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

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON23675

**Source**
Nationaal Trial Register

**Brief title**
N/A

**Health condition**

Functional constipation.

### Sponsors and support

**Primary sponsor:** This research was funded by grants from the MLDS (SWO 02-16).
**Source(s) of monetary or material Support:** This research was funded by grants from the MLDS (SWO 02-16).

### Intervention

### Outcome measures

**Primary outcome**

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.

### Secondary outcome

Secondary outcome measures were: stool-withholding behavior, mean CBCL T-scores and the proportion of children with behavioral scores in the clinical range (T-score>63). Assessments were done posttreatment and at 6-months follow-up during a clinical visit or by telephone.

## Study description

### Background summary

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.

### Study objective

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

### Study design

N/A

### Intervention

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.

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# Eligibility criteria

## Inclusion criteria

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.

## Exclusion criteria

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.

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-11-2002 |
| Enrollment: | 129 |
| Type: | Actual |

# Ethics review

Positive opinion

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|---|---|
| Date: | 15-01-2007 |
| 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 | NL846 |
| NTR-old | NTR860 |
| Other | : SWO 02-16 |
| ISRCTN | ISRCTN25185569 |

# Study results

**Summary results**
Pediatrics. 2008 May;121(5):e1334-41.