

Letter to the Editor

A self-regulation intervention can improve quality of life for families with food allergy

To the Editor:

Food allergy (FA) affects 3.9% to 8% of children. Children with FA and families have a lower quality of life (QoL) and might have maladaptive coping strategies.^{1,2} Such psychological aspects of living with children with FA are overlooked in traditional FA education, which instead focuses on anaphylaxis management and avoidance measures. Our group has extensive experience with interventions using the theory of self-regulation that can improve QoL in families with chronic illness. Self-regulation states that a crucial element for health-related behavioral change is engagement of the patient. Self-regulation boosts one's confidence toward completing a specific activity through observational and active learning to promote sequential steps of targeted behavioral changes.³ A self-regulation education model allows parents to (1) acknowledge their concern, (2) discuss the likelihood the concern might occur and critically appraise potential barriers, and (3) contemplate a coping mechanism.⁴

The purpose of this pilot study was to assess whether FA-related QoL in parents of children with FA could be improved through a self-regulation intervention. We designed a blind randomized controlled study of parents of new and established patients 17 years and younger from the University of Michigan Allergy Clinic. Eligible parents had children with a convincing history of FA and evidence of both skin and serum food-specific IgE. Oral food challenges were not required at enrollment. The study was approved by the University of Michigan Institutional Review Board (ClinicalTrials.gov #NCT01054950).

At enrollment, subjects were randomized to intervention or control groups. Both groups completed the Food Allergy Quality of Life—Parental Burden (FAQL-PB) questionnaire,⁵ as well as a nonvalidated, 8-item self-efficacy questionnaire developed by the authors (see [Tables E1 and E2](#) in this article's Online Repository at www.jacionline.org). After completing the questionnaires, all parents received our clinic's standard FA educational packet (see [Table E3](#) in this article's Online Repository at www.jacionline.org). The control group received a telephone call 2 weeks after enrollment answering any questions regarding the FA packet.

The intervention group then received 3 telephone calls (each approximately 25 minutes) at 2-week intervals from a nurse who had previously received a 2-hour training session on self-regulation for chronic disease management (similar to our previous work with self-regulation interventions).⁶ The initial call addressed concerns, goals, and barriers. Strategies to overcome the potential barriers were also discussed. The second call reviewed progress in making changes and coping mechanisms used and provided an opportunity to identify any additional problems. The final call addressed any additional problems and reviewed coping strategies for future problems using the self-efficacy construct.

Three months after enrollment, the questionnaires were readministered to assess the primary outcome (change in questionnaire scores from baseline) between the 2 groups. Twenty subjects per arm were needed to have 80% power at an α value of .05 to detect a 1-point difference between groups. The secondary

TABLE I. Subjects' characteristics

Clinical characteristics	Control group (n = 30)	Intervention group (n = 28)
Age (y)	6.1 (3.6)	5.1 (3.8)
Male sex, no. (%)	14 (47)	17 (61)
Years since diagnosis	3.5 (3.9)	3.5 (3.6)
Race, no. (%)		
White	26 (87)	20 (71)
Black	2 (6.7)	1 (3.6)
Asian	0 (0)	5 (18)
Other/unknown	2 (6.7)	2 (7.2)
No. of allergist's office visits	5.6 (4.6)	5.2 (5.7)
No. of allergic foods	2.4 (1.3)	2.4 (1.6)
History of anaphylaxis, no. (%)	10 (33)	6 (21)
Median Income, USD	51,300 (2,063)	53,200 (1,964)

All data are presented as means (SDs), unless otherwise noted.

outcome assessed the absolute difference in scores between the groups at 3 months. Data were analyzed by using the *t* test and backwards stepwise linear regression with SPSS version 17.0 software (SPSS, Inc, Chicago, Ill). In the regression model factors entered included all variables listed in [Table I](#).

Of 169 eligible subjects, 58 consented to participate, and 47 (81%) completed questionnaires at the 3-month follow-up. Baseline characteristics of the children with FA are detailed in [Table I](#). Concerns most frequently discussed with the nurse are shown in [Table E4](#) in this article's Online Repository at www.jacionline.org. At 3 months, compared with the control group, the intervention group had a statistically significant improvement from baseline on 4 of 17 FAQL-PB questionnaire factors, with a mean difference of 1 point ([Fig 1](#)). There was no significant difference between groups from baseline to 3 months on the self-efficacy items. When looking at absolute scores at the 3-month time point, 2 FAQL-PB questionnaire items and 1 self-efficacy item were significantly improved in the intervention group compared with the control group (see [Table E5](#) in this article's Online Repository at www.jacionline.org).

By using multiple linear regression, the 4 significant primary outcome factors identified in [Fig 1](#) remained significant. When comparing the absolute final outcome scores, 1 FAQL-PB questionnaire factor and 1 self-efficacy factor remained significant (see [Table E6](#) in this article's Online Repository at www.jacionline.org). An additional FAQL-PB questionnaire factor (concerns for child's health) also was significant on analysis of final outcome scores after adjusting for confounding.

This is the first individualized educational intervention to improve FA-related QoL for parents of children with FA. As shown in [Fig 1](#), the specific domains significantly improved through this intervention included frustration, helplessness, anxiety, and confidence, all of which would be targeted in a self-regulation intervention. A recent study demonstrated that psychological distress in children with FA was significantly associated with maternal anxiety, and these authors suggested that treatment of parental anxiety would improve outcomes for children with FA.⁷ By improving self-confidence to overcome specific challenges, a self-regulation intervention can potentially improve QoL in families with FA dramatically. To our

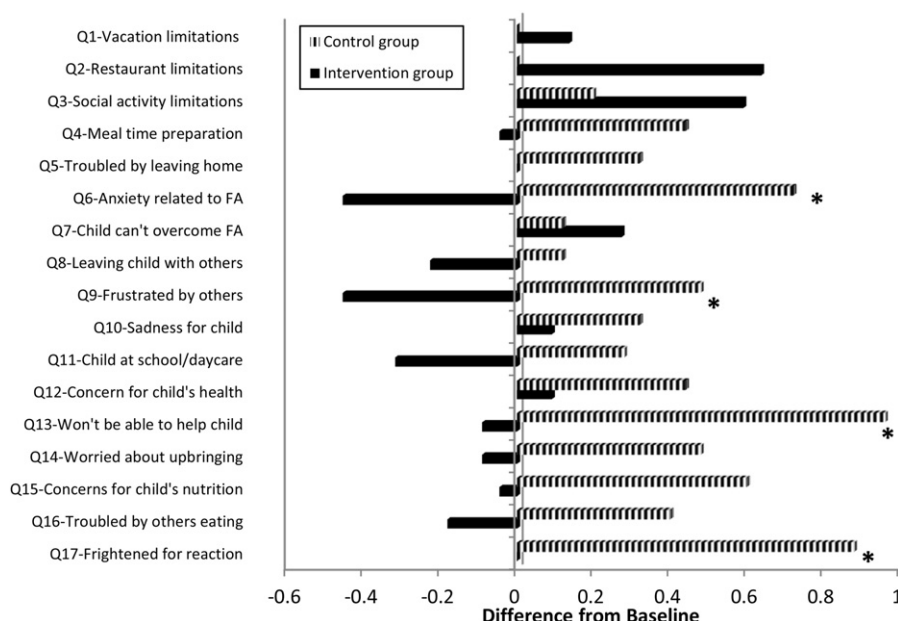


FIG 1. Change from baseline for each item of the FAQL-PB questionnaire. Decreasing values indicate improvement. *Difference between the intervention and control groups for a *P* value of .05 or less.

knowledge, only one other study evaluated an intervention to improve FA-related QoL, although it was uncontrolled and involved a group intervention.⁸ Although this is a promising complementary result, group intervention is not always feasible and does not allow individualization.

The limitations of this study include the small sample size, the demographic data (predominantly middle-class white subjects), the relatively short follow-up period, and the fact that the self-efficacy outcome measure was not validated. We acknowledge that not all QoL/self-efficacy factors were affected, and therefore further refinement might be necessary.

In summary, we have shown that a self-regulation intervention for improving FA-related QoL for parents of children with FA appears to be effective. Further research into this promising intervention is needed.

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TABLE E1. FAQL-PB questionnaire

1. If you and your family were planning a holiday/vacation, how much would your choice of vacation be limited by your child's food allergy?						
0–Not limited	1–Hardly limited at all	2–Somewhat limited	3–Moderately limited	4–Quite a bit limited	5–Very limited	6–Extremely limited
2. If you and your family were planning to go to a restaurant, how much would your choice of a restaurant be limited by your child's food allergy?						
0–Not limited	1–Hardly limited at all	2–Somewhat limited	3–Moderately limited	4–Quite a bit limited	5–Very limited	6–Extremely limited
3. If you and your family were planning to participate in social activities with others involving food (eg, parties or a holiday), how limited would your ability to participate in social activities that involve food be because of your child's food allergy?						
0–Not limited	1–Hardly limited at all	2–Somewhat limited	3–Moderately limited	4–Quite a bit limited	5–Very limited	6–Extremely limited
4. In the past week, how troubled have you been by your need to spend extra time preparing meals (eg, label reading, extra time shopping, or preparing extra meals) because of your child's food allergy?						
0–Not troubled	1–Hardly troubled at all	2–Somewhat troubled	3–Moderately troubled	4–Quite a bit troubled	5–Very troubled	6–Extremely troubled
5. In the past week, how troubled have you been about your need to take special precautions before going out of the home with your child because of his or her food allergy?						
0–Not troubled	1–Hardly troubled at all	2–Somewhat troubled	3–Moderately troubled	4–Quite a bit troubled	5–Very troubled	6–Extremely troubled
6. In the past week, how troubled have you been by anxiety relating to your child's food allergy?						
0–Not troubled	1–Hardly troubled at all	2–Somewhat troubled	3–Moderately troubled	4–Quite a bit troubled	5–Very troubled	6–Extremely troubled
7. In the past week, how troubled have you been that your child might not overcome his or her food allergy?						
0–Not troubled	1–Hardly troubled at all	2–Somewhat troubled	3–Moderately troubled	4–Quite a bit troubled	5–Very troubled	6–Extremely troubled
8. In the past week, how troubled have you been by the possibility of actually leaving your child in the care of others because of his or her food allergy?						
0–Not troubled	1–Hardly troubled at all	2–Somewhat troubled	3–Moderately troubled	4–Quite a bit troubled	5–Very troubled	6–Extremely troubled
9. In the past week, how troubled have you been by frustration over others' lack of appreciation for the seriousness of food allergy?						
0–Not troubled	1–Hardly troubled at all	2–Somewhat troubled	3–Moderately troubled	4–Quite a bit troubled	5–Very troubled	6–Extremely troubled
10. In the past week, how troubled have you been by sadness regarding the burden your child carries because of his or her food allergy?						
0–Not troubled	1–Hardly troubled at all	2–Somewhat troubled	3–Moderately troubled	4–Quite a bit troubled	5–Very troubled	6–Extremely troubled
11. In the past week, how troubled have you been about your child's attending school, camp, day care, or another group activity with children because of his or her food allergy?						
0–Not troubled	1–Hardly troubled at all	2–Somewhat troubled	3–Moderately troubled	4–Quite a bit troubled	5–Very troubled	6–Extremely troubled
12. In the past week, how troubled have you been by your concerns for your child's health because of his or her food allergy?						
0–Not troubled	1–Hardly troubled at all	2–Somewhat troubled	3–Moderately troubled	4–Quite a bit troubled	5–Very troubled	6–Extremely troubled
13. In the past week, how troubled have you been with the worry that you will not be able to help your child if he or she has an allergic reaction to food?						
0–Not troubled	1–Hardly troubled at all	2–Somewhat troubled	3–Moderately troubled	4–Quite a bit troubled	5–Very troubled	6–Extremely troubled
14. In the past week, how troubled have you been with the worry that your child will not have a normal upbringing because of his or her food allergy?						
0–Not troubled	1–Hardly troubled at all	2–Somewhat troubled	3–Moderately troubled	4–Quite a bit troubled	5–Very troubled	6–Extremely troubled
15. In the past week, how troubled have you been about concerns for your child's nutrition because of his or her food allergy?						
0–Not troubled	1–Hardly troubled at all	2–Somewhat troubled	3–Moderately troubled	4–Quite a bit troubled	5–Very troubled	6–Extremely troubled
16. In the past week, how troubled have you been with issues concerning your child being near others while eating because of his or her food allergy?						
0–Not troubled	1–Hardly troubled at all	2–Somewhat troubled	3–Moderately troubled	4–Quite a bit troubled	5–Very troubled	6–Extremely troubled
17. In the past week, how troubled have you been with being frightened by the thought that your child will have a food-induced allergic reaction?						
0–Not troubled	1–Hardly troubled at all	2–Somewhat troubled	3–Moderately troubled	4–Quite a bit troubled	5–Very troubled	6–Extremely troubled

TABLE E2. Self-efficacy questionnaire

1. How confident do you feel about recognizing an allergic reaction in your child?				
Highly confident	Very confident	Confident	Somewhat confident	Not at all confident
5	4	3	2	1
2. How confident do you feel treating your child's allergic reaction?				
Highly confident	Very confident	Confident	Somewhat confident	Not at all confident
5	4	3	2	1
3. How confident do you feel about reading food labels?				
Highly confident	Very confident	Confident	Somewhat confident	Not at all confident
5	4	3	2	1
4. How confident do you feel about identifying possible food cross-contamination?				
Highly confident	Very confident	Confident	Somewhat confident	Not at all confident
5	4	3	2	1
5. How confident do you feel that your child is safe at school or day care or with a babysitter or relatives?				
Highly confident	Very confident	Confident	Somewhat confident	Not at all confident
5	4	3	2	1
6. How confident do you feel that you can control your child's environment to prevent an accidental exposure?				
Highly confident	Very confident	Confident	Somewhat confident	Not at all confident
5	4	3	2	1
7. How confident do you feel about teaching others about your child's food allergy?				
Highly confident	Very confident	Confident	Somewhat confident	Not at all confident
5	4	3	2	1
8. How confident do you feel that you have the resources and support needed to deal with your child's allergy?				
Highly confident	Very confident	Confident	Somewhat confident	Not at all confident
5	4	3	2	1

TABLE E3. Allergy food packet contents**UM food allergy packet**

From Food Allergy and Anaphylaxis Network pamphlets:

“What you should know about living with food allergy,” “Managing Food Allergies,” “Food allergy basics”

EpiPen information

MedicAlert information brochure

Health Education Resource Center bookmark

Anaphylaxis Canada pamphlet: “Does someone you know have a life-threatening allergy”

American Academy of Allergy, Asthma & Immunology pamphlet: “Food allergy”

Food Allergy Initiative “Saving Lives” pamphlet

TABLE E4. Concerns frequently discussed with the nurse

Topic
Concern about leaving the child with another adult
Concern about the child having a reaction at school
Difficulties in eating at a restaurant
Nutrition concerns caused by excluded foods
Sadness the parent feels about the stigma associated with food FAs
Difficulties in meal preparation for the entire family
Concern about letting the child attend social activities alone
Concern about going on a vacation

TABLE E5. Final questionnaire significant mean changes (bivariate analysis)

	Control (mean)	Intervention (mean)	<i>P</i> value
FAQL-PB questionnaire factor			
Limits social activities	2.88	2.05	.048
Concern over leaving child in care of others	2.80	1.73	.031
Self-efficacy factor			
Confidence child is safe in the care of others	2.60	3.23	.039

TABLE E6. Effect of the intervention on primary and secondary outcome factors after controlling for confounding through a linear regression model

Factor	β value	P value
1° Outcome: Change in score		
Anxiety related to FA	1.26	.004
Frustration over others' lack of appreciation	0.892	.039
Worry that cannot help child with food reaction	0.961	.023
Frightened that child will have a reaction	1.02	.006
2° Outcome: Final score		
Concerned for child's health because of FA	0.873	.010
Troubled at having to leave child in care of others	1.16	.007
Confident that child is safe at school or with relatives (self-efficacy item)	−0.752	.008

Factors entered into the regression model: group assignment, age, sex, years since diagnosis, race, history of anaphylaxis, median household income, number of allergic foods, and number of previous allergist's office visits.