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Behavioral Therapy for Childhood Constipation: A Randomized, Controlled Trial

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What's Known on This Subject	What This Study Adds
Stool-withholding behavior is probably the major cause for development and/or persistence of childhood constipation. There is some evidence that the adjunct of behavioral interventions to laxative therapy, rather than laxative therapy alone, improves continence in children with constipation.	This is the first large, randomized, controlled trial evaluating the effectiveness of behavioral therapy in constipated children. The study showed that conventional treatment should remain the first choice of treatment. When behavioral problems are present, behavioral therapy should be considered.

ABSTRACT

OBJECTIVE. It has been suggested that the 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 with 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 to 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 ≥3 times per week and fecal incontinence frequency of ≤1 times per 2 weeks irrespective of laxative use. Secondary outcomes were stool-withholding behavior and behavior problems. Outcomes were evaluated at the end of treatment and at 6-months follow-up. All of the analyses were done by intention to treat.

RESULTS. Defecation frequency was significantly higher for conventional treatment. 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 of 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%).

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.

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 more than 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 (BT) for constipated children and their parents. The present study results aimed to evaluate this BT with laxatives compared with conventional treatment (CT). It was hypothesized that BT 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 to 18 years referred by general practitioners, school doctors, and pediatricians to the gastrointestinal outpatient clinic at the Emma Children's Hospital. Inclusion took place between November 2002 and August 2004. At entry, patients had to meet at least 2 of 4 criteria: defecation frequency <3 times per week, fecal incontinence ≥2 times per week, passage of large amounts of stool at least once every 7 to 30 days (large enough to clog the toilet), or a palpable abdominal or rectal fecal mass.[19] Children were excluded if they had received a comprehensive BT 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 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 of the 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 who accompanied the child to the outpatient clinic filled out the questionnaire for the secondary outcomes.

Design

The study had a 2-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.

Random assignment was stratified by age (4–8 years or ≥8 years) and gender. Within 2 weeks after random assignment, patients received their first treatment session.

Intervention

The intervention period for both CT and BT consisted of 12 visits during 22 weeks with similar intervals between treatment sessions. CT and BT used similar laxative therapy. Disimpaction with daily Klyx enemas (PCH Pharmachemie BV-Teva Pharmaceutical Industries, Haarlem, Netherlands, sodium-dioctylsulfosuccinate and sorbitol; 60 mL per day for children ≤6 years of age; 120 mL per day for children >6 years of age) for 3 consecutive days was prescribed by pediatric gastroenterologists before starting treatment. Maintenance therapy consisted of polyethylene glycol 3350, 1 sachet (10 g) per day, and if treatment was considered to have insufficient effect, the dose was increased by 1 sachet. If spontaneous defecation was delayed for >3 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 BT, pediatric psychologists adjusted the laxative dose and consulted a pediatric gastroenterologist when necessary. In both treatment groups, patients kept a bowel diary.

CT

CT was conducted by pediatric gastroenterologists and consisted of visits lasting ~20 to 30 minutes, during which laxative treatment (polyethylene glycol 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 BT

BT was developed by pediatric psychologists of the psychosocial department of our hospital.[21] The 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 his or her parents. The protocol consists of 2 age-related modules: a module for children aged 4 to 8 years and a module for children aged ≥8 years. The learning process for child and parents consists of 5 sequential steps: know, dare,

can, will, and do. This approach is derived from a multi-disciplinary BT 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 ~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 2 weeks, irrespective of laxative use.

Secondary outcome measures were stool-withholding behavior and behavior problems. Stool-withholding behavior was scored on a 3-point scale (yes, sometimes, or 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 6 months. Behavioral ratings were compared with a normative sample of Dutch children.[25] The CBCL yields scores for a total problem scale and for an internalizing (withdrawal, somatic complaints, and anxiety or depression) and externalizing (delinquency and aggression) behavior problem scale. Derived from standard scores, a normalized T-score >63 (90th percentile) is a well-validated cutoff discriminating between nonreferred and referred children to mental health centers. It indicates whether a child needs professional help for his or her problems.[24]

Assessments in each intervention arm took place at the last visit (posttreatment time point) and 6 months after the 22-week treatment was ended (follow-up). Time between baseline assessment and follow-up was ~1 year. Follow-up assessment was conducted by telephone by pediatric gastroenterologists. Assessment of behavior problems at both time points was done by a research assistant who sent parents one CBCL 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 BT and CT. It was estimated that CT 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 9.1.3 (SAS Institute, Inc, Cary, NC) and Stata 9.2 (Stata Corp, College Station, TX). Because of withdrawal before treatment start, dropouts 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.[27] Missing data were imputed using Imputation and Variance Estimation Software (IVEware: Imputation and Variance Estimation Software, Survey Methodology Program, Survey Research Center, Institute for Social Research, University of Michigan. T. E. Raghunathan, Peter W. Solenberger, John Van Hoewyk), which uses a general-purpose multivariate imputation procedure (sequential regression imputation method[28]) 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 of the values observed for that individual. In this manner, 10 different data sets were created. All of the analyses were performed using these 10 data sets and then aggregated by averaging the individual results.

Independent sample t tests were used to test differences in continuous variables and χ^2 tests when the variables were categorical for the sample description at baseline. The proportion of patients who dropped out before the end of treatment was tabulated and compared using χ^2.

To determine the effect of treatment on defecation frequency and fecal incontinence frequency, negative binomial regression models were fitted with treatment (CT or BT), time (posttreatment and 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 of the 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 (normalized 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 3 CBCL scales, the proportion of children at baseline was included, whereas 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 article unless otherwise specified. A P value <.05 was considered statistically significant.

RESULTS

Sample

A total of 134 patients were assigned to CT or BT (Fig 1). During treatment 2 (3.1%) of 64 in the CT group and 9 (13.8%) of 65 in the BT group discontinued intervention (P = .054). At follow-up, 4 patients dropped out in CT. There was 1 loss of contact, and 3 children were referred for BT directly after CT, making them unsuitable for follow-up measurements. Questionnaires were not returned by 3 patients in both intervention arms at post-
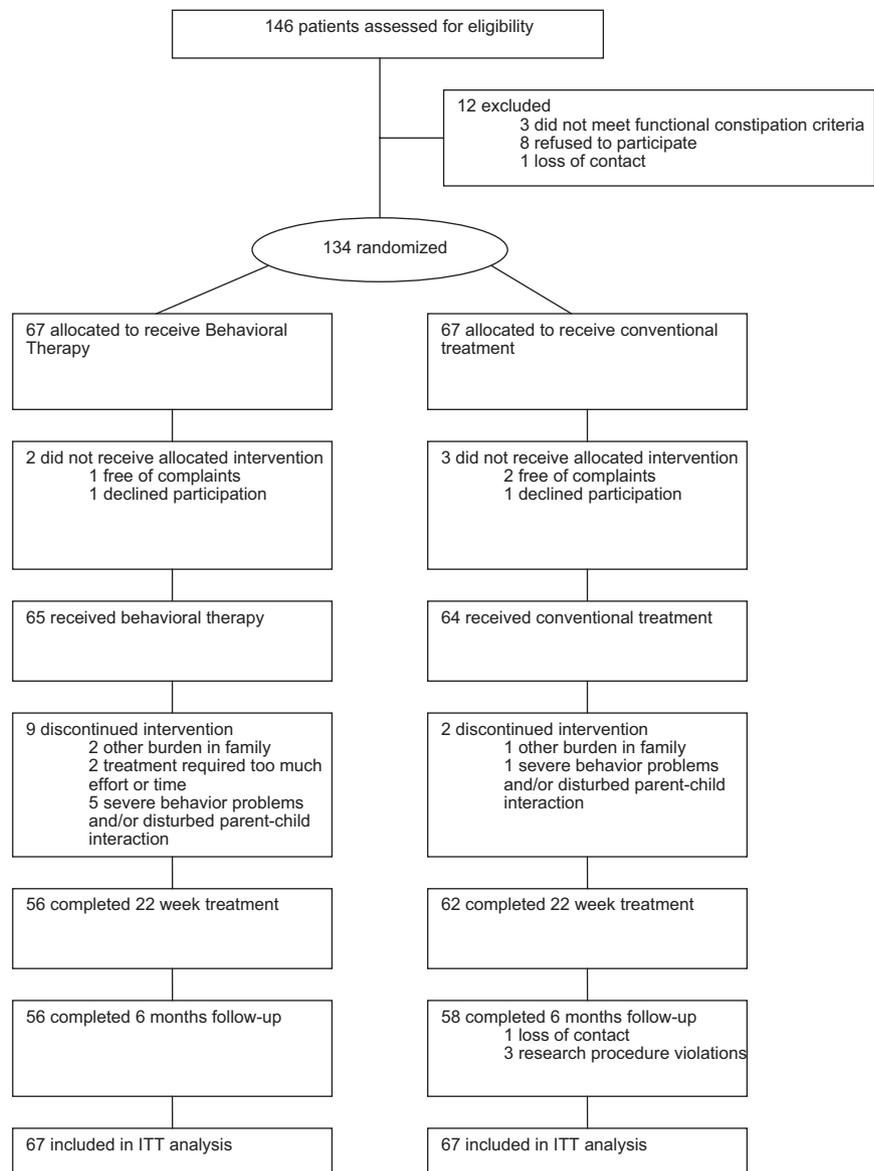
FIGURE 1
Patient flowchart.

treatment and by 9 patients (CT: 6; BT: 3) at follow-up. Baseline characteristics are presented in Table 1. Except for painful defecation (*P* = .014), there were no significant differences found between the 2 groups in sociodemographic factors or for clinical characteristics.

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 with the BT group, defecation frequency in CT was significantly higher (incidence rate ratio: 0.75; 95% confidence interval [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). However, no statistically significant difference between treatments was found (*P* value = .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 nonsignificant (*P* = .095).

Secondary Outcomes
Baseline data are presented in Table 1. Stool-withholding behavior was reduced from baseline to follow-up in both treatments conditions; from more than two thirds of the children withholding their stools to 13.8% in CT

TABLE 1 Baseline Characteristics of Children Allocated to CT or BT

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

[a] Missing characteristics were unknown to parents.
[b] Data show the proportion children with CBCL normalized T-score >63 (90th percentile).
[c] One CBCL questionnaire was not filled out.
[d] Physical examination is missing because the child was too anxious to perform examination.

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%; ie, stepmothers and stepfathers). In 59.6% of the full cases, the same responder filled out the CBCL at all of the assessment points, with no difference between the 2 treatment groups (CT: 58.5%; BT: 60.7%; $P =$

.813). More than one third of the children exhibited behavior problems (CBCL normalized 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 with 29.2% in CT (relative risk: 0.42; 95% CI: 0.18–0.96; $P = .039$).

TABLE 2 The Effect of Treatment on Primary Outcome Measures: Defecation Frequency, Fecal Incontinence Frequency, and the Proportion of Success

Variable	CT	BT	Group[a]		Group × Time[b]	
			IRR/RR (95% CI)	P	IRR/RR (95% CI)	P
Defecation frequency per week, mean (95% CI)			IRR = 0.75 (0.59–0.96)	.021	IRR = 1.06 (0.75–1.50)	.758
Posttreatment[c]	7.2 (6.1–8.5)	5.4 (4.3–6.7)				
Follow-up[d]	6.6 (5.0–8.8)	5.3 (4.4–6.3)				
Fecal incontinence per week, mean (95% CI)			IRR = 2.36 (0.77–7.31)	.135	IRR = 0.57 (0.12–2.61)	.467
Posttreatment	2.1 (0.8–5.8)	5.0 (2.1–12.0)				
Follow-up	6.4 (3.5–11.7)	8.6 (4.0–18.3)				
Success, % (95% CI)						
Posttreatment	62.3 (51.1–76.1)	51.5 (39.7–66.9)	RR = 0.83 (0.60–1.14)	.249	—	—
Follow-up	57.3 (46.6–70.4)	42.3 (31.8–56.4)	RR = 0.74 (0.52–1.05)	.095	—	—

RR indicates relative risk, derived from generalized linear models for the binomial family with group (CT or BT), defecation frequency, and fecal incontinence frequency at baseline as factors in the model; IRR, incidence rate ratio, derived from negative binomial regression models with group (CT or BT), time (posttreatment or follow-up), the interaction term of group by time as factors, and baseline score as covariate included in the model.
[a] Group is the main effect of BT.
[b] Group × time is the interaction effect of BT with measurement at follow-up.
[c] Posttreatment is the assessment of clinical outcomes at the last treatment visit.
[d] Follow-up is the assessment of clinical outcomes 6 months after the 22-week treatment was ended.

TABLE 3 The Effect of Treatment on Secondary Outcome Measures: The Proportion of Children Exhibiting Stool-Withholding Behavior and Behavior Problems (CBCL Total Score >63)

Variable	CT		BT		Group[a]		Group × Time[b]	
	%	95% CI	%	95% CI	RR (95% CI)	P	RR (95% CI)	P
Stool-withholding behavior					0.77 (0.24–2.46)	.654	1.72 (0.43–6.91)	.444
Posttreatment[c]	13.8	7.3–26.3	10.6	3.7–30.1				
Follow-up[d]	14.2	7.3–27.8	18.7	9.3–37.7				
CBCL total score[e]					1.04 (0.65–1.68)	.863	0.42 (0.18–0.96)	.039
Posttreatment	22.8	13.7–37.7	21.9	12.5–38.2				
Follow-up	29.2	19.3–44.3	11.7	5.1–26.7				
CBCL internalizing score[e]					1.16 (0.66–2.03)	.600	0.55 (0.24–1.26)	.156
Posttreatment	17.3	9.2–32.3	18.9	10.8–33.2				
Follow-up	23.4	13.3–41.0	14.0	6.1–31.7				
CBCL externalizing score[e]					1.00 (0.52–1.90)	.990	0.97 (0.40–2.34)	.947
Posttreatment	15.9	8.4–30.1	15.6	8.0–30.3				
Follow-up	16.4	8.3–32.2	15.6	7.3–33.1				

RR indicates relative risk, derived from generalized linear models for the binomial family with group (CT or BT), time (posttreatment or follow-up), the interaction term of group by time, and the proportion of children having stool-withholding behavior or having CBCL total score >63 at baseline as factors in the model.

[a] Group is the main effect of behavioral treatment.

[b] Group × time is the interaction effect of behavioral treatment with measurement at follow-up.

[c] Posttreatment is the assessment of clinical outcomes at the last treatment visit.

[d] Follow-up is the assessment of clinical outcomes 6 months after the 22-week treatment was ended.

[e] Proportion children with CBCL normalized T-score >63 (90th percentile).

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) or for the influence of BT 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 seemed equally effective in reducing externalizing problems (P = .990).

DISCUSSION

This study is the first large randomized, controlled trial evaluating the clinical effectiveness of BT with laxatives for functional constipation in childhood. The results indicate that this BT with laxatives has no advantage over CT in treating childhood constipation. Both treatments decreased fecal incontinence frequency and increased defecation frequency. However, CT resulted in a higher defecation frequency than BT. Behavior problems were common, with more than one third of the participating children exhibiting these problems. This study shows that BT is superior in addressing behavior problems in constipated children.

Our results can only be compared with 1 other randomized, controlled trial[18] and 1 quasirandomized trial,[29] which also evaluated the effect of an extensive behavioral intervention with laxatives compared with CT. Borowitz et al[18] also found no differences in treatment success among 3 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, because more children responded to treatment with decreases in fecal incontinence. This latter finding is in contrast with our outcome. Taitz et al[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 BT would result in more children ceasing their stool withholding behavior than CT 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 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]

CT 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 BT, 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 BT relieved more children from coexisting behavior problems. This is not surprising, because 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, because 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, as well as the influence of behavior problems on treatment outcome. Because in this study no difference in success rate was revealed between the 2 intervention arms, the beneficial effect of BT on behavioral functioning seems not to be (directly) related to the resolution of constipation-related symptoms.

Some limitations of this study need to be considered. The visit frequency and duration of treatment of the CT were made equivalent to that of the BT 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 with those studies with 2 to 6 visits in a time period of 6 months.[18,19,26,31,34,35] Generalization of the findings may also be hampered, because the pediatric gastroenterologists involved in this study are highly specialized and experienced in treating chronic constipation. However, CT in our study was based on the clinical practice guideline from the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition,[36] which provides recommendations for the management of functional constipation by the primary care provider. These guidelines are generally available and used 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 BT condition, which possibly resulted in differences in laxative treatment. Despite the aforementioned 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, 2 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 BT with laxatives has no advantage over CT in treating childhood constipation. CT should remain the first choice of treatment. BT 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.[13,36] Positive screening should lead to considering BT or referral to mental health services.

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