

Does the 'Sleep on number 1' intervention lead to better parental sleep management and to better sleep quality in 0 - 2 year-old children?

Submission date 03/03/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 10/03/2023	Overall study status Ongoing	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/08/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

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 parental sleep management and prevents sleep problems in children. The 'Sleep on number 1' intervention is designed to be implemented in regular Dutch Youth Health Care.

Who can participate?

Participants that can enter the study are adult mothers (or fathers/other primary caregivers) of healthy-born newborns. The newborn can enter the study at the age of 0 - 10 weeks old and has to be registered in one of the Dutch Youth Health Care centres that participate in the study. The intervention 'Sleep on number 1' is provided to parents via the Youth Health Care professionals. To be able to enter the study, the parent's child has to be healthy, born at term (37 weeks of pregnancy or more), from a singleton birth and may not be diagnosed with a sleeping disorder nor 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 must be able to speak Dutch and may not receive care from the VoorZorg program: a special Youth Health Care program for vulnerable families.

What does the study involve?

In the study, there are two Youth Health Care regions that receive the intervention. These regions form the intervention group. All other Youth Health Care regions in the Netherlands, that have not been exposed to (elements of) the intervention, form the care-as-usual control group. In this group, regular care is provided.

Parents are asked to join the study and fill in diaries on their child's sleep and questionnaires on how they manage their infant's sleep. This has to be done at 5 points in time in the first two years of life of the child, starting from birth until the child is two years old.

What are the possible benefits and risks of participating?

Possible benefits of this study are that parents may be more able to manage their infant's sleep and reduce and prevent infant sleep problems. The 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 September 2026

Who is funding the study?

ZonMW (The Netherlands).

Who is the main contact?

Dr Ree Meertens, r.meertens@maastrichtuniversity.nl

Study website

<https://www.zonmw.nl/nl/onderzoek-resultaten/preventie/programmas/project-detail/effectiviteitsonderzoek/sleep-on-number-1-development-implementation-and-evaluation-of-an-intervention-tailored-to-youth-h/>

Contact information

Type(s)

Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

555002012

Study information

Scientific Title

Sleep on Number 1! Evaluation of an intervention tailored to Youth Health Care regions to improve sleep in 0-2-year-olds.

Study objectives

The 'Sleep on number 1' intervention will lead to better parental knowledge, attitude, efficacy and management of their infant's sleep and to better sleep quality in 0-2 year-old children than 'care as usual'.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/12/2022, Faculty of Health Medicine and Life Sciences Research Ethical Committee (FHML-REC) Maastricht University (FHML-REC (Department HES) P.O. box 616, 6200 MD Maastricht, the Netherlands; +31616333110; fhml-rec@maastrichtuniversity.nl), ref: FHML-REC/2022/009/Addendum01_22

Study design

Quasi-experimental non-blinded trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Built environment/local authority, Other

Study type(s)

Prevention

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Prevention of sleep problems in 0 - 2 year-old children

Interventions

Current interventions as of 27/03/2024:

This study is a two-arm quasi-experimental trial that compares an intervention group with a care-as-usual control group. Regions have not been assigned randomly to conditions. The

intervention is offered to all YHC professionals in the intervention group, through which in principle all parents of 0-2 year children are reached. Intervention implementation in the intervention group started on 01/06/2020 and was completed in 2023, before the start of the study measurements. After full intervention implementation, the intervention will continue to be used, since it is incorporated as the new working practice of Youth Health Care professionals. Trial follow-up is 2 years.

Intervention regions: The intervention 'Sleep on number 1' is tailored to the specific YHC region, and consists of (1) a 'kick-off symposium' for YHC professionals addressing knowledge on sleep in children, (2) an e-learning module on sleep in children for YHC-professionals, (3) a skills training for YHC-professionals to practice communicating about infant sleep problems, (4) implementation of two conversation cards in YHC practice to facilitate communication with parents, (5) Implementation of a series of age-tailored digital newsletters on infant sleep and crying.

Control group: Care as usual

Previous interventions:

This study is a two-arm quasi-experimental trial that compares two Youth Health Care (YHC) regions which have implemented the 'Sleep on number 1' intervention with a 'Care as Usual' YHC control region. Regions have not been assigned randomly to conditions. The intervention is offered to all YHC-professionals in the intervention regions, through which in principle all parents of 0-2 year children are reached. Intervention implementation in the intervention regions started at 01/06/2020 and is completed in 2023, prior to the start of the study measurements. After full intervention implementation, the intervention will continue to be used, since it is incorporated as the new working practice of Youth Health Care professionals. Trial follow-up is 2 years.

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Control region: Care as usual

Intervention Type

Behavioural

Primary outcome measure

Sleep quality as measured by a sleep diary (total sleep duration, time to sleep onset, number and duration of night-time awakenings, bedtime regularity and sleeping problems) and the Infant Sleep and Parent Perception subscales of the Brief Infant Sleep Questionnaire at the child's age of 10 weeks and 6, 9, 14 and 24 months.

Secondary outcome measures

1. Parental management of infant sleep as measured with the 'Parent Behaviour' subscale items from the Brief Infant Sleep Questionnaire when their child is 10 weeks and 6, 9, 14 and 24 months old.

2. Parental self-efficacy in the management of infant sleep, as measured with the self-efficacy item from the Brief Infant Sleep Questionnaire when their child is 10 weeks and 6, 9, 14 and 24 months old.
3. Parental knowledge on the management of infant sleep, as measured with a questionnaire on parental sleep knowledge when the child is 10 weeks, 6 months and 14 months old.
4. Beliefs about the management of infant sleep, as measured with the limit-setting items from the 'Maternal Cognitions about Infant Sleep Questionnaire' when the child is 9 and 14 months old.
5. Satisfaction with YHC with respect to communication about the child's sleep when the child is 6 and 24 months old.
6. Number of parents seeking help for the child's sleep outside of YHC when the child is 9 and 24 months old.

Overall study start date

01/06/2020

Completion date

30/09/2026

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 27/02/2024:

1. Adult, mentally competent mothers (or fathers/other primary caregivers) of healthy newborns.
2. The child is 0 to 10 weeks old.
3. The child has to be registered at a YHC centre in either the intervention group or the control group.

Previous participant inclusion criteria:

1. Adult, mentally competent first-time mothers (or fathers/other primary caregivers of babies of first-time mothers) of healthy newborns.
2. The child is 0 to 10 weeks old.
3. The child has to be registered at the local YHC centre in one of the intervention regions or in the control region.

Participant type(s)

Other

Age group

Mixed

Sex

Both

Target number of participants

324

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(s) of the child do not speak Dutch

8. The parent receives care from the VoorZorg program: a special Youth Health Care program for vulnerable families.

Date of first enrolment

15/03/2023

Date of final enrolment

15/09/2024

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

Study participating centre

Municipal Health Services of South-Limburg (GGD Zuid-Limburg)

Het Overloon 2

Heerlen

Netherlands

6411 TE

Sponsor information

Organisation

Netherlands Organisation for Health Research and Development

Sponsor details

Laan van Nieuw Oost-Indië 334
The Hague
Netherlands
2593 CE
+31 70 349 51 11
info@zonmw.nl

Sponsor type

Research council

Website

<http://www.zonmw.nl/en/>

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

Publication and dissemination plan

The study and study results will be published in national and international peer reviewed scientific journals (preferably open source journals) and in a PhD thesis.

Intention to publish date

31/12/2026

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			29/03/2023	No	Yes
Statistical Analysis Plan			27/03/2024	No	No
Protocol article		16/07/2024	17/07/2024	Yes	No