

Accesible behavioural interventions in Youth Healthcare for sleeping problems in young children.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33258

Source

ToetsingOnline

Brief title

Sleeping problems in young children

Condition

- Other condition
- Lifestyle issues

Synonym

sleeping problems, sleepshortage

Health condition

gedragsstoornis

Research involving

Human

Sponsors and support

Primary sponsor: TNO

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Behavioural treatment, Children, Schregardus, Sleeping problems

Outcome measures

Primary outcome

Reduction of sleeping problems

- reduction of bedtime problems
- reduction of night wakings
- reduction of sleepshortage
- reduction of behavioural problems related to sleep.

Secondary outcome

- improvement of parenting style
- reduction of parenting problems
- improvement of well-being and psychosocial problems of the parents (reduction of stress, tiredness, depression)

Study description

Background summary

Sleeping problems are common in young children. Correlations have been shown between sleepshortage in children and behavioural, cognitive and social problems, parental stress, family problems and child abuse. Furthermore, in children of all ages, a consistent relationship has been found between sleepshortage and overweight and obesity. It can be expected that when sleep improves in children, these problems can be reduced, and health and well-being of both child and parent can be improved. A recent meta-analysis study showed

that giving parents information about sleep prior to the existence of sleepingproblems can have a preventive effect on the development of sleepingproblems in children. When sleepingproblems are already present, behavioural therapy based on extinction and stimuluscontrol is most effective.

Study objective

In the Netherlands, there is no accesible evidence-based method for the prevention and treatment of sleepingproblems in young children, that can be carried out by Youth Healthcare nurses.

This study will, in addition to existing knowlede about the treatment of excessive crying in Youth Healthcare, lead to: an accesible evidence-based intervention for children with sleepingproblems, which can be carried out by Youth Healthcare nurses, and is applicable to families from different ethnical backgrounds and different socio-economical status.

Study design

10 Youth Healthcare teams will be randomly assigned to the intervention group or the control group (care-as-usual).

Each team will include 35 children with mild to severe sleepingproblems, aged from 6 months to 4 years.

The intervention consists of behavioural treatment applied for two weeks. This will be intensively supported by trained Youth Healthcare nurses through an extensive anamnesis, three home-visits and four consults by telephone, spread over six weeks.

Intervention

Behavioural therapeutical intervention:

Modified intervention 'sleeping problems in children' of Schregardus (2001), with patient-preference (parents can choose between direct extinction and gradual extinction). Control group receives care-as-usual as offered by the Youth Healthcare organisation.

Study burden and risks

Negative effects are not expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

Children aged 6 months to 4 years who have sleeping problems:

- mild to severe bedtime problems
 - mild to severe night wakings
 - mild to severe sleep shortage
- (also see research protocol page 12-13)

Exclusion criteria

Infants with a somatic cause for their sleeping problems, infants with severe family problems (abuse, neglect) as a cause for their sleeping problems, infants who are ill or who have a form of mental retardation, or infants whose parents have psychopathological problems (f.e. a psychosis). Multiproblem families can be excluded when the healthcare worker feels the need to refer to more intensive care.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	30-06-2010
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO	
Date:	09-07-2009
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	14-07-2010
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL27488.028.09
Other	NTR nummer in aanvraag