

Does the 'Sleep on number 1' intervention changes practices of Youth Health Care professionals in their sleep communication and advice to parents of young children?

Submission date 11/07/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/07/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/07/2025	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. However, sleep problems are not always discussed by nurses and doctors during appointments at Youth Health Care centers. This study investigates whether the 'Sleep on number 1!' intervention leads to improved discussion of sleep problems in Youth Health Care.

Who can participate?

There are not really individuals participating in this study, as only child record data are studied. Child records are provided by three Youth Health Care centers: two intervention regions that implemented the 'Sleep on Number 1!' intervention and one control region. Records of children born to first-time mothers before and after the intervention, are studied.

What does the study involve?

Child records from Youth Health Care centers are studied to determine whether Youth Health Care professionals in intervention regions show greater positive changes in attention for sleep and sleep advice to parents of young children from pre- to post-intervention, than Youth Health Care professionals in the control region.

What are the possible benefits and risks of participating?

The study contributes to improving sleep-related care in Youth Health Care by giving insight in the effectiveness of the 'Sleep on Number 1' intervention, and potentially enhancing the quality of support provided to parents. While there are no direct benefits for the participants, the findings could inform better practices for future patients. There are no anticipated risks for participants, as this is a retrospective study analyzing child records.

Where is the study run from?

Maastricht University (The Netherlands)

When is the study starting and how long is it expected to run for?
Child records about at least seven months from 01/01/2018 and 01/10/2023 onwards will be extracted.

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

Contact name

Dr Ree Meertens

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Effectiveness of the 'Sleep on number 1' intervention in changing sleep-related communication of Youth Health Care professionals to parents of young children: a quasi-experimental controlled child records study

Study objectives

1. Compared to Youth Health Care (YHC) child records in the control region, YHC child records in intervention regions will show a stronger increase in sleep-related notes of YHC professionals from pre-intervention to post-intervention.
2. Compared to Youth Health Care (YHC) child records in the control region, YHC child records in intervention regions will show a stronger increase in sleep-related advice by YHC professionals from pre-intervention to post-intervention.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 27/11/2020, 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/2020/091

Study design

Multi-center interventional quasi-experimental patient record study no random assignment no masking

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Promotion of healthy sleep practices in young children

Interventions

This study evaluates an intervention designed to improve the provision of sleep information and advice by YHC professionals in three youth health care regions. Two regions serve as intervention groups, while one serves as a control. The intervention is co-created with youth health care practitioners and informed by interviews with parents. For YHC professionals, the intervention consists of sleep-knowledge enhancing components (kick-off symposium and e-learning module), a skill-enhancing component (sleep communication training), and materials developed to enhance sleep communication with parents (two conversation cards accompanied by explaining clips, sleep diary, sleep plan). Parents are referred to infant sleep information and advice on the YHC internet site. In the control region, no interventional activities related to sleep are planned, neither addressing YHC professionals, nor the parents (no treatment, care as usual). Regions are pre-allocated to intervention or control groups, with no randomization of YHC professionals/ parents.

YHC child records are used to gather data from 0-7 months of age.

Intervention Type

Behavioural

Primary outcome(s)

Attention for sleep by YHC professionals in contact moments with parents, measured by the frequency of sleep-related notes in YHC child records of children of first-time mothers, before and after the intervention during at least 7 months

Key secondary outcome(s)

1. Sleep advice provided by YHC professionals in contact moments with parents, measured by the frequency of sleep-related advice in YHC child records of children of first-time mothers, before and after the intervention, during at least 7 months
3. Sleep problems in children, measured by the frequency of sleep problem notes in YHC child records of children of first-time mothers, before and after the intervention, during at least 7 months

Completion date

01/10/2025

Eligibility

Key inclusion criteria

All child records of children of first-time mothers in the study regions will be included, for the first 1000 children born in each study region from 01/01/2018 onwards (pre-test), and for the first 1000 children born from 01/10/2023 onwards (post-test).

Participant type(s)

Other

Healthy volunteers allowed

No

Age group

Child

Lower age limit

0 months

Upper age limit

24 months

Sex

All

Key exclusion criteria

No exclusion criteria

Date of first enrolment

01/01/2018

Date of final enrolment

18/04/2024

Locations

Countries of recruitment

Netherlands

Study participating centre

Public Health Center Limburg-North (GGD Limburg-Noord)

Drie Decembersingel 50

Venlo

Netherlands

5921 AC

Study participating centre

Public Health Center Brabant South-East (GGD Brabant Zuid-Oost)

Clausplein 10

Eindhoven

Netherlands

5611 XP

Study participating centre

Public Health Center South Limburg (GGD Zuid Limburg)

Het Overloon 2

Heerlen

Netherlands

6411 TE

Sponsor information

Organisation

ZonMw, The Dutch Organisation for knowledge and innovation in health, healthcare and well-being

ROR

<https://ror.org/01yaj9a77>

Funder(s)

Funder type

University/education

Funder Name

Universiteit Maastricht

Alternative Name(s)

Maastricht University, UM

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

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.

IPD sharing plan summary

Stored in non-publicly available repository, Available on request