

# Sleepingproblems in young children; prevention and intervention in Youth Healthcare.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON29177

### Source

Nationaal Trial Register

### Brief title

"Lekker slapen en morgen gezond weer op"

### Health condition

Sleeping problems

## Sponsors and support

**Primary sponsor:** TNO Quality of Life

**Source(s) of monetary or material Support:** ZonMW

## Intervention

## Outcome measures

### Primary outcome

1. Sleeping problems:

A. Bedtime problems;

- B. Night wakings;
  - C. Sleep shortage.
- 2. Behavioural problems of the child.

### **Secondary outcome**

- 1. Parenting;
  - A. Parenting style of parents;
  - B. Parenting problems of parents;
  - C. Parental efficacy.
- 2. Psychosocial problems of parents.

## **Study description**

### **Background summary**

Sleeping problems are common in young children; international studies have shown a prevalence of 20-30% in infants, toddlers and pre-school children. Correlations have been shown between sleep shortage 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 sleep shortage 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 sleeping problems can have a preventive effect on the development of sleeping problems in children. When sleeping problems are already present, behavioural therapy based on extinction and stimulus control is most effective.

This study will examine the effectiveness of two interventions: A preventive and a therapeutical intervention, both carried out by Youth Healthcare nurses. The preventive intervention consists of giving information about sleep to parents of children younger than 2 months old. We expect that this will reduce the prevalence of sleeping problems in these children between the age of 2 to 18 months old, as compared to care-as-usual. 2400 children will be included in this study. The therapeutical intervention consists of a modified behavioural intervention based on extinction ('sleeping problems in children' by Schregardus, 2001) given to children aged 6 months to 4 years old with moderate to severe

sleeping problems. 350 children will be included in this study. We expect to see a reduction of sleeping problems (bedtime problems, night wakings and sleep shortage) and of behavioural problems related to sleep. Secondary outcomes are improvement of parenting style, reduction of parenting problems and improvement of well-being and psychosocial problems of the parents (reduction of stress, tiredness, depression). In both studies, the control group receives care-as-usual as offered by the Youth Healthcare organisation.

This study will, in addition to existing knowledge about the treatment of excessive crying in Youth Healthcare, lead to accessible evidence-based interventions for the prevention and treatment of sleeping problems in young children.

### **Study objective**

1. Giving specific information about sleep to parents with children younger than 2 months old will reduce the prevalence of sleeping problems in children in the age of 2 months to 4 years;
2. The modified behavioural intervention of Schregardus is more effective in reducing the degree and intensity of sleeping problems in children in the age of 6 months to 4 years old than to care-as-usual, and is expected to improve parenting competence.

### **Study design**

1. T0: at inclusion (sleeping problems, behavioural problems of the child, parenting, psychosocial problems of parents);
2. T1: 1 week after intervention (sleeping problems, behavioural problems of the child);
3. T2: 3 weeks after intervention (sleeping problems, behavioural problems of the child);
4. T3: 6 weeks after intervention (sleeping problems, behavioural problems of the child);
5. T4: 6 months after intervention (sleeping problems, behavioural problems of the child, parenting, psychosocial problems of parents).

### **Intervention**

Behavioural therapeutical intervention: Modified intervention of Schregardus with patient-preference (parents can choose between direct extinction and gradual extinction).

Control group receives care-as-usual as offered in Youth healthcare.

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

Children aged 6 months to 4 years with sleeping problems:

1. Mild to severe bedtime problems;
2. Mild to severe night wakings;
3. Mild to severe sleep shortage.

### **Exclusion criteria**

1. Infants with a somatic cause for their sleeping problems;
2. Infants with severe family problems (abuse, neglect) as a cause for their sleeping problems;
3. Infants who are ill or who have a form of mental retardation;
4. Infants whose parents have psychopathological problems (f.e. a psychosis);

5. 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

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2009
Enrollment:	350
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	26-04-2009
Application type:	First submission

## 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
NTR-new	NL1677
NTR-old	NTR1778
Other	ZonMW : 80-82430-98-8044
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Study results

### Summary results

N/A