

Food-Allergic Adolescents at Risk for Anaphylaxis: A Randomized Controlled Study of Supervised Injection to Improve Comfort with Epinephrine Self-Injection



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What is already known about this topic? Anxiety and discomfort related to the need to self-inject epinephrine in an emergency contributes to food-allergic adolescents' occasional failure to use an autoinjector, and may increase their risk when an anaphylactic reaction occurs.

What does this article add to our knowledge? A supervised self-injection procedure with an empty syringe improved adolescents' comfort with self-injection, and decreased anxiety related to the anticipated need to self-inject.

How does this study impact current management guidelines? A simple self-injection procedure (needle and empty syringe) in addition to standard training is beneficial for adolescents with food allergy who are willing to perform this maneuver.

BACKGROUND: Epinephrine self-injection is a key element in the management of food allergy, yet many adolescents report that they may not be able to use the autoinjector when needed. We hypothesized that supervised self-injection with an empty syringe would increase adolescents' comfort with self-injection. **OBJECTIVE:** The objective of this study was to examine the effect of supervised self-injection on self- and parent-reported comfort and anxiety during and after clinic visits in a food allergy center.

METHODS: Sixty adolescent/parent pairs were randomized to self-injection versus control (education only). The predefined primary outcome was a self-reported comfort level with the

injection before versus after the intervention on a Likert scale with scores of 1 (Not at all comfortable) to 10 (Extremely comfortable). The primary outcome was evaluated via within-group and between-group analyses. Secondary outcomes included adolescent and parent reports before versus after the injection, and changes in quality of life (QoL) and anxiety a month later.

RESULTS: Self-injection was associated with a significant immediate increase in comfort levels (primary outcome; within-group comparison: mean scores: 6.93 preintervention vs 8.37 postintervention, $P < .01$; between-group ANOVA: 8.37 vs 6.69, $P < .01$) and with significant improvements in all other predefined (secondary) measures. On follow-up, QoL improved in 52% of intervention patients as compared with 25% of controls; similar differences were observed for anxiety. Those differences were not statistically significant.

CONCLUSIONS: A self-injection (with an empty syringe) procedure in a clinic setting improves adolescents' and parents' comfort level with self-injecting. It may translate into substantial clinical benefits should self-injection be needed. © 2017 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2017;5:391-7)

Key words: Food allergy; Epinephrine; Anxiety; Exposure; Self-management

Up to 8% of children in the United States have food allergy, with nearly 40% having experienced a severe allergic reaction.^{1,2} Food-allergic reactions can be life threatening, although fatality is rare³ likely because effective treatments for anaphylaxis are usually available. An important component of the immediate management of an anaphylactic reaction is self-injection (via an autoinjector)—by a parent or a child—of epinephrine. Although guidelines may vary in different countries, in the United States, it

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*Abbreviations used**PedsQL- Pediatric Quality of Life Inventory**QoL- Quality of Life**SCARED- Screen for Child Anxiety-Related Emotional Disorders*

is recommended that all patients who experienced anaphylaxis, and those with food allergy and asthma and/or known allergy to potent triggers such as peanut, tree nuts, fish, or shellfish, should be prescribed self-injectable epinephrine.^{4,5} Unfortunately, adolescents are at higher risk for fatal food-allergic reactions in part because of reluctance to self-inject epinephrine.⁶⁻⁸

Our previous studies found that adolescents who become increasingly responsible for their own care are at risk for not carrying the self-injector.⁹ We also found that patients with food allergy report substantial levels of anxiety related to the food allergy, and (anecdotally) that they are nervous about the prospect of having to use the autoinjector to inject themselves with epinephrine, should the need arise. It appears therefore that anxiety about the injection interferes with the development of appropriate food allergy self-management skills. We also found that patients who used the autoinjector in the past were *not* more anxious later on,¹⁰ which strongly suggests that future anxiety would not be increased, and perhaps even be decreased, by guided self-injection. Indeed, investigators demonstrated that guidance offered on the use of an autoinjector in a clinic setting could be helpful in increasing parent confidence.¹¹ It would therefore be important to identify a means to improve comfort with self-injection for adolescents as a part of routine clinical education.

Exposure to an attenuated or imagined stressor in a controlled setting as a way to relieve the distress associated with the actual stressor is grounded in cognitive-behavioral theory, especially as it is related to the treatment of phobias.¹² We hypothesized that supervised self-injection during a routine clinic visit may benefit adolescents who will be responsible to self-inject in an emergency. To avoid side effects of epinephrine¹³ and do so it safely, we devised an intervention using a sterile needle without injection of medication.

We conducted a prospective, randomized controlled trial in which food-allergic adolescents who did not previously use an autoinjector were randomized into an “education-only” versus “self-injection” groups in a pediatric food allergy clinic in New York (ClinicalTrials.gov registration: NCT02417493). The primary outcome chosen is the difference in patient-reported comfort with injection in the clinic pre-post intervention, which was evaluated via within-group and between-group analyses. The in-clinic assessment was chosen as a primary outcome because it most closely mimics the anxiety that might occur during an allergic reaction, as opposed to scores obtained at home, long after the injection, in a relaxed setting. We also predefined a set of secondary outcomes that evaluate the degree to which patients or parents report that the patients will be comfortable using the self-injector in the future when needed, both before versus after the intervention, and at follow-up (questionnaires were sent to families a month after the intervention). Exploratory analyses included assessment of the evolution of quality of life (QoL) (adolescent report) and anxiety (parent report of the adolescent’s anxiety and adolescent self-report) between the immediate postinjection period and follow-up in the control versus the intervention groups.

METHODS**Participants, sample size, and procedures**

Participants were adolescents (aged 13-17.5 years) who were accompanied by a parent or guardian to their appointment, and had previously been diagnosed with a food allergy and prescribed an autoinjector but never used it. The study was approved by the Icahn School of Medicine at Mount Sinai’s Institutional Review Board and involved a full written parental consent and child assent procedure.

After the consent procedure, before randomization, patients and parents were asked to complete self-report questionnaires about their (or their child’s) comfort with self-injection. Then, half of the sample ($n = 30$) was randomized to the intervention (self-injection group) and the other half ($n = 30$) was randomized to the control condition (standard education, control group), by research assistants’ pulling a number out of a sealed envelope. Intervention group participants answered a set of questionnaires on the same day immediately after the injection, and control patients answered the same set of questionnaires on the same day, after the education was given. One month after the clinic visit, participants and their parents were mailed a follow-up questionnaire packet that was identical to that completed by the participant and parent on the day of recruitment. Patients who did not send the packet back within a week were called twice to remind them to send it.

Power considerations

The primary analytic strategy involved a repeated-measure (pre-post) analysis of the primary outcome in the intervention group (below); a secondary analysis of the primary outcome involved a between-group analysis. For the repeated measures analysis, we determined that to detect a medium effect size (using Cohen’s definitions¹⁴ operationalized with a G*Power software¹⁵), we would need 34 unique tests (pre-post information on 17 subjects). We assumed a substantial level of attrition because we were concerned that some patients would decline to answer the questionnaires immediately after the injection if they became upset or distressed. On the basis of our previous study in a similar sample, that recorded 40% to 50% failure to complete repeated-measures procedures,¹⁶ we determined that a final recruitment goal of $n = 30$ in each group, after attrition, would provide the required number of subjects to detect a small-to-medium effect size for both the primary and secondary analytic strategies of the primary outcome.

Intervention

Participants watched while a sterile 25-gauge needle was mounted on an empty 5 cc syringe, with the plunger pushed down to expel any air. The participant’s leg was uncovered and precleaned with alcohol. The participant was coached how to hold the syringe firmly in the fist, put the point of the needle very near the skin, and gently insert the needle at a 90° angle through the skin overlying the anterolateral thigh. On completion, the syringe was disposed of securely. In cases in which the participant was reluctant to inject, the parents and researchers were allowed to verbally coach and encourage injection, but without coercion. We expected that in some cases, adolescents would not be able to self-inject (would ultimately refuse, even if they agreed to participate in the study).

Control

Control group patients were provided with education about the importance of self-injection and were shown and then asked to demonstrate use of a dummy self-injector as per existing guidelines.¹⁰

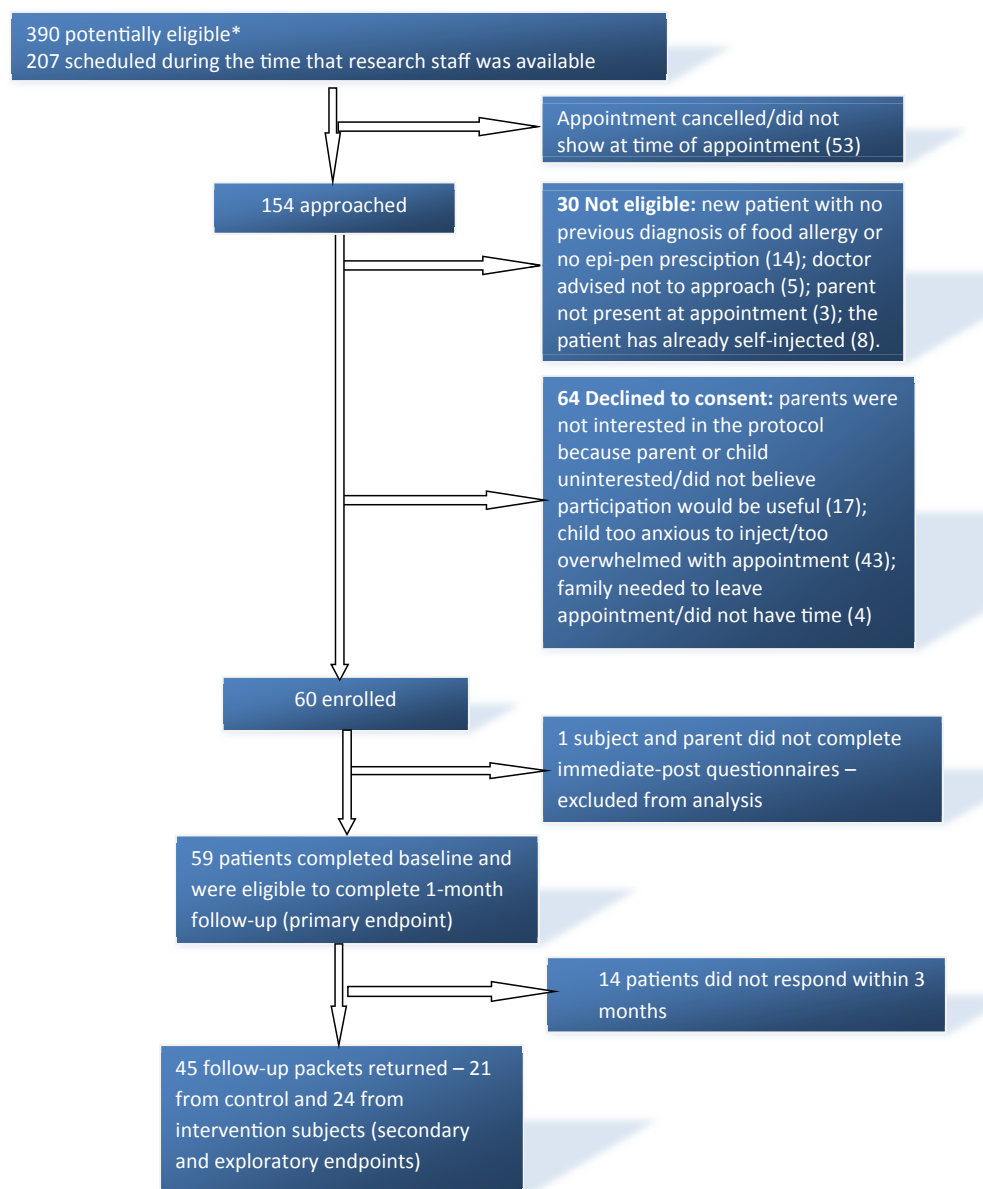


FIGURE 1. CONSORT diagram. *Potentially eligible = all adolescents (13-17 years) who were scheduled for either a consult or follow-up appointment during the study period.

Outcome measures

Primary and secondary outcome measures were predefined as follows.

Primary outcome measure. Differences in the Likert scale score obtained on the child-reported “comfort with self-injection” item before as compared with immediately after the injection. The primary analytic strategy for the primary outcome measure involved the pre-post differences in a within-subject comparison. This was chosen *a priori* because of the overarching clinical concern that the intervention might decrease comfort in the injection group. A secondary analytic strategy of the primary outcome measure compared the change in scores between the education-only controls and the intervention group.

Secondary and exploratory outcome measures.

Secondary outcome measures included child- and parent-reported pre-post questionnaire scores on other scales that are described below, and the difference at the 1-month follow-up anxiety and QoL questionnaires.

Acceptability. Participants and parents in the intervention group ($n = 30$) completed an acceptability questionnaire immediately after the self-injection and at follow-up. Another measure of acceptability was whether all the patients who were randomized to the injection intervention actually self-injected.

Measures

The questionnaires are available in this article’s [Online Repository](https://www.jaci-inpractice.org) at www.jaci-inpractice.org and are described below.

Child's self-report of her or his comfort with self-injection of epinephrine, worry about the need to use epinephrine, and likelihood that the child will be able to self-inject if needed.

Three items assess the child's comfort with performing a self-injection (1 = Not at all comfortable, 10 = Extremely comfortable), worry regarding his or her ability to perform a self-injection of epinephrine (1 = Extremely worried, 10 = Not at all worried), and the child's assessment of the likelihood that she or he would self-administer epinephrine if an allergic reaction were to occur (1 = Not at all likely, 10 = Extremely likely).

Parents' report of the child's comfort with self-injection of epinephrine, worry about the need to use epinephrine, and likelihood that the child will be able to self-inject if needed.

Three items assess, on a Likert scale, the parent's perception of the child's comfort with performing a self-injection (1 = Not at all comfortable, 10 = Extremely comfortable), the parent's perception of the child's worry regarding the child's ability to perform a self-injection of epinephrine (1 = Extremely worried, 10 = Not at all worried), and the parent's perception of the likelihood that the child would self-administer epinephrine if an allergic reaction were to occur (1 = Not at all likely, 10 = Extremely likely).

Demographics, allergy characteristics, and health care responsibilities. We recorded family demographics, patient's history of allergic reactions/epinephrine use, and the patient's responsibility for allergy management.

Screen for Child Anxiety-Related Emotional Disorders (SCARED—parent version). This is a 17-item questionnaire revised from the original 39-item SCARED to assess the symptoms of generalized anxiety and separation anxiety in children/adolescents (8-18 years). Items are scored on a 3-point Likert scale ranging from 0 = Not true or hardly ever true to 2 = Very true or often true. The SCARED is a reliable and valid screening tool for clinically referred or primary care populations.¹⁷⁻¹⁹

Screen for Child Anxiety-Related Emotional Disorders (SCARED—child version). This is a 17-item questionnaire to assess symptoms of generalized anxiety and separation anxiety in children/adolescents (8-18 years). Items are scored on a 3-point Likert scale ranging from 0 = Not true or hardly ever true to 2 = Very true or often true. Validity was established in several settings and pediatric populations.^{20,21}

Pediatric Quality of Life Inventory (PedsQL—adolescent version) (age 13-18 years). This validated measure is widely used to assess health-related QoL in healthy and medically ill children aged 8-17 years.^{22,23} It consists of 23 items and is scored on a 5-point Likert scale, with 0 = Never and 4 = Almost always. Higher scores (scored 0 to 100) are associated with better health-related QoL.

Acceptability and feasibility questionnaire. This questionnaire asks the parent whether the self-injection procedure was beneficial to both parent and child. It also assesses how helpful the parent found the self-injection protocol to be on a Likert scale (1 = Not at all helpful to 10 = Extremely helpful) for promoting communication between parent and child about self-management responsibilities.

TABLE I. Demographic characteristics of the sample by condition

	Intervention (N = 30)	Control (N = 29)	t or χ^2	P value
Age, mean years (SD)	14.82 (1.66)	15.03 (1.36)	-0.50	.62
Gender			0.18	.67
% Male	57%	62%		
% Female	43%	38%		
Race			2.97	.09
% Caucasian	97%	83%		

TABLE II. Primary and secondary outcomes in the intervention group from pre to immediate post (N = 30)

	Pre	Immediate post	t	P value
Primary outcome: child self-reported comfort with future injection	6.93 (2.21)	8.37 (1.25)	4.34	<.01
Child report about his or her willingness to inject in the future	7.10 (2.40)	8.13 (1.70)	2.89	<.01
Parent report of child's comfort with injection	5.86 (2.35)	7.21 (2.31)	3.80	<.01

Results presented as means (SD).

Statistical analyses

All analyses were conducted using the IBM SPSS 20.0 statistical package. For the primary and secondary analyses, 2-tailed paired-samples *t*-tests were conducted to investigate immediate post minus immediate preintervention (or education) scores. Analyses of variance were conducted to assess between-group comparisons. Exploratory comparisons between control and intervention group follow-up QoL and anxiety measures primarily investigated the number of people who reported improvement/worsening/no change, to minimize the effect of outliers; means were also computed for a between-group analysis of the difference in 1-month exploratory (SCARED and QOL) outcomes. A *P* value (alpha level) of less than .05, 2-tailed, was chosen as the level of statistical significance. All analyses presented were predefined before the study commenced.

RESULTS

Participation rates and demographics

Figure 1 is a Consolidated Standards of Reporting Trials (CONSORT) diagram reflecting the recruitment efforts. Of 124 patients who were assessed, deemed eligible to participate, and approached for the study, 60 patients (48%) enrolled. Demographic information is presented in Table I. There were no differences between conditions.

All intervention subjects eventually self-injected (no one decided to withdraw), although coaching and encouragement by the parents or investigators was sometimes necessary. The average number of days it took to receive follow-up packets was 69.71 (SD = 36.02).

Primary and secondary outcomes

As a randomization check, scores were compared between the 2 conditions at baseline; there were no significant differences. Table II shows the within-group primary and secondary pre-versus postintervention changes in the predefined outcomes, and

TABLE III. Outcomes from pre to immediate post

	Pre		Post		P value*
	Intervention (N = 30)	Control (N = 29)	Intervention (N = 30)	Control (N = 29)	
Primary outcome: child self-reported comfort with future injection (1-10, 1 = Not at all comfortable)	6.93 (2.21)	6.38 (2.40)	8.37 (1.25)	6.69 (2.56)	<.01
Parent report of child's comfort with injection (1-10, 1 = Not at all comfortable)	5.86 (2.35)	5.34 (3.13)	7.21 (2.32)	5.90 (3.26)	.07
Child self-reported worry about future injection (1-10, 1 = Extremely worried)	6.60 (2.46)	6.62 (2.47)	8.00 (1.84)	6.66 (2.27)	<.01
Parent report of child's worry (1-10, 1 = Extremely worried)	5.76 (2.75)	4.90 (3.09)	7.45 (2.05)	5.43 (2.99)	.06
Child report about his or her willingness to inject in the future (1-10, 1 = Not at all likely)	7.10 (2.40)	7.86 (2.10)	8.13 (1.70)	7.76 (7.95)	<.01
Parent report of the child's willingness to inject (1-10, 1 = Not at all likely)	7.38 (2.14)	6.90 (3.12)	8.28 (1.81)	7.03 (2.96)	.08

Results presented as means (SD).

*Repeated measures between-group ANOVA.

TABLE IV. Patient anxiety and quality of life at 1-month follow-up

Questionnaire	Intervention (N = 24)	Change from baseline*	Control (N = 21)	Change from baseline*
PedsQL†	84.24 (14.01)	52% better	84.73 (11.79)	25% better
		35% worse		50% worse
		12% none		25% none
Child-SCARED‡	6.52 (6.19)	70% better	8.35 (5.59)	50% better
		26% worse		40% worse
		4% none		10% none
Parent-SCARED‡	6.00 (4.75)	61% better	6.30 (6.03)	35% better
		22% worse		35% worse
		17% none		30% none

Results presented as means (SD).

*baseline = immediate postinjection (intervention group), end of clinic visit (controls).

†Pediatric Quality of Life Inventory, Adolescent Version.

‡Screen for Child Anxiety-Related Emotional Disorders. Higher score = more anxiety.

Table III shows the between-group outcomes. The primary outcome (child report of comfort before to immediately after the intervention) significantly increased from 6.93 (SD = 2.21) to 8.37 (SD = 1.25), $t(29) = -4.34$, $P < .01$, in the intervention group (Table II), whereas the control subjects did not improve (Table III). Similar patterns were found for the secondary outcomes. The effect size of the intervention, calculated for the primary outcome, was $d = 0.802$, corresponding to a Cohen's¹⁴ "large" effect size.

Exploratory analyses of longer term outcomes

In exploratory analyses, we examined between-group scores on the standardized measures of patient anxiety (SCARED, both child and parent report of the child's symptoms) and quality of life (PedsQL) at 1-month follow-up. Table IV displays outcomes by condition. There were no significant differences between group means (SCARED-child; $P = .89$; SCARED-parent, $P = .24$; PedsQL, $P = .47$), but scores on all measures consistently improved more in the intervention group as compared with controls.

Acceptability

At follow-up, 83% of children and 88% of parents described finding the intervention beneficial. In addition, 70% of children

said that the intervention helped improve their ability to self-inject; this was echoed by 88% of parents. When asked on a scale of 1-10 how helpful the intervention was, children rated it on average 7.04 (SD = 2.29), whereas the average parent rating was 8.17 (SD = 2.26).

DISCUSSION

We evaluated the potential benefit of a simple self-injection procedure for improving food-allergic adolescents' comfort with autoinjectors. Our primary outcome measure, a pre-post evaluation immediately after the injection, is not subject to recall bias as it was assessed immediately after the event. The procedure was beneficial as determined by a statistically significant improvement in the adolescents' self-reported comfort with self-injection (our predefined primary endpoint) both in within-subject and between-subject analyses, with a large effect size, and as further demonstrated by multiple additional indicators. The nonsignificant improvements in QoL and anxiety observed between the immediate postinjection period and follow-up are encouraging. The effects of an intervention that is specifically targeting subject's feeling at the time of an urgent event (the need to auto-inject) may not be apparent in the absence of such an event.

Therefore, the signal that the procedure may have generalized into an improvement even in the safety of one's home on follow-up is a positive sign, but we caution that we were unable to investigate whether intervention patients who undergo this procedure are, in fact, able to use the autoinjector more easily or accurately when needed. The study was not designed to evaluate responses during a true anaphylactic emergency given the rarity of such events. Such a study would require extremely large numbers of patients followed over years. Our results show that patients are less anxious about self-injecting and more comfortable with it. In addition, although the intervention effect size was large, the minimal clinical effect threshold for some of the instruments is not known, and therefore a larger and longer investigation would need to be conducted to prove that the benefits that we saw translate into lasting clinical benefits.

Imaginal or gradual exposure to a stressor is a hallmark of cognitive-behavioral procedures that were shown to be effective in the treatment of phobias¹² and anxiety disorders.^{24,25} Our approach has important features of these well-accepted approaches in that we exposed subjects to a simulation of the very circumstance that they may fear. In other settings, exposure techniques were shown to reduce avoidance behaviors and improve adherence to medical recommendations.^{26,27} In the food-allergy setting, this may translate into a higher likelihood of using the autoinjector when indicated; epinephrine administered by intramuscular self-injectors is safe and generally well tolerated.²⁸

Anecdotally, investigators in our study reported that the most anxious patients, who were reluctant to participate in the trial at first, were also those who showed the most benefit, but our study was not designed to evaluate which patients would benefit the most. Our study was limited by the fact that the procedure, by necessity, was not masked, and by a likely selection bias. Because of the requirement for patient assent (not only parent consent), only subjects who agreed to the procedure were enrolled, likely resulting in exclusion of the most anxious patients or parents. Indeed, we have observed instances in which the adolescent would not provide assent despite parental consent. It could be that anxious patients might have been even more likely to benefit from the procedure. Alternatively, it could also be that very anxious patients, who might have been excluded by the required assent process, would not have benefitted if enrolled. The correct interpretation of our results is that the procedure can be helpful for adolescents who agree to do it. Another source of potential selection bias is the fact that the majority, but not all, of the patients returned the follow-up questionnaires. It could be that the observed sustained improvements in QoL and anxiety are because only those patients who improved returned the questionnaires. This is unlikely, however, because almost as many control subjects returned the follow-up questionnaire as intervention subjects (21 controls vs 24 intervention). Finally, our results are further limited by the fact that the procedure was offered in one specialized center with a specific patient characteristic profile—mainly white, highly educated, and high-income parents. A larger study incorporating measures of actual adherence (likelihood of carrying an autoinjector after the procedure, for example) is needed to conclusively prove a lasting clinical benefit.

Our study showed that self-injection with a needle (without epinephrine) in the office setting improved comfort with self-injection and was well received. We did not have access to a

sham autoinjector with an actual needle as this kind of device is not currently being manufactured, and therefore used a simple needle, which is available in any clinic. A sham autoinjector, if it becomes available, might have been an even better simulator. As it stands, our intervention could be offered in select clinical circumstances (eg, when adolescents and parents agree; when the adolescent seems to be anxious about the prospect of needing an injection). This simple, quick, behavioral intervention is easy to deliver, does not require special expertise, and may result in improved QoL and attendant clinical benefits.

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ONLINE REPOSITORY**Food-Allergic Adolescents at Risk for Anaphylaxis: A Randomized Controlled Study of Supervised Injection to Improve Comfort with Epinephrine Self-Injection**

ID#: _____

Parent Survey_Pre-Intervention.I am the child's a. ☐ mother b. ☐ father c. ☐ OTHER _____***Child Comfort with Self-injection of Epinephrine***

- Has your child ever had to self-inject epinephrine during an allergic reaction? a. Yes b. No
- On a scale of 1-10, where 1 = NOT AT ALL COMFORTABLE and 10 = EXTREMELY COMFORTABLE, how comfortable is your child with self-injecting epinephrine, if an allergic reaction is to occur?

Not at all comfortable 1	2	3	4	5	6	7	8	9	Extremely comfortable 10
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- On a scale of 1-10, where 1 = EXTREMELY WORRIED and 10 = NOT AT ALL WORRIED, how worried are you about your child being able to self-inject epinephrine during an allergic reaction?

Extremely worried 1	2	3	4	5	6	7	8	9	Not at all worried 10
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- On a scale of 1-10, where 1 = NOT AT ALL LIKELY and 10 = EXTREMELY LIKELY, how likely is it that your child would self-administer epinephrine, if an allergic reaction were to occur?

Not at all likely 1	2	3	4	5	6	7	8	9	Extremely likely 10
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ID#: _____

Adolescent Survey_Pre-Intervention. Please select your gender (circle one): MALE FEMALE***Comfort with Self-injection of Epinephrine***

- Have you ever had to self-inject epinephrine during an allergic reaction? a. Yes b. No
- On a scale of 1-10, where 1 = NOT AT ALL COMFORTABLE and 10 = EXTREMELY COMFORTABLE, how comfortable are you with self-injecting epinephrine, if an allergic reaction is to occur?

Not at all comfortable 1	2	3	4	5	6	7	8	9	Extremely comfortable 10
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- On a scale of 1-10, where 1 = EXTREMELY WORRIED and 10 = NOT AT ALL WORRIED, how worried are you about being able to self-inject epinephrine during an allergic reaction?

Extremely worried 1	2	3	4	5	6	7	8	9	Not at all worried 10
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4. On a scale of 1-10, where 1 = NOT AT ALL LIKELY and 10 = EXTREMELY LIKELY, how likely is it that you would self-administer epinephrine, if an allergic reaction were to occur?

Not at all likely 1	2	3	4	5	6	7	8	9	Extremely likely 10
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Parent Survey_Post-Intervention.

ID#: _____

Acceptability and Feasibility. Parent Form

- Did your child complete the self-injection protocol?
a. Yes b. No
- Did you find the procedure beneficial to you and your child?
a. Yes b. No c. Unsure
- Do you think this procedure has improved your child's ability to self-inject epinephrine?
a. Yes b. No c. Unsure
- On a scale of 1-10, where 1 = NOT AT ALL HELPFUL and 10 = EXTREMELY HELPFUL, how helpful was this self-injection procedure for promoting communication between you and your child about self-management responsibilities?

Not at all helpful 1	2	3	4	5	6	7	8	9	Extremely helpful 10
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ID#: _____

Parent Survey_Post-Intervention. PART 1: Demographic Information and Allergy Characteristics

- I am the child's a. ☐ mother b. ☐ father c. ☐ OTHER _____
- The age of the child is: (years) _____ (months) _____
- The gender of the child is: a. ☐ Male b. ☐ Female
- The ethnic origin of the child is: a. ☐ Hispanic b. ☐ Non-Hispanic
- The race of the child is (check ALL that apply):
a. ☐ American Indian/Alaskan native b. ☐ Asian c. ☐ White/Caucasian d. ☐ Native Hawaiian/Pacific Islander
e. ☐ African American f. ☐ Prefer not to answer
- The child is allergic to the following foods (check ALL that apply):
a. ☐ Milk b. ☐ Egg c. ☐ Peanut d. ☐ Tree nut e. ☐ Wheat f. ☐ Soy g. ☐ Fin fish h. ☐ Shellfish i. ☐ Other (please specify): _____
- The child's food allergy was diagnosed by (check ALL that apply):
a. ☐ Allergist b. ☐ Family Physician c. ☐ Pediatrician d. ☐ Emergency Physician e. ☐ None f. ☐ Self-diagnosis g. ☐ Other (specify): _____
- The child has been diagnosed with eosinophilic esophagitis (EE): a. ☐ Yes b. ☐ No
- Has the child ever had an allergic reaction to a food? (Please do not consider a positive skin test alone, without a reaction to the food, to be an allergic reaction.) If NO, Proceed to Q10. a. ☐ Yes b. ☐ No c. ☐ Unsure
9a. Has the child ever had a reaction that included breathing trouble or reduced consciousness? a. ☐ Yes b. ☐ No c. ☐ Unsure
9b. Has the child ever received epinephrine for an allergic reaction? a. ☐ Yes b. ☐ No c. ☐ Unsure
- What is your annual household income?
a. ☐ Less than \$25,000 per year b. ☐ \$25K to \$50K c. ☐ \$50K to \$75K d. ☐ \$75K to \$100K e. ☐ \$100K to \$150K
f. ☐ More than \$150,000/year g. ☐ I prefer not to specify
- What is the highest level of schooling you have completed?
a. ☐ High School b. ☐ Some college c. ☐ 2-y college degree, or technical school d. ☐ 4-y college degree e. ☐ Graduate degree
f. ☐ Other (specify): _____

ID#: _____

Parent Survey_Post-Intervention.***PART 2: Health Care Responsibility***

12. Please answer the following:

My child is able to tell an adult when he or she is having an allergic reaction	Never	Sometimes	Most of the time	Always
My child can be trusted to follow his or her dietary restrictions on his or her own	Never	Sometimes	Most of the time	Always

13. Please use the following choices to enter a response in the table below:

	Adult/s (parent/caregiver/someone else at home is fully responsible)	Youth and adult share responsibility	Youth is fully responsible	Someone else in the home	Nobody really does this
Who carries self-injectable epinephrine (EpiPen)?	1	2	3	4	5
Who notices allergic reactions?	1	2	3	4	5
Who follows dietary restrictions?	1	2	3	4	5
Who explains food allergy to others?	1	2	3	4	5

14. On a scale of 1-10, where 1 = NOT AT ALL GOOD and 10 = EXTREMELY GOOD, how good is your child at managing his or her food allergy on his or her own (without your help)?

Not at all good 1	2	3	4	5	6	7	8	9	Extremely good 10
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15. On a scale of 1-10, where 1 = EXTREMELY WORRIED and 10 = NOT AT ALL WORRIED, how worried are you about your child's ability to successfully manage his or her food allergy on his or her own (without your help)?

Extremely worried 1	2	3	4	5	6	7	8	9	Not at all worried 10
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16. Have you ever had to administer epinephrine to your child during an allergic reaction? a. Yes b. No

ID#: _____

Parent Survey_Post-Intervention. PART 3: Child Comfort with Self-injection of Epinephrine

17. Has your child ever had to self-inject epinephrine during an allergic reaction? a. Yes b. No

18. On a scale of 1-10, where 1 = NOT AT ALL COMFORTABLE and 10 = EXTREMELY COMFORTABLE, how comfortable is your child with self-injecting epinephrine, if an allergic reaction is to occur?

Not at all comfortable 1	2	3	4	5	6	7	8	9	Extremely comfortable 10
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19. On a scale of 1-10, where 1 = EXTREMELY WORRIED and 10 = NOT AT ALL WORRIED, how worried are you about your child being able to self-inject epinephrine during an allergic reaction?

Extremely worried 1	2	3	4	5	6	7	8	9	Not at all worried 10
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20. On a scale of 1-10, where 1 = NOT AT ALL LIKELY and 10 = EXTREMELY LIKELY, how likely is it that your child would self-administer epinephrine, if an allergic reaction were to occur?

Not at all likely 1	2	3	4	5	6	7	8	9	Extremely likely 10
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ID#: _____

Adolescent Survey Post-Intervention
Acceptability and Feasibility. Adolescent Form

- Did you complete the self-injection procedure?
a. Yes b. No
- Did you find the procedure beneficial for you and your parent?
a. Yes b. No c. Unsure
- Do you think this procedure has improved your ability to self-inject epinephrine?
a. Yes b. No c. Unsure
- On a scale of 1-10, where 1 = NOT AT ALL HELPFUL and 10 = EXTREMELY HELPFUL, how helpful was this self-injection procedure for promoting communication between you and your parent about self-management responsibilities?

Not at all helpful 1	2	3	4	5	6	7	8	9	Extremely helpful 10
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ID#: _____

Adolescent Survey Post-Intervention. PART 2: Comfort with Self-injection of Epinephrine

- Have you ever had to self-inject epinephrine during an allergic reaction? a. Yes b. No
- On a scale of 1-10, where 1 = NOT AT ALL COMFORTABLE and 10 = EXTREMELY COMFORTABLE, how comfortable are you with self-injecting epinephrine, if an allergic reaction is to occur?

Not at all comfortable 1	2	3	4	5	6	7	8	9	Extremely comfortable 10
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- On a scale of 1-10, where 1 = EXTREMELY WORRIED and 10 = NOT AT ALL WORRIED, how worried are you about being able to self-inject epinephrine during an allergic reaction?

Extremely worried 1	2	3	4	5	6	7	8	9	Not at all worried 10
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- On a scale of 1-10, where 1 = NOT AT ALL LIKELY and 10 = EXTREMELY LIKELY, how likely is it that you would self-administer epinephrine, if an allergic reaction were to occur?

Not at all likely 1	2	3	4	5	6	7	8	9	Extremely likely 10
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