Internet-Delivered Exposure-Based Cognitive-Behavioral Therapy for Adolescents With Functional Abdominal Pain or Functional Dyspepsia: A Feasibility Study

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Functional abdominal pain (FAP) and functional dyspepsia (FD) are common in adolescents and associated with low quality of life. Exposure-based cognitive-behavioral therapy (CBT) is efficient for adult and adolescent irritable bowel syndrome (IBS), but has never been evaluated for adolescent FAP/FD. The aim of this study was to evaluate the feasibility and potential efficacy of a novel disorder-specific Internet-delivered CBT (Internet-CBT) for adolescents with FAP or FD, using an uncontrolled open pilot including 31 adolescents. The Internet-CBT consisted of 10 weekly online modules, which focused mainly on exposure to abdominal symptoms. Parents received modules to help them reduce unhelpful parental behaviors. Participants reported the treatment to be credible, and an overall satisfaction with the treatment. Data attrition rate was low (7%) and adherence to treatment was acceptable. We saw a significant and large effect on the primary outcome, pain intensity, at posttreatment ($d = 1.20$, $p < .001$) that was further improved after 6 months ($d = 1.69$, $p < .001$). Participants also made significant and large improvements on gastrointestinal symptoms ($d = 0.84$, $p < .001$) and quality of life ($d = 0.84$, $p < .001$) that were sustained or further improved at follow-up 6 months after treatment. This study demonstrated that exposure-based Internet-CBT, tailored for adolescents with FAP or FD, is a feasible treatment that potentially improves pain intensity, gastrointestinal symptoms, and quality of life.

ADOLESCENT FUNCTIONAL ABDOMINAL PAIN (FAP) and functional dyspepsia (FD) belong to the pain-predominant functional gastrointestinal disorders (P-FGIDs) according to the Rome III criteria, and are characterized by weekly abdominal pain with a duration of at least 2 months (Rasquin et al., 2006). In FD the pain is located to the upper abdomen and is often coupled with other gastrointestinal (GI) symptoms, such as nausea and early satiety (Rasquin et al., 2006). The prevalence of FAP and FD among adolescents is estimated to 8% worldwide (Korterink, Diederen, Benninga, & Tabbers, 2015). Pharmacological or dietary treatments are not yet proven effective for adolescents but probiotics may have some beneficial effect (Newlove Delgado et al., 2017). In contrast, psychological treatments have shown promising effects (Rutten, Korterink, Venmans, Benninga, & Tabbers, 2015). Of these treatments, cognitive-behavioral therapy (CBT) is the most evaluated (Eccleston et al., 2014).

Even though CBT is effective, there are few adolescents with FAP/FD who get access to the treatment (Reed-Knight, Claar, Schurman, & van Tilburg, 2016). The treatment gap (i.e., the great need for evidence-based psychological treatment in contrast to the few well-educated therapists geographically concentrated to the major cities and university centers) is a well-known problem (Barlow, Bullis, Comer, & Ametaj, 2013; Kazdin, 2017; Kazdin & Blase, 2011; Shafran et al., 2009). Internet-delivered CBT (Internet-CBT) could potentially increase the availability of CBT since all content is delivered online and thereby can be delivered over any distance (Hedman, Ljótsson, & Lindefors, 2012). Internet-CBT also has the potential to provide specialized care for disorders that few therapists have been trained to treat (Comer & Barlow, 2014). This type of treatment has been evaluated for many somatic and psychiatric disorders in the pediatric population (Vigerland et al., 2016) with positive effects.

Most CBT protocols for P-FGIDs include multiple components, such as behavioral activation, sleep hygiene, advice on diet and eating, relaxation, and interventions targeting parental behavior (Brent, Lobato, & LeLeiko, 2009; Reed-Knight, Claar, Schurman, & van Tilburg, 2016; Sprenger, Gerhards, & Goldbeck, 2011). In contrast, exposure-based CBT for P-FGIDs is based on one main treatment strategy, which is exposure to GI symptoms—all components in the treatment directed at the adolescents and their parents serve to aid effective exposure. Exposure-based CBT is based on the evidence for heightened visceral sensitivity among adults with irritable bowel syndrome (IBS; one of the functional GI disorders) that is characterized by fear and avoidance behaviors related to GI symptoms. This has been shown to perpetuate and exacerbate symptoms in adults with IBS (Jerndal et al., 2010; Labus, Mayer, Chang, Bolus, & Naliboff, 2007; Reme, Darnley, Kennedy, & Chalder, 2010). Exposure to GI symptoms has been shown to be a successful treatment strategy in adult IBS (Craske et al., 2011; Ljótsson et al., 2010, 2011, 2014).

Our research group has previously investigated exposure-based Internet-CBT for 101 adolescents with IBS and found significant and stable improvements on all relevant outcomes (Bonnert et al., 2017). Prior to this randomized controlled trial, we conducted an uncontrolled feasibility study on 29 adolescents with P-FGIDs (i.e., including IBS, FAP, and FD) with promising and stable treatment effects (Bonnert et al., 2014). However, unpublished subgroup analyses indicated that the participants with IBS improved more from the treatment than participants with FAP/FD. Furthermore, the clinical observation was that participants with FAP/FD did

not adhere to the treatment to the same extent as the participants with IBS. Taking this into account we adapted the exposure-based treatment and developed one treatment protocol for adolescents with FAP/FD. Primarily, we replaced all examples and exercises that targeted specific IBS symptoms (i.e., the disturbed defecation pattern) with examples and exercises targeting FAP/FD symptoms.

Overall treatment effects for pediatric somatic disorders are in general moderately sized (Vigerland et al., 2016) and treatment adherence in Internet-CBT is generally low (Richardson, Stallard, & Velleman, 2010), with a mean adherence of 58% reported (Richardson, Stallard, & Velleman, 2010; Wildeboer, Kelders, & Gemert-Pijnen, 2016). Feasibility studies can establish procedures that increase treatment adherence and yield preliminary effect size estimates for subsequent randomized controlled trials (Mohr et al., 2009). The main objective of this study was to evaluate the feasibility and potential efficacy of exposure-based Internet-CBT for adolescents with FAP or FD.

Method

Design and Setting

This was an open feasibility study with a pretest/posttest design without a control group. All participants received 10 weeks of Internet-CBT. Thirty-one adolescents from all of Sweden, ages 13–17, were recruited through their physicians from March 2015 until April 2016. The adolescents participated in the treatment together with one of their parents. Assessments were conducted at pretreatment, posttreatment, and at 6-month follow-up. This study is reported according to the TREND Statement Checklist for Nonrandomized Interventions (Des Jarlais, Lyles, Crepaz, and TREND Group, 2011). The study was approved by the Regional Ethical Review Board in Stockholm in September 2014 and is registered on clinicaltrials.gov (reg. no. NCT02306941).

Feasibility Criteria

Factors that have been suggested to be important for an Internet-CBT to be regarded as acceptable and efficient are adherence to treatment as well as alliance with the therapist (Andersson & Titov, 2014). Other factors that have been considered important are credibility and client satisfaction with treatment (Ritterband, Thorndike, Vasquez, & Saylor, 2010). Adherence in Internet-CBT has been defined as the extent to which participants use the Web site material (Christensen, Griffiths, & Farrer, 2009). In the present study, we used the proportion of completed modules as indicator of adherence.

In summary, the feasibility criteria for this study were treatment adherence $\geq 70\%$, at least intermediate level of treatment credibility, a rated working alliance with the therapist comparable to other trials on Internet-CBT, and satisfaction with the treatment. We also included potential efficacy as a feasibility criterion and expected at least a moderate within-group effect size on the primary measure of effect.

Eligibility Criteria

Adolescents (13–17 years) with FAP/FD and residing in Sweden were referred to the study by a physician who had signed a health form ensuring no suspected or confirmed organic disease that could explain the abdominal symptoms. Moreover, the adolescent and one parent had to have access to the Internet. The adolescents had to fulfill the Rome III diagnoses of FAP or FD at the time of the clinical interview. The following were causes for exclusion: school absence due to abdominal symptoms on more than 40% of the days in the month before inclusion, ongoing psychological treatment, or serious psychiatric condition or severe psychosocial distress.

Procedure

Participants were recruited nationally in Sweden through physicians who were informed about the study via e-mails and lectures. After submitting the signed health form, the families were invited to conduct an online screening. The screening included the Rome III Questionnaire (Caplan, Walker, & Rasquin, 2005) to confirm an FAP/FD diagnosis. After completion of the screening, a clinical psychologist conducted a 90-minute assessment interview to investigate presence of psychosocial or psychiatric problems and to confirm that the adolescent met the Rome III criteria for FAP/FD (Rasquin et al., 2006). Criteria include weekly abdominal pain for at least 2 months located to the upper abdomen (FD) or all abdomen (FAP) with no disturbed defecation pattern. After the interview, eligible parents and adolescents signed an informed consent form and completed the online pretreatment assessment before starting treatment.

Outcome Measures

Acceptability of Treatment

Credibility Rating Scale (C-Scale). The C-Scale includes five items rated on a 11-point scale from 0 (*not at all*) to 10 (*very*) and was developed to assess the participant's expectations of the treatment

(Borkovec & Nau, 1972). Credibility was assessed during the second week of treatment. The scale was slightly adapted to fit the target group and included items such as "How sure are you that this treatment can successfully decrease your abdominal symptoms?" and "How much do you expect to improve due to this treatment?"

Working Alliance Inventory (WAI). The WAI was used to assess the adolescents' perceived alliance with the online therapist, and were collected during the fourth week of treatment. The original instrument includes 36 items scored on a scale from 1 (*never*) to 7 (*always*; Horvath & Greenberg, 1989). For this study we used a short six-item version, adapted for the Internet (Andersson et al., 2012; Falkenström, Hatcher, Skjulsvik, Larsson, & Holmqvist, 2015).

Client Satisfaction Questionnaire (CSQ-8). The CSQ-8 is an eight-item questionnaire with items such as "Did you get the kind of service you wanted?" and "To what extent has our program met your needs?" with answers ranging from 1 (*bad*) to 4 (*very good*; Attkisson & Zwick, 1982). The CSQ-8 was collected at postassessment. The CSQ-8 has been evaluated in children ages 8–17 and their mothers with good psychometric properties (Copeland, Koeske, & Greeno, 2016). Information about *adverse events* were collected at posttreatment with the following questions: (a) "Have you experienced any unwanted effects during treatment?" and "If yes, describe the unwanted event or unwanted effect"; (b) "How negative do you think this unwanted effect affected your mood when it occurred?"; and (c) "How negative do you think this undesirable effect affects your mood today?"

Primary Measure of Potential Efficacy
The Faces Pain Rating Scale—Revised (Faces; Hicks, von Baeyer, Spafford, van Korlaar, & Goodenough, 2001) was used as the primary outcome measure of pain intensity. Faces includes one item that is scored between 0 (*no pain*) and 10 (*worst pain*), in two-step intervals. Each score has a graphic anchor, which is a face that expresses an increasing degree of pain for each two-step increase in score. Faces is validated for children and adolescents with good psychometric properties (e.g., test–retest $r = .79$; Stinson, Kavanagh, Yamada, Gill, & Stevens, 2006), and is one of the recommended scales to assess pain intensity in treatment trials (Huguet, Stinson, & McGrath, 2010)

Secondary Outcomes
Pediatric Quality of Life Inventory (PedsQL). The PedsQL is a 23-item scale used to measure quality of life during the last month in pediatric somatic samples (Varni, Seid, & Kurtin, 2001). PedsQL has shown excellent internal consistency (Cronbach's α = .88; Varni, Seid, & Kurtin, 2001). Responses are transformed to a 0–100 scale with higher scores indicating fewer problems.

Pediatric Quality of Life Inventory Gastrointestinal Symptoms Module (PedsQL-GI). The PedsQL-GI comprises 14 subscales developed for assessing symptom severity in the pediatric FGIDs during the last month (Varni et al., 2014). For the current study, we selected three of the subscales measuring abdominal pain and hurt (six items), abdominal discomfort when eating (five items), and nausea and vomiting (four items). These subscales have shown good internal consistency both in children with P-FGIDs (Cronbach's α between .85 and .92) and healthy controls (Cronbach's α between .88 and .98; Varni et al., 2015). Responses are transformed to a 0–100 scale with higher scores indicating fewer symptoms.

Children's Somatization Inventory 24 (CSI-24). The CSI-24 is a scale measuring somatic symptoms in children during the last 2 weeks on a 0- to 4-point scale (Walker, Beck, Garber, & Lambert, 2009). For the current study we used seven items describing GI symptoms (CSI-GI) for comparability with other treatment studies in the field on this dimension (Levy et al., 2010). Good internal consistency has been reported for CSI-GI (Chronbach's α = .80; Vila et al., 2009).

Behavioral Response Questionnaire (BRQ). The BRQ was used to assess GI-specific avoidant behavior. The scale was originally developed for adult IBS showing good reliability and internal consistency (Reme, Darnley, Kennedy, & Chalder, 2010). For the present study, nine items dealing with typical IBS behaviors (e.g., toilet behavior) were dropped, leaving 17 items scored on a 1- to 7-point scale.

Visceral Sensitivity Index (VSI). The VSI was used to assess visceral sensitivity and has demonstrated good concurrent, divergent, and discriminant validity. The VSI was also originally developed for adult IBS (Labus et al., 2004), and for the present study four items dealing with IBS-specific symptom fear were dropped, leaving 11 items on a 0- to 5-point scale.

Parent-Rated Outcomes
The parent-rated versions of the PedsQL, CSI-GI, and Spence Children's Anxiety Scale (SCAS;

Spence, Barrett, & Turner, 2003) were used to measure parents' perceptions of their children's symptoms, quality of life, and anxiety, respectively. Parents also rated their own behavior related to their child's symptoms on the Adult Responses to Children's Symptoms (ARCS; Walker, Levy, & Whitehead, 2006). The ARCS comprises four subscales assessing monitoring behavior, protective behavior, minimizing behavior, and distraction from pain.

The Intervention

The intervention was an adapted version of the exposure-based Internet-CBT that was developed for adolescent IBS and is described in detail elsewhere (Bonnert et al., 2017; Lalouni et al., 2017). The main feature is exposure to GI symptoms (i.e., to engage in situations and behaviors that could trigger GI symptoms and to deliberately provoke GI symptoms). The following adjustments were made to the original protocol based on clinical experience from our previous trials and tailored to better suit adolescents with FAP/FD: (a) all examples were based on adolescents with FAP/FD with symptoms (i.e., pain, nausea, fullness); (b) labeling was taught as a strategy to reduce the negative valence of symptoms (i.e., to describe, without evaluating, symptoms and thoughts and feelings about symptoms); (c) all exposure exercises were targeting symptoms related to FAP/FD (i.e., postpone resting when in abdominal pain; drinking orange juice that might provoke nausea; if activity was used as a distraction, the adolescent was encouraged to pause and do labeling when in pain); (d) the psychoeducation on the explanatory model was delivered through an illustrated video instead of text; (e) two optional modules were added, one at Week 4 and one at Week 7, with further examples of avoidance behaviors and exposure exercises presented in clinical vignettes with adolescents of different ages and with different symptoms and difficulties; and (f) the parents were taught the principles of operant reinforcement, and how these apply to abdominal pain disorders. They were instructed to reduce reinforcement of their child's symptom-related behavior, and instead increase reinforcement of more functional behaviors.

The Adolescents' Treatment

This was a 10-week-long treatment consisting of 10 weekly online modules. The first module described how the behavioral pattern of avoidance maintains and exacerbates GI symptoms as well as fear of symptoms. In the second module, the adolescents mapped their GI-specific behaviors in detail, and

were taught functional analysis. In the third module, adolescents were encouraged to let go of symptom-controlling behaviors (e.g., not lie down to rest after a meal, or not take pain medication), and labeling of thoughts and feelings was introduced as a way to disengage from symptoms. In the fourth module, exposure exercises were introduced and individually planned. The adolescents were taught to gradually provoke symptoms (e.g., eating dairy products) without letting symptoms interfere with normal activities. The rationale was that exposure exercises would teach the brain that abdominal symptoms are not unbearable or dangerous and it would thereby become less reactive to gastrointestinal sensations. From the fifth to the ninth module, exercises were followed up and new ones were planned to gradually increase exposure. An exposure exercise with increased difficulty could be to eat symptom-provoking food (e.g., pancakes) in larger amounts than normal, before going to soccer training. Or to drink orange juice at breakfast and then hurry to school, stay active in school all day and not use any safety behavior to prevent nausea or belching, like drinking water or eating a snack. The tenth module included relapse prevention.

The Parents' Treatment

The main purpose of the parental intervention was to enhance their support of the adolescent's exposure exercises. A further purpose was to decrease parents' reinforcement of the adolescent's avoidance behavior. There were five modules directed at the parents, distributed every second week. The first module included an explanation of the treatment model and how parental responses can reinforce child symptom-related behavior. To increase the focus on things that work well and reduce focus on abdominal problems, the parents were encouraged to regularly spend time with their child and to engage in activities that they both enjoyed. In the second module, the parents mapped their adolescent's symptom behavior and their own responses, and were taught how to validate their adolescent's feelings and reduce the focus on symptoms. In the third module, the principles of exposure were explained and the parents were given instructions on how to support their child in his or her work with the exposure exercises. The fourth module offered strategies on how to handle frustration and worry about their adolescent's GI symptoms, and the fifth module taught relapse prevention. The parents had access to the modules in the adolescent treatment but could not see the interaction between their child and the therapist.
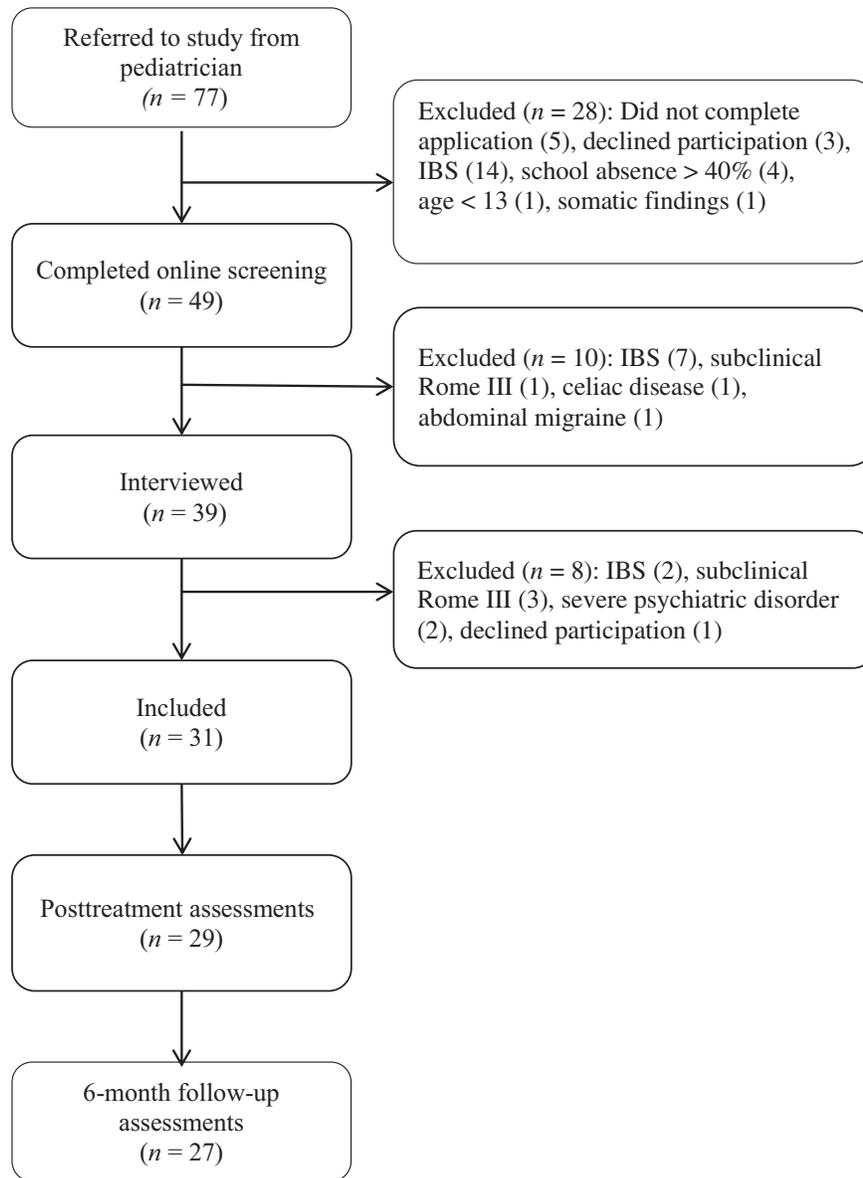
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│  Referred to study from │
│      pediatrician       │
│       (n = 77)          │
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            │            ┌────────────────────────────────────────┐
            │───────────▶│ Excluded (n = 28): Did not complete     │
            │            │ application (5), declined participation │
            ▼            │ (3), IBS (14), school absence > 40% (4), │
┌─────────────────────────┐ age < 13 (1), somatic findings (1)     │
│ Completed online        │└────────────────────────────────────────┘
│ screening               │
│       (n = 49)          │
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            │───────────▶│ Excluded (n = 10): IBS (7), subclinical │
            │            │ Rome III (1), celiac disease (1),       │
            ▼            │ abdominal migraine (1)                  │
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│     Interviewed         │
│       (n = 39)          │
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            │───────────▶│ Excluded (n = 8): IBS (2), subclinical  │
            │            │ Rome III (3), severe psychiatric        │
            ▼            │ disorder (2), declined participation (1)│
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│      Included           │
│       (n = 31)          │
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│ Posttreatment           │
│ assessments             │
│       (n = 29)          │
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┌─────────────────────────┐
│ 6-month follow-up       │
│ assessments             │
│       (n = 27)          │
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FIG. 1   Study flowchart.

Therapist Contact

The therapists were three clinical psychologists (coauthors MB, ML, and JS) with substantial experience of child and adolescent CBT and Internet-delivered CBT. The adolescents and parents had weekly written contact with their therapist, who gave feedback on questions and homework reports, and provided support and guidance on how to work with the treatment. The participants worked independently with all treatment content and planned their own homework. The therapists wrote short supportive messages or, if needed, suggestions on individual exercises. The therapist answered questions within 48 hours. The contact with the therapist and all treatment material was administered through a secure online platform, which was accessed using a personal login and password. Automatic SMS messages reminding participants to log on to the platform were sent once every week, and therapists could also send customized SMS messages to inactive participants.

ANALYSIS

Linear mixed models in R were performed to detect significant within-group differences between baseline and posttreatment, as well as changes between posttreatment and 6-month follow-up. For each

Table 1
Sample Characteristics at Baseline (*N* = 31)

Age, *m* (SD)	15.2 (1.3)
Sex, female, *n* (%)	20 (65%)
Rome III diagnosis	
FAP	25 (81%)
FD	6 (19%)
Duration of symptoms, years, *m* (SD)	3.7 (2.4)
Parent in treatment, mother, *n* (%)	25 (81%)
Geographic reach	
Living in Stockholm **county, n** (%)	21 (67%)
Distance, [a] km, *m* (**SD**)	14.1 (6.8)
Living in other parts of Sweden, ***n*** (%)	10 (32%)
Distance, [a] km, *m* (**SD**)	491.5 (63.5)

Note. SD = standard deviation; FAP = functional abdominal pain; FD = functional dyspepsia.
[a] Distance from home to the research clinic in central Stockholm, 1 km = 0.62 mile.

outcome, all three time points were included in the same model, using piecewise regression estimating one effect from pretreatment to posttreatment and one effect from posttreatment to 6-month follow-up. Effect sizes and 95% confidence intervals of changes between assessments were calculated as within-groups *d* (Borenstein, Hedges, Higgins, & Rothstein, 2009)—that is, the standardized mean difference between pre- and posttreatment assessments. Effect sizes were categorized according to Cohen's suggestion where small, medium, and large effect sizes are $d \geq 0.20$, 0.50, and 0.80, respectively (Cohen, 1992). To define clinically significant change, we used $\geq 30\%$ improvement on the primary outcome. This cutoff is recommended for use in studies on chronic pain (Moore et al., 2010), and has been applied in studies on both adults and children (Dear et al., 2016; Lalouni et al., 2017).

Power
We aimed to include 30 participants to be able to detect a within-group effect size of $d = 0.50$, with a power of 0.80 and alpha-level of .05.

Results

Inclusion Procedure
There were 77 signed health forms submitted to the study, 49 families completed the online screening, 39 were interviewed, and 31 were included in the study and received treatment. The most common reason for exclusion was a diagnosis of IBS ($n = 23$; 30%). See Fig. 1 for full details on the flow of participants through the study.

Of the included 31 adolescents, 20 were girls (65%), 25 had a diagnosis of FAP (81%), 6 had FD (19%), and the mean age was 15 years. See Table 1 for details on baseline characteristics.

Adherence and Attrition

The adolescents completed an average of 7.2 modules out of 10 ($SD = 3.2$, Md = 9), or 72% of the total treatment. See Supplement 1 for a visual presentation of treatment adherence. Two modules were optional bonus modules that included additional examples on how to work with exposure exercises. Nine (29%) adolescents completed both bonus modules, 9 (29%) completed one bonus module, and 13 (42%) adolescents completed none of the optional modules. The parents completed on average four modules out of five ($SD = 1.2$, Md = 5).

The therapist reminded the adolescents to login on average three times during the whole treatment (range = 0–10). Four (13%) adolescents dropped out after one module and two (7%) after four modules. Reasons were lack of time ($n = 2$), bereavement in the family ($n = 1$), technical problems with own computer ($n = 1$), treatment not helpful ($n = 1$), and no reason provided ($n = 1$).

There were no missing data at preassessments or at Week 2 when C-Scale was assessed. Twenty-eight (90%) adolescents completed the WAI at Week 4 and 27 (87%) adolescents completed the CSQ and the adverse events questions at posttreatment. Regarding outcomes for potential efficacy, 29 (93%) adolescents provided data on the primary outcome at postassessments, while 28 (90%) of the adolescents provided data on the secondary outcomes at postassessments. At 6-month follow-up, 27 (87%) adolescents contributed to the primary outcome and 26 (84%) to secondary outcomes. Because of the low attrition, no imputation of missing data was performed.

Therapist Time
Mean therapist time spent on the whole treatment (including contact with both adolescents and parents) was 193.9 minutes ($SD = 86.3$). Mean therapist time per completed module was 16.3 minutes ($SD = 6.7$) for the adolescents and 16.5 minutes ($SD = 6.6$) for the parents.

Acceptability of Treatment
Most adolescents ($n = 25$; 80%) rated the treatment as credible (C-scale total mean = 30.97, $SD = 10.04$). Nineteen (61%) adolescents expected to improve much or very much from the treatment; eight (26%) participants expected some improvement. Only four (13%) adolescents did not expect much change from the treatment. Adolescents rated a working alliance with their therapist in the higher range, WAI total mean = 32.6 ($SD = 10.0$) out of 42. All item means on WAI ranged from 5.1 ($SD = $

Table 2
Adolescent-Reported Results on Preliminary Effect With Estimated Means, Standard Errors (*SE*), and Cohen's *d* Effect Sizes With 95% Confidence Intervals (CI)

	Pretreatment mean (*SE*)	Posttreatment mean (*SE*)	6-month FU mean (*SE*)	Pretreatment to 6-month FU *d* [95% CI]
		Pre–post *d* [95% CI]	Post-FU *d* [95% CI]	
Pain intensity (Faces)	7.03 (0.40)	4.56 (0.55)	3.56 (0.57)	
		d = 1.20***	*d* = 0.48	*d* = 1.69***
		[0.49, 2.01]	[−0.15, 1.23]	[0.78, 2.53]
GI symptoms (CSI-GI)	9.06 (0.72)	5.25 (0.76)	3.19 (0.79)	
		d = 0.84***	*d* = 0.45*	*d* = 1.29***
		[0.48, 1.25]	[0.16, 0.80]	[0.90, 1.73]
Quality of life (PedsQL)	68.65 (2.60)	80.81 (2.67)	83.58 (2.73)	
		d = 0.84***	*d* = 0.19	*d* = 1.03***
		[0.55, 1.18]	[−0.07, 0.46]	[0.61, 1.46]
Symptom fear (VSI)	20.23 (1.48)	9.66 (1.55)	6.98 (1.59)	
		d = 1.09***	*d* = 0.28	*d* = 1.37***
		[0.79, 1.43]	[0.02, 0.64]	[0.90, 1.80]
Avoidance (BRQ)	43.39 (1.87)	30.32 (1.96)	27.16 (2.02)	
		d = 1.08***	*d* = 0.26	*d* = 1.34***
		[0.63, 1.61]	[0.06, 0.58]	[0.87, 1.87]

Note. Faces = Faces Pain Rating Scale; CSI-GI = Children's Somatization Inventory Gastrointestinal Symptoms; PedsQL = Pediatric Quality of Life Inventory; (improvement leads to increased scores); VSI = Visceral Sensitivity Index; BRQ = Behavior Response Questionnaire.
*$p < .05$, ** $p < .01$, *** $p < .001$.

1.9) to 5.7 (SD = 1.8) on the 0–7 scale. Most (81%) often or always trusted the therapist to be able to help (item mean = 5.7 of 7, SD = 1.8). Twenty-four (86% of 27 responding adolescents) answered that they often or always felt valued by their therapist (item mean = 5.6, SD = 1.8). Satisfaction with treatment was in the higher range with a CSQ-8 mean of 25.4 (SD = 4.7) out of 32. When investigating specific items, 25 (93%) of the adolescents thought they had been helped to deal more effectively with their problems (item mean = 3.4, SD = 0.6) and 25 (92.6%) were satisfied or very satisfied with the amount of help they had received. However, nine (33%) adolescents believed the treatment had helped them with only a few or none of their needs (item mean = 2.7, SD = 0.9). Yet, 22 (82%) reported overall satisfied or very satisfied with the intervention (item mean = 3.3, SD = 0.8).

Adverse Events
When asked about any adverse events during treatment, 22 (81% of 27 responding adolescents) reported that they had no such experience, while 5 reported that they had (19%). The adverse events included increased stress due to participation in the treatment (*n* = 1), increased abdominal pain when reading the online modules (*n* = 1) or during exposure exercises (*n* = 2), and feeling irritated about too many questions in the assessments (*n* = 1). One adolescent rated the event as highly

negative when it occurred while the other 4 rated the event as somewhat negative. One adolescent reported that the adverse event had sustained mild effects at the posttreatment while the other 4 did not report any persistence of the negative effect. One participant who had experienced pain during exposure exercises noted that these were the exercises that had been most helpful in the long run.

POTENTIAL EFFICACY
The primary outcome, pain intensity, decreased significantly ($p < .001$) and with a large effect size, d = 1.20, 95% CI [0.49, 2.01], from pre- to posttreatment. See Table 2 for all details on estimated means, standard errors, and Cohen's d effect sizes with 95% confidence intervals. At the follow-up, 6 months after treatment completion, the improvement was stable and the effect size on the primary outcome slightly larger, d = 1.69, 95% CI [0.69, 2.53]. We saw clinically significant change (≥ 30% improvement on pain intensity) in 17 (55%) of the participants at posttreatment and at 6-month follow-up after treatment completion.

Secondary Outcomes
Significant improvement with large effect size from pre- to posttreatment was observed on global GI symptoms as measured by the CSI (d = 0.84), as well as on quality of life measured with the PedsQL (d = 0.84). See Table 2 for all details. Global GI symptoms were further significantly improved

between posttreatment and 6-month follow-up ($p =$ .016), leading to overall large effect sizes from pretreatment to follow-up ($d = 1.29$). The improvement in quality of life was stable after 6 months. The adolescents also reported decreased avoidant behavior ($d = 1.08$) and fear of symptoms ($d = 1.09$) with large effect sizes that were sustained at 6-month follow-up.

Specific GI symptoms assessed with the PedsQL-GI symptoms modules suggested that the main reduction in GI symptoms were pain-related symptoms that decreased with large effect size from pre- to posttreatment ($d = 1.60$), and a further significant and large improvement from posttreatment to follow-up ($d = 0.91$). See Supplement 2 for all details on adolescent-rated PedsQL-GI symptoms modules. Symptoms induced by eating were significantly increased at posttreatment ($d = -0.43$), but improved with almost a strong effect size from posttreatment to follow-up ($d = 0.79$), leading to an overall significant improvement from pretreatment to follow-up ($d = 0.36$). There was no effect on nausea immediately after treatment, but a moderately sized improvement from posttreatment to follow-up ($d = 0.54$).

Parents reported large improvements in their children's GI symptoms ($d = 0.87$) and quality of life ($d = 0.96$). See Supplement 3 for all details on parent-reported results. Parents' reinforcing responses to their child's abdominal symptoms decreased with large effect size regarding monitoring behavior ($d = 1.11$) and moderate effect size regarding protective behavior ($d = 0.72$). There were no changes in parents' minimizing or distracting responses from pre- to posttreatment. At 6 months after the treatment conclusion, all parent-reported effect sizes were sustained.

Discussion

We investigated the feasibility and potential efficacy of exposure-based Internet-CBT specifically tailored for adolescents diagnosed with FAP or FD. Our aim was to create a treatment manual where all examples, vignettes, and interventions would fit the FAP/FD population. The results showed that the intervention was feasible and acceptable, as well as potentially efficacious in reducing pain intensity, GI symptoms, avoidant behavior, fear of symptoms, and quality of life with large within-group effect sizes. Six months after treatment the improvements were sustained or significantly further increased across outcomes.

The adolescents perceived the treatment as credible and reported a high degree of satisfaction with the treatment. The alliance with the therapist was rated in the higher range, and comparable to other studies on Internet-CBT (Andersson et al., 2012). The high rating of alliance with the therapist is in line with qualitative data on the experience of adolescents participating in an Internet treatment (Lenhard et al., 2016). Treatment adherence was 72%, which is considerably higher than the 58% adherence that has been reported in adult Internet-CBT (Wildeboer, Kelders, & Gemert-Pijnen, 2016). In comparison to our prior pilot trial on adolescent FGID (Bonnert et al., 2014), adherence seemed to be higher in this study for participants with FAP. They completed 71% of the total treatment content in the current study compared with 60% in the prior study (unpublished data). Adolescents with FD had comparable completion rates in both studies (75% vs. 77%). Importantly, the adverse events that were reported in the present study were few and not of a severe or lasting nature. Furthermore, preliminary effects were significant and large, both on the primary outcome and on all important secondary outcomes as reported by both adolescents and parents. Thus, the criteria for feasibility were met.

When investigating specific GI symptoms, we observed that the treatment seemed to target the pain-related symptoms very well, but that symptoms of nausea did not change, and that eating-induced symptoms even worsened immediately after treatment. One might therefore make the assumption that the treatment works better for adolescents with FAP than for adolescents with FD, because nausea and eating-induced symptoms are characteristic of FD. However, at baseline, the nausea symptoms in this sample were lower than in a clinical sample and eating-induced symptoms were even at the same level as a healthy sample (Varni et al., 2015). Despite the limited room for improvement, both nausea and eating-induced symptoms were significantly improved between pretreatment and 6-month follow-up.

We conclude that the adaptations that were made for the target group seem to have been successful. The effect sizes observed in this study are comparable to, and possibly higher, than the within-group effect sizes reported in our previous pilot trial with a mixed adolescent sample of IBS, FAP, and FD diagnoses (Bonnert et al., 2014). The mixed sample in the prior study may have caused a dilution of treatment effect because the protocol was originally developed for IBS, and this trial may indicate that an exposure-based protocol should be tailored for the specific diagnoses rather than be general for all P-FGIDs. Importantly, the treatment was not only

probably efficacious but also acceptable to the participants, despite the prominent feature of provoking the painful symptoms that the adolescents have sought treatment for. As the report on the adverse events showed, this was a bit challenging for a few, but most performed the exercises and found them helpful. In order to increase adherence to treatment, we have over time developed a rather rigorous treatment procedure in our Internet-delivered treatment studies. Participants receive automatic weekly reminders and clear instructions on when they are expected to complete their modules, and when new modules are opened. The defined structure together with a content that reflect the symptoms and difficulties that adolescents with FAP/FD can identify themselves with can be important factors for increased adherence in this study. This is in line with factors that have been suggested to be important for adherence in Internet-delivered treatments (Mohr, Cuijpers, & Lehman, 2011). The study design does not allow us to conclude whether all treatment components are necessary to achieve treatment effect, or their relative importance. However, all components are theoretically congruent and presented to serve the same purpose—namely, to aid the adolescents to exposure to symptoms instead of using avoidance and controlling behavior. Further research is needed to elucidate whether this purpose is best achieved for FAP/FD patients with the interventions used in our protocol or whether further adaptations could be beneficial. Interestingly, exposure has been shown to provide a unique additive effect in adults with IBS (Ljótsson et al., 2014). It is reasonable to believe that exposure plays a similar important role in the treatment of adolescents with FAP/FD.

The strengths of this study include a thorough inclusion procedure ensuring Rome III diagnosis, low data attrition, the comprehensive assessment of feasibility, and outcomes in several important domains. Moreover, using the Internet to deliver the treatment ensured that all participants took part in the same treatment content in a highly standardized manner. The national recruitment from all care levels is a strength in terms of generalization to the health care-seeking part of the adolescent FAP/FD population that is interested in receiving psychological treatment. Due to the fact that this study was conducted before the launch of the Rome IV criteria, the generalizability is somewhat limited. An obvious limitation of this study is the uncontrolled design, and the results need to be verified in a randomized controlled trial.

CONCLUSIONS

This is the first study that used exposure-based Internet-CBT to specifically target adolescent FAP and FD. This study demonstrated that Internet-CBT based on exposure is a feasible treatment that potentially improves pain intensity, global GI symptoms, and quality of life.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.beth.2018.05.002.

Conflict of Interest Statement

The authors declare that there are no conflicts of interest.

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