concentration

5. Nutrition information

Study description

Background summary

An increased incidence of cot death at day-care centres compared to child

deaths which occur at home during daytime, both in the Netherlands and in other countries, is the reason to conduct this study. Data from the Netherlands from 1996 to 2002 showed a relative risk of cot death in day-care of 4.2 compared to at home deaths (de Jonge et al., 2003). These data added with data up to 2012 showed a somewhat lower, but still increased, relative risk of cot death in day-care of 2.0 compared to sudden death at home (Voorhout et al., 2013)(unpublished).
Recent analysis, including cot death children up to 2017, shows a relative risk of 1.3.
A study from the US showed that about 34% of all cot death cases in day-care occurred in the first week of day-care (Moon, Patel, & Mcdermott Shaefer, 2000). Because the number of children in the Netherlands attending formal day-care dramatically increased from 357.000 in 2007 to 467.580 in 2017 (CBS StatLine, 2018a), it is important to identify factors that contribute to the increased risk of cot death at day-care.

Study objective

Primary Objective: To describe the sleep and arousal patterns of firstborn infants between two and six months of age in day-care compared to home settings during and after the transition from home to day-care.
Secondary Objective: To identify differences between the day-care and the home environment that may influence sleep and arousal patterns of firstborn infants, specifically ambient noise, light, temperature, CO2 concentrations and nutrition information.

Study design

A observational pilot study will be performed to investigate changes in sleep and arousal patterns of firstborn infants during and after transition from home to day-care. The infants will be monitored for three weeks: one week at home, one week both at home and at the day-care during transition from home to the day-care, and one week both at home and at the day-care. Sleep and arousal patterns of infants will be monitored via a sensor under the mattress.

Study burden and risks

Risks associated with this study are considered negligible, due to the observational nature of this study and the non-invasive sleep measurements and ambient factors measurements (weather station). Filling in the logs, diaries, and questionnaires are not very time consuming and the burden of filling in these questionnaires is considered to be minimal. This burden will be evaluated after the pilot study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Babies and toddlers (28 days-23 months)

Inclusion criteria

• The infant is the firstborn child of both parents.
• The infant is between the two and six months of age during transition from home to day-care.
• The infant is attending day-care at least two days a week, preferably three days.

Exclusion criteria

• The infant was born prematurely, with a gestational age less than 37 weeks at birth.
• The infant is part of a multiple birth.
• The infant had a birth weight of less than 2500 g.

• The infant is currently receiving medications that influence sleep patterns and arousal.
• The infant was exposed in utero to drugs or medications that influence sleep patterns, i.e. cocaine, methamphetamine, marijuana, benzodiazepines, antidepressants, antihistamines, or theophylline/caffeine.
• The infant has a diagnosis of brainstem dysfunction, developmental delay, respiratory system malformations, seizure disorder, congenital cardiovascular lesions, or hearing impairment.
• The infant is evaluated with or treated for obstructive sleep apnoea or has craniofacial anomalies associated with obstructive sleep apnoea.
• The infant is swaddled during sleep.
• The household of the infant is multi-problem family and/or excessive psychosocial problems, according to the GGZ-guidelines, are present in the household of the infant (Trimbos Institute, 2019).

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-01-2022
Enrollment:	5
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-04-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO

Date:	30-03-2022
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	NL68391.081.18