A non-traditional complex intervention for the treatment of paediatric sleep problems.

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Assessing the feasibility of the research procedures, the burden on participants, the degree of dropout and reason, the interest in participating.What is the main treatment effect for parents / carers motivating them to participate in this study?•…

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

Summary

ID

NL-OMON52044

Source
ToetsingOnline

Brief title
Paediatric sleep problems; a different approach.

Condition

- Other condition

Synonym
self regulation, sleep problems

Health condition

Ontwikkelingsstoornissen van het jonge kind

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Fondsen en sponsors

Intervention

Keyword: Children, Integrative medicine (I.M.), Self regulation, Sleep problems

Outcome measures

Primary outcome

Outcome variables

The feasibility study

Stage 1:

The feasibility of methods and instruments

The possible dropout of participants and reason, if given

Preferred treatment outcomes by parents/ caregivers

The feasibility of the use of the TIDieR guideline by health professionals and

possible reasons for not completing all questions

The number of included participants per week and its origin of referral

Secondary outcome

Not applicable

Study description

Background summary

Sleep problems and insomnia among infants (aged 6 months -1 year), toddlers (aged 1-3 years) and (pre-)school children (aged 3-5 years) are highly prevalent in paediatric care, which can seriously compromise quality of life of

both children and their families. Current prevalence estimations of insomnia based on the first five years of life range from 10-30% among the general paediatric population. 25-50% of infants and toddlers older than six months have frequent night wakening*s, 10-15% of toddlers have bedtime resistance and 15-30% of preschool children suffer from daytime sleepiness and have wakening*s at night. Most sleep problems are temporarily but they have a tendency to develop at the long-term into insomnia.
Paediatric insomnia tends to persist throughout childhood and adolescence and is associated with a higher prevalence of negative functional outcomes, such as cognitive and behavioural problems. It might also result in an increased risk of obesity and other negative metabolic consequences later in live.
Most of the interventions for paediatric sleep problems and insomnia, in particular sleep hygiene and behavioural interventions, are deemed effective.
In 2017 the Dutch guideline *Healthy sleep and paediatric sleep problems* was published, to offer professionals in paediatric care a standardised diagnostic and intervention model. The guideline offers a stepped care intervention model, introducing sleep hygiene interventions to create optimal sleep conditions. In case of insufficient responding, behavioural interventions are offered.
Referral to a specialised sleep centre is advised in case of persisting sleep problems not responding to sleep hygiene and behavioural interventions.
The number of children or their parents who do not profit from the recommended interventions remains unclear and evidence of long-term effectiveness is still missing.
In this study we hypothesize a delayed development of the self-regulating abilities as a underlying cause of the originating of a subtype of common sleep problems. Self-regulating abilities, including self-soothing, promote the possibility to fall asleep and are of high importance for the development of autonomous sleeping skills. Sleep problems in early infancy (2-6 months) are negatively correlated with a delayed maturation of various (neuro-)physiological processes such as those regarding the cardiorespiratory system, the digestive system and the developing brain functioning. Persisting sleep problems in infants above the age of six months often originate from an insufficient developmental process of one or more domains of (neuro-)physiological functioning. The physical inconvenience related to the disfunctioning maturing process is disruptive to the state control of the child and may cause signs of dysregulation (fuzziness, irritability and poor self-calming).
Initial adequate parental strategies to relief the physiological inconvenience may result in a delayed development of self-regulating abilities and/or the origin and maintenance of dysfunctional sleep habits. Parents not responding to the guideline often prefer *sensitive parenting* and/or experience the behavioural interventions as stressful. The stress provoking effect on parents and child practicing some of the behavioural interventions (in particular unmodified extinction) remains unclear.
The guideline *Healthy sleep and sleep problems* does not address to the underlying disruptive (neuro-)physiological regulation. We hypothesize in this study that intervening to support the maturing process of the disfunctioning

(neuro-)physiological process might enable good functioning and will contribute to the treatment of sleep problems. Early intervening can be useful to prevent the development of insomnia.
In a Dutch paediatric practice a personalised integrative sleep intervention is developed and practised. Clinical effectiveness is available, scientific evidence is missing.
This study will compare the effects of the treatment as usual to a complex intervention type. A complex intervention can be described as an intervention containing several interacting components, with a range of possible outcomes and a variability in the target population. The interacting components comprise the state of development of the self-regulating abilities of the child, the parental pedagogic possibilities and preferences and the environmental factors related to the sleep problem. Herbal treatment, massage interventions, sensory information interventions, parental counselling and dietary advise are possible elements of the complex intervention.
This two staged study, composed of a feasibility study and a randomised controlled trial (RCT), will evaluate the effectiveness of an used complex intervention for paediatric sleep problems in the paediatric field compared to treatment as usual. The feasibility study (ABR form) only examines the feasibility of the research procedures, the burden on parents and child with regard to the measuring instruments and the interest in participating in the study. The feasibility study does NOT investigate the efficacy of the complex intervention.
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Study objective

Assessing the feasibility of the research procedures, the burden on participants, the degree of dropout and reason, the interest in participating.

What is the main treatment effect for parents / carers motivating them to participate in this study?
• Is it feasible for parents / carers to fill in all measuring instruments during the study?
• What is the number of students who drop out and for what reasons?
• Do participating professionals fill in all questions of the TIDieR guideline, and if not for what reasons?
• What is the average number of participants recruited in a week? And where does the reference come from?
• Are parents / carers willing to accept the randomization procedure in the RCT?

Study design

It concerns a phased study design, in which in phase 1, the feasibility study, the feasibility of the study design is investigated without a control group.

24 children are included.

Intervention

Stage 1:
Complex intervention of paediatric sleep problems, a combination of two or more intervention types; herbal treatment, massage interventions, sensory information interventions, parental counselling and dietary advise.

Stage 2:
Experimental group: complex intervention of paediatric sleep problems
Control group: treatment as usual (TAU) according to the Dutch guideline *Healthy sleep and paediatric sleep problems*

Study burden and risks

The following items of risk associated with participation are assessed in the feasibility study and RCT:
The deviation of the Dutch guideline *Healthy sleep and paediatric sleep problems* may result in a treatment effect which is less predictable.

The burden to comply with the data collection procedures for parents is to fill out all questionnaires during the four measuring waves over a period of 18 weeks for a total of approximately 3,5 hours.

The possible benefits associated with participation of the study are:
A reduction of sleep problems
A more comprehensive view and guidance on parental and environmental sleep factors
A guidance to handle parental stress in relation to paediatric sleep problems and
The contribution to the development of a scientific basis of the complex sleep intervention

The risks for carrying out this study with minors is considered negligible due to the reason the complex intervention is an used intervention and is common practice in the Kindertherapeuticum for children with sleep problems. All participating professionals can be considered as experts, screened in advance on expert knowledge and available experience with the participating intervention groups.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

Children aged 6-36 months.
Sleep problems; according to the ICSD-3, Insomnia type behavioural; specified to sleep onset, sleep maintenance or a combination of both.
One or more signs of dysregulation (crying, unwilling to eat and sleep and inability to state regulation).

Exclusion criteria

Other diagnostic sleep categories according to the ICSD-3
Earlier diagnosed comorbidity provoking sleep problems (e.g. pain, trauma, itch, cancer)
Genetic syndrome
Prematurity (<37 weeks gestural age)
Former IM treatment for sleep problems

Former professional behavioural interventions for sleep problems
Untreated gastroesophageal reflux (GER) or untreated symptoms of food intolerances/ allergy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-06-2021
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	15-04-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	26-04-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL75358.058.20