CME

Development of the Aim to Decrease Anxiety and Pain Treatment for Pediatric Functional Abdominal Pain Disorders

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ABSTRACT

Objectives: To evaluate the feasibility and acceptability of the Aim to Decrease Anxiety and Pain Treatment (ADAPT), a brief, on-line and in-person behavioral intervention targeting pain and anxiety in youth with functional abdominal pain disorders (FAPDs).

Methods: Patients were recruited from several outpatient pediatric gastroenterology clinics. Nine participants (ages 9–13) completed the full protocol. Thematic analysis of detailed qualitative feedback was obtained via semistructured patient and caregiver interviews after treatment was conducted. Feasibility and preliminary outcomes were examined using nonparametric tests.

Results: Preliminary results indicate that the ADAPT treatment is feasible, acceptable, and potentially effective for youth with FAPD. Treatment completers reported that they enjoyed the program and used the skills to manage their pain and worry. Results also indicated that the majority of participants experienced a reduction in anxiety and several reported reductions in pain and functional disability levels.

Conclusions: Findings from this study suggest that targeting both pain and anxiety may positively impact outcomes in youth with FAPD. The ADAPT intervention has the potential to provide a cost effective and practical application of cognitive behavioral therapy using an innovative combination of in-person and technology-based platforms. Overall, the ADAPT intervention is a promising and innovative intervention to improve the outcomes of youth with FAPD.

Key Words: anxiety, cognitive behavioral therapy, functional abdominal pain

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What Is Known

- Anxiety is related to poor outcomes in youth with functional abdominal pain disorder.
- Anxiety attenuates response to cognitive behavioral therapy for chronic pediatric pain.
- Anxiety is not traditionally addressed in pain-focused cognitive behavioral therapy.

What Is New

- The Aim to Decrease Anxiety and Pain Treatment intervention has been developed and is tailored to target both pain and anxiety symptoms to improve outcomes in youth with functional abdominal pain disorder.
- This innovative intervention includes a blend of in-person and Web-based sessions.
- Findings suggest that patients and families find Aim to Decrease Anxiety and Pain Treatment feasible and beneficial.

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Functional abdominal pain disorders (FAPDs), at least 4 abdominal pain episodes per month for at least 2 months which cannot be fully explained by another medical condition (1), are among the most common medical problems in childhood (2). Medical costs associated with FAPD are substantial and include invasive and unnecessary medical procedures, such as endoscopic studies (3,4). For a large subset, FAPD are associated with significant functional disability including school avoidance, peer difficulties, and socioemotional problems (5–9). Anxiety disorders are highly prevalent in children with FAPD, affecting 42% to 85% (10–13), and pain-related impairment is magnified in the presence of co-occurring anxiety (13–15). Youth with FAPD and anxiety are at higher risk for long-term problems including persistent pain and pain-related disability (16,17). Anxiety attenuates response to pain-focused cognitive behavioral therapy (CBT) in pediatric chronic pain (18); thus, a targeted treatment approach may improve patient outcomes.

There is limited research examining CBT tailored specifically to the needs of youth with FAPD and anxiety (19,20), which is further limited by mixed results and delivery that involves lengthy in-person sessions. Thus, the aim of this study was to develop and test a brief intervention for youth with FAPD and comorbid anxiety, called the Aim to Decrease Anxiety and Pain Treatment (ADAPT), based on evidence-based CBT protocols for

the management of pediatric pain (21) and childhood anxiety disorders (22). ADAPT was designed in a convenient and user-friendly format (requiring only 2 in-person sessions and the remaining sessions administered using Web-based, self-paced modules) to be easily integrated into a busy clinical setting and applicable to the majority of patients with FAPD and anxiety. The present study sought to determine the feasibility of the new intervention, obtain detailed qualitative feedback from participants, and explore effects on functional disability, pain levels, and anxiety.

METHODS

Participants

Patients (ages 9–14) and their caregivers were recruited from one of several outpatient pediatric gastroenterology clinics within a children's hospital. Eligible youth were diagnosed with FAPD by their pediatric gastroenterologist and reported daily to weekly pain episodes for at least 3 months, and thus meeting Rome IV diagnostic criteria (1). Other inclusionary criteria were more than minimal disability levels (Functional Disability Inventory [FDI] > 7), moderate pain (pain rating ≥4/10), and clinically significant anxiety (Screen for Child Anxiety–Related Disorders [SCARED] ≥25). Patients were ineligible if they had a significant medical condition with an identifiable organic cause (eg, inflammatory bowel diseases such as ulcerative colitis and Crohn disease and a documented developmental delay or cognitive impairment.

Procedures

Patients were introduced to the institutional review board–approved study by their physician during a medical visit, and if interested, the study staff explained the study in greater detail. After providing consent, participants completed study measures. Those meeting eligibility criteria completed a comprehensive baseline assessment within 1 week of the medical visit. Assessments were administered by a trained research coordinator (A.J.) supervised by a licensed psychologist (N.R.C.). Participants then completed the ADAPT intervention (see below). After ADAPT, participants and their caregivers completed outcome measures and were asked in a semistructured interview for detailed feedback on the treatment content, format, ease of use, and whether they would recommend the treatment.

Intervention

ADAPT (Table 1) was developed from: an established CBT protocol for pain management (15) and ''Cool Kids'' to treat anxiety (22). ADAPT also includes elements of mindfulness meditation (ie, deep breathing). ADAPT is novel because it is brief, targets both pain and anxiety, and utilizes Web modules that are designed to be easily accessible and ensure consistent content delivery for all participants. Two in-person sessions (90 minutes) were administered by a licensed clinical psychologist (N.R.C.) followed by 4 Web-based sessions (45 minutes each) with therapist support phone calls (15 minutes). Web sessions included educational videos, therapist/patient videos, handouts, and interactive activities (ie, forms, quizzes).

Measures

Measures used in this study (eg, FDI and SCARED) were previously validated (23,24) in pediatric chronic pain populations and are freely available.

TABLE 1. ADAPT protocol for youth with functional abdominal pain disorder and co-occurring anxiety

Session	Protocol used (focus of skill)
In person session 1 (90 min)	Psychoeducation (pain and anxiety)
	Parent guidelines (pain)
	Deep breathing/guided imagery (pain)
In person session 2 (90 min)	Progressive muscle relaxation (pain)
	Calming statements (pain)
	Activity pacing (pain)
Web session 3 (45 min)	Pleasant activity scheduling (pain)
	Problem solving (pain)
Web session 4 (45 min)	Cognitive restructuring (anxiety)
Web session 5 (45 min)	Graded exposure (anxiety)
	Assertiveness training (anxiety)
Web session 6 (45 min)	Maintenance planning (pain and anxiety)

One session administered per week; Web sessions followed by 15 minute phone call with therapist. The majority of the call is conducted directly with the child, with a brief caregiver check-in provided. Calls involve a brief review of the skills learned and related activities completed on the Web, a review of pain and anxiety episodes in the past week, and past and future use of coping skills for managing pain and worries.

ADAPT = Aim to Decrease Anxiety and Pain Treatment; FAPD = functional abdominal pain disorders.

Demographic/Background Information

Participant characteristics (age, race/ethnicity, SES) and pain features (eg, duration, frequency) were collected at screening.

Pain Intensity Via a Visual Analog Scale

Average pain levels (0–10) in the past 2 weeks were collected at screening and after treatment (25).

Screen for Child Anxiety–Related Disorders

Validated measure of child anxiety (24), completed at screening and post-treatment (26,27). Scores ≥25 indicate clinical anxiety.

Anxiety Disorder Interview Schedule—Child Version

A psychometrically reliable interview (28,29) conducted by a clinician at baseline and post-treatment to assess for childhood psychiatric disorders. A clinician severity rating (CSR; 0–8) was assigned to each diagnosis, with higher scores indicting greater severity. CSR scores ≥4 indicate presence of a clinical disorder.

Functional Disability Inventory—Child Version

Fifteen-item validated measure of disability in youth with chronic pain (23) completed at screening and post-treatment (30). Higher scores indicate greater disability, with scores >7 indicating more than minimal disability. There are established cut-offs for mild (0–12), moderate (13–29), and severe (30+) disability (23). A change of >7.8 points indicates a *clinically significant* difference (31).

Adherence

Number of in-person sessions and calls completed as prescribed was calculated. For Web sessions, a numeric score was

calculated based on number of videos watched (n = 11), handouts downloaded (n = 13), and forms completed (n = 11) for a total adherence score of 35.

Data Analysis

Qualitative interviews with the parent and child were audio taped and transcribed. Transcripts were independently reviewed by 3 trained coders: a clinical psychologist (N.R.C.), a postdoctoral fellow (S.N.), and a post-baccalaureate research coordinator (E.M.). Information was analyzed by identification of themes and coded by the team into key content domains based on a priori categories (ie, pace, content) and new themes that may have emerged. Coders discussed the discrepant themes to foster consensus. This process was based on previous work (32), informed by grounded theory (33), and thematic analysis (34).

The number of patients who agreed or declined to participate was monitored to measure program feasibility. Dropout rates and program adherence rates were also recorded. Intervention tolerability was assessed by number of treatment completers and participant feedback. Descriptive information and changes in outcomes (disability, average pain, and anxiety) were explored via nonparametric (Wilcoxon signed-rank) tests using SPSS v23.

RESULTS

Aim to Decrease Anxiety and Pain Treatment Participant Characteristics

Participants in ADAPT included 7 females and 2 males (mean age 11.56; standard deviation (SD) = 1.42; range 9–13) with 7 identifying as Caucasian and 2 identifying as biracial. Six patients were diagnosed with functional abdominal pain (without a subtype) and 3 were diagnosed with IBS. Eight of 9 received bloodwork and 2 participants received an endoscopy study as part of their medical evaluation. Participants reported being an average of 37.3 miles (range 10.2–60.7 miles) from the pediatric medical center. Participants were categorized by moderately elevated levels of pain (m = 4.6, SD = 1.3, range = 2–6), moderate functional disability (m = 14.7, SD = 6.4, range = 9–29), and clinically significant anxiety levels (m = 43.3, SD = 13.8, range 25–69). Participating caregivers were all mothers and most (89%) had completed at least some college. Seven out of 9 participants reported pain duration for a year or more, with the remaining reporting pain for at least 3 months.

Feasibility

During recruitment, 34 prospective participants potentially meeting criteria for FAPD were initially approached. Of these, 27 participants (79.4%) agreed to participate, were consented, and screened further for inclusion into the study. Of the 7 who declined to participate, the most common reasons included lack of interest (n = 6) and scheduling conflicts (n = 1). Following screening, 15 of 27 (55.6%) participants were deemed eligible for the study based on inclusion/exclusion criteria for anxiety, functional disability, and pain levels. Of the 12 who did not qualify, the reasons were due to failure to meet screening scores for anxiety (n = 10), functional disability (n = 9), and pain levels (n = 1). Of the 15 participants that did qualify, 1 was later excluded due to a subsequent diagnosis of Crohn disease and 3 could not be contacted for scheduling baseline assessments. Baseline assessments were administered to 11 qualifying participants and 1 failed to begin the intervention after the assessment. Of those who started ADAPT (n = 10), only 1 was lost to follow-up after beginning the protocol. In total, 9 out of 10 (90%) participants completed the full ADAPT protocol.

With regards to adherence, all 9 treatment completers completed the 2 in-person sessions and the weekly therapist phone calls. Concerning the online content, only 1 participant did not complete any of the Web content. One third of the group (3/9) accessed a smaller portion (1–4 items) of the online content (ie, forms/interactive activities). The remainder (5/9) accessed 11 to 18 items (blend of videos, handouts, and interactive activities).

Qualitative Interviews

Qualitative feedback was obtained from participants regarding program feasibility, tolerability, and patient outcomes (see Supplemental Table 1, Supplemental Digital Content 1, *http://links.lww.com/MPG/B86*).

Domain 1: Feasibility

All participants reported that they utilized specific skills to manage pain and anxiety demonstrating the overall *usability of the skills*. Participants reported that the program fit well into their schedules and the skills could be applied to everyday situations. Common *barriers to feasibility* included difficulty practicing certain skills in school or when in front of peers. Several parents also mentioned that demanding schedules can make it challenging for their child to remember to practice the skills.

Domain 2: Tolerability/Acceptability

Feedback on program structure and content was predominantly positive. The *format* of the program was reported as well organized and accommodating. Several parents and children remarked that the phone calls were particularly beneficial to reinforce understanding of online skills training. All participants gave positive feedback regarding the *pace and progression* of learning the skills throughout the program.

In addition, participants noted their *least favorite content*, which varied by participant. Participants generally expressed more favorable impressions of the in-person sessions over skills learned in online modules. Suggested program *modifications* included making the online content more interactive (ie, more forms to complete) and easier to understand.

Domain 3: Outcomes

Children and their parents provided feedback about how the program improved their overall *confidence and self-efficacy.* Generally, children felt that the skills presented in the program led to more effective management of daily stressors and pain. Parents noted overall improvements in school performance, pain management, and anxiety.

Preliminary Exploration of Treatment Effect

Approximately 78% (7/9) of patients experienced decreases in anxiety symptoms, which was statistically significant (average reduction 16.78 points, $z = -2.20$, $P < 0.05$) and decreases in pain-intensity, which approached statistical significance (average reduction 1.72 points, $z = -1.93$, $P = 0.05$) at the post-treatment assessment (Table 2). Furthermore, 56% (5/9) of participants experienced reductions in pain-related functional disability (an average 10 point reduction for responders), which is clinically significant (31), although these differences were not statistically significant overall (mean reduction was 2.22 points, $z = 0.048$p, $P = 0.64$). A total of 4 participants (44%) experienced at least some reduction across all 3

TABLE 2. Pre- and post-treatment assessment of Functional Disability Inventory, pain, and SCARED scores

	FDI (0–60)			Pain (0–10)			SCARED (0–82)*		
Participant	Pre	Post	Change	Pre	Post	Change	Pre	Post	Change
1	29	7	−22	4	2	−2	36	27	−9
2	19	24	+5	5	7	+2	46	33	−13
3	18	10	−8	3	2	−1	33	20	−13
4†	13	7	−6	5	3	−2	52	26	−26
5	12	13	+1	5	0	−5	30	26	−4
6†	11	6	−5	2	2.5	+0.5	45	19	−26
7†	11	23	+12	6	4	−2	25	27	+2
8	10	1	−9	6	2	−4	69	1	−68
9	9	21	+12	5	3	−2	54	60	+6
Average	14.67	12.44	−2.22	4.56	2.83	−1.72	43.33	26.56	−16.78

Average pain in the past 2 weeks via the visual analogue scale.
FDI = Functional Disability Inventory; SCARED = Screen for Anxiety and Related Disorders.
*Wilcoxon signed-rank test indicate a significant difference from pre- to post-treatment ($z = -2.539$, $P < 0.05$).
†IBS diagnosis.

primary outcomes, with the 5 remaining participants (56%) experiencing a reduction in 1 or 2 categories. Diagnostically, 8 of 9 (89%) participants experienced reductions in the CSR associated with their primary anxiety diagnosis (Supplemental Table 2, Supplemental Digital Content 2, *http://links.lww.com/MPG/B87*). On average, participants experienced a 2.33 point CSR reduction, which was statistically significant ($z = -2.539$, $P < 0.05$), with 3 of 9 (33%) considered diagnosis free (ie, CSR of primary anxiety disorder <4) after treatment.

DISCUSSION

Findings of this study suggest that ADAPT, a tailored CBT intervention developed to treat both pain and anxiety in youth with FAPD, is feasible and has the potential to improve outcomes for youth with FAPD. The majority of qualifying patients with FAPD agreed to participate in this study and also completed the intervention. In addition, all patients experienced reductions in at least 1 outcome area (pain, functional disability, or anxiety), with the most sizable reductions evident in anxiety. This is important because presence of clinical anxiety as measured by the SCARED has been shown to attenuate response to pain-focused CBT to pediatric chronic pain conditions (18) such as FAPD.

Given that current medical approaches to treating FAPD are limited in evidence and effect, the development of targeted and effective nonpharmacological interventions such as ADAPT is essential (35). It is known that anxiety is highly comorbid in youth with FAPD (10,11,13), exacerbates pain and pain-related disability (14,15,17), and limits response to CBT for pain (18). Thus, an intervention that targets both pain and anxiety in this population may be important for improving patient outcomes. The pilot study suggests ADAPT has the potential to improve outcomes in youth with chronic pain and comorbid anxiety who may not respond to traditional pain-focused CBT (18). Targeting both pain and anxiety may be important in positively impacting pain-related outcomes in this highly prevalent and disabled group of patients.

Furthermore, the ADAPT intervention has the potential to provide a cost effective and practical application of CBT using an innovative combination of in-person and technology-based platforms. It is noteworthy that families lived on average >35 miles from their medical care and the majority were willing to participate in the study, which speaks to utility of the current approach and the potential barriers to obtaining care using traditional delivery platforms (ie, 6–8 in person sessions). Although there has been some prior work examining anxiety-focused intervention for youth with FAPD (19,20), these approaches were limited by requiring lengthy in-person visits that may be impractical in medical settings. Thus, use of technology-supported approaches may be especially beneficial. Web-based treatments for pediatric chronic pain that are, however, delivered exclusively online may limit rapport building and treatment response. In our study, the patients reported appreciating the relationship with the therapist via the in-person sessions and that this enhanced rapport, retention, and perhaps treatment effect. Thus, the multimethod approach offered by ADAPT may be optimal. We have found that a model of 2 in-person sessions with a psychology provider followed by 4 weeks of Web-based self-paced modules with phone support is feasible and may positively impact patient outcomes and reduce burden on patients, families, and clinicians.

We used a small sample size in this treatment development study which limits generalizability given the influence of outliers (ie, 1 participant experienced a 68-point reduction in anxiety symptoms) and there was an absence of a control group. Based on our learnings from this preliminary development study and the modifications made as a result, ADAPT is now ready for testing in a controlled trial (currently underway). If ADAPT is shown to be effective, we plan to make this intervention available for trained clinicians.

Based on our study findings, we have modified ADAPT to make the intervention even more accessible and feasible for our patient population. We note that a large subset (n = 12 or 44.4%) of interested participants failed to qualify for this study based on their scores on the screening measures of anxiety, pain, and disability. In particular, a large portion of those youth (83.3%) failed to qualify based on their anxiety score. Thus, we have modified ADAPT by removing the presence of clinically significant anxiety as a criterion for qualification. Relatedly, we have reduced the Web content requirement from 4 sessions to 2 sessions for participants who do not have clinically significant levels of anxiety (13). To further promote future uptake, in person sessions were condensed from 90 to 60 minutes to align with sessions that are traditionally covered by insurance in real-world settings. We have also used qualitative feedback garnered from this preliminary pilot study to modify and enhance the intervention content (ie, the intervention is now more interactive and easier to understand). For example, the wording in the quizzes was simplified to be comprehendible to the target age

range. To increase the interactive nature of the Web-based format, we included more forms for participants to complete in order to reinforce learning of the session content and to practice the application of skills. These completed forms are visible to clinicians and as such, are reviewed as part of therapist-supported phone calls.

It would be important for future research to distinguish subtypes of FAPD as recommended by ROME-IV guidelines (1). We also recognize it would be valuable to offer intervention to a more clinically complex and older group of adolescents. We note that we have initiated the development of ADAPT in a younger patient population (target age 9–14) with the explicit goal of prevention of the increased psychological complexities that commonly occur as youth age. It might also be beneficial to consider integrating this program into the school environment to promote better adherence.

Another promising future direction would be to make screening for anxiety, pain, and functional disability part of the clinical process in pediatric gastroenterology clinics. In addition, it would be prudent to initiate screenings in primary care or school settings to identify patients early and to potentially prevent the progression to pediatric subspecialty care. Overall, the ADAPT intervention is an innovative and feasible intervention with the potential to improve the outcomes of youth with FAPD.

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