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Development of a brief cognitive-behavioral treatment for avoidant/restrictive food intake disorder in the context of disorders of gut-brain interaction: Initial feasibility, acceptability, and clinical outcomes

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Abstract

Background: Avoidant/restrictive food intake disorder (ARFID) symptoms are common (up to 40%) among adults with disorders of gut-brain interaction (DGBI), but treatments for this population (DGBI + ARFID) have yet to be evaluated. We aimed to identify initial feasibility, acceptability, and clinical effects of an exposure-based cognitive-behavioral treatment (CBT) for adults with DGBI + ARFID.

Methods: Patients (N=14) received CBT as part of routine care in an outpatient gastroenterology clinic. A two-part investigation of the CBT included a retrospective evaluation of patients who were offered a flexible (8–10) session length and an observational prospective study of patients who were offered eight sessions. Feasibility benchmarks were ≥75% completion of sessions, quantitative measures (for treatment completers), and qualitative interviews. Acceptability was assessed with a benchmark of ≥70% patients reporting a pos-treatment satisfaction scores ≥3 on 1–4 scale and with post-treatment qualitative interviews. Mixed model analysis explored signals of improvement in clinical outcomes.

Results: All feasibility and acceptability benchmarks were achieved (and qualitative feedback revealed high satisfaction with the treatment and outcomes). There were improvements in clinical outcomes across treatment (all p's<.0001) with large effects for ARFID fear (−78%; Hedge's

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g=1.5; 95% CI=0.6, 2.5) and gastrointestinal-specific anxiety (−42%; Hedge's g=1.0; 95% CI=0.5, 16). Among those who needed to gain weight (n=10), 94%−103% of expected weight gain goals were achieved.

Discussion: Initial development and testing of a brief 8-session CBT protocol for DGBI + ARFID showed high feasibility, acceptability, and promising clinical improvements. Findings will inform an NIH Stage 1B randomized control trial.

Keywords

disorders of gut-brain interaction; functional gastrointestinal disorders; functional dyspepsia; avoidant/restrictive food intake disorder; ARFID; feeding and eating disorders; cognitive-behavioral therapy; CBT; feasibility; patient satisfaction

INTRODUCTION

Cognitive-behavioral treatments (CBTs) for avoidant/restrictive food intake disorder (ARFID) have been pilot tested showing improvements in ARFID symptom severity with 47–80% remission rates (Dumont et al., 2019; Thomas et al., 2021; Thomas et al., 2020). CBT for ARFID protocols have been created in outpatient feeding and eating disorder clinics, but have yet to be adapted to other clinic settings or populations. Due to emerging research suggesting that a significant subset of patients with medical conditions can develop ARFID, there is an opportunity to develop CBT approaches for ARFID in the context of these conditions and their treatment settings.

Disorders of gut-brain interaction (DGBI; also known as functional gastrointestinal disorders; Drossman 2016) are characterized by gastrointestinal symptoms without underlying structural abnormalities (i.e., no cancer, ulcers) and affect approximately 40% of adults (Sperber et al., 2021). Food avoidance via exclusion diets is commonly self-initiated or prescribed for patients with DGBI (Atkins et al., in press; Lenhart et al., 2018; Manning & Biesiekierski, 2018). While food avoidance may be adaptive, helpful, and non-problematic for some DGBI patients, a significant subset may develop nutritional and/or quality of life impairments crossing the line into ARFID (Burton Murray & Staller, 2021). In fact, ARFID symptoms have been identified in 13–40% of adults with DGBI (Burton Murray, Bailey, et al., 2020; Burton Murray, Jehangir, et al., 2020; Burton Murray, Kuo, et al., 2021; Burton Murray, Rao, et al., 2022; Burton Murray, Riddle, et al., 2022; Harer et al., 2018) and have been significantly associated with a history of using exclusion diets (Atkins et al., in press). While CBT approaches have demonstrated efficacy for DGBI (Keefer et al. 2022; Laird et al. 2016), they do not directly address food avoidance/restriction in the context of DGBI.

CBTs for ARFID primarily include exposure and response prevention principles to systematically expose patients to avoided foods, food amounts, and/or eating-related situations. Some CBTs for DGBI have also included exposure and response prevention to varying degrees (some protocols as a primary component; Craske et al. 2011; Lalouni et al. 2021; Ljótsson et al. 2014) and others as one component of many (Hunt et al. 2009; Lackner et al. 2018) to target gastrointestinal-specific anxiety. Preliminary evidence in

irritable bowel syndrome suggests that in exposure-based CBT (versus stress management), avoidance of specific foods significantly decreased and was associated with decreased symptom severity (Biesiekierski et al., 2022). Thus, decreasing food avoidance/restriction in DGBI is a potential target mechanism for reducing DGBI severity. However, no protocol for DGBI to our knowledge has included techniques to address food volume or nutritional disturbances that occur in ARFID, particularly for those who need to gain weight. Similarly, no protocol for ARFID to our knowledge has included techniques to educate patients on DGBI and target gastrointestinal-specific anxiety and avoidance behaviors.

As an NIH Stage 1A (ORBIT Phase 1B; Czajkowski et al. 2015) study and consistent with current guidelines for behavioral treatment development (Powell et al., 2021), our overall aim was to formalize an exposure-based CBT package for DGBI + ARFID and evaluate initial feasibility, acceptability, and change in clinical outcomes. CBT content was created from adapted portions of a CBT protocol for ARFID (Thomas & Eddy, 2019) and tenets of exposure-based CBTs for DGBI (e.g., Craske et al. 2011; Lalouni et al. 2021; Ljótsson et al. 2014). Among adults who received CBT for DGBI + ARFID in routine outpatient care, we conducted a two-part study—(1) a retrospective evaluation of patients who received CBT with structured materials but not a formalized protocol (Part 1) and (2) a prospective observational study of a formalized (8-session) protocol (Part 2). We hypothesized the protocol would be feasible and acceptable, meeting *a priori* benchmarks based on previous studies for adults with DGBI with weight loss (Jiang et al., 2016; Tack et al., 2016) and other CBT trials (Craske et al., 2011; Lackner et al., 2018; Thomas et al., 2021). We expected that post-treatment qualitative interviews would facilitate our further optimization of the protocol prior to conducting a clinical trial. We also explored signals of improvement in ARFID and DGBI symptom severity, and possible mechanistic targets (e.g., gastrointestinal-specific anxiety).

METHODS

We conducted a two-part study to inform development and refinement of the 8-session CBT protocol, which included evaluation of patients who received CBT as part of routine care. In Part 1, a retrospective evaluation of consecutive patients with any DGBI + ARFID who received structured materials and offered a flexible treatment length (eight and 10 sessions). In the Part 2 study, the same content was delivered but the length of treatment was formalized into eight sessions and focused on patients with a specific DGBI (functional dyspepsia). The studies were approved by the Mass General Brigham Institutional Review Board (#2021P001737; #2021P001049) and all patients completed informed consent.

Participants

Participants included patients in the Massachusetts General Hospital (MGH) Gastroenterology Division, a tertiary care center in Boston. All patients were diagnosed with ARFID by a clinical psychologist as part of routine care (see Supplemental Content for more detail). In Part 1, inclusion criteria were: consecutive patients with previous completion of CBT for DGBI + ARFID and aged 18 years or older. In Part 2, inclusion criteria were: consecutive patients aged 18 years or older, Rome IV functional dyspepsia, and offered CBT

for DGBI + ARFID as part of routine care. Functional dyspepsia was the target DGBI in Part 2 as it is the DGBI with the highest rates of ARFID symptoms (in up to 40%; Burton Murray, Bailey, et al. 2020; Burton Murray, Jehangir, et al. 2020) and the population of focus in the next-step planned NIH Stage 1B randomized control trial.

Procedure

Part 1 informed formalization of the manualized 8-session CBT protocol that was then evaluated in Part 2. In Part 1, self-report surveys were administered in treatment by the clinician as part of routine care and results were extracted from the medical record. In Part 2, research assessments with self-report surveys were administered before Session 1, after Session 4, and after Session 8; remuneration for survey completion was: $20 for Session 1, $20 for Session 4, and $30 for Session 8. A trained research coordinator conducted a brief 15-minute qualitative interview over the phone with patients in the Part 1 retrospective cohort who elected to participate and with participants in the Part 2 prospective cohort. For both studies, we extracted the following information from the medical record: DGBI duration, percent weight suppression (i.e., percent below previous usual weight status after weight loss; see Supplemental Content), psychiatric comorbidity, ARFID presentation, pre-treatment gastrointestinal medications, and pre-treatment gastrointestinal diagnoses. Demographic information included age, sex, gender identity, race, and ethnicity.

Treatment

Participants received individual CBT as a part of routine care via HIPAA-compliant Zoom healthcare software or in-person. CBT was delivered by a psychology behavioral health provider over 8–12 weeks. The CBT protocol (Table 2) included education about DGBI, regularizing eating patterns, behavioral exposures tailored to the patient (e.g., food amounts, food types, food/non-food situations), and post-treatment maintenance planning, with corresponding handouts/worksheets. Patients monitored food intake throughout treatment either by hand/electronic documentation or via mobile application (*Recovery Record*; Record 2022).

Measures

Feasibility.—In Part 1, we reported the average and range of CBT sessions completed to inform refinement of the protocol number of sessions. In Part 2, we set a benchmark of ≥75% completion of: sessions, quantitative measures (for treatment completers), and qualitative interviews.

Acceptability.—We set a benchmark of ≥70% patients reporting a satisfaction score ≥3 on a 1–4 scale from **Client Satisfaction Questionnaire** item 7 at post-treatment (Attkisson and Zwick 1982). To further characterize acceptability and identify any areas for protocol refinement, trained research coordinators conducted semi-structured **Qualitative Interviews** over the phone which were audio-recorded and responses transcribed (interview script in Supplemental Content).

Quantitative measures.—Self-report surveys in both Part 1 and Part 2 included measures of ARFID severity, upper gastrointestinal symptom severity, and gastrointestinal-

specific anxiety at pre-, mid-, and post-treatment (Table 1). The **Nine Item ARFID Screen (NIAS)** is a 9-item measure of ARFID symptoms summed into three subscales (fear of adverse consequences, lack of interest/appetite, and sensory sensitivity; each range=0 to 15), with higher scores indicating greater severity (Burton Murray, Dreier, et al., 2021). The **Patient Assessment of Upper GI Symptoms (PAGI-SYM)** is a 20-item measure of gastrointestinal symptom severity over a 2-week recall period averaged into six subscales (nausea/vomiting, heartburn/regurgitation, fullness/early satiety, bloating, upper abdominal pain, and lower abdominal pain) and a total score (each range=0–5), with higher scores indicating greater severity (Rentz et al., 2004). The **Visceral Sensitivity Index (VSI)** is a 15-item measure of gastrointestinal-specific anxiety summed into a total score (range=0–75), with higher scores indicating greater gastrointestinal-specific anxiety (Labus et al., 2004). For patients who needed to gain weight, weight across pre-treatment, mid-treatment, and post-treatment was evaluated; weight gain goals were established in collaboration between the treating psychologist and the patient's gastroenterologist. Approximately 3 months post-treatment in the Part 1 retrospective study, patients who participated in the interview self-reported their current weight and completed the NIAS.

The Part 2 observational study also included a battery of additional self-report measures at pre-, mid-, and post-treatment. The **Pica, ARFID, and Rumination Disorder Interview, ARFID Questionnaire (PARDI-AR-Q)** is a 32-item measure based on the interview version that assesses presence of ARFID and four subscales (ARFID severity of impact, ARFID sensory sensitivity, ARFID lack of interest in eating, ARFID fear of adverse consequences; each range=0–6), with higher scores indicating higher ARFID symptoms (Bryant-Waugh et al., 2022). The **Short Form Nepean Dyspepsia Index Quality of Life** (**SF-NDI-QOL)** has 10 quality of life items rated in the past two weeks (1=not at all to 5=extremely) summed into five subscales (tension, interference with daily activity, eating/drinking, knowledge/control, work/study; each range=2–10) and summed into a total score, with higher scores indicating poorer quality of life (Talley et al., 2001). The **Patient Assessment of Upper Gastrointestinal Disorders Quality of Life (PAGI-QOL)** is a 20-item measure of upper gastrointestinal-related quality of life averaged into five subscales (daily activities, clothing, diet and food habits, relationship, and psychological well-being and distress) and a total score (each range=0–5), with lower scores indicating greater quality of life (De La Loge et al., 2004). The **Fear of Food Questionnaire (FFQ)** is an 18-item measure of food-related fears averaged into five subscales (GI fears, food fears, food avoidance, social impairment, and distress/loss of pleasure) and a total score (each range=0–5), with higher scores indicating greater food-related fears (Zickgraf et al., 2022). The **Food Neophobia Scale (FNS)** is a 10-item measure of food neophobia summed into a total score (range=10–70), with higher scores indicating less willingness to try new foods (Pliner & Hobden, 1992). The **Hospital Anxiety and Depression Scale (HADS)** is a 14-item measure summed into two subscales (anxiety, depression; each range=0–21), with higher scores indicating greater severity (Zigmond & Snaith, 1983); we used the HADS to characterize baseline general anxiety/depression symptoms.

Data Analysis

Feasibility and acceptability markers.—We evaluated feasibility and acceptability markers based on the proportion of participants who achieved each benchmark (defined above). For acceptability with the qualitative interview data, we used the rapid analysis method, which has been validated and recommended for pilot studies of this nature to provide immediate feedback to inform changes to the intervention (Gale et al., 2019). Immediately after each interview, the interviewer created a summary table with exemplar quotes. We generated overall themes from each participant's summary table, integrated themes across interviews to identify commonly occurring subthemes, and selected exemplar quotes across interviews aligned with each subtheme.

Quantitative analysis.—Because the treatment content in the Part 1 and Part 2 studies was the same, we explored changes in primary measures administered in both Part 1 and Part 2 studies (NIAS; PAGI-SYM, VSI; weight for those who needed to gain) and secondary measures administered in Part 2 study (PARDI-ARQ; SF-NDI; PAGI-QOL; FFQ; FNS). We reported average percent change from pre- to post-treatment and calculated Hedge's g as a measure of effect size for pre- to post-treatment change (0.2=small; 0.5=medium; 0.8=large) for measures' total and subscale scores. We adjusted Hedge's g for correlated measures using the pre-treatment standard deviation and calculated corresponding 95% intervals (using the standardized mean change calculation within the metafor package in R; Viechtbauer 2021). For patients who elected to complete the Part 1 post-treatment surveys, we also descriptively reported change from post-treatment to their 3-month follow-up interview on the NIAS and weight.

RESULTS

The total study sample included 14 patients—n=9 in the retrospective Part 1 study and n=5 in the observational prospective Part 2 study. In Part 1, one patient did not complete the 3-month qualitative interview or surveys, so we only obtained data from medical record extraction. Table 3 shows sample characteristics.

Feasibility and Acceptability Markers

In Part 1, patients (n=9) completed 8–10 (M=8.4; SD=1.1) sessions. In Part 2 (n=5), one patient dropped out of treatment after session 4 due to lack of treatment engagement/progress; our feasibility benchmark of ≥75% complete was achieved for session completion (90% of 40), quantitative measure completion for treatment completers (100% of 13), and qualitative interviews (100% of 13). Our acceptability benchmark of ≥70% satisfaction scores ≥3 was achieved with 100% of treatment completers—all patients reported a 4 ("very satisfied") on the 1–4 scale.

Results from the qualitative analysis are in Table 4. Three main themes emerged from the qualitative interviews—treatment acceptability, change in symptoms, and the treatment format/process. All patients reported that CBT exceeded their expectations and was better than other treatments they had tried. All patients who completed treatment reported that they achieved improvement (in symptoms, quality of life, and/or coping). While feedback

on the structured material (e.g., handouts) was uniformly positive, there was mixed feedback on working with a psychologist (n=2 reported negative perception bias about working with a mental health professional at the beginning of treatment) and video-based format (n=2 reported preference for in-person format).

Quantitative Analysis

Table 1 includes the number of participants with completed data per self-report measure. Table 5 shows descriptive data on changes in self-report measures across treatment, including average percent change, effect sizes (pre- to post-treatment change included n=11 who completed post-treatment assessments in Part 1 and n=4 who completed treatment in Part 2), and corresponding 95% confidence intervals. One patient in Part 1 did not receive the PAGI-SYM as they only had lower gastrointestinal symptoms.

Primary Measures (Part 1 + Part 2 studies).—Pre- to post-treatment changes (n=11) showed: ARFID severity decreased with large effects overall on the NIAS, specifically on the fear subscale (Hedge's g=1.5). Gastrointestinal symptom severity decreased with medium effects overall on the PAGI-SYM, specifically on the PAGI-SYM-Fullness/Satiety scale (Hedge's g=0.7). GI-specific anxiety decreased with large effect on the VSI by (Hedge's g=1.0). Of those who needed to gain weight (n=10), weight increased on average by 6% and 98% of weight gain goals were achieved on average (range=94%−103% of expected weight gain goal achieved).

Of patients who completed the Part 1 interview (n=8): five had needed to gain weight and showed overall maintained weight gain improvements from post-treatment to 3-month follow-up (−0.01% to +0.04% change); seven completed the NIAS-Fear subscale and had overall maintained improvements from post-treatment to 3-month follow-up (−1.0% to + 1.3%).

Secondary Measures (Part 2 study).—Pre- to post-treatment changes (n=4) showed medium to large improvements in measures of ARFID-related fears on the: PARDI-AR-Q Concern about Aversive Consequences scale (Hedge's g=0.6) and the FFQ Food Fears subscale (Hedge's g=2.4). There were large improvements in overall gastrointestinal-related quality of life on the SF-NDI (Hedge's g=1.7) and on the PAGI-QOL (Hedge's g=3.5), with the largest change on the PAGI-QOL Diet and Food Habits subscale (Hedge's g=4.0). Three treatment completers (60%) still met criteria for ARFID by the PARDI-ARQ at post-treatment.

DISCUSSION

This study provides novel information on a behavioral treatment targeting symptoms of both DGBI and ARFID among adults. In a two-part study, we found that all feasibility and acceptability benchmarks were achieved, qualitative feedback revealed high satisfaction with the treatment and outcomes, and there were medium to large improvements in some clinical outcomes. Effect sizes for clinical outcomes should be interpreted with caution as, due to the small sample size, power was low and confidence intervals were wide. Taken together, these findings suggest an 8-session exposure-based treatment is a promising intervention for adults

with ARFID in the context of a DGBI, which we plan to test in a more rigorous evaluation in an NIH-funded Stage 1B/ORBIT Phase IIB randomized controlled trial (Czajkowski et al 2015).

Overall, there was high feasibility and acceptability with the treatment. One patient in the Part 2 study dropped out of treatment due to lack of progress. Of patients who did complete treatment, satisfaction was high both through qualitative interviews and self-report ratings, even though two patients reported they initially held a negative bias towards seeing a psychologist. Notably, there was mixed feedback on virtual versus in-person delivery formats, but it is unknown whether delivery format influenced treatment effects.

While exploratory, there were improvements in ARFID outcomes, including almost 100% of weight gain goals being achieved and particularly large improvements related to the ARFID fear of aversive consequences presentation. For ARFID, symptom severity (predominantly on the NIAS Fear subscale) had large decreases and overall maintained in the Part 1 group at 3-month follow-up. In Part 2, the FFQ also showed large decreases, but the FNS did not. While the FNS showed large improvements in CBT for ARFID in adults (Thomas et al., 2021), the items focus more on mistrust and fear of new foods, versus food in general. It is possible that items on the NIAS and FFQ capture constructs most relevant to patients with ARFID in the context of a DGBI (i.e., fear around gastrointestinal symptoms). In fact, the largest effect size was on the FFQ Food Fears subscale. Fear of aversive consequences has been consistently the most frequent ARFID presentation among DGBI samples (Burton Murray, Bailey, et al., 2020; Burton Murray, Jehangir, et al., 2020; Burton Murray, Riddle, et al., 2022) and was present in the majority (93%) of our sample. While future research is needed to identify which self-report measures are best to capture changes in ARFID within the context of a DGBI, our study suggests that measures of ARFID fear motivations are likely most relevant.

There were also notable improvements in DGBI outcomes. The PAGI-SYM is a measure of upper gastrointestinal symptom severity, on which the Fullness/Satiety subscale was the highest among our sample. The Fullness/Satiety subscale was the only subscale with medium decreases and exceeded the clinically significant benchmark for improvement on average (1-point decrease or greater; Rentz et al. 2004). We have proposed that treating ARFID in the context of DGBI may improve DGBI symptoms, as ARFID may perpetuate DGBI (Burton Murray, Doerfler, et al., 2022). One finding from our study in support of this model is that in the Part 2 study, the subscale with the largest improvements of gastrointestinal-related quality of life was the Diet/Food Habits—that is, decreased impact of DGBI symptoms on eating could lead to decreases in DGBI symptom severity. While this study is the first to our knowledge to show that upper gastrointestinal symptoms improve from an exposure-based CBT for DGBI, the mechanisms through which this occurs need to be further elucidated.

Notably, we do not know when changes in treatment occurred and what mechanisms were responsible for improvements in ARFID and DGBI outcomes. For example, it is possible that increases in food intake over time improved fundic accommodation (i.e., ability of the fundic portion of the stomach to expand and hold ingested food material)

which then decreased fullness/satiety severity. However, the reasons fundic accommodation may improve could be related to both mechanic and neurosensory changes—for example, through repeated exposure, the patient learns they can tolerate more food intake than they thought. In fact, inhibitory learning is possibly a key mechanism through which brain-gut behavior therapies work. Consistent evidence shows that gastrointestinal-specific anxiety is a mediator of exposure-based CBT for DGBI (Bonnert et al., 2018; Burton Murray & B, 2022; Hesser et al., 2018; Lalouni et al., 2021; Ljótsson, 2019; Wolitzky-Taylor et al., 2012), which is consistent with our large decreases in gastrointestinal-specific anxiety (via VSI).

Limitations of our pilot findings should be considered. Our sample included individuals across the adult age spectrum (up to age 75) and our sample's female predominance mirrors DGBI epidemiology (Sperber et al., 2021). However, our sample lacked diversity in gender identity and racial and ethnic backgrounds, and we did not assess other factors associated with social determinants of health (e.g., education, financial background). Given underreporting of race and ethnicity (and in some cases, underrepresentation of individuals identifying with minority groups) in both eating disorder (Flores et al., 2022) and DGBI (Bar et al., under review) clinical trials, future research is needed to understand feasibility and acceptability of our protocol with a larger, more diverse sample. Our protocol is also focused on food and behavioral exposure; we did not include other techniques from CBT for ARFID (e.g., 5 Steps for sensory sensitivity; non-food based interoceptive exposure + strategies to increase reward around eating for lack of interest/low appetite) (Thomas & Eddy, 2019). Five participants also started a neuromodulator (e.g., tricyclic antidepressant, gabapentin) within one month of starting CBT, which could have contributed to improvements in clinical outcomes; thus, further research is needed to identify the primary versus augmenting effect of an exposure-based CBT for DGBI + ARFID. Finally, the one patient who dropped out of treatment did not complete end of treatment assessments, limiting our ability to evaluate acceptability of the treatment for all those who initiated treatment.

In this two-part study, initial development and testing of a brief 8-session CBT protocol for DGBI + ARFID showed high feasibility, acceptability, and promising clinical improvements. Findings from these pilot investigations will inform an NIH Stage 1b/ORBIT Phase IIb randomized control trial for further evaluation of feasibility/acceptability, as well as preliminary clinical outcomes and target mechanisms.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Conflict of interest:

IW and EM have no personal or financial conflicts to declare. HBM and JJT receive royalties from Oxford University Press for her forthcoming book on rumination syndrome. KS has received research support from Ironwood and Urovant and has served as a consultant to Arena, Gelesis, GI Supply, and Shire/Takeda. BK has received research support from AstraZeneca, Takeda, Gelesis, Medtronic, Genzyme and has served as a consultant to Shire, Takeda, and Ironwood. JJT receives royalties from Cambridge University Press for the sale of their book, *Cognitive-Behavioral Therapy for Avoidant/Restrictive Food Intake Disorder: Children, Adolescents, and Adults*. JJT and KRB receive royalties from Cambridge University Press for their book *The Picky Eater's Recovery Book: Overcoming Avoidant/Restrictive Food Intake Disorder*. BL receives royalties from Pear Therapeutics Inc. for a cognitive behavioral treatment manual for irritable bowel syndrome.

Data availability statement:

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Public significance statement:

While cognitive-behavioral treatments (CBTs) for ARFID have been created in outpatient feeding and eating disorder clinics, they have yet to be developed and refined for other clinic settings or populations. In line with recommendations for behavioral treatment development, we conducted a two-part investigation of an exposure-based CBT for a patient population with high rates of ARFID—adults with disorders of gut-brain interaction (also known as functional gastrointestinal disorders). We found patients had high satisfaction with treatment and there were promising improvements for both gastrointestinal and ARFID outcomes. The refined treatment includes 8 sessions delivered by a behavioral health care provider and the findings reported in this paper will be studied next in an NIH Stage 1B randomized controlled trial.

Table 1.

Overview of Quantitative Measures.

Primary Outcomes	Part 1 Study	Part 2 Study	Pre-treatment sample size	Mid-treatment sample size[a]	Post-treatment sample size[b]
Primary Outcomes					
NIAS	X	X	14	10	11
PAGI-SYM[c]	X	X	13	8	11
VSI	X	X	14	9	11
Weight	X	X	10	10	9
Secondary Outcomes					
PARDI-ARQ		X	5	5	4
SF-NDI Quality of Life		X	5	5	4
PAGI-QOL		X	5	5	4
Fear of Food Questionnaire		X	5	5	4
Food Neophobia Scale		X	5	5	4

Note.NIAS=Nine Item AFRID Screen; PAGI-SYM=Patient Assessment of Gastrointestinal Disorders Symptom Severity Index; VSI=Visceral Sensitivity Index; ARFID=Avoidant/Restrictive Food Intake Disorder; GI=gastrointestinal; PARDI=Pica, ARFID, and Rumination Disorder Interview; SF-NDI=Short Form Nepean Dyspepsia Index; PAGI-QOL=Patient Assessment of Upper Gastrointestinal Disorders Quality of Life.

[a]Missing mid-treatment data for the NIAS, PAGI-SYM, and VSI if they were not administered at mid-treatment in clinical care (in Part 1 retrospective study).

[b]Missing data for n=1 because the participant dropped out of treatment at Session 4 (in Part 2 observational prospective study) and n=2 participants because the NIAS, PAGI-SYM, and VSI were not administered in clinical care (in Part 1 retrospective study).

[c]Missing data n=1 participant because the PAGI-SYM was not administered in clinical care (in Part 1 retrospective study).

Table 2.

Overview of 8-Session Cognitive-Behavioral Treatment for DGBI + ARFID.

Session	Summary	Content
(Consult) [a]		• Pre-session self-monitoring record • Handout on what is the CBT model for DGBI
1	CBT Education + Regular Eating[b]	• Gut-brain dysregulation in DGBI • CBT model of avoidance around DGBI symptoms • Eating-related avoidance • Weight gain tips[c] • Homework assignment
2–7	Behavioral and Food Exposure	• Homework review • DGBI + personalized model • Exposure and Response prevention introduction • Homework assignment
8	Maintenance Planning	• Homework review • Personalized maintenance plan

Note. DGBI=Disorders of Gut-Brain Interaction; ARFID=avoidant/restrictive food intake disorder; CBT=cognitive behavioral treatment. A new handout/worksheet was provided at Session 1, Session 2, and Session 8.

[a]Patients were provided with self-monitoring records or asked to monitor eating for 1 week prior to session 1 and read a handout on CBT.

[b]Tailored to the patient, depending on deficits in food frequency, volume, and/or variety.

[c]For patients who need to gain weight.

Table 3.

Pre- Treatment Clinical Characteristics of Patients who Received CBT for DGBI + ARFID (*N*=14).

	n*(%) or M(SD), *range
Age, *Range*	40(17.9), *20 – 75*
age 65+	2(14%)
Sex- Female	10(71%)
Gender [1]	
Cis Woman	10(71%)
Cis Man	4(29%)
Race- White	14(100%)
Ethnicity- Hispanic/Latino	0(0%)
BMI kg/m [2]	20(3), *16.4 – 30.5*
Weight Gain Needed	10(71%)
% weight suppression	10(0.06), *3 – 25*
GI Symptom Duration (years)	5.4 (4.0), *0.5 – 10*
Comorbid Psychiatric Diagnoses	
Generalized Anxiety Disorder	2(14%)
Depression, Unspecified	1(7%)
Anxiety, Unspecified	3(21%)
GI Medications	
Neuromodulators[b]	8(57%)
Proton pump inhibitor	4(28%)
Laxative	5(36%)
D_2 receptor antagonist	1(7%)
H_2 blocker	1(7%)
Anticholinergic	3(21%)
Antidiarrheal	1(7%)
Antiemetic	1(7%)
GI Diagnosis	
Functional Dyspepsia	8(57%)
Gastroesophageal Reflux Disease	2(14%)
Fecal Incontinence	1(7%)
Eosinophilic Gastrointestinal Disorder	1(7%)
Irritable Bowel Syndrome	1(7%)
Unspecified Nausea and Vomiting Syndrome	1(7%)
ARFID Presentation [c]	
Sensory Sensitivity	0(0%)

	n*(%) or M(SD), *range
Sensory Sensitivity + Lack of Appetite/Interest	0(0%)
Sensory Sensitivity + Fear of Adverse Consequences	0(0%)
Lack of Appetite/Interest	1(7%)
Lack of Appetite/Interest + Fear of Adverse Consequences	8(57%)
Fear of Adverse Consequences	4(28%)
All three presentations	1(7%)
Hospital Anxiety and Depression Scale [d]	
Anxiety	1.4(0.5)
Depression	0.9(1.0)

Note. DGBI=Disorder of Gut-Brain Interaction; ARFID=Avoidant/Restrictive Food Intake Disorder; GI=gastrointestinal. Retrospective evaluation *n*=9 and observational prospective study *n*=5.

[a]No other gender identity options selected.

[b] *n*=2 anxiolytics; *n*=2 anticonvulsants; *n*=3 tricyclic antidepressants; *n*=1 selective serotonin and norepinephrine reuptake inhibitors (SNRIs). The (fully-titrated) neuromodulator doses for each patient was initiated prior to CBT as follow: <one month for n=2; one month for n=3; four months for n=1; >1 year for n=2. One patient had a change in neuromodulators during the course of treatment (n=1 at session 6 of 8).

[c]The Diagnostic and Statistical Manual of Mental Disorders, fifth edition (*DSM-5*) describes three primary ARFID presentation types that can occur individually or in combination – fear of adverse consequences, lack of interest in eating/low appetite, and sensory sensitivity. Presentations were conferred with clinician diagnosis.

[d]Only administered in part 2 observational prospective study (*n*=5).

Table 4.

Themes from Post-Treatment Qualitative Interview (n=13).[a]

THEME	*Subtheme*	*Exemplar Quotes*
Treatment Acceptability	Expectancy	"It definitely exceeded my expectations; I wasn't sure what to expect." (treatment dropout) "I read about it before I participated, So I sort of knew going into to it what was going to happen." "I guess I didn't really know what to expect going into it…this was a good starting point for me that this was a little different."
	Credibility	"It [CBT] was better, definitely…It was teaching me how I could better approach my body, my digestive system and what I eat and things that I could eat." "I would say this one definitely beat out the treatments that I've come up with for myself"
Symptom Outcomes	Symptom Severity	"Eight weeks later it's great to see the change [in symptoms] I was able to make" "I think it got me better faster, I'm not sure I would have gotten better [symptom severity] with the medicine alone."
	Quality of Life	"We set out a bunch of goals when I started and a lot of them, I couldn't imagine them being possible. It's definitely impacted my life in a positive way." "A goal for me was not have this be such a big part of my life anymore, and I think that's what's happened." "It really allowed me to look a little differently on how I eat and mostly how I approached food."
	Cognitive/ Affective Changes	"I think it taught me different ways to think about my pain, especially as it relates to eating."
Treatment Format and Process	Clinician Factors	"She was very easy to talk to and easy to work with." "It [working with a psychologist] was something that made me nervous just because of the perception."
	Treatment Structure	"It was helpful to have those [treatment handouts] as a guiding reference throughout the treatment." "I'm a visual person so I liked having a physical copy of something [treatment handouts] to look at and read." "They [treatment handouts] were super easy to understand and I would have liked having more of them" "I think it [treatment handouts] really helps you stick to it by having all the appointments, it holds you accountable"
	Video Format[b]	"I think it [video format] made it more personal and it made me more comfortable faster." "We met in-person the first time, but maybe another half-way through or at the end, if we met in person one more time, it could be helpful just to have that kind of in-person contact." "At the time, I'm on zoom for work, I'm on zoom for other volunteer activities, so it was sort of a zoom burnout." "My illness was already burdensome enough, I didn't need another [non-video format] burdensome approach."

Note. CBT=Cognitive Behavioral Treatment.

[a] n=1 in the Part 1 retrospective study did not complete the 3-month follow-up post-treatment interview.

[b] n=1 (treatment dropout) completed all sessions in-person. n=1 completed some sessions in-person and some sessions virtually. All other patients had 100% virtual visits.

Table 5.

Primary and secondary quantitative outcome descriptive data across treatment.

Primary Outcomes (Retrospective and Prospective Study Samples Combined)						
	Pre-treatment (*N*=14)	**Mid-treatment[a] (*n*=10)**	**Post-treatment[b] (*n*=11)**	**% Change[c]**	**Hedge's g[c]**	**95% CI**
NIAS (range=0–45)	27.6(9.6)	23.5(8.8)	15.7(8.3)	−43%	1.3	0.5, 2.1
Fear (range=0–15)	11.4(4.2)	9.7(3.7)	5.5(3.1)	−52%	1.5	0.6, 2.5
Interest (range=0–15)	8.9(5.8)	8.5(5.3)	5.5(4.5)	−38%	0.4	0.0, 0.9
Picky (range=0–15)	7.4(3.3)	5.3(2.2)	4.6(2.9)	−38%	0.8	0.0, 1.7
	(n=13) [d]	**(n=8)**	**(n=11)**			
PAGI-SYM (range=0–5)	2.1(1.0)	2.1(1.0)	1.4(0.9)	−33%	0.5	0.2, 0.8
Nausea/vomiting	1.0(1.1)	1.2(1.0)	0.6(0.7)	−40%	0.2	−0.2, 0.7
Heartburn/Regurgitation	1.1(1.0)	1.3(0.9)	1.0(0.7)	−9%	0.02	−0.5, 0.5
Post-Prandial Fullness/Early Satiety	3.2(1.6)	3.2(1.8)	1.7(1.4)	−47%	0.7	0.3, 1.2
Bloating	2.6(1.6)	2.8(1.6)	1.8(1.5)	−31%	0.4	−0.2, 0.9
Upper Abdominal Pain	2.3(1.3)	2.3(1.1)	1.6(1.3)	−30%	0.4	−0.1, 0.9
Lower Abdominal Pain	2.1(1.3)	1.9(1.3)	1.7(1.3)	−19%	0.3	−0.2, 0.8
	(N=14)	**(n=9)**	**(n=11)**			
VSI (range=0–75)	50.4(15.4)	42.5(16.1)	29.4(14.3)	−42%	1.0	0.5, 1.6
	(n=10)	**(n=10)**	**(n=9)**			
Weight Change (lbs) [e]	--	3.57(1.0)	5.9(4.5)	6%	--	--
Secondary Outcomes (Prospective Observational Study Sample Only)						
	Pre-treatment (*n*=5)	**Mid-treatment (*n*=5)**	**Post-treatment (*n*=4)**	**% Change**	**Hedge's g**	**95% CI**
PARDI-ARQ						
ARFID diagnosis-n(%)	5(100%)	5(100%)	3(75%)	n/a	--	--
ARFID severity of impact (range=0–6)	2.6(2.1)	3.2(1.9)	1.3(0.6)	−50%	0.3	−1.2, 1.9
Concern about aversive consequences (range=0–6)	2.8(1.7)	2.8(1.5)	1.3(1.7)	−54%	0.6	0.0, 1.1

Lack of interest in food or eating (range=0–6)	3.1(1.2)	2.7(1.8)	2.1(1.3)	−32%	0.4	0.1, 0.8
Sensory-based avoidance (range=0–6)	0.5(0.7)	0.3(0.4)	0.6(1.2)	+20%	0.3	1.4, 1.9
SF-NDI Quality of Life (range=10–50)	34.0 (8.4)	28.6 (6.3)	19.5 (4.9)	−43%	1.7	0.3, 3.0
Tension (range=2–10)	7.4(1.8)	4.8(1.9)	4(0.0)	−46%	1.6	--
Interference with daily activity (range=2–10)	6.4(2.3)	6(2)	3.8(1.3)	−41%	1.0	−0.7, 2.7
Eating/Drinking (range=2–10)	8.8(1.8)	7.2(2.9)	4.5(2.6)	−49%	1.5	−0.3, 2.7
Knowledge/Control (range=2–10)	5.6(1.3)	5.2(1.6)	3.5(1.0)	−38%	1.0	−0.5, 2.5
Work/Study (range=2–10)	5.8(2.9)	5.4(2.7)	3.8(1.3)	−34%	0.4	0.1, 0.6
PAGI-QOL (range=0–5)	2.7(1.1)	2.1(1.0)	0.8(0.4)	−71%	3.5	0.8, 6.2
Daily activities	2.4(1.3)	2(1.1)	0.7(0.4)	−71%	1.0	0.3, 1.8
Clothing	1.8(1.8)	1.7(1.7)	1.3(1.6)	−28%	-0.1	−1.0, 0.8
Diet and food habits	4.0(0.7)	3.3(1.3)	1.0(1.0)	−75%	4.0	0.9, 7.2
Relationship	1.1(1.1)	0.6(1.0)	0.2(0.2)	−82%	0.8	0.0, 1.6
Psychological well-being and distress	2.6(1.4)	1.9(1.2)	0.8(0.4)	−69%	1.6	0.2, 3.0
Fear of Food Questionnaire (range=0–5)	3.6(0.8)	3.6(0.8)	1.3(0.4)	−34%	2.5	0.0, 5.0
GI fears	4.5(0.9)	4.2(0.4)	1.9(0.6)	−58%	1.9	0.0, 3.8
Food fears	3(1.5)	3.1(1.1)	0.9(0.6)	−70%	2.4	0.4, 4.3
Food avoidance	4.6(0.9)	4.3(0.6)	1.3(0.5)	−72%	1.0	−0.5, 2.5
Social impairment	1.8(1.3)	2.3(1.7)	0.7(0.5)	−61%	0.7	−0.3, 1.6
Distress/loss of pleasure	4.3(1.0)	4.2(1.0)	2.2(1.3)	−49%	1.2	−0.7, 3.2
Food Neophobia Scale (range=10–70)	38.8(13.9)	39.2(17.9)	28.8(13.1)	−26%	0.4	−0.3, 1.0

Note: Mean (SD) represented unless otherwise noted. Percent change and Hedge's g calculated from pre- to post-treatment. NIAS=Nine Item AFRID Screen; PAGI-SYM=Patient Assessment of Gastrointestinal Disorders Symptom Severity Index; VSI=Visceral Sensitivity Index; ARFID=Avoidant/Restrictive Food Intake Disorder; GI=gastrointestinal; PARDI=Pica, ARFID, and Rumination Disorder Interview; SF-NDI=Short Form Nepean Dyspepsia Index; PAGI-QOL=Patient Assessment of Upper Gastrointestinal Disorders Quality of Life; CI=confidence interval.

[a]Missing mid-treatment data for the NIAS, PAGI-SYM, and VSI if they were not administered at mid-treatment in clinical care (in Part 1 retrospective study).

[b]Missing data for *n*=1 because the participant dropped out of treatment at Session 4 (in Part 2 observational prospective study) and *n*=2 participants because the NIAS, PAGI-SYM, and VSI were not administered in clinical care (in Part 1 retrospective study).

[c]Calculated only with participants who had both pre- and post-treatment data complete. Hedge's g with adjustment for correlated measures between pre- and post-treatment. Hedge's g is a measure of effect size for sample sizes less than 20. 0.2= Small effect, 0.5=Medium effect, 0.8=Large effect. We were not able to calculate a 95% CI for weight change and SF-NDI variables given a standard deviation of 0 at one of the timepoints.

[d]Missing data *n*=1 participant because the PAGI-SYM was not administered in clinical care (in Part 1 retrospective study).

[e] Weight change is reported if a goal in treatment was to gain weight. Only n=9 at post-treatment because *n*=1 dropped out of treatment.