ISRCTN27246394 https://doi.org/10.1186/ISRCTN27246394

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
Recruiting

Registration date
10/03/2023

Overall study status
Ongoing

Last Edited
17/07/2024

Condition category
Not Applicable

✓ Prospectively registered
✓ Protocol added
✓ SAP added
– Results not yet expected
– Raw data not yet expected
✓ Record updated in last year

Plain English Summary
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. 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 December 2024

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
Dr Ree Meertens

ORCID ID
http://orcid.org/0000-0001-8424-9142

Contact details
Department of Health Promotion
NUTRIM School of Nutrition and Translational Research in Metabolism
Maastricht University
Maastricht
Netherlands
6200 MD
+31 43-3882407
r.meertens@maastrichtuniversity.nl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Protocol/serial number
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 hypothesis
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

Condition
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

Overall study end date
31/12/2024

Eligibility

Participant 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

Participant 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.

Recruitment start date
15/03/2023

Recruitment end date
01/08/2024

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
31/12/2024

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