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Behavioural therapy for treatment of childhood constipation: a randomised controlled trial

Submission date	Recruitment status	[_] Prospectively registered
15/01/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/01/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/05/2008	Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SWO 02-16

Study information

Scientific Title

Study objectives
Behavioural therapy in addition to conventional treatment is more effective than conventional treatment alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Medisch Ethische Commissie (Medical Ethical Committee) Academisch Medisch Centrum (AMC) on the 16th October 2002 (ref: MEC02/175 #02.17.1108).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Constipation

Interventions
Intervention period for both Conventional Treatment (CT) and Behavioural Therapy (BT) consisted of 12 visits to the outpatient clinic during 22 weeks.

1. Conventional Treatment:
CT was conducted by pediatric gastroenterologists of the gastrointestinal outpatient clinic and consisted of visits lasting approximately 20 to 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 defaecate. Motivation was enhanced by praise and small gifts from the pediatric gastroenterologists.

Protocolised Behavioural Therapy:
BT was developed by pediatric psychologists of the psychosocial department of our hospital and is based on clinical experience and behavioural theories. It includes two age-related modules: a module for children aged four to eight years and a module for children aged more than or equal to eight 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 behavioural treatment developed in a tertiary hospital in Nijmegen in the Netherlands, to treat children with defaecation disorders. Basic assumption of this BT is that fearful and phobic reactions related to defaecation and faecal incontinence can be reduced and that adequate defaecation straining and toileting behaviour can be (re-)acquired by teaching parents behavioural procedures and by behavioural play therapy with the child. Pediatric psychologists in cooperation with co-therapists for children aged four to eight years and without co-therapists for children more than or equal to eight 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.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Defaecation Frequency (DF) per week, Faecal Incontinence Frequency (FIF) per week, successful treatment and relapse. Success was defined as DF more than or equal to three times/week and FIF less than or equal to one time/two weeks irrespectively of laxative use.

A relapse was defined as being unsuccessful at follow-up, while being successful at post-treatment. Assessments were done post-treatment and at six-months follow-up during a clinical visit or by telephone.

Secondary outcome measures
Secondary outcome measures were:
1. Stool-withholding behaviour
2. Mean CBCL T-scores
3. The proportion of children with behavioural scores in the clinical range (T-score more than 63)

Assessments were done post-treatment and at six-months follow-up during a clinical visit or by telephone.

Overall study start date
01/11/2002

Completion date
01/09/2005

Eligibility

Key inclusion criteria
1. Children aged four to 18 years with functional constipation as defined by the classic Iowa criteria
2. Patients had to meet at least two of four criteria of paediatric constipation:
2.1. Defaecation frequency less than three times per week
2.2. Faecal incontinence frequency two or more times per week
2.3. Passage of large amounts of stool at least once every seven to 30 days (large enough to clog the toilet)
2.4. A palpable abdominal or rectal faecal mass

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
129

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

Date of first enrolment
01/11/2002

Date of final enrolment
01/09/2005

Locations

Countries of recruitment
Netherlands

Study participating centre

Academic Medical Center (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Center (AMC) (The Netherlands)

Sponsor details
Emma Children's Hospital
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Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Research organisation

Funder Name
Dutch Digestive Diseases Foundation (Maag-Lever en Darm Stichting) (MLDS) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/05/2008		Yes	No