App providing psychosocial and educational supports benefits caregivers of children with newly diagnosed food allergies

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ABSTRACT

Background: Approximately 6 million children in the United States have a diagnosed food allergy, and 32% of caregivers experience significant psychological distress due to the diagnosis. Despite substantial impacts on psychosocial health and quality of life, few interventions aim to help caregivers of newly diagnosed children. There is a clear, unmet need for interventions to address caregiver distress, especially after the initial diagnosis.

Objective: We developed a mobile psychosocial health intervention, the Food Allergy Symptom Self-Management with Technology (FASST) app. Primary end points were to determine the app's feasibility and caregiver satisfaction.

Methods: This was a phase II, randomized controlled, implementation study (4-week duration) in caregivers (N = 30) of children ≤ 18 years of age who were newly diagnosed with a food allergy (≤ 90 days after the diagnosis). Caregivers (n = 20) were randomized to use the FASST app (intervention group) with access to individualized, self-help symptom relief interventions and food allergy support, and educational resources; or to use a limited app with a basic FASST interface and links to a few educational resources (control group [n = 10]). Ten participants (intervention group, n = 5; control group, n = 5) participated in semistructured interviews at week 4.

Results: Both groups found the app relatively easy to use. The intervention group scores for safety preparedness during social activities increased by 24%, whereas those in the control group experienced a 1% decline. The intervention group participants increased the use of websites to find food allergy information by 17% at week 4 compared with 4% for the control group. Although the intervention group participants showed greater gains than did those in the control group in their confidence to prepare for and prevent allergic reactions, and greater declines in perceived social limitations, more participants in the control group endorsed confidence in their ability to recognize (11% versus 5%, respectively) and treat (10% versus 6%, respectively) allergic reactions.

Conclusion: Analysis of our results suggests that the FASST app may provide a feasible means of delivering psychosocial and educational supports to caregivers of children recently diagnosed with a food allergy.

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A pproximately 6 million children in the United States have a diagnosed food allergy, and 32% of their caregivers experience clinically significant psychological distress due to the diagnosis.^{1–7} Food allergic reactions can produce a variety of symptoms, which range from hives to severe reactions, including food-induced anaphylaxis (FIA). FIA occurs in > 40% of children with a food allergy and, although rare, FIA reactions are responsible for > 200 deaths and 30,000 emergency department visits in the U.S. annually.⁴ Currently there is no cure for food allergies, and standard treatment focuses on strict avoidance of food and emergency symptom management after reactions.⁴ Recent research efforts focused on immunotherapy (both oral and epicutaneous) as a treatment that can, over time, induce immune tolerance to specific food proteins. Research has been promising with oral immunotherapy (OIT), and there now is an U.S. Food and Drug Administration approved drug (Palforzia,

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Aimmune Therapeutics, Brisbane, California) for the treatment of peanut allergy in children ages 4–17 years.

However, it must be noted that OIT is still not a cure for food allergy and, without continued daily medication, patients remain at risk for reactions. In fact, a robust systematic review revealed that peanut OIT regimens increased the risk for reactions and anaphylaxis over avoidance and placebo, which may be stressful and anxiety provoking to both the child receiving OIT and the child's caregiver.⁸ New research has shown that earlier initiation of peanut OIT (ages < 4 years) was associated with an increase in both tolerance and remission.⁹

Because food allergens can be ubiquitous substances and are often not visible in food products, accidental exposure is common. On initial diagnosis of a food allergy, the risks of reaction are discussed at length with parents by the provider and an individualized food allergy action plan is provided to the family. Food allergy action plans include specific medications and doses for various symptoms that may present after exposure. The risk for a reaction is variable for each patient; some patients may be able to eat products that are "made in a facility with peanut," whereas others may react to these products.

In addition, the extent of the reaction may be variable for each patient, one patient may only have hives after an exposure one time but develop anaphylaxis after exposure another time. Generally, providers educate patients and families about these risks at each visit. Although caregiver responses to managing food allergies is also variable, the risk for accidental exposures can promote an environment of hypervigilance and stress fatigue. Although some patients outgrow a food allergy, caregivers of children newly diagnosed with a food allergy must learn to manage it as a potentially fatal and chronic condition and respond to food-induced reactions as acute medical events that require immediate care.

The first 6 months after a diagnosis is particularly challenging, as caregivers try to balance appropriate vigilance and management strategies while preserving quality of life for everyone in the household.¹⁰ Managing the condition is time consuming and requires persistence. Caregivers must not only monitor the child's food consumption at and away from home (at school and with friends) and prepare special meals but must also notice everything the child touches, including surfaces (*e.g.*, playground equipment, water fountains, shopping cart handles) that may be contaminated with invisible allergenic proteins that could elicit a dangerous reaction. These ongoing, daily tasks are reported to have a substantial impact on a caregiver's quality of life.¹⁰

The unpredictability of food-induced reactions further magnifies caregiver stress and anxiety because previous mild or moderate reactions do not indicate the severity of future reactions, which may be severe or fatal.⁵ The ever-present risk of severe or life-threatening reactions causes significant continuous stress for caregivers who report fatigue, uncertainty, social isolation, reduced spontaneity, and persistent anxiety, fear, and depression.^{1,3,6,11–15} These symptoms are most severe immediately after diagnosis during the period of caregiver adjustment.¹⁶ Although a certain level of anxiety is helpful to adequately manage the condition, high levels of sustained anxiety in caregivers of children with a food allergy can be maladaptive, which increases the overall caregiving burden for the child with an allergy and diminishes the caregivers' ability to appropriately attend to the overall family unit.¹⁷

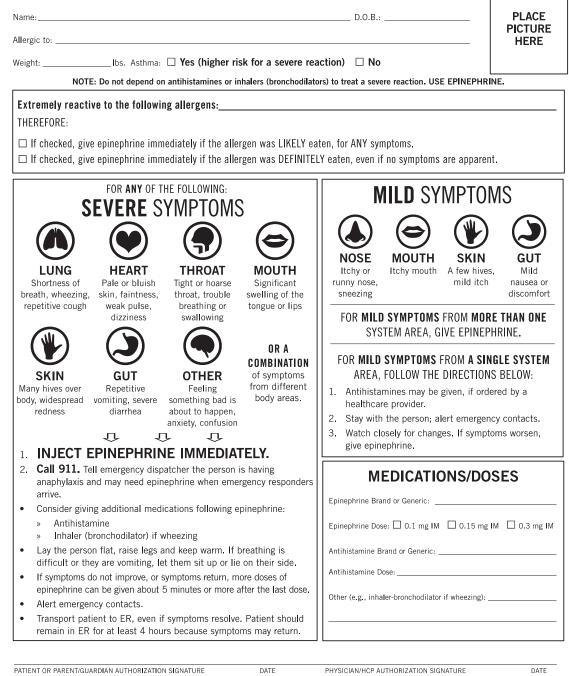
Despite substantial evidence of negative impacts on a caregiver's psychosocial health and quality of life, apart from the assistance of mental health-care professionals, few interventions exist to help caregivers of newly diagnosed children with food allergies manage stress-related fatigue, depression, and anxiety.^{3,18} The unmet need for symptom self-management tools to improve quality of life is likely to become even more pressing as the U.S. prevalence of food allergy rose by 50% from 1997 to 2011, and FIA events increased by 377% from 2007 to 2016.¹⁸ Thus, there is a clear and growing need for interventions to address caregivers' significant distress and negative impacts on quality of life, especially near the time of initial diagnosis.³ Here we report the results of a feasibility study for a technology-enhanced, self-management mobile health (mHealth) application (app) intervention for caregivers of children newly diagnosed with food allergies. The goal of this intervention was to promote effective self-management behaviors to improve caregiver psychosocial well-being and knowledge. We are not aware of any other reports of similar interventions designed for this population and purpose.

METHODS

We conducted a two-phase study to develop and test the feasibility of a multicomponent, smartphone selfhelp app to promote increased food allergy knowledge and self-management of symptoms such as fatigue, stress, depression, and anxiety among caregivers of children newly diagnosed with a food allergy (\leq 90 days from diagnosis). Caregivers were recruited from the allergy and immunology clinics at the Medical University of South Carolina. Before initiating the study activities, this research was approved by the Medical University of South Carolina Institutional Review Board.

Phase I (results not published) used qualitative feedback from key informant interviews (n = 10 caregivers of children with established food allergies [≥ 1 year after the diagnosis]) to adapt an existing technology-

FOOD ALLERGY & ANAPHYLAXIS EMERGENCY CARE PLAN



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Figure 1. Food allergy and anaphylaxis emergency care plan.

enhanced, self-management mHealth app that was originally designed to address the psychosocial needs of disaster survivors. We chose these informants to help optimize the app because they had experience with food allergy management and were able to predict the concerns of caregivers of newly diagnosed

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children. We named our modified tool the Food Allergy Symptom Self-Management with Technology (FASST) app.

Here we report the results of a phase II, randomized controlled, implementation study among caregivers (n = 30) of children ≤ 18 years of age who were newly

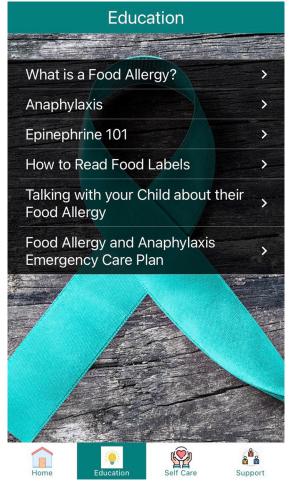


Figure 2. Education screen image.

diagnosed with food allergies (\leq 90 days since diagnosis). Primary end points were to determine the FASST app feasibility and caregiver satisfaction. The caregivers were randomized to use the FASST app (intervention group [n = 20]) or a more limited app (control group [n = 10]) for 4 weeks. The intervention group received a full-service app, which provided access to a three-component, technology-based package.

Component 1 provided continuous access to educational resources about food allergies and their management. Materials included embedded pdf documents (Fig. 1) and website links to authoritative resources such as, FARE (Food Allergy Education and Research), a leading nonprofit national organization dedicated to food allergy awareness. Component 2 was a tracking feature for the participants to record their daily psychosocial symptoms, such as fatigue and anxiety. The participants could view their symptom trends graphically illustrated in the app. Component 3 directed intervention group participants to symptom-based interventions (selected based on individual participant feedback) that the participants could use in real-time as symptoms arose. For example, a participant who logged symptoms related to anxiety

Short Term Coping Skills



Figure 3. Short-term coping skills screen image.

was directed to a brief, guided relaxation intervention (*e.g.*, meditation or deep breathing exercises). A participant who logged fatigue symptoms was directed to a short audio clip offering ideas to improve sleep or sleep hygiene. Sample smartphone screen images from the FASST app are provided for illustrative purposes in Figs. 2 and 3.

The control group participants received an app with only the basic FASST interface and links to resources without the individualized content. After the end of the 4-week study period, five participants from each arm were randomly selected to participate in a postintervention key informant interview by using a semistructured interview protocol. These interviews provided in-depth information about app accessibility, usability, and participant adherence.

The participants completed a basic demographic questionnaire at baseline. Outcomes were measured by using the Reach, Effectiveness, Adoption, Implementation, and Maintenance framework to evaluate process measures, surveys, and key informant interviews. Participant symptom measures reported here include the following: Food Allergy Quality of Life-Parental Burden, and Food

Caregiver Characteristics	Control $(n = 10)$	Intervention ($n = 20$)
Women, <i>n</i> (%)	9 (90.0)	20 (100)
White, <i>n</i> (%)	7 (70.0)	14 (70.0)
Hispanic or Latino, <i>n</i> (%)	0 (0.0)	3 (15.0)
Age, mean \pm SD, y	34.0 ± 4.6	32.3 ± 6.6
Marital status, n (%)		
Married	6 (60.0)	15 (75.0)
Never married	4 (40.0)	5 (25.0)
Education, <i>n</i> (%)		
High school or less	1 (10.0)	4 (21.1)
Some college or technical school	2 (20.0)	4 (21.1)
Undergraduate	2 (20.0)	3 (15.8)
Graduate or higher	5 (50.0)	8 (42.1)
Employment, <i>n</i> (%)		
Not employed	1 (10.0)	4 (20.0)
Currently employed	9 (90.0)	16 (80.0)
Income, $n(\%)$		
<\$50,000	2 (20.0)	7 (35.0)
\$50,000-\$99,999	2 (20.0)	4 (20.0)
>\$100,000	6 (60.0)	9 (45.0)
No. children ages <18 y in the household, mean \pm SD	1.8 ± 0.8	1.8 ± 0.8
Children with food allergies, mean \pm SD	1.1 ± 0.3	1.1 ± 0.2

Allergy Self-Efficacy Scale for Parents. All the outcomes were measured at baseline and study end (week 4) for comparison. An mHealth app usability questionnaire was included as the primary study end point was app feasibility. This seven-point Likert scale measure of 18 variables was administered once at the end of the 4-week study period. Here, we report on 11 of those 18 variables that most closely align with the aims of this feasibility study.

Data Management

Because this was a pilot study and did not test hypotheses or use inferential statistics, a target sample size of 30 was appropriate.¹⁹ Due to the small sample size, we are only providing descriptive results. The frequency with percentages were assessed for categorical variables and mean with 95% confidence intervals were assessed for continuous variables. All statistical analyses were conducted by using SAS version 9.4 (SAS Institute, Cary, NC). The study used the Research Electronic Data Capture (REDCap) system for data capture and management.^{20,21} It includes secure, web-based, flexible applications, including real-time validation rules with automated data type and range checks at the time of data entry. The study-specific REDCap electronic data base was designed and developed by the study staff.

By using a convenience sample, this descriptive pilot study gathered both quantitative and qualitative data. Each measure was scored and the frequency distribution and the median and mean responses (with 95% confidence intervals) were obtained. Qualitative interviews were recorded with the participants and were transcribed and analyzed by using thematic analysis, and interpreted. Univariate descriptive statistics and frequency distributions were calculated as appropriate. Demographic variables obtained at baseline were described *via* measures of central tendency (mean and median), variability, and frequency distributions as appropriate.

RESULTS

The participants in the control (n = 20) and intervention (n = 10) groups were parents of children with food allergies, and the groups were similar in age, gender, household income, and educational status (Table 1). The majority in both groups were white and women, and had at least some post–high-school education at a college or technical school. Most participants in both groups reported a household income > \$50,000 per year. On average, the participants reported having two children at home, with one of them having a

Table 2 Results of mHealth app usability		
mHealth App Usability Questionnaire Responses	Control Group	Intervention Group
The app was easy to use.	5.7 (4.3, 7.1)	5.5 (4.4, 6.6)
The interface of the app allowed me to use all the functions (such as entering information, responding to reminders, viewing information) offered by the app.	5.2 (3.9, 6.5)	5.7 (4.6, 6.8)
The information in the app was well organized, so I could easily find the information I needed.	4.9 (3.5, 6.3)	6.0 (5.0, 7.0)
The app adequately acknowledged and provided information to let me know the progress of my action.	4.8 (3.5, 6.1)	5.8 (4.8, 6.8)
The amount of time involved in using this app has been fitting for me.	4.7 (3.4, 6.0)	5.8 (4.8, 6.8)
I would use this app again.	4.4 (3.0, 5.8)	5.7 (4.6, 6.8)
Overall, I am satisfied with this app.	4.4 (2.9, 5.9)	5.7 (4.8, 6.7)
The app improved access to useful information relevant to managing both my child's food allergy and my health and well-being.	4.7 (3.4, 6.0)	5.9 (5.0, 6.8)
The app helped me manage my health effectively.	4.1 (3.0, 5.2)	5.4 (4.3, 6.4)
This app has all the functions and capabilities I expected it to have.	4.0 (2.7, 5.3)	5.5 (4.5, 6.6)
This mHealth app provides an acceptable way to access information relevant to managing my child's food allergy and my health and well-being, such as educational materials, tracking my own activities/behaviors, and engaging with self-management activities.	, ,	5.7 (4.8, 6.7)
mHealth app = Mobile health application.		

newly diagnosed food allergy. Results for the mHealth app usability questionnaire the measured the app's feasibility as reported by the participants are shown in Table 2.

The app usability was also reflected in the participants' comments on functionality and engagement during poststudy interviews. With regard to functionality, the participants recommended esthetic improvements and commented that the app was easy to use, with one participant stating that it was, "easy to access with trusted information that I could understand." Suggestions to improve app functionality included a search tool to facilitate faster access to specific information of interest.

With regard to app engagement, several participants identified the time required to access and use the app features as a key issue. One intervention group participant stated, "I would spend no more than 2 minutes" engaging with self-care activities. Another commented that the app content was static and, thus, continued use was unrewarding. This participant suggested automatically varying content weekly and sending push notifications to alert users to new content. Another participant suggested providing links to current evidencebased research. Future testing of the FASST app will incorporate suggestions offered by the study participants to improve app functionality.

Results from the Food Allergy Self-Efficacy Scale for Parents found that the scores related to taking precautions to prevent an allergic reaction improved for the intervention group participants more than for the control group. For example, safety preparedness during social activities with informal care providers (family, friends, babysitters) were 15% and 19% at baseline for the intervention group and the control group, respectively. At study end, the intervention group scores related to safety preparedness during social activities had increased by 24%, whereas the control group participants experienced a 1% decline on this item (Table 3).

Interestingly, at study end, more of the control group than the intervention group participants endorsed increased confidence in their ability to recognize (11% versus 5%, respectively) and treat (10% versus 6%, respectively) an allergic reaction in their child (Table 3). A possible explanation may be that allergic reaction prevention and treatment information was among the few educational items included in the control group app and, therefore, among the few topics on which the control group participants could focus their attention. By contrast, the intervention group app included education, support, and self-care resources, which may have drawn attention away from the prevention and treatment topics. Between-group differences in the number of food allergies their child had may have also made this information less salient to the intervention group participants. The majority (3/5 [60%]) of the intervention group participants had children with a single food allergy. One of these participants stated in a poststudy interview that, because she only had to manage one food allergy, "I didn't have as much

	Baseline – Week-4 (% Change)		
I Am Confident in My Ability To	Control Group	Intervention Group	
Have a plan to make sure my child is safe at school or nursery	67.7 - 73.4 (8)	79.9 - 87.4 (10)	
Prepare for social activities with relatives, friends, or a babysitter	67.2 - 79.4 (15)	79.3 - 94.7 (19)	
Plan to participate in social activities with others involving food	72.6 - 71.9 (-1)	63.5 - 79.0 (24)	
Teach others about my child's food allergy	83.6 - 86.4 (3)	90.3 - 92.6 (3)	
Recognize an allergic reaction in my child	72.7 - 80.6 (11)	88.0 - 92.5 (5)	
Treat my child if they had an allergic reaction	78.7 - 86.5 (10)	87.2 - 92.6 (6)	
Find reliable websites with information about food allergies	69.7 - 72.8 (4)	68.3 – 79.7 (17)	

pressure to try and read about it. If I had more to manage, I'd want to know more."

By week 4, the intervention group participants increased their use of websites to find information about food allergies by 17% compared with a 4% increase among the control group participants (Table 3). In a poststudy interview, one control group participant said, "I did not want to become overwhelmed, so I didn't do more research outside of the app." The need to be socially connected to other caregivers of children with food allergies was a common topic among participants in poststudy interviews. Both intervention group and control group participants endorsed a desire to connect with others. As one participant said, "I would like more options to connect with other parents. My time after the diagnosis was spent trying to figure things out. Now that I'm managing it, it would be helpful to have people that understand (to talk to)." The app did provide a resource to help the participants locate local support groups through an external website link, where they could enter a Zip code to find existing support groups.²²

The Food Allergy Quality of Life-Parental Burden measure was used to assess the degree of limitation of the participants associated with managing a child with food allergy. Overall, analysis of the results suggests that the use of the app may help decrease perceived social limitations related to the food allergy. At baseline, the intervention group reported less limitation ("do not feel limited" or "hardly feel limited") than the control group in their ability to attend social events. At week 4, the proportion of the intervention group participants who endorsed "do not feel limited" or "hardly limited" nearly doubled (Table 4). By contrast, at study end, 70% of the control group participants felt "somewhat limited" or "moderately limited" in their ability to attend social events (Table 4).

In both groups, the proportion of the participants who reported "somewhat" or "moderate" social limitation decreased from ~45% to ~30% (baseline to study end) (Fig. 1). Notably, there was a substantial decline in the proportion of the participants overall who felt "quite limited" and an increase in the overall proportion of the participants who reported that they felt "not limited" or "hardly limited" by their child's food allergy (Table 4). At week 4, 10.5% of the intervention group and 10% of the control group reported that their ability to engage in social activities was at least "quite limited;" and 50% of the control group and 15.8% of the intervention group reported being "somewhat limited" due to their child's food allergy (Table 4). Of note, within the

Table 4 Results of the Food Allergy Quality of Life Parental Burden Scale						
How Limited Would Your Ability To Participate in Social Activities That Involve Food Be Because of Your Child's Food Allergy?	Baseline Control Group, %	Week-4 Control Group, %	Baseline Intervention Group, %	Week-4 Intervention Group, %		
Not limited	0	10	10	15.8		
Hardly limited	10	10	15	42.1		
Somewhat limited	40	50	20	15.8		
Moderately limited	30	20	25	15.8		
Quite a bit limited	0	0	10	5.3		
Very limited	10	0	10	5.3		
Extremely limited	10	10	10	0		

intervention group, the scale reflected an ~10% shift toward the next improved level of social activity limitation due to the child's food allergy. In other words, although ~20% of the participants endorsed feeling "quite limited" at baseline, only ~10% felt "quite limited" at study end; whereas ~30% felt "moderately limited" at baseline, this proportion fell to ~20% at the end of the study period.

DISCUSSION

After a new diagnosis of a food allergy, caregivers experience a period of upheaval, which many describe as "crisis mode." Our previous work indicates that these caregivers engage in a process of becoming experts in managing their child's food allergy.³ This study extends our previous work by indicating that support is a primary caregiver need. As one participant stated, "Not only am I trying to figure out how to be a parent, now I'm trying to figure out how to be a parent of a child with a severe food allergy." Another caregiver noted that protecting a child from food allergies is "a whole other level (in parenting)."

Analysis of our results suggests that caregivers need both emotional and cognitive support. Most caregivers report seeking information from online resources in addition to patient and/or caregiver education shared from their health-care provider. The participants in our study said that they considered that websites affiliated with academic medical centers reliable sources of information. Caregivers also reported needing tangible support, including access to safe foods that they could be sure were free of allergens. However, caregivers also must be able to read and interpret food packaging labels. Thus, filling this unmet need requires that both tangible and educational supports be delivered together.

Also, the caregivers of children with newly diagnosed food allergies expressed a need for peer support from others with children who have food allergies. This is consistent with published evidence that found that formal and informal peer support networks can effectively help caregivers of people with serious health conditions.^{23–25} Interacting and sharing tips with others are important resources for caregivers learning to navigate this invisible yet life-threatening condition. In poststudy interviews, the caregivers described a sense of relief when speaking to another caregiver of a child with a food allergy because there was no need to explain the condition, necessary precautions, or their feelings of stress and anxiety. Before participating in this study, many caregivers had sought opportunities to connect with other caregivers of children with a food allergy through social media platform, e.g., Facebook (Meta, Menlo Park, California).

CONCLUSION

Analysis of the results suggests that the FASST mHealth app might provide a feasible means of delivering educational and self-care resources to caregivers of children recently diagnosed with a food allergy. Although the intervention group participants showed greater gains than the control group participants in confidence to prepare for and prevent allergic reactions and greater declines in perceived limitations to participants also experienced some benefits from using a more limited version of the app. Further study is needed in a larger population to refine the FASST app intervention, optimize its use, and document its psychosocial and educational impacts.

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