Behavioral therapy for treatment of childhood constipation: a randomized controlled trial.

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Behavioral therapy in addition to conventional treatment is more effective than conventional treatment alone.

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

Samenvatting

ID

NL-OMON23675

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Functional constipation.

Ondersteuning

Primaire sponsor: This research was funded by grants from the MLDS (SWO 02-16).
Overige ondersteuning: This research was funded by grants from the MLDS (SWO 02-16).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Defecation frequency (DF) per week, fecal incontinence frequency (FIF) per week, successful

treatment and relapse. Success
was defined as DF >= 3 times/week and FIF <= 1 times/two weeks irrespectively of laxative use. A relapse was defined as being unsuccessful at follow-up, while being successful at posttreatment. Assessments were done posttreatment and at 6-months follow-up during a clinical visit or by telephone.

Toelichting onderzoek

Achtergrond van het onderzoek

It is suggested in literature that the addition of behavioral components to laxative therapy improves continence in children with functional fecal incontinence associated with constipation. In this study it is hypothesized that behavioral therapy in addition to conventional treatment is more effective than conventional treatment alone. 129 children aged 4-18 years with functional constipation were included and randomly assigned to either behavioral therapy or conventional treatment. Main outcomes measures were: defecation frequency/week, fecal incontinence frequency/week, success rate, relapse, stool-withholding behavior and general behavioral problems.

Doel van het onderzoek

Behavioral therapy in addition to conventional treatment is more effective than conventional treatment alone.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Intervention period for both conventional treatment (CT) and behavioral therapy (BT) consisted of 12 visits to the outpatient clinic during 22 weeks.

Conventional Treatment:

CT was conducted by pediatric gastroenterologists of the gastrointestinal outpatient clinic and consisted of visits lasting approximately 20-30 minutes during which laxative treatment and the bowel diary were discussed. Patients and their parents received education. Furthermore, patients were instructed not to withhold stool when they felt urge to defecate. Motivation was enhanced by praise and small gifts from the pediatric gastroenterologists.

Protocolized Behavioral Therapy:

BT was developed by pediatric psychologists of the psychosocial department of our hospital

and is based on clinical experience and behavioral theories. It includes two age-related modules: a module for children aged 4-8 years and a module for children aged >= 8 years. The learning process for child and parents consists of five steps: Know, Dare, Can, Will, and Do. This approach
was derived from a multidisciplinary behavioral treatment developed in a tertiary hospital in Nijmegen in the Netherlands, to treat children with defecation disorders (van Kuyk EM, Brugman-Boezeman AT, Wissink-Essink M, Severijnen RS, Festen C, Bleijenberg G. Defecation problems in children with Hirschsprung's disease: a biopsychosocial approach. Pediatr Surg Int. 2000;16:312-316). Basic assumption of this BT is that fearful and phobic reactions related to defecation and fecal incontinence can be reduced and that adequate defecation straining and toileting behavior can be (re)acquired by teaching parents behavioral procedures and by behavioral play therapy with the child. Pediatric psychologists in cooperation with co-therapists for children aged 4-8 years and without co-therapists for children >= 8 years, carried out BT. BT consisted of visits lasting approximately 45 minutes. For all involved psychologists a detailed manual for both age related modules was available to ensure a standard delivery of BT. Pediatric psychologist adjusted laxative dose and if necessary consulted a pediatric gastroenterologists.

Contactpersonen

Publiek

Kinderarts MDL, AMC, H7-248
P.O. Box 22660
Marc A. Benninga
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663053 / +31 (0)20 5666297

Wetenschappelijk

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Amsterdam 1100 DD
The Netherlands
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Children aged 4-18 years with functional constipation as defined by the classic Iowa criteria. Patients had to meet at least two of four criteria of pediatric constipation: defecation frequency less than three times per week, fecal incontinence frequency two or more times per week, passage of large amounts of stool at least once every 7-30 days (large enough to clog the toilet), or a palpable abdominal or rectal fecal mass.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Children were excluded from the study if they had already been treated at our gastrointestinal outpatient clinic or had received a comprehensive behavioral treatment in the previous 12 months. In addition, children using drugs influencing gastrointestinal function other than laxative and children with organic causes for defecation disorders such as Hirschsprung's disease, spina bifida occulta, hypothyroidism or other metabolic or renal abnormalities were excluded.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2002
Aantal proefpersonen:	129
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	15-01-2007
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	NL846
NTR-old	NTR860
Ander register	: SWO 02-16
ISRCTN	ISRCTN25185569

Resultaten

Samenvatting resultaten
Pediatrics. 2008 May;121(5):e1334-41.