Childhood constipation treatment, long-term prognosis and quality of life
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Behavioral therapy for childhood constipation: a randomized controlled trial

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ABSTRACT

Objective
It has been suggested that addition of behavioral interventions to laxative therapy improves continence in children with functional fecal incontinence associated with constipation. Our aim was to evaluate the clinical effectiveness of behavioral therapy with laxatives compared to conventional treatment in treating functional constipation in childhood.

Patients and methods
In this randomized controlled trial conducted in a tertiary hospital in the Netherlands 134 children aged 4-18 years with functional constipation were randomly assigned to 22 weeks (12 visits) of either behavioral therapy or conventional treatment. Primary outcomes were defecation frequency, fecal incontinence frequency and success rate. Success was defined as defecation frequency of $\geq 3$ times per week and fecal incontinence frequency of $\leq 1$ times per two weeks irrespectively of laxative use. Secondary outcomes were stool-withholding behavior and behavior problems. Outcomes were evaluated at end of treatment and at 6-months follow-up. All analyses were done by intention to treat.

Results
Defecation frequency was significantly higher for conventional treatment (IRR=0.75, 95%CI=0.59-0.96; $p=.021$). Fecal incontinence frequency showed no difference between treatments. After 22 weeks, success rates did not differ between conventional treatment and behavioral therapy (respectively 62.3% and 51.5%), nor did it differ at 6-months follow-up (respectively 57.3% and 42.3%). The proportion of children withholding stools was not different between interventions. At follow-up, the proportion of children with behavior problems was significantly smaller for behavioral therapy (11.7% vs. 29.2%; RR=0.42, 95%CI=0.18-0.96; $p=.039$).

Conclusion
Behavioral therapy with laxatives has no advantage over conventional treatment in treating childhood constipation. However, when behavior problems are present, behavioral therapy or referral to mental health services should be considered.
INTRODUCTION

Constipation in children is a worldwide problem with a prevalence ranging from 0.7% to 29.6% 1. Up to 84% of functional constipated children suffer from fecal incontinence 2 and over one third exhibit behavior problems 3, 4. It remains unclear whether behavior problems are primary or secondary to functional constipation.

In the vast majority of patients no somatic cause can be found and therefore these patients are considered to have a functional defecation disorder 5. Retentive posturing or stool-withholding behavior is probably the major cause for development and/or persistence of childhood constipation 6-11. Retained stools become progressively more difficult and painful to evacuate, leading to fear and avoidance of defecation 12, 13. This vicious cycle can be described as learned behavior.

Based on clinical experience, constipated children are traditionally treated by pediatricians combining laxative treatment with behavioral approaches, like toilet training and education. Long-term follow-up studies showed, however, that despite intensive medical treatment functional constipation persists into young adulthood in one-third of patients 14, 15.

In treating childhood constipation, it seems important to address defecation avoidance and to treat behavior problems. There is some evidence that the adjunct of behavioral interventions to laxative therapy, rather than laxative therapy alone, improves continence in children with functional fecal incontinence associated with constipation 16-18. We developed a protocolized behavioral therapy for constipated children and their parents. The present study aimed to evaluate this behavioral therapy with laxatives compared to conventional treatment. It was hypothesized that behavioral therapy with laxatives would result in more success regarding constipation, stool-withholding behavior, and behavior problems.

METHODS

Patients

The study population consisted of children with functional constipation aged 4-18 years referred by general practitioners, school doctors, and pediatricians to the gastrointestinal outpatient clinic at the Emma Children’s Hospital in Amsterdam, the Netherlands. Inclusion took place between November 2002 and August 2004. At entry patients had to meet at least two of four criteria: defecation frequency <3 times per week, fecal incontinence ≥2 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. Children were excluded if they had received a comprehensive behavioral therapy in the previous 12 months. Children using drugs influencing gastrointestinal function other than laxatives and children with organic causes for defecation disorders such as Hirschsprung’s disease, spina bifida occulta, hypothyroidism or other metabolic or renal abnormalities were also excluded. The medical ethics committee of the Academic Medical Center of Amsterdam approved the study protocol. All patients and/or parents gave written informed consent.

Baseline assessment
One week before baseline assessment the pediatric gastroenterologist asked the parents to consider participation in the study. Parents were assigned to discontinue any laxative treatment and to record in a bowel diary frequency of stools and episodes of fecal incontinence. The criterion of a standard amount of stool was illustrated to parents with a clay model. Fecal incontinence was defined as any amount of feces in the underwear.

The next week eligibility was verified and a physical examination, including digital rectal examination, was performed to evaluate presence of an abdominal or rectal fecal mass. Baseline data for primary and secondary outcome measures were obtained. The parent that accompanied the child to the outpatient clinic filled out the questionnaire for the secondary outcomes.

Design
The study had a two parallel group, randomized controlled design. After baseline measurement and if written informed consent was given, a research assistant performed a telephone call to a randomization center and revealed the allocation to parents immediately. A computer-based system was used to generate a sequence of random group assignment for consecutive patients. Randomization was stratified by age (4-8 years or ≥ 8 years) and gender. Within two weeks after randomization, patients received their first treatment session.

Intervention
The intervention period for both conventional treatment (CT) and behavioral therapy (BT) consisted of 12 visits during 22 weeks with similar intervals between treatment sessions. CT and BT employed similar laxative therapy. Disimpaction with daily Klyx® enemas (sodium-dioctylsulfosuccinate and sorbitol; 60 ml/day for children ≤ 6 years of age; 120 ml/day for > 6 years of age) for three
consecutive days was prescribed by pediatric gastroenterologists before starting treatment. Maintenance therapy consisted of polyethylene glycol 3350 (PEG 3350) one sachet (10 g) per day and if treatment was considered to have insufficient effect the dose was increased by one sachet. If spontaneous defecation was delayed for more than three days, parents were advised to give an enema or bisacodyl suppository of 5 mg. In BT, it was preferred to give oral bisacodyl tablets of 5 mg instead of rectal laxatives. During behavioral therapy pediatric psychologists adjusted laxative dose and consulted a pediatric gastroenterologist when necessary. In both treatment groups patients kept a bowel diary.

Conventional Treatment

CT was conducted by pediatric gastroenterologists and consisted of visits lasting approximately 20-30 minutes during which laxative treatment (PEG 3350 and if necessary Klyx® enemas or bisacodyl suppositories) and the bowel diary were discussed. Patients and their parents received education to explain that symptoms are not harmful and are common in children with functional constipation and that a positive, nonaccusatory approach is essential 20. Furthermore, children were instructed not to withhold stool when they feel 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 21. Basic assumption is that phobic reactions related to defecation can be reduced and that adequate toileting behavior and appropriate defecation straining can be (re)acquired by teaching parents behavioral procedures and by behavioral play therapy with the child in presence of its parents. The protocol consists of 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 sequential steps: Know, Dare, Can, Will, and Do. This approach is derived from a multidisciplinary behavioral therapy to treat children with defecation disorders 22, 23. For all involved psychologists a detailed manual for both age-related modules was available to ensure a standard delivery of therapy. Visits lasted approximately 45 minutes.
Clinical Outcomes

Primary outcome measures were: defecation frequency per week, fecal incontinence frequency per week and successful treatment. Treatment was considered successful if patients achieved a defecation frequency of ≥3 times per week and a fecal incontinence frequency of ≤1 times per two weeks irrespectively of laxative use.

Secondary outcome measures were: stool-withholding behavior and, behavior problems. Stool-withholding behavior was scored on a three-point scale (yes, sometimes, no) by asking parents if they observed that their child holds his legs stiffly together or crosses them when feeling urge to defecate. Behavior problems were assessed by the Child Behavior Checklist (CBCL/4–18) 24. This questionnaire obtains parent’s report of their child’s behavior problems at the time of administration and for the preceding six months. Behavioral ratings were compared with a normative sample of Dutch children 25. The CBCL yield scores for a Total problem scale, and for an Internalizing (withdrawal, somatic complaints and anxiety/depression) and Externalizing (delinquency and aggression) behavior problem scale. A T-score higher than 63 (90th percentile) is a well-validated cut-off discriminating between non-referred and referred children to mental health centers. It indicates whether a child needs professional help for his problems 24.

Assessments in each intervention arm took place at the last visit (posttreatment time point) and six months after the 22 week-treatment was ended (follow-up). Time between baseline assessment and follow-up approximately was one year. Follow-up assessment was carried out by telephone by pediatric gastroenterologists. Assessment of behavior problems at both time points was done by a research assistant who sent parents one Child Behavior Checklist with a stamped addressed envelope to return the questionnaire. Parents decided whether the mother or the father filled out the questionnaire at home.

Sample size

The sample size was calculated to allow detection of a 25% difference in the proportion of success between behavioral therapy and conventional treatment. It was estimated that conventional treatment reached success in 35% of the children at follow-up 26. Under the additional assumption of a significance level of .05, a power of .80, and 2-sided hypothesis testing, a minimal sample size of 124 with 62 children in each group was determined.
Statistical analysis

Intent-to-treat analyses were conducted using SAS version 9.1.3 and STATA version 9.2. Due to withdrawal before treatment start, drop-outs during the study, failure to fill out questionnaires, or research procedure violations missing data occurred. Imputation of missing values was used to make intent-to-treat analyses feasible. Missing data were imputed using IVEware (Imputation and Variance Estimation Software), which uses a general-purpose multivariate imputation procedure (sequential regression imputation method) that can handle relatively complex data structures when data are missing. It produces imputed values for each individual in the data set conditional on all the values observed for that individual. In this manner ten different datasets were created. All analyses were performed using these ten datasets and then aggregated by averaging the individual results.

Independent sample t-tests were used to test differences in continuous variables and Chi-square tests when the variables were categorical for the sample description at baseline. The proportion of patients that dropped out before end of treatment was tabulated and compared using Chi-square or Fisher’s Exact tests.

To determine the effect of treatment on defecation frequency and fecal incontinence frequency, negative binominal regression models were fitted with treatment (conventional treatment, behavioral therapy), time (posttreatment, follow-up), and treatment-by-time as factors. To control for possible differences in baseline values, defecation or fecal incontinence frequency at baseline were included in the model as covariates. For these regression models a robust variance estimator was used. For all binary outcome measures, a risk ratio model was applied. The effect of treatment condition on the proportion of successfully treated children, stool-withholding behavior and CBCL behavior problems (T-score>63) was derived using generalized linear models for the binomial family with treatment, time, and treatment-by-time interaction as factors in the model. Again, baseline measures were included to control for differences in baseline values. For stool-withholding behavior and the three CBCL scales, the proportion of children at baseline was included, while success rate was adjusted for the baseline value of defecation and fecal incontinence frequency. Adjusted means and proportions were derived from the regression models based on their linear predictions. Estimated values (adjusted) rather than observed (unadjusted) values are presented throughout the paper unless otherwise specified. A p-value < 0.05 was considered statistically significant.
RESULTS

Sample
A total of 134 patients were assigned to conventional treatment or behavioral therapy (Fig 1). During treatment 2/64 (3.1%) in the CT group and 9/65 (13.8%) in the BT group discontinued intervention (p=.054). At follow-up four patients

Figure 1. Patient flow chart
dropped out in CT. There was one loss of contact and three children were referred for behavioral therapy directly after conventional treatment, making them unsuitable for follow-up measurements. Questionnaires were not returned by three patients in both intervention arms at posttreatment and by nine patients (CT: 6, BT: 3) at follow-up. Baseline characteristics are presented in Table 1. Except for painful defecation (p=0.014), there were no significant differences found between the two groups in sociodemographic factors, nor for clinical characteristics.

Table 1. Baseline characteristics of children allocated to conventional treatment or behavioral therapy

<table>
<thead>
<tr>
<th></th>
<th>Conventional Treatment (n=67)</th>
<th>Behavioral Therapy (n=67)</th>
<th>N</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>6.5 (2.1)</td>
<td>6.9 (2.5)</td>
<td>134</td>
<td>.367</td>
</tr>
<tr>
<td>Boys, N (%)</td>
<td>37 (55.2)</td>
<td>39 (58.2)</td>
<td>134</td>
<td>.727</td>
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<tr>
<td>History</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age of onset constipation, mean (SD), y</td>
<td>3.0 (2.0)</td>
<td>2.8 (1.9)</td>
<td>134</td>
<td>.551</td>
</tr>
<tr>
<td>Period of treatment, mean (SD), mo</td>
<td>17.1 (19.4)</td>
<td>18.7 (21.7)</td>
<td>129†</td>
<td>.673</td>
</tr>
<tr>
<td>Positive family history, N (%)</td>
<td>28 (43.8)</td>
<td>33 (50.8)</td>
<td>131†</td>
<td>.338</td>
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<tr>
<td>Outcome measures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Defecation frequency/week, mean (SD)</td>
<td>1.9 (2.7)</td>
<td>2.0 (2.3)</td>
<td>134</td>
<td>.961</td>
</tr>
<tr>
<td>Fecal incontinence/week, mean (SD)</td>
<td>15.6 (15.9)</td>
<td>15.0 (14.2)</td>
<td>134</td>
<td>.831</td>
</tr>
<tr>
<td>Stool-withholding behavior, N (%)</td>
<td>44 (68.8)</td>
<td>43 (67.2)</td>
<td>128†</td>
<td>.850</td>
</tr>
<tr>
<td>CBCL Total score, N (%)*</td>
<td>26 (38.8)</td>
<td>23 (34.3)</td>
<td>133‡</td>
<td>.591</td>
</tr>
<tr>
<td>CBCL Internalizing score, N (%)*</td>
<td>25 (37.3)</td>
<td>23 (34.3)</td>
<td>133‡</td>
<td>.719</td>
</tr>
<tr>
<td>CBCL Externalizing score, N (%)*</td>
<td>18 (26.9)</td>
<td>18 (26.9)</td>
<td>133‡</td>
<td>1.00</td>
</tr>
<tr>
<td>Additional clinical symptomatology</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Painful defecation, N (%)</td>
<td>39 (65.0)</td>
<td>28 (43.1)</td>
<td>125†</td>
<td>.014</td>
</tr>
<tr>
<td>Hard stools, N (%)</td>
<td>19 (32.2)</td>
<td>14 (22.2)</td>
<td>122†</td>
<td>.215</td>
</tr>
<tr>
<td>Large amount of stool, N (%)</td>
<td>46 (68.7)</td>
<td>45 (67.2)</td>
<td>134</td>
<td>.853</td>
</tr>
<tr>
<td>Abdominal pain, N (%)</td>
<td>46 (69.7)</td>
<td>46 (68.7)</td>
<td>133†</td>
<td>.897</td>
</tr>
<tr>
<td>Day time urinary incontinence, N (%)</td>
<td>12 (17.9)</td>
<td>10 (14.9)</td>
<td>134</td>
<td>.641</td>
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<tr>
<td>Night time urinary incontinence, N (%)</td>
<td>23 (34.3)</td>
<td>19 (28.4)</td>
<td>134</td>
<td>.456</td>
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<tr>
<td>Physical examination</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal scybalus, N (%)</td>
<td>20 (31.3)</td>
<td>22 (35.5)</td>
<td>126§</td>
<td>.614</td>
</tr>
<tr>
<td>Rectal scybalus, N (%)</td>
<td>27 (49.1)</td>
<td>38 (58.5)</td>
<td>120§</td>
<td>.305</td>
</tr>
</tbody>
</table>

Abbreviations. SD: Standard deviation; y: year; mo: month; CBCL: Child Behavior Checklist.
† Missing characteristics were unknown to parents.
‡ One CBCL questionnaire was not filled out.
§ Missing physical examination, because the child was too anxious to perform examination.
* Proportion children with CBCL T-score >63 (90th percentile).
Primary outcomes

Baseline data are presented in Table 1. Defecation frequency increased from an average of 2.0 stools per week to 7.2 in the CT group and 5.4 in the BT group at posttreatment (Table 2). Compared to the BT group, defecation frequency in CT was significantly higher (IRR=0.75, 95% CI=0.59-0.96; p=.021). Planned comparisons showed that this effect was mainly caused by a difference between interventions at posttreatment (7.2 vs. 5.4; p=.021), and not at follow-up (6.6 vs. 5.3; p=.150).

Fecal incontinence frequency dropped from an average of 15 per week at start of the study to 2.1 and 5.0 per week at posttreatment for respectively CT and BT (Table 2). From posttreatment to follow-up, fecal incontinence frequency increased to an average of 6.4 in CT and 8.6 in BT. There was no statistically significant difference found between treatment conditions (p=.135).

At posttreatment, success rate was higher in CT (62.3%) than in BT (51.5%) (Table 2). No statistically significant difference between treatments was found, though (p=.249). At follow-up, the number of children successfully treated declined to 57.3% in CT and 42.3% in BT. Again, the difference proved statistically non-significant (p=.095).

Table 2. The effect of treatment on primary outcome measures: defecation frequency, fecal incontinence frequency and the proportion of success.

<table>
<thead>
<tr>
<th></th>
<th>Conventional Treatment</th>
<th>Behavioral Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Defecation frequency/week, mean (95%CI)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posttreatment §</td>
<td>7.2 (6.1-8.5)</td>
<td>5.4 (4.3-6.7)</td>
</tr>
<tr>
<td>Follow-up *</td>
<td>6.6 (5.0-8.8)</td>
<td>5.3 (4.4-6.3)</td>
</tr>
<tr>
<td><strong>Fecal incontinence/week, mean (95% CI)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posttreatment</td>
<td>2.1 (0.8-5.8)</td>
<td>5.0 (2.1-12.0)</td>
</tr>
<tr>
<td>Follow-up</td>
<td>6.4 (3.5-11.7)</td>
<td>8.6 (4.0-18.3)</td>
</tr>
<tr>
<td><strong>Success, % (95% CI)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posttreatment</td>
<td>62.3 (51.1-76.1)</td>
<td>51.5 (39.7-66.9)</td>
</tr>
<tr>
<td>Follow-up</td>
<td>57.3 (46.6-70.4)</td>
<td>42.3 (31.8-56.4)</td>
</tr>
</tbody>
</table>

Abbreviations. CI: Confidence Interval; RR: Relative Risk, derived from generalized linear models for the binomial family with group (conventional treatment, behavioral therapy), defecation frequency and fecal incontinence frequency at baseline as factors in the model; IRR: Incidence Rate Ratio, derived from negative binominal regression models with group (conventional treatment, behavioral therapy), time (posttreatment, follow-up), the interaction term of group by time as factors and baseline score as covariate included in the model.
Secondary outcomes

Baseline data are presented in Table 1. Stool-withholding behavior was reduced from baseline to follow-up in both treatments conditions; from over two-third of the children withholding their stools to 13.8% in CT and 10.6% in BT at posttreatment (Table 3). The proportion of children with stool-withholding behavior did not differ between interventions (p=.654).

Most CBCL forms were filled out by mothers (72.3%), followed by fathers (15.4%) and others (10.8%) (i.e. stepmothers and stepfathers). In 59.6% of the full cases, the same responder filled out the CBCL at all assessment points with no difference between the two treatment groups (CT: 58.5%; BT: 60.7%, p=.813). Over one-third of the children exhibited behavior problems (CBCL T-score>63) at baseline. At end of treatment, this percentage was decreased to 22.8% in CT and 21.9% in BT (Table 3). At follow-up, BT was found to have influenced behavior problems significantly by reducing the proportion of children with these problems to 11.7% compared to 29.2% in CT (RR=0.42, 95% CI=0.18-0.96; p=.039).

The proportion of children with internalizing problems also declined from an average of 35.8% to 17.3% and 18.9% for respectively CT and BT (Table 3). At follow-up, this proportion increased in CT, but decreased further in BT (23.4%...
vs. 14.0%). However, no statistically significant effect was found for the effect of treatment condition (p=.600), nor for the influence of behavioral therapy at follow-up (p=.156).

The proportion of children exhibiting externalizing problems changed from an average proportion of 26.9% to 15.9% in CT and 15.6% in BT at posttreatment (Table 3). Both treatments appeared equally effective in reducing externalizing problems (p=.990).

DISCUSSION

This study is the first large randomized controlled trial evaluating the clinical effectiveness of behavioral therapy with laxatives for functional constipation in childhood. The results indicate that this behavioral therapy with laxatives has no advantage over conventional treatment in treating childhood constipation. Both treatments decreased fecal incontinence frequency and increased defecation frequency. However, conventional treatment resulted in a higher defecation frequency than behavioral therapy. Behavior problems were common with over one-third of the participating children exhibiting these problems. This study shows that behavioral therapy is superior in addressing behavior problems in constipated children.
Our results can only be compared with one other randomized controlled trial 18 and one quasi-randomized trial 29, which also evaluated the effect of an extensive behavioral intervention with laxatives compared to conventional treatment. Borowitz et al. 18 also found no differences in treatment success between three different treatment modalities: medical therapy, medical therapy plus enhanced toilet training and, medical therapy plus enhanced toilet training plus biofeedback training. Still, the enhanced toilet training intervention was considered to be more effective, since more children responded to treatment with decreases in fecal incontinence. This latter finding is in contrast with our outcome. Taitz and colleagues 29 investigated in 47 children the additional effect of play therapy with both a focus on the individual child and on parent-child interaction. In accordance with our results, their findings indicated that psychotherapeutic elements do not add to medical treatment, which traditionally already incorporates behavioral management techniques such as toilet training, positive reinforcement and education.

Our hypothesis that behavioral therapy would result in more children ceasing their stool withholding behavior than conventional treatment was not confirmed. The main assumption underlying our behavior therapy was that fear for defecation perpetuates chronic constipation with stool-withholding behavior as avoidance response. Prescribed laxative treatment may have

<table>
<thead>
<tr>
<th>Group†</th>
<th>Group x Time‡</th>
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<tbody>
<tr>
<td>RR=0.77 95% CI=(0.24-2.46)</td>
<td>RR=1.72 95% CI=(0.43-6.91)</td>
</tr>
<tr>
<td>p=.654</td>
<td>p=.444</td>
</tr>
<tr>
<td>RR=1.04 95% CI=(0.65-1.68)</td>
<td>RR=0.42 95% CI=(0.18-0.96)</td>
</tr>
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<td>p=.863</td>
<td>p=.039</td>
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<tr>
<td>RR=1.16 95% CI=(0.66-2.03)</td>
<td>RR=0.56 95% CI=(0.24-1.26)</td>
</tr>
<tr>
<td>p=.600</td>
<td>p=.156</td>
</tr>
<tr>
<td>RR=1.00 95% CI=(0.52-1.90)</td>
<td>RR=0.97 95% CI=(0.40-2.34)</td>
</tr>
<tr>
<td>p=.990</td>
<td>p=.947</td>
</tr>
</tbody>
</table>

† Group: the main effect of behavioral treatment on CBCL score.
‡ Group x Time: the interaction effect of behavioral treatment with CBCL score at follow-up.
§ Posttreatment: assessment of clinical outcomes at the last treatment visit.
* Follow-up: assessment of clinical outcomes 6 months after the 22-week treatment was ended.
# Proportion children with CBCL T-score >63 (90th percentile).
caused large improvement of this aberrant behavior in both interventions. Laxatives facilitate transport and expulsion by softening of stools and thus seem to prevent stool-withholding behavior sufficiently 8, 17. Conventional treatment was associated with more frequent bowel movements per week. Before starting treatment, optimal laxative dosages were established for each child by the pediatric gastroenterologists. However, during behavioral therapy pediatric psychologists adjusted laxative dosages and only consulted the pediatric gastroenterologist when necessary in their opinion. This possibly resulted in prescribing suboptimal dosages and less use of rescue medication. This stresses the important role for experienced pediatricians in regulating laxatives, one of the main components in the treatment of childhood constipation 30.

As expected behavioral therapy relieved more children from coexisting behavior problems. This is not surprisingly, since the behavioral protocol aims at decreasing anxiety and teaches parents behavior modification procedures. Part of the reduction of behavior problems in both treatments may be explained by normalized behavioral functioning after successful treatment, since it is assumed that the social impact of fecal incontinence is mainly responsible for disturbed behavior in children with functional defecation disorders 31-33. The exact relationship between functional constipation and behavior problems still remains unclear though, as well as the influence of behavior problems on treatment outcome. Since in this study no difference in success rate was revealed between the two intervention arms, the beneficial effect of behavioral therapy on behavioral functioning seems not to be (directly) related to resolution of constipation-related symptoms.

Some limitations of this study need to be considered. The visit frequency and duration of treatment of the conventional treatment were made equivalent to that of the behavioral treatment group to strengthen the comparison of treatments, which however could also jeopardize generalizing the findings to general practice. Regardless of high visit frequency and duration this did not lead to a higher success rate compared to those studies with two to six visits in a time period of six months, though 18, 26, 31, 32, 34, 35. Generalization of the findings may also be hampered as the pediatric gastroenterologists involved in this study are highly specialized and experienced in treating chronic constipation. However, conventional treatment in our study was based on the clinical practice guideline from the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) 36 that provides recommendations for management of functional constipation by the primary care provider. These guidelines are generally available and employed by many pediatric gastroenterologists and primary care providers. Furthermore, primary
outcome measures and stool-withholding behavior were not blindly rated. Another limitation was that pediatric psychologists were partly responsible for laxative treatment in the behavioral therapy condition, which possibly resulted in differences in laxative treatment. Despite the afore-mentioned limitations, we feel that our study has several strong points such as a large sample that approximates the average patient in primary care settings with no restrictions regarding psychiatric abnormalities. Furthermore, two well-controlled and protocolized specialized treatments were used with similar frequency of visits and a 6-months follow-up period. Also, this study showed a low attrition rate. This randomized controlled trial showed that behavioral therapy with laxatives has no advantage over conventional treatment in treating childhood constipation. Conventional treatment should remain the first choice of treatment. Behavioral therapy may be considered when children experience behavior problems concurrently. Quality of care for chronically constipated children may be improved by adding a behavioral screening to the clinical evaluation of constipated children. Positive screening should lead to considering behavioral therapy or referral to mental health services.

Acknowledgements
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REFERENCES


