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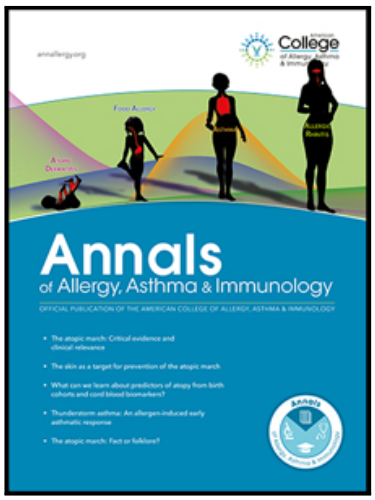

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Cognitive-Behavioral Intervention for Anxiety Associated with Food Allergy in a Clinical Sample of Children

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Keywords: food allergy; anxiety; children; parent; family; treatment study; CBT; group therapy

Abbreviations/Acronyms: Cognitive Behavioral Therapy (CBT); Food Allergy (FA); Food Allergy Anxiety (FAA); Food Allergy Quality of Life Questionnaire (FAQLQ); Health-Related Quality of Life (HRQOL); Quality of Life (QOL); Scale of Food Allergy Anxiety (SOFAA); Screen for Child Anxiety Related Disorders (SCARED)

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Abstract

Background: Multiple reviews have identified a lack of evidence-based treatments for excessive anxiety in the context of food allergy (FAA) as an unmet need.

Objective: This study examined the feasibility, acceptability, and proof-of-concept of Food Allergy Bravery (FAB), a brief, novel, manualized cognitive behavioral-based intervention for anxiety in a clinical sample of children with FAA.

Methods: Three cohorts of children (ages 8-12 years) with clinically impairing FAA and their parents were offered a course of FAB delivered in a group format. Ratings of anxiety severity

and quality of life (QOL) were collected at pretreatment, posttreatment, and at 2-4 month follow-up.
Results: All families offered treatment completed the full course of FAB, attended at least 5/6 active treatment sessions, and rated the intervention as highly satisfactory. All children were rated as very much improved or much improved on the Clinician Global Impression scale at posttreatment. Anxiety severity scores on the Scale of Food Allergy Anxiety (SOFAA) and the Scale of Child Anxiety-Related Emotional Disorders (SCARED) significantly declined per both child- and parent-report. Scores on the Food Allergy Quality of Life Questionnaire-Parent Form (FAQLQ-PF) were significantly improved. Gains were maintained at follow-up.
Conclusion: This is the first study of an outpatient manualized psychosocial treatment for FAA in a clinically ascertained sample of children. Findings provide initial evidence of feasibility, acceptability, and proof of concept for the FAB intervention protocol. Randomized controlled trials are needed.

INTRODUCTION

Although some measure of caution is healthy and adaptive for those with food allergy in order to reduce risk of accidental ingestion, clinically impairing food allergy-related anxiety (FAA) contributes to poorer health-related quality of life (HRQOL),[1,2] increased condition-specific burden,[3] and poorer allergy management.[4] Individuals with clinically impairing levels of FAA tend to overestimate the risks of casual contact with their allergens, and then needlessly avoid social situations involving food, overly restrict their eating to a limited number of familiar foods they deem "safe," and delay or refuse potentially life-altering medical interventions such as oral food challenges or immunotherapies.[5] Recent reviews on the unmet needs of this population have rightly noted that FAA is a high priority and called for more research to improve the evidence base on FAA treatment.[6–12]

With regard to the evidence base for treatment of anxiety disorders *generally*, results of numerous, high quality intervention studies have identified cognitive-behavioral therapy (CBT) as both efficacious and effective, and CBT is currently the only therapeutic modality deemed well-established for treatment of child anxiety disorders.[13–15] However, no published studies have evaluated the outcome of CBT-based intervention in a sample of children with clinically

impairing FAA.

CBT protocols for anxiety disorders *unrelated* to food allergy generally recommend graded exposures to avoided situations in order to provide corrective learning experiences, improve faulty risk assessment, and lessen anxious avoidance. None are ideal for FAA specifically. For example, CBT-based protocols for common fears and phobias – such as dogs, injections, or public speaking – prescribe graded exposures to very safe stimuli that are universally encountered by the general population. Although these stimuli are undoubtably anxiety-inducing for those affected, they are not nearly as routine as eating, which occurs, at minimum, on a daily basis. Such manuals, moreover, lack the very specific guidance required by FAA treatment providers regarding appropriate exposures to anxiously avoided social situations involving allergens that are potentially lethal for the patient.[5,7,16] Moreover, food allergies remain far from universal, and myths regarding risks of casual contact with allergens abound among the lay public, creating confusion and exacerbating anxiety.[17,18] This necessitates a highly specific manual that educates providers on best food allergy safety practices such that they can counter such misinformation and provide appropriate advice and intervention regarding both necessary ("safe") and unnecessary ("anxious") avoidance.

Many previous studies of psychosocial interventions for emotional or QOL concerns in pediatric FA have been directed at parents.[19-22] Of the intervention studies that have involved children as participants, one involved half-day educational workshops and did not directly target anxiety nor collect outcome data from children.[23] The other two were randomized controlled trials with non-clinically ascertained samples that examined outcomes after one-time exposures (self-injection; touching an allergen) versus education alone. Both found reduced anxiety and improved QOL for both their intervention and control groups.[24,25]

Results of the above are promising and have informed the current study. However, they are limited in that none involved a clinically ascertained sample – that is, children whose FAA is so chronically excessive and impairing that they meet criteria for a separate diagnosis of an Anxiety Disorder. This limits interpretation of their results within the context of the wider (non-food allergy) anxiety treatment literature, which typically describes clinical samples. This also limits their ability to inform allergy practitioners who encounter such patients in their offices and desire to refer them for a full course of anxiety treatment that will be evidence-based and effective.

Moreover, because there were no validated, disease-specific measures of pediatric FAA until quite recently,[26] these studies relied on unvalidated indicators of outcome (i.e., a few Likert scale questions unique to the study) or on validated but *generic* measures of anxiety, limiting interpretation of the clinical significance of their results with regard to the specific concerns of the FA population.[11,27,28] Indeed, a recent study validating the *Scale of Food Allergy Anxiety* (SOFAA), the first disease-specific measure of FAA in children, showed moderate correlations between it and the *Scale for Child Anxiety-Related Emotional Disorders* (SCARED), the generic measure used in the two youth exposure studies above, suggesting overlapping but distinct constructs.[26]

The primary aim of this pilot study was to evaluate the feasibility, acceptability, and proof-of-concept of *Food Allergy Bravery (FAB)*, a novel, brief, manualized, CBT-based intervention for children identified as having clinically impairing anxiety related to their FA. With regard to feasibility, we hypothesized that the majority of families offered group FAB would enroll in the intervention, attend most sessions, complete treatment, and that there would be few adverse events. With regarding to acceptability, we hypothesized that families would rate

FAB as highly satisfactory upon completion on a Treatment Satisfaction questionnaire. With regard to proof-of-concept, we hypothesized that there would be significant reductions in therapist, parent, and patient reports of anxiety and significant improvements in HRQOL on pre-posttreatment measures, and that these gains would endure after active treatment to the follow-up booster session several months later.

METHODS

Participants

Participants were 10 children aged 8-12 years (mean age: 10.12 years; SD=1.47; 80% female) referred by their allergists specifically for evaluation and treatment of FAA. Inclusion criteria were (a) age range 6-18 years; (b) confirmed presence of IgE mediated food allergy/allergies that were well-controlled; (c) excessive anxiety and medically unnecessary and impairing anxious avoidance related specifically to their food allergy such that the child met *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; DSM-5)[29] criteria for Specific Phobia-Other Type (i.e., Specific Phobia of Anaphylaxis; 9 children) or Other Specified Anxiety Disorder (1 child). Exclusion criteria were: (a) presence of Autism Spectrum Disorder, Intellectual Delay, Anorexia or Bulimia; (b) other medical complications that would interfere with the ability to take part in a group treatment protocol; (c) current psychosocial or psychopharmacological treatment for an anxiety disorder; treatment for other co-morbid psychiatric diagnoses (e.g., ADHD) was permitted. Table 1 summarizes the demographic characteristics as well as relevant medical and psychiatric histories for all participants.

Measures

Scale of Food Allergy Anxiety, Child-Rated (SOFAA-C) and *Parent-Rated (SOFAA-P).* The SOFAA-C is a 21-item self-report questionnaire intended for use with children and adolescents ages 8–18 to assess FAA and related anxious avoidance behaviors. The SOFAA-P is the corresponding parent-rated version; parents rate their perceptions of their child's FAA. Responses are given on a 5-point Likert scale. Ratings from all items are summed to create a Total Score; higher scores indicate greater anxiety. The SOFAAs show excellent parent-child agreement and excellent reliability and validity.[26] Because the SOFAA was still under development during these treatment groups, an earlier, 19-item version was used; scores were prorated to result in a Total Score corresponding to 21 items.

Screen for Child Anxiety Related Emotional Disorders Child Report (SCARED–Child) and *Parent Report (SCARED–Parent).* The SCARED is a *generic* (non-disease specific) 41-item screen for childhood anxiety disorder symptoms in children 8-18. The child and parent versions of the SCARED show moderate parent-child agreement and excellent reliability and validity. Items are scored on a 5-point Likert scale and summed to derive a Total Score. Higher scores indicate greater anxiety.[30]

Food Allergy Quality of Life Questionnaire Parent Form (FAQLQ-PF) is a valid and reliable parent-report disease-specific HRQOL questionnaire for food-allergic children ages 0-12. Items are rated on a 7-point Likert scale and Total Scores are calculated by dividing the sum of completed items by the number of completed items; higher scores indicate lower HRQOL.[31]

Treatment Satisfaction Questionnaire. At the end of active treatment, parents completed a satisfaction questionnaire specifically created for this group version of FAB to generate information for quality improvement. Parents rated their satisfaction with various aspects of the FAB intervention and its overall helpfulness for their child and themselves on a 5-point Likert

scale; higher scores indicate greater satisfaction. Parents also answered two open-ended questions regarding what aspect of the treatment was most helpful and what suggestions they had for improvement.

Clinical Global Impression Scale (CGI). The CGI provides a global rating of symptom change with scores ranging from 1 (*very much improved*) to 7 (*very much worse*).[32] The psychologist who completed all initial evaluations and co-directed all treatment sessions rated children at the close of active treatment. In line with larger RCTs of child anxiety disorders, we interpreted a score of 1 (very much improved) or 2 (much improved) as indicating substantial, clinically meaningful treatment response.[33]

Procedure

Families attended an initial evaluation appointment for 1-2 hours to assess severity of anxiety related to FA (subjective distress, frequency/duration, functional impairment) and appropriateness for the group treatment completed by the first author, a psychologist specializing in CBT for pediatric anxiety disorders. Children were diagnosed via clinical interview based on DSM-5 criteria as well as information on symptom severity and functional impairment gathered from the battery of child- and parent-report questionnaires described above.

The FAB intervention followed a protocol developed by the first author, a CBT psychologist, in consultation with the second author, an experienced nurse practitioner in pediatric food allergy.[34] The FAB protocol initially was applied in individual treatment sessions with other (non-participating) children with FAA in a specialty anxiety clinic embedded within an outpatient food allergy center at a large pediatric hospital. The group treatment protocol described here was intended as a quality improvement project to improve patient access to care and families were advised of the pilot nature of the groups as part of informed consent to

treatment. All measures were collected as part of standard treatment procedures and participant and parent responses and other demographic and background information were later recorded in a de-identified data set. In consultation with the Hospital's Institutional Review Board, it was determined that this project did not meet the federal definition of Human Subjects Research and was not advanced for further IRB review (IRB 19-016764).

Manualized FAB is a flexible, brief individual treatment for children, adolescents, and adults typically comprising 5-8 proximity exposure sessions with the patient and, if appropriate, family members present. Each session typically lasts 30-45 minutes and can be led by an allergy practitioner or mental health provider. A variety of graded exposures (e.g., sniffing an allergen, touching an allergen, eating a needlessly feared and avoided food) are performed in each session and then assigned for homework. Optional, additional sessions are offered if indicated (usually 2-3) to provide problem-solving around a particular area of anxious avoidance and/or coach basic parental behavioral management strategies if younger patients are encountering difficulty completing homework assignments. Initial sessions focus on psychoeducation regarding FAA, identification of medically unnecessary anxious avoidance, and the rationale for exposure-based treatment. Later sessions focus on refining and individualizing exposures based on patient age and specific areas of avoidance; improving patient's or family members' skill in becoming their own exposure coaches; collaborative problem-solving regarding challenges and setbacks; and relapse prevention.

The group adaptation of FAB tested in this study consisted of six 90-minute sessions attended by the child participants and their parents. The first four sessions were typically spaced one week apart; Sessions 5 and 6 were each spaced 3-4 weeks apart to allow families time to practice the assigned homework exposures in ecologically valid settings (e.g., home, parties,

restaurants) and generalize gains. A seventh optional "booster" session was offered 2-4 months later and focused on relapse prevention. Because the group treatment protocol described here followed the flexible FAB manual originally developed for individual patients, additional individual sessions were provided if indicated. Two families received additional individual sessions outside of group: One attended a single individual session (total time=one hour) to provide support and problem-solving after an anaphylactic event unrelated to the study and the second attended two parent-only sessions (total time= two hours) that focused on parental behavior management strategies.

Three cohorts participated, consisting of 2-5 families each (mean=3.33). Group 1 met for all sessions in person; due to the ensuing COVID-19 pandemic, Group 2 met via video for booster session 7, and Group 3 met for all sessions via video. All sessions for all groups were co-led by a psychologist (first author) and a pediatric allergy specialist from the hospital's food allergy center.

Statistical Analysis

Paired-samples t-tests were conducted to investigate changes in mean Total scores on the SOFAA-C, SOFAA-P, SCARED-child, SCARED-parent, and FAQLQ-PF from pretreatment-to-posttreatment and pretreatment-to-follow-up. Associated effect sizes (Cohen's *d*) were calculated using the following equation, which accounts for the correlation between pretest and posttest values in a within-group comparison: $d_{RM} = tc[2(1-r)/n]1/2$.[35]

RESULTS

Treatment Feasibility and Acceptability

Eleven children were initially referred and evaluated for excessive FAA, with 10 then referred to the group treatment with their families; one child was evaluated and not referred due to the absence of excessive anxiety (during evaluation, it became clear that only the parent had excessive anxiety and was offered outside referrals for their own therapy). All 10 families meeting inclusion/exclusion criteria and referred for group treatment opted to participate. Of these, all (100%) completed at least 5/6 active treatment sessions and 70% completed all six. The majority of children (70%) had both parents attend at least 5/6 sessions (including the one pair of divorced parents). There were no dropouts from treatment. One adverse event was recorded during the treatment period, although it was not related to the study: A patient experienced an anaphylactic event via unknown cross-contamination while on a vacation with their family between sessions 2 and 3 but returned to the group and completed all remaining sessions. Although the seventh booster session was optional, 80% of families chose to attend. The two families that could not attend completed the follow-up questionnaires.

One or both parents of 100% of the children completed a treatment satisfaction questionnaire at posttreatment, for a total of 13 completed satisfaction questionnaires. Parents rated the treatment as highly satisfactory and helpful: 100% of their responses fell into the *Very Helpful* (4) or *Extremely Helpful* (5) designations for the questions regarding how helpful parents found the treatment overall *for their child* (M=4.62, SD=0.51) and how helpful they found it overall *for themselves as parents* (M=4.77, SD=0.44). Parents' responses to open-ended questions about treatment were extremely positive, with group support and training in exposures ("bravery challenges") and education regarding what types of casual contact with allergens are extremely low risk ("safe enough") frequently mentioned as the most beneficial aspects.

Proof of Concept

All 10 children were rated as much improved (2) or very much improved (1) on the CGI at posttreatment. Table 2 displays changes in mean Total scores on the SOFAA-C, SOFAA-P, SCARED-child, SCARED-parent, and FAQLQ-PF at pretreatment, posttreatment, and at the 2-to-4-month follow-up booster session, as well as comparisons from pretreatment-to-posttreatment and pretreatment-to-follow-up. Results showed significant reductions on the SOFAA (measuring food allergy-specific anxiety) for both child-rated and parent-rated forms from pretreatment to posttreatment (all $p < .01$) with large within-group effect sizes at posttreatment (d=1.48 for child; d=1.58 for parent). Results also showed significant reductions on SOFAA-C and SOFAA-P from pretreatment to follow-up (all $p < .01$), with similarly large within-group effect sizes (d=1.86 for child; d=2.43 for parent). There were no significant changes on either the SOFAA-C or SOFAA-P from posttreatment to follow-up (all $p > .05$), indicating that gains were maintained two-to-four months after active treatment.

SCARED ratings of general anxiety (non-specific to food allergy) also declined significantly from pretreatment to follow-up on both child-rated and parent-rated forms (all $p < .05$) with moderate within-group effect sizes (d=.64 for child; d=.71 for parent). Declines from pretreatment to posttreatment were nonsignificant for both the SCARED-child and SCARED-parent (all $p > .05$).

FAQLQ-PF scores showed significant increases in HRQOL from pretreatment to posttreatment and pretreatment to follow-up (all $p < .05$) with large within-group effect sizes (d=1.39 and 1.92, respectively). There was no significant change on FAQLQ-PF scores from posttreatment to follow-up, suggesting that gains in HRQOL were maintained two-to-four months after active treatment ($p > .05$).

DISCUSSION

This initial study provides preliminary evidence of feasibility, acceptability, and proof of concept for the CBT-based FAB intervention in a group setting for an outpatient sample of children with moderate-to-severe anxiety related to their food allergies such that they met criteria for a separate DSM-5 Anxiety Disorder diagnosis. This brief group treatment protocol, adapted from the manualized treatment already employed with individual patients within an outpatient food allergy center, appears feasible, as evidenced by the high enrollment rates among eligible families, high attendance rates, absence of dropouts, and lack of adverse events. The treatment was also deemed *very-to-extremely helpful* by all participating parents on a Treatment Satisfaction measure.

Though the sample size of 10 is small and results are preliminary, findings also suggest that the FAB intervention can significantly improve clinical outcomes. All children were rated by the psychologist co-leading the groups as *much improved* or *very much improved* on the CGI at the close of active treatment. On standardized measures, children showed both significant reductions in food-allergy specific anxiety and significant increases in HRQOL at the end of treatment, and those gains were maintained at a follow-up booster session that occurred several months later, all with large effect sizes.

Interestingly, general (non-specific) anxiety as measured by the SCARED declined significantly from pretreatment to follow-up, but the decline from pretreatment to posttreatment was non-significant, and this pattern occurred for both child- and parent-ratings. This could be interpreted as a sleeper effect: Perhaps significant declines in food allergy-specific anxiety as

measured by the SOFAA during active treatment fueled declines in more general anxiety as the months wore on. Alternatively, it could be interpreted as further evidence that generic measures of anxiety are not sufficient in capturing clinical change in the FA population.[11]

Results are consistent with large, randomized controlled trials of youth who receive CBT for Anxiety Disorders unrelated to food allergy in both individual and group formats.[13–15] They are also consistent with studies in the pediatric food allergy literature showing that in-office exposures can reduce anxiety[24,25,36] and those showing that brief psychosocial interventions involving parents result in improvements in QOL.[19]

The results of the current study extend upon this prior research specifically by delivering full course of manualized treatment with a clinically ascertained sample of children and suggest it can lead to a significant and lasting FAA reduction even when delivered via a relatively brief format of 6 sessions. Although CBT manuals deployed in the larger RCTs for child anxiety disorders typically involve 10-16 sessions, they often wait to deploy exposures mid-way through treatment, after cognitive restructuring and relaxation training.[37] The FAB manual employed in this study emphasizes exposures early (Session 1), consistently (every session thereafter), and often (typically several within each session), in line with literature suggesting that exposure is the most active ingredient in effective treatment of any child anxiety disorder.[38–40]

Moreover, our treatment included parents in every session with the goal of training them to coach their children through homework exposures in home and community settings. Although the literature on whether parental involvement enhances outcomes in CBT for child anxiety remains equivocal,[41] a recent metanalysis showed that parental involvement in youth CBT – and not other treatment features such as relapse prevention and booster sessions – predicted larger pre-post treatment and follow-up effect sizes.[42] Moreover, studies indicate that more intensive

parental involvement in CBT sessions predicts better treatment response and that children whose parents encourage and facilitate exposures in and out of session are more likely to complete treatment and have better outcomes.[43–45] Given that parental anxiety, overaccommodation, and overprotection has been linked to higher anxiety and lower QOL in children with food allergies[46] and given the number of parents in our groups who informally told us that FAB lowered their own anxiety, perhaps our dual emphasis on 1) exposure as 2) facilitated by parents enhanced treatment outcomes even in this relatively brief treatment.

In line with this, a limitation of our study is that we did not formally assess for parental anxiety and our small sample size would have precluded analyzing it as a possible moderator of treatment outcome.[12,46] Future studies with larger samples could do this, as well as afford for analysis of other patient variables as they relate to outcome (e.g., demographic, medical/psychiatric history). Our small sample size and lack of control group also mandates that *p*-values and effect sizes be interpreted with caution and that other hypotheses regarding symptom improvement – such as natural history, therapist attention, or the general social support provided by a group treatment format – be considered. Statistical testing of potential differences in outcome between the group that attended all sessions in person versus the group that attended only their booster session via video versus the group that attended all sessions via video was precluded due to small sample size. However, our informal clinical observation was that the children fared well with the treatment – and parents reported great satisfaction with it – regardless of how many sessions they experienced in-person or by video. Our small sample of highly motivated families with children allergic to the most common food allergens may not be representative of a broader sample of food allergy families and future studies with larger samples are needed to examine if FAB is more broadly feasible and generalizable. The sample was 80%

female and entirely non-Hispanic White, limiting generalizability to males and more diverse samples. Moreover, this initial study was limited to a group treatment involving patients with a relatively narrow age range (8-12) and hence may not generalize to individual treatment with a wider age range of children. However, our clinical experience applying the FAB protocol in our specialty anxiety clinic with individual patients ranging from young children to young adults has shown similarly promising outcomes and reports of parent and patient satisfaction.

This study has important strengths. This is the first study of an outpatient psychosocial treatment for anxious food allergic children formally diagnosed with an Anxiety Disorder via clinical interview. These patients were treated via a manualized protocol that affords for replication by other intervention researchers. Symptom improvement was reported by multiple informants (child, parent, therapist) and across multiple domains (disease-specific anxiety, general anxiety, and health-related quality of life). This study included a follow-up assessment 2-4 months past active treatment, with results suggesting gains were maintained.

This is also the first treatment study that we know of that employed a disease-specific measure of FAA to assess treatment effects. In a previous study, the SOFAAs showed impressive test-retest values from baseline to follow-up (*M*=16.0 days), suggesting they are not vulnerable to random fluctuation.[26] In the current study, the significant reductions in SOFAA scores provide preliminary evidence that both the SOFAA-C and the SOFAA-P are sensitive to change following intervention.

This study also suggests several clinical implications. As the prevalence of food allergy increases, we can expect that the number of our patients presenting with prolonged and impairing anxiety in the context of their food allergies will also increase. This study took place in a specialty anxiety clinic embedded within a large outpatient food allergy center. Our experience

was that of families and their allergists eager for our services and grateful for the ease and speed with which patients could be referred and receive what appears to be an effective treatment for their anxiety. Given that the majority of children with any anxiety disorder has difficulty accessing evidence-based treatment[47] and that this may be particularly the case for those with anxiety in the context of their food allergies,[5] other allergy practices might similarly benefit by including a trained provider within their staff dedicated to offering exposure-based intervention. The lack of adverse effects among the 10 patients in this study, each of whom completed dozens of proximity exposures over the course of treatment, suggests that exposure-based interventions need not be limited to taking place under medical supervision in allergists' offices, but are safe enough for mental health practitioners, in consultation with a patient's allergist, to deploy in regular outpatient settings. Finally, three of the children participating in this study were found to have food restriction related to FAA of such severity that they warranted an additional diagnosis of Avoidant-Restrictive Food Intake Disorder (ARFID) and clinical attention specifically to expanding their food repertoire and/or weight restoration as monitored by their pediatrician. Given that other reports have documented the presence of eating disorders, including ARFID, among the FA population,[48,49] our study further supports the assessment of restricted eating and weight concerns when working with this population.

In conclusion, the initial evidence of feasibility, acceptability, and proof-of-concept lays groundwork for larger, randomized studies to compare the FAB intervention to waitlist control as well as other active treatments to test and inform efficacy.[50] The ease with which we were able to transmit the FAB intervention to one group entirely via video sessions in response to the COVID-19 pandemic – and the positive response of these families – suggests that FAB via telehealth may be effective even during a time of generally heightened anxiety, as well as a

promising treatment for dissemination to underserved or difficult to reach populations.[51]

Table 1. *Sample characteristics at pretreatment (N=10)*

Variables	*M (SD)*	*% (N)*
Age, years	10.12 (1.71)	
Gender, female		80% (8)
Race, White		100% (10)
Clinical Characteristics		
Number of Food Allergies[a]	4.40 (2.59)	
History of Anaphylaxis		70% (7)
Prescribed Epinephrine Auto-Injector		100% (10)
History other psychiatric diagnoses		
Other Anxiety Disorder		30% (3)
Mood Disorder		10% (1)
ADHD or Behavior Disorder		20% (2)
ARFID		30% (3)

Note. [a]=IgE mediated food allergy to milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat or soybeans. ARFID = Avoidant/restrictive food intake disorder.

Table 2. *Descriptive statistics and pairwise comparisons at pretreatment-to-posttreatment and pretreatment-to-follow-up (N = 10)*

	Pretreatment	Posttreatment	Follow-up	Pretreatment-to-Posttreatment Comparison			Pretreatment-to-Follow-up Comparison		
Measures	*M (SD)*	*M (SD)*	*M (SD)*	*t*-ratio	*SE*	*ES*	*t*-ratio	*SE*	*ES*
SOFAA									
Child-Report	31.72 (14.57)	14.25 (6.36)[a]	11.72 (5.66)	3.63**	5.01	1.48	3.80**	5.27	1.86
Parent-Report	40.84 (15.33)	20.59 (9.38)[a]	12.05 (7.70)	4.26**	5.01	1.58	4.78***	6.03	2.43
SCARED									
Child-Report	26.50 (18.40)	20.59 (15.53)	15.30 (12.18)	1.71	3.45	0.34	2.89*	3.87	0.64
Parent-Report	26.11 (15.80)[a]	22.38 (18.84)[b]	14.10 (10.71)	1.85	3.04	0.31	3.07*	3.48	0.71
FAQLQ-PF[c]	5.03 (0.81)	3.89 (1.12)[a]	3.20 (1.09)	3.12*	0.41	1.39	4.09**	0.45	1.92

Note. SOFAA = Scale of Food Allergy Anxiety. SCARED = Screen for Child Anxiety Related Emotional Disorders. FAQLQ-PF = Food Allergy Quality of Life Questionnaire – Parent Form. *SE* = standard error; *ES* = effect size in Cohen's *d*, adjusted due to the correlated nature of the dependent sample per Dunlap et al. (1996). [a]*n*=9 due to missing data. [b]*n*=8 due to missing data. [c]Lower scores indicate higher quality of life
* $p < .05$; ** $p < .01$; *** $p < .001$

References

1. Miller J, Blackman AC, Wang HT, Anvari S, Joseph M, Davis C, et al. Quality of life in food allergic children. *Ann Allergy Asthma Immunol*. 2020;124:379-384.
2. Thörnqvist V, Middelveld R, Wai HM, Ballardini N, Nilsson E, Stromquist J, et al. Health-related quality of life worsens by school age amongst children with food allergy. *Clin Transl Allergy*. 2019;9:10.
3. Feng C, Kim JH. Beyond Avoidance: the Psychosocial Impact of Food Allergies. *Clin Rev Allergy Immunol*. 2019;57:74-82.
4. Fedele DA, McQuaid EL, Faino A, Strand M, Cohen S, Robinson J, et al. Patterns of adaptation to children's food allergies. *Allergy*. 2016;71:505-513.
5. Dahlsgaard KK, Lewis MO, Spergel JM. New issue of food allergy: Phobia of anaphylaxis in pediatric patients. *J Allergy Clin Immunol*. 2020;146:780-782.
6. Chan ES, Dinakar C, Gonzales-Reyes E, Green TD, Gupta R, Jones D, et al. Unmet needs of children with peanut allergy. *Ann Allergy Asthma Immunol*. 2020;124:479-486.
7. Engel ML, Bunning BJ. The Unmet Needs of Patients with Food Allergies. *Immunol Allergy Clin North Am*. 2021;41:321-330.
8. Herbert L, DunnGalvin A. Psychotherapeutic Treatment for Psychosocial Concerns Related to Food Allergy: Current Treatment Approaches and Unmet Needs. *J Allergy Clin Immunol in Pract*. 2021;9:101-108.
9. Knibb R, Halsey M, James P, du Toit G, Young J. Psychological services for food allergy: The unmet need for patients and families in the United Kingdom. *Clin Exp Allergy*. 2019;49:1390-1394.
10. Polloni L, Muraro A. Anxiety and food allergy: A review of the last two decades. *Clin Exp Allergy*. 2020;50:420-441.
11. Soller L, To S, Hsu E, Chan ES. Current tools measuring anxiety in parents of food-allergic children are inadequate. Peters R, ed. *Pediatr Allergy Immunol*. 2020;31:678-685.
12. Westwell-Roper C, To S, Andjelic G, et al. Food-allergy-specific anxiety and distress in parents of children with food allergy: A systematic review. *Pediatr Allergy Immunol*. 2022;33:e13695.
13. Comer JS, Hong N, Poznanski B, Silva K, Wilson M. Evidence Base Update on the Treatment of Early Childhood Anxiety and Related Problems. *J Clin Child Adolesc Psychol*. 2019;48:1-15.
14. Higa-McMillan CK, Francis SE, Rith-Najarian L, Chorpita BF. Evidence Base Update: 50 Years of Research on Treatment for Child and Adolescent Anxiety. *J Clin Child Adolesc Psychol*. 2016;45:91-113.
15. Sigurvinsdóttir AL, Jensínudóttir KB, Baldvinsdóttir KD, Smárason O, Skarphedinsson G. Effectiveness of cognitive behavioral therapy (CBT) for child and adolescent anxiety disorders across different CBT modalities and comparisons: a systematic review and meta-analysis. *Nord J Psychiatry*. 2020;74:168-180.
16. Manassis K. Managing Anxiety Related to Anaphylaxis in Childhood: A Systematic Review. *J Allergy*. 2012;2012:1-7.
17. Cuervo-Pardo L, Barcena-Blanch MA, Gonzalez-Estrada A, Schroer B. Apps for food allergy: A critical assessment. *J Allergy Clin Immunol Pract*. 2015;3:980-981.
18. Egan M, Greenhawt M. Common questions in food allergy avoidance. *Ann Allergy Asthma Immunol*. 2018;120:263-271.

19. Sugunasingha N, Jones FW, Jones CJ. Interventions for caregivers of children with food allergy: A systematic review. *Pediatr Allergy Immunol*. 2020;31:805-812.
20. Boyle RJ, Umasunthar T, Smith JG, Hanna H, Procktor A, Phillips K, et al. A brief psychological intervention for mothers of children with food allergy can change risk perception and reduce anxiety: Outcomes of a randomized controlled trial. *Clin Exp Allergy*. 2017;47:1309-1317.
21. Knibb RC. Effectiveness of Cognitive Behaviour Therapy for Mothers of Children with Food Allergy: A Case Series. *Healthcare*. 2015;3:1194-1211.
22. Vreeken-Ross SC, Cartwright-Hatton S, Harris SA, Hanna P, Jones CJ. Feasibility of an online CBT group intervention for parents of children with food allergy. *Clin Exp Allergy*. 2022;52:171-175.
23. LeBovidge JS, Timmons K, Rich C, Rosenstock A, Fowler K, Strauch H, et al. Evaluation of a group intervention for children with food allergy and their parents. *Ann Allergy Asthma Immunol*. 2008;101:160-165.
24. Shemesh E, D'Urso C, Knight C, Rubes M, Picerno K, Posillico A, et al. Food-Allergic Adolescents at Risk for Anaphylaxis: A Randomized Controlled Study of Supervised Injection to Improve Comfort with Epinephrine Self-Injection. *J Allergy Clin Immunol Pract*. 2017;5:391-397 e394.
25. Weinberger T, Annunziato R, Riklin E, Shemesh E, Sicherer SH. A randomized controlled trial to reduce food allergy anxiety about casual exposure by holding the allergen: TOUCH study. *J Allergy Clin Immunol Pract*. 2019;7:2039-2042 e2014.
26. Dahlsgaard KK, Wilkey LK, Stites SD, Lewis MO, Spergel JM. Development of the Child- and Parent-Rated Scales of Food Allergy Anxiety (SOFAA). *J Allergy Clin Immunol Pract*. 2022;10:161-169 e166.
27. Coelho GL de H, Byrne A, Hourihane J, DunnGalvin A. Development of the Food Allergy Anxiety Scale in an Adult Population: Psychometric Parameters and Convergent Validity. *J Allergy Clin Immunol Pract*. 2021;9:3452-3458 e3451.
28. Poehacker S, McLaughlin A, Humiston T, Peterson C. Assessing Parental Anxiety in Pediatric Food Allergy: Development of the Worry About Food Allergy Questionnaire. *J Clin Psychol Med Settings*. 2021;28:447-456.
29. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition: DSM-5*. American Psychiatric Publishing; 2013.
30. Birmaher B, Brent DA, Chiappetta L, Bridge J, Monga S, Baugher M. Psychometric Properties of the Screen for Child Anxiety Related Emotional Disorders (SCARED): A Replication Study. *J Am Acad Child Adolesc Psychiatry*. 1999;38:1230-1236.
31. DunnGalvin A, de BlokFlokstra BMJ, Burks AW, Dubois AEJ, Hourihane JO. Food allergy QoL questionnaire for children aged 0–12 years: content, construct, and cross-cultural validity. *Clin Exp Allergy*. 2008;38:977-986.
32. Guy W. *ECDEU Assessment Manual for Psychopharmacology*. U.S. Dept. of Health, Education, and Welfare, Public Health Service, Alcohol, Drug Abuse, and Mental Health Administration, National Institute of Mental Health, Psychopharmacology Research Branch, Division of Extramural Research Programs; 1976.
33. Walkup JT, Albano AM, Piacentini J, Birmaher B, Compton S, Sherrill J, et al. Cognitive Behavioral Therapy, Sertraline, or a Combination in Childhood Anxiety. *N Engl J Med*. 2008;359:2753-2766.

34. Dahlsgaard KK, Lewis MO. *Food Allergy Bravery (FAB): A Manual for Brief Cognitive-Behavioral Treatment of Anxiety in Patients with Food Allergy*. 2019.
35. Dunlap WP, Cortina JM, Vaslow JB, Burke MJ. Meta-analysis of experiments with matched groups or repeated measures designs. *Psychol Methods*. 1996;1:170-177.
36. Dinakar C, Shroba J, Portnoy JM. The transforming power of proximity food challenges. *Ann Allergy Asthma Immunol*. 2016;117:135-137.
37. Reynolds S, Wilson C, Austin J, Hooper L. Effects of psychotherapy for anxiety in children and adolescents: A meta-analytic review. *Clin Psychol Rev*. 2012;32:251-262.
38. Ale CM, McCarthy DM, Rothschild LM, Whiteside SPH. Components of Cognitive Behavioral Therapy Related to Outcome in Childhood Anxiety Disorders. *Clin Child Fam Psychol Rev*. 2015;18:240-251.
39. Peris TS, Compton SN, Kendall PC, Birmaher B, Sherrill J, March J, et al. Trajectories of change in youth anxiety during cognitive—behavior therapy. *J Consult Clin Psychol*. 2015;83:239-252.
40. Whiteside SPH, Sim LA, Morrow AS, Farah W, Hilliker D, Murad M, et al. A Meta-analysis to Guide the Enhancement of CBT for Childhood Anxiety: Exposure Over Anxiety Management. *Clin Child Fam Psychol Rev*. 2020;23:102-121.
41. Reuman L, Thompson-Hollands J, Abramowitz JS. Better Together: A Review and Recommendations to Optimize Research on Family Involvement in CBT for Anxiety and Related Disorders. *Behav Ther*. 2021;52:594-606.
42. Sun M, Rith-Najarian LR, Williamson TJ, Chorpita BF. Treatment Features Associated with Youth Cognitive Behavioral Therapy Follow-Up Effects for Internalizing Disorders: A Meta-Analysis. *J Clin Child Adolesc Psychol*. 2019;48:S269-S283.
43. Pereira AI, Muris P, Mendonça D, Barros L, Goes AR, Marques T. Parental Involvement in Cognitive-Behavioral Intervention for Anxious Children: Parents' In-Session and Out-Session Activities and Their Relationship with Treatment Outcome. *Child Psychiatry Hum Dev*. 2016;47:113-123.
44. Reynolds SA, Clark S, Smith H, Langdon PE, Payne R, Bowers G, et al. Randomized controlled trial of parent-enhanced CBT compared with individual CBT for obsessive-compulsive disorder in young people. *J Consult Clin Psychol*. 2013;81:1021-1026.
45. Thompson-Hollands J, Edson A, Tompson MC, Comer JS. Family involvement in the psychological treatment of obsessive–compulsive disorder: A meta-analysis. *J Fam Psychol*. 2014;28:287-298.
46. Chow C, Pincus DB, Comer JS. Pediatric food allergies and psychosocial functioning: Examining the potential moderating roles of maternal distress and overprotection. *J Pediatr Psychol*. 2015;40:1065-1074.
47. Merikangas KR, He J ping, Burstein M, et al. Service Utilization for Lifetime Mental Disorders in U.S. Adolescents: Results of the National Comorbidity Survey–Adolescent Supplement (NCS-A). *J Am Acad Child Adolesc Psychiatry*. 2011;50:32-45.
48. Jafri S, Frykas TL, Bingemann T, Phipatanakul W, Bartnikas LM, Protudjer JLP. Food Allergy, Eating Disorders and Body Image. *J Affect Disord Rep*. 2021;6:100197.
49. Patrawala MM, Vickery BP, Proctor KB, Scahill L, Stubbs KH, Sharp WG. Avoidant-restrictive food intake disorder (ARFID): A treatable complication of food allergy. *J Allergy Clin Immunol Pract*. 2022;10:326-328 e322.

50. Czajkowski SM, Powell LH, Adler N, Naar-King S, Reynolds KD, Hunter CM, et al. From Ideas to Efficacy: The ORBIT Model for Developing Behavioral Treatments for Chronic Diseases. *Health Psychol*. 2015;34:971-982.
51. Protudjer JLP, Golding M, Salisbury MR, Abrams EM, Roos, LE. High anxiety and health-related quality of life in families with children with food allergy during coronavirus disease 2019. *Ann Allergy Asthma Immunol*. 2021;126:83-88 e81.