

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

Gepubliceerd: 26-04-2009 Laatste bijgewerkt: 18-08-2022

1. Giving specific information about sleep to parents with children younger than 2 months old will reduce the prevalence of sleepingproblems in children in the age of 2 months to 4 years;
2. The modified behavioural intervention of Schregardus is...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29177

Bron

Nationaal Trial Register

Verkorte titel

"Lekker slapen en morgen gezond weer op"

Aandoening

Sleeping problems

Ondersteuning

Primaire sponsor: TNO Quality of Life

Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Sleeping problems:

 - A. Bedtime problems;

 - B. Night wakings;

 - C. Sleep shortage.

2. Behavioural problems of the child.

Toelichting onderzoek

Achtergrond van het onderzoek

Sleepingproblems are common in young children; international studies have shown a prevalence of 20-30% in infants, toddlers and pre-schoolchildren. Correlations have been shown between sleepshortage in children and behavioural, cognitive and social problems, parental stress, family problems and childabuse. 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.

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 sleepingproblems 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 sleepingproblems. 350 children will be included in this study. We expect to see a reduction of sleeping problems (bedtime problems, night wakings and sleepshortage) 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 accesible evidence-based interventions for the prevention and treatment of sleepingproblems in young children.

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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

Control group receives care-as-usual as offered in Youthhealthcare.

Contactpersonen

Publiek

Postbus 2215
L. Nawijn
TNO Quality of Life,
Wassenaarseweg 56,
Leiden 2301 CE
The Netherlands
+31 (0)71 5181380

Wetenschappelijk

Postbus 2215
L. Nawijn
TNO Quality of Life,
Wassenaarseweg 56,
Leiden 2301 CE
The Netherlands
+31 (0)71 5181380

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-01-2009
Aantal proefpersonen:	350
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	26-04-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1677
NTR-old	NTR1778
Ander register	ZonMW : 80-82430-98-8044
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A