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Case studies on whether the 'Sleep on number 1' intervention leads to better sleep quality in children aged 0-2

Submission date 21/02/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 21/02/2024	**Overall study status** Ongoing	
Last Edited 04/04/2025	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Sleep problems are common in young children (0 - 2 years old) and parents often have difficulties managing their infant's sleep. This study investigates whether the 'Sleep on number 1!' intervention improves sleep quality in children.

Who can participate?
Participants are mainly recruited from the participants of the sleep-monitoring study, a bigger study registered under number ISRCTN27246394. Participants can enter the study when they are adult mothers (or fathers/other primary caregivers) of healthy born newborns. To be able to enter the study, the parent's child has to be healthy, born at term (37 weeks of pregnancy or later), from a singleton birth and not diagnosed with a sleeping disorder or excessive crying. Furthermore, the child may not have a serious medical condition that impedes their sleep or wakefulness, or receive medication that impacts their sleep or wakefulness (such as melatonin). The parent of the child may not receive care from the VoorZorg program: a special Youth Health Care program for vulnerable mothers. For the N-of-1 study parents of 40 children between 3 and 20 months from various ages and various backgrounds will be recruited.

What does the study involve?
The child's sleep is measured during at least 30 days with an Emfit sleep monitor. Then, the part of the 'Sleep on number 1! Intervention that is relevant for the age of the child and/or that is relevant because the parents are experiencing a problem with the sleep of the child will be provided to the parent. During the intervention and at least 30 days after the intervention the child's sleep is again measured by the Emfit sleep monitor.

What are the possible benefits and risks of participating?
Possible benefits of this study are that parents may learn better to manage their infant's sleep and reduce and prevent infant sleep problems. Risks of participation are very unlikely.

Where is the study run from?
Maastricht University (The Netherlands)

When is the study starting and how long is it expected to run for?
June 2020 to March 2026

Who is funding the study?
ZonMw (The Netherlands)

Who is the main contact?
Dr Ree Meertens, r.meertens@maastrichtuniversity.nl

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
555002012

Study information

Scientific Title
Evaluation of the 'Sleep on number 1'' intervention in 0-2-year-olds: a series of N-of-1 studies

Acronym
Sleep on number 1; N-of-1

Study objectives
The ‘Sleep on number 1!’ intervention will lead to an improvement in sleep quality in children aged 0-2.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 31/01/2022, Faculty of Health Medicine and Life Sciences Research Ethical Committee (FHML-REC) (FHML-REC (Department HES), Maastricht University, PO Box 616, Maastricht, 6200 MD, Netherlands; +31 (0)616333110; fhml-rec@maastrichtuniversity.nl), ref: FHML-REC/2022 /011

Study design
Series of interventional N-of-1 studies, with at least 30 measurements before and after the intervention

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Sleep problems in children aged 0-2

Interventions
The intervention consists of an age-tailored digital newsletter on infant sleep and crying and/ or a consultation with a trained (YHC) sleep expert who gives advice with the help of 'Sleep on number 1' conversation cards on a problem parents experience. The time that it takes to provide the intervention to the parents may last from 1 day (e.g. only providing an age-tailored newsletter with oral explanation) to a few weeks (e.g. when a home visit or a visit to the Youth Health Care centre needs to be scheduled), dependent on the needs of the parents.

Intervention Type
Behavioural

Primary outcome(s)
Sleep quality, defined as the number and duration of nighttime awakenings, measured by a sleep monitoring device (Emfit QS) every night for at least 30 days before the intervention, every night during the intervention, and every night for at least 30 days after the intervention.

Key secondary outcome(s))
1. Bedtime regularity, as measured by a sleep monitoring device (Emfit QS) during day- and night-time for at least 30 days before the intervention, during day- and night-time during the intervention, and during day- and night-time for at least 30 days after the intervention.
2. Nighttime sleep duration, as measured by a sleep monitoring device (Emfit QS) during night-time for at least 30 days before the intervention, during nighttime during the intervention, and during nighttime for at least 30 days after the intervention.
3. Daytime sleep duration, as measured by a sleep monitoring device (Emfit QS) during daytime for at least 30 days before the intervention, during daytime during the intervention, and during

daytime for at least 30 days after the intervention.
4. Time to sleep onset, as measured by a sleep monitoring device (Emfit QS) during day- and night-time for at least 30 days before the intervention, during day- and night-time during the intervention, and during day- and night-time for at least 30 days after the intervention.

Completion date
01/03/2026

Eligibility

Key inclusion criteria
Participants are mainly recruited from the participants of the sleep-monitoring study, a bigger study registered under number ISRCTN27246394. From this study and via other channels the researchers will select participants of various ages and backgrounds, who are willing to participate. For the present study participants are recruited when:
1. The child is a healthy newborn of an adult, mentally competent mother (or father/other primary caregiver.
2. The child is 3 to 20 months old at time of recruitment
3. The child has to have access to the intervention, for example by being registered at the local YHC center in one of the intervention regions.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 months

Upper age limit
24 months

Sex
All

Key exclusion criteria
1. The child is born prematurely (<37 weeks of pregnancy)
2. The child is diagnosed with a sleep disorder (such as pavor nocturnus, iactatio capitis, sleep walking, non-benign sleep myoclonic, obstructive sleep apnea, primary hypersomnia, circadian rhythm disorders, parasomnias, sleep-related movement disorders)
3. The child is diagnosed with excessive crying
4. The child has a serious medical condition that impedes their sleep or wakefulness
5. The child receives medication that impacts their sleep or wakefulness (such as melatonin)
6. The child is part of a multiple birth
7. The parent receives care from the VoorZorg program: a special Youth Health Care program for vulnerable mothers.

Date of first enrolment
01/03/2024

Date of final enrolment
01/11/2025

Locations

Countries of recruitment
Netherlands

Study participating centre
Municipal Health Services of Limburg-North (GGD Limburg-Noord)
Drie Decembersingel 50
Venlo
Netherlands
5921 AC

Study participating centre
Municipal Health Services of Brabant-Southeast (GGD Brabant-Zuidoost)
Clausplein 10
Eindhoven
Netherlands
5611 XP

Sponsor information

Organisation
Netherlands Organisation for Health Research and Development

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research council

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the study will be stored in a non-publicly available repository (DataHub Maastricht University) and will be available upon request from Ree Meertens (r.meertens@maastrichtuniversity.nl) via Maastricht University. The data will become available for a period of 10 years following publication. Stored data consists of anonymized data. Participants provided informed consent for data collection as well as for data storage and data sharing for future research purposes. Access criteria: non-commercial research.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes