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A counseling video with pre- and posttesting and checklist for oral immunotherapy consent improves participant knowledge

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ABSTRACT

Background: The use of oral immunotherapy (OIT) for food allergies has been expanding in North America. Although families are interested in this therapeutic approach, misconceptions are common; therefore, education of these families is essential before obtaining informed consent.

Objective: To improve parent and patient knowledge about OIT by investigating the use of a counseling video (CV) and checklist.

Methods: This retrospective review was conducted in a pediatric outpatient clinic. After consultation and review of the information package, 467 parents and patients (>12 years old) performed pre- and posttests in conjunction with a CV during a checklist-based 2-hour counseling session for OIT.

Results: The evaluation of pre- and posttest performance suggested an improvement in the ability of patients to answer relevant questions pertaining to OIT. This was statistically significant for all groups, including mothers, fathers, and children ($P < .001$). Mothers performed better than fathers and patients in mean number of correct responses in both pre- and posttest scores and in posttest scores after adjustment for pretest scores. Fathers performed better than patients in both pre- and posttest scores but not on posttest scores after adjustment for pretest scores. A checklist-based format resulted in 100% of all major topics being discussed in a 1-hour discussion. Reported satisfaction was high among the participants.

Conclusion: This is the first study to evaluate the use of a CV in conjunction with pre- and posttesting to educate families about the key principles of OIT. We suggest that as part of extensive counseling for OIT, an educational video is beneficial in a pediatric outpatient clinic.

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Introduction

Food allergy affects approximately 5% to 10% of the North American population.^{1,2} For many of these patients, food allergy is a lifelong diagnosis.³ Accidental exposures are common, with many accidental reactions being moderate to severe.⁴ Although fatal anaphylaxis is uncommon, this potential outcome is often of major concern for families,⁵ and food allergy remains a considerable

burden.^{6,7} The quality of life is greatly affected among caregivers of children with food allergy, especially for mothers.⁸ The current standard of care in North America is avoidance of the offending food coupled with reactive treatment including the use of epinephrine and other adjunctive medications.⁹

Oral immunotherapy (OIT) for the treatment of food allergy has been studied in the pediatric population in phase 2 and phase 3 trials, and its use in private practice is expanding in North America.^{10–12} Families and physicians are interested in OIT to proactively manage food allergy. Of note, OIT is an elective, noncurative procedure with risk of anaphylaxis, and its adherence requires a long-term, daily commitment.¹³ Parent and patient goals and expectations may vary and may not be fully aligned with the reality of current medical treatment options.^{14–17} Comprehensive and effective education for families to ensure informed consent is essential as part of the shared decision making (SDM) process and is key to successful OIT implementation.

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Although obtaining an informed consent is a fundamental aspect of any medical SDM process, many allergists have limited experience in facilitating a detailed informed consent. A recent survey by Greenhawt and Vickery¹⁸ revealed that only 68.9% of allergists obtained informed consent before initiation of OIT. In contrast, surgical specialties have extensively evaluated the use of optimization of informed consent procedures.^{19,20} The surgical research data suggest that properly educated patients seem to have more realistic expectations, improved outcomes and satisfaction, and more effective participation in their care.²¹ Despite this research, consent discussions for surgical procedures vary, and those obtaining consent may not discuss all key issues pertaining to the procedure.²² Adjunctive aids, including multimedia presentations and checklists, have been evaluated in surgical environments as an effective way to improve patient knowledge.²⁰ Educational materials for food allergy management have been validated previously.^{23,24} To our knowledge, the use of a multimedia teaching aid and a checklist-based discussion during OIT counseling and consent process has not been evaluated.

We investigated the use of a pre test-counseling video (CV)-posttest approach as part of an extensive checklist-based SDM counseling and consent process to improve parent and patient knowledge and understanding of OIT.

Methods

This is a retrospective quality assurance analysis of patients seen in a pediatric private practice clinic from November 2017 to June 2019. The participants that took part in an SDM counseling and consent discussion (CCD) for OIT were identified. During chart review, the participants were anonymized with a random number generator without patient identifiers by a nurse. Patient and family characteristics were determined by chart review, and parental employment was voluntarily reported at initial consultation. The grade of index allergic reactions was determined using the previously reported grading scale of the Consortium of Food Allergy Research.²⁵

Material Development

In September 2017, an informative CV and a corresponding pretest/posttest (PPT) were developed, scripted, and narrated by 2 authors. The CV was 35 minutes long and designed to present a balanced description of the OIT procedure, including practical elements of OIT, and a discussion of the current scientific literature. It also included a discussion of the risks, benefits, complications, and alternatives to OIT. This video contained statements, diagrams, images, and photographs relevant to the OIT discussion. The CV was designed to highlight key consent issues addressed in a written OIT information package that was given to all participants at the initial consultation. The examples of slides used in the CV can be found in eFig 1A and eFig 1B. The video was made using Microsoft PowerPoint for Windows.

The 21-question, true-false PPT can be found in eFig 2A. The PPT questions were developed to highlight key practical, safety, and efficacy issues about OIT. A question about the standard of care was presented in duplicate, but with positive and negative wordings. A total of 8 questions were predetermined to be “high priority.” These questions dealt with key concepts, including the long-term nature of OIT, the noncurative nature of OIT, the severity of reactions during OIT, and that OIT is not the current standard of care. All answers to the questions in the PPT could be found in the CV and the OIT information package received at the time of consultation. The CV and PPT were evaluated for clarity, accuracy, and readability by 3 medical doctors, 5 clinic staff, 5 lay people, a parent of a child with food allergy, and an educational consultant.

A checklist-based framework for the SDM CCD was developed on the basis of the guidelines for informed consent of the College of Physicians and Surgeons of Ontario.²⁶ This checklist can be found in eFig 2B.

A 5-point Likert-scale exit questionnaire (eFig 3) was developed to assess patient satisfaction with the SDM process.

Standardized operating procedures were developed on the basis of these materials, and the clinic staff reviewed and implemented these in November 2017.

Patient Counseling and Consent Procedure

Our clinic's intake evaluation and educational and counseling procedures can be found in Figure 1.

During an initial food allergy consultation, the families were given a written information package about OIT outlining key information regarding OIT. This package included information about the OIT process, risks, benefits, alternatives, and current knowledge base. All answers to the questions in the PPT could be found in the information package. Both parents were then required to watch an unbiased online documentary called “The Allergy Fix” about food allergy and OIT.²⁷ This Canadian documentary was selected because it is current and balanced, presents a visual picture of the challenges associated with OIT, and provides the views of both medical and patient/caregiver on OIT. Before arranging the CCD, all other medical concerns were addressed including the following: adequate asthma control, asthma educator assessment, and possible pediatric pulmonology/respirology referral; pediatric gastroenterology referral, if there were concerns about gastroesophageal reflux or dysphagia; psychology/counseling assistance if anxiety was believed to be a barrier; and any necessary or requested oral challenges.

Subsequently, a separate 2-hour SDM CCD was arranged on a different day than the initial consultation. The structure of this meeting is outlined in Figure 1. Unless physically impossible, both parents were required to attend the CCD. At the beginning of this CCD, the PPT (eFig 2A) was administered by a medical office assistant or nurse to both parents and patients older than 12 years. Communication among participants was not allowed during the test. This first administration of the PPT was considered as the “pretest.” The patient was made aware that there would be a posttest, and the family then watched the CV. After watching the CV, the PPT was administered again, and this was considered as the “posttest.” The family then proceeded to the SDM CCD.

During the CCD interview, physicians used an itemized, checklist-based structure that identified practical aspects, including diagnosis, test results, presence of comorbidities, and other aspects of the medical history (eFig 2B). The results of both the pretest and posttest were reviewed, and each incorrect answer on both tests was reviewed with the family. The families then had an opportunity to ask unlimited questions regarding OIT, and family goals were reviewed.

Finally, a checklist-based discussion regarding numerous key aspects of OIT was reviewed. After this interview, the families had the opportunity to ask further questions and then decide whether to give consent for OIT. All children aged 13 years or older were able to sign consent if deemed capable. All children aged 5 years or older were given the opportunity to assent.

After completion of the CCD, an optional anonymous counseling feedback exit questionnaire to evaluate the counseling session was administered by the administrative staff, and the families were asked if they had any further questions.

The results of these PPTs and evaluations were anonymized without patient identifiers by a nurse, although identification of mother, father, and patient was preserved to allow group analysis. Individual scores were analyzed for each participant. The

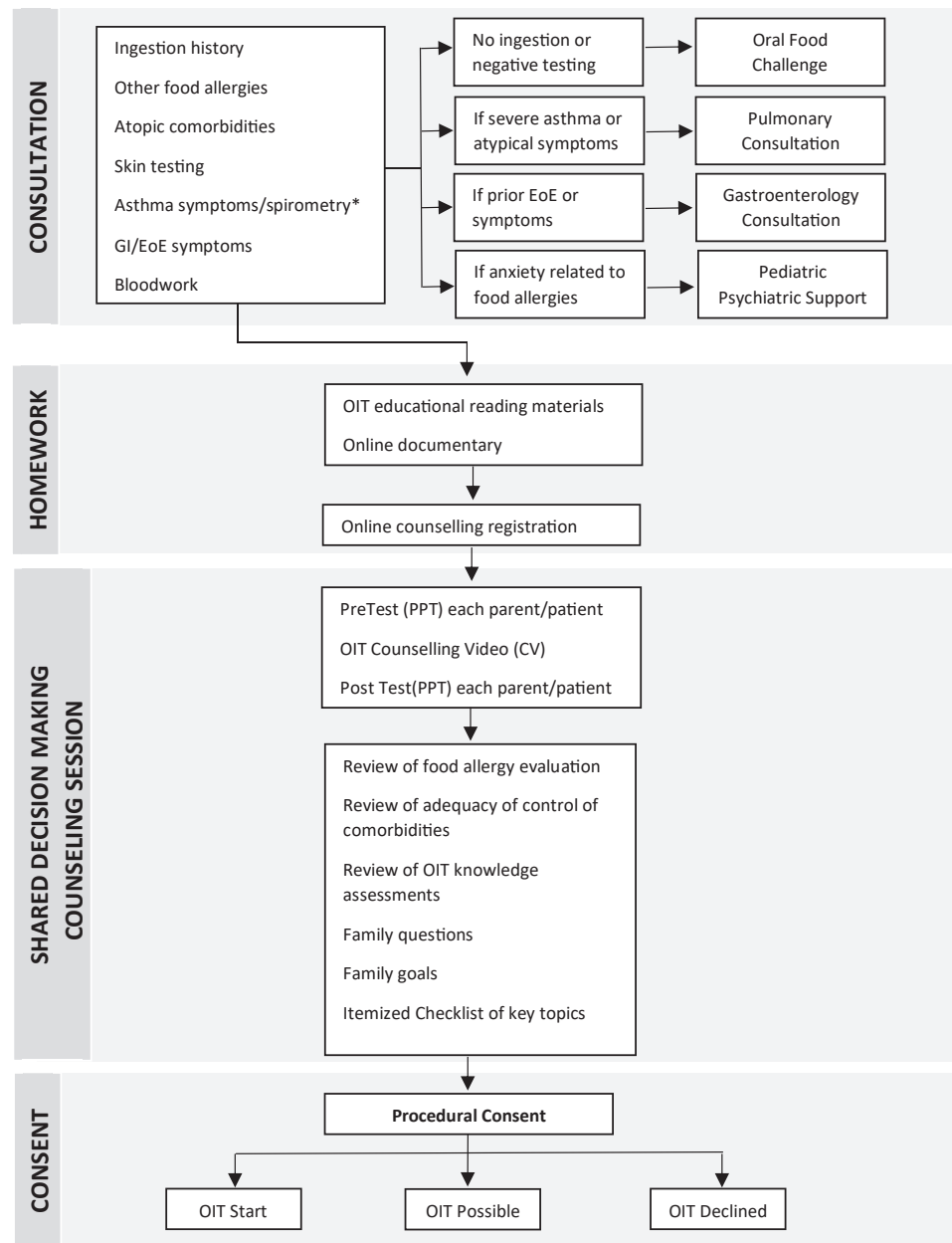


Figure 1. Structured patient flow from initial consultation to informed consent. CV, counselling video; EoE, eosinophilic esophagitis; GI, gastrointestinal; OIT, oral immunotherapy; PPT, pre-/posttest. The asterisk symbol indicates that all patients aged 4.5 years and older are evaluated with spirometry pre- and postbronchodilator if able.

performance for each individual question was also analyzed. An assessment of the 5-point Likert-scale questionnaire was also performed. Finally, the percentage of checked checkboxes during the CCD was assessed.

This quality improvement initiative was considered to be exempt from ethics approval by the Hamilton Integrated Research Ethics Board of the Hamilton Health Sciences.

Statistical Analysis

A descriptive summary of baseline patient characteristics was presented. Categorical variables were reported as frequencies and percentages and continuous variables as mean (SD) or median (quartile 1, quartile 3: Q1, Q3), depending on the distribution. The performance of each question was analyzed using the McNemar test for paired data, in which only discordant cells in 2 by 2 contingency tables were considered. The change in the mean number

of correct posttest minus pretest scores for each family member group was analyzed using paired *t* tests. The comparisons of mean pretest, posttest, and difference scores among family member groups were performed using analysis of variance. To control for multiplicity, *P* values were adjusted using the Dunnett test. Similarly, a comparison of mean posttest scores among family member groups, after adjusting for pretest scores, was carried out using analysis of covariance, and *P* values were adjusted using the Dunnett-Hsu test.

Results

In total, 467 participants took part in pre-/posttesting in 221 separate CCD sessions for 226 prospective patients. Overall, 220 mothers and 221 fathers took part, and 26 patients aged 13 to 17 years participated.

Table 1
Baseline Participant and Patient Characteristics

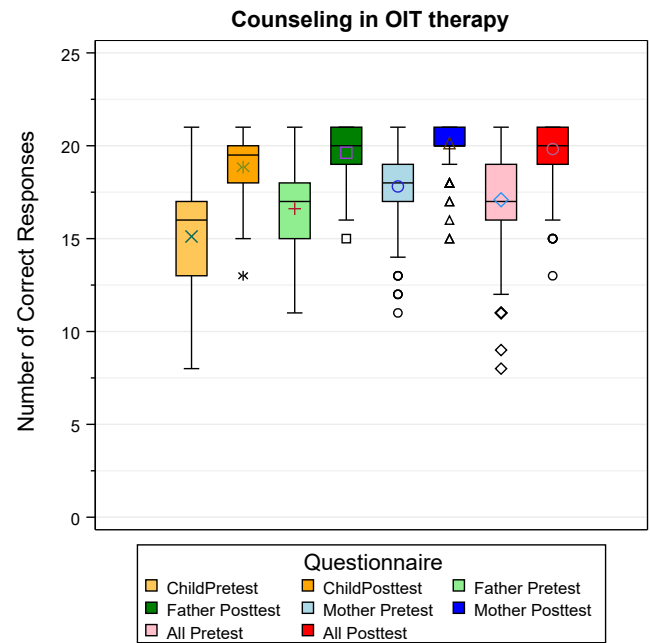
Characteristic	Value
Age at counseling (y), median (Q1, Q3)	5.39 (2.89, 9.10)
Mean time from initial consult to counseling (mo), median (Q1, Q3)	3.13 (1.68, 6.77)
Sex, n (%)	
Male	138 (58.5)
Race/ethnicity, n (%)	
White	150 (63.6)
Asian	57 (24.2)
Hispanic	15 (6.4)
Black	1 (0.42)
Other	13 (5.51)
Family history of atopy, n (%)	
Positive	171 (72.5)
Atopic comorbidities, n (%)	
Eczema	125 (53.0)
Asthma	124 (52.5)
Allergic rhinitis	95 (40.3)
Food being considered for OIT, n (%)	
Peanut	128 (54.2)
Peanut/tree nuts	53 (22.5)
Tree nuts	37 (15.7)
Peanut/sesame	5 (2.12)
Milk	4 (1.69)
Peanut/tree nuts/sesame	3 (1.27)
Tree nuts/sesame	3 (1.27)
Sesame	2 (0.85)
Egg	1 (0.42)
Other food allergies not being considered for OIT, n (%)	
Egg	38 (16.10)
Milk	16 (6.78)
Tree nuts	11 (4.66)
Sesame	7 (2.97)
Peanut	7 (2.97)
Other	19 (7.63)
None	139 (58.9)
Grade of index reaction, n (%)	
Grade 1	122 (40.3)
Grade 2	86 (36.4)
Grade 3	21 (8.90)
Grade 4	3 (1.27)
Never reacted	4 (1.69)
Self-reported parental employment, n (%)	
Health care	82 (24.1)
Financial	68 (20.0)
Education	43 (12.7)
Information technology	33 (9.71)
Self-employed	17 (5.00)
Stay at home	15 (4.41)
Public service	12 (3.53)
Other	70 (20.6)
Decision, n (%)	
Consent to OIT	189 (80.1)
Declined consent	31 (13.1)
Not having allergy by subsequent oral challenge	10 (4.24)
Not eligible because of medical condition	3 (1.27)
Pursued OIT with other provider	3 (1.27)

Abbreviation: OIT, oral immunotherapy.

The patient characteristics are summarized in Table 1. The median (Q1, Q3) age at counseling was 5.39 (2.81, 9.10) years, and the primary food of concern was peanut. The reported employment of parents suggested a high level of education, with nearly 25% in the health care–related field. Although most index reactions were of grade 1, nearly half were of grades 2 to 4.

A box plot of the number of correct responses to questions before and after counseling in all groups is shown in Figure 2. All the groups had improvement in the mean number of test scores after the CV (Table 2). However, 11 parents (no patients) had a lower score after the CV.

Pretest results indicate that the mean scores for mothers were better than those for fathers or patients ($P < .001$ for both) and

**Figure 2.** Performance on pre- and posttests by patient group revealing median, mean, Q1 and Q3, maximum observation below upper fence and minimum observation above lower fence, and outliers beyond the fences. OIT, oral immunotherapy.

fathers had better scores than patients ($P < .001$). Posttest scores revealed a similar result in which mothers fared better than fathers or patients ($P < .0001$ for both) and fathers fared better than patients ($P < .003$). The analyses of individual family member groups revealed statistically significant improvement in the mean difference (posttest minus pretest) scores ($P < .001$ for all). In the comparison between groups, fathers and patients had significantly higher mean difference scores than mothers ($P < .001$ and $P < .001$, respectively), whereas the mean difference scores for fathers and patients were not significantly different ($P = .11$). When adjusting for pretest scores in the analysis of covariance model, mothers had a higher mean number of correct posttest responses than fathers and patients ($P = .04$ and $P = .054$, respectively). Fathers also had a higher mean number of correct posttest responses than patients, but this was not statistically significant ($P = .28$).

The performance of each question was analyzed (Table 3) using the McNemar test for paired data, in which only discordant cells in a 2 by 2 contingency table were analyzed. For 12 of the 21 questions, a significantly higher proportion of responses moved from incorrect at pretest to correct at posttest ($P < .05$) than the other way around. A higher proportion of responses did move from incorrect to correct for question 4 regarding the necessity of an oral challenge, but this difference was not statistically significant ($P = .14$). The other 8 questions had a ceiling effect in that each was answered correctly 94% of the time or higher at the pretest. The proportion of responses moving from incorrect to correct for each

Table 2
Mean Difference in Number of Correct Responses on 21-Item Questionnaire Pretest vs Posttest by Family Member

Family member	N	Pretest, mean (SD)	Posttest, mean (SD)	Difference (post-pre) estimate (95% CI)	P value
Child	26	15.1 (3.10)	18.9 (1.99)	3.73 (2.92-4.54)	<.001
Father	221	16.6 (2.13)	19.6 (1.25)	3.01 (2.74-3.29)	<.001
Mother	220	17.8 (1.92)	20.1 (1.01)	2.33 (2.09-2.56)	<.001
Overall	467	17.1 (2.23)	19.8 (1.24)	2.73 (2.53-2.93)	<.001

Table 3

Performance on Individual Questions Pre- and Postcounseling Video Using the McNemar Test for Paired Data

Question	Question	Priority question	Pre (% correct)	Post (% correct)	Post-pre (% correct)	Sum of discordant cells <20	McNemar P value
1	OIT is the standard of care in the management of food allergy.	Yes	89.32	95.94	6.62	No	<.001
2	OIT is currently being offered only in Canada.	No	96.15	98.08	1.92	Yes/no	Ceiling, >.05 ^a
3	Currently available alternatives to OIT include the peanut patch and homeopathy.	No	35.47	48.50	13.03	No	<.05
4	An oral challenge is mandatory before considering OIT.	No	66.88	72.44	5.56	No	<.14
5	Most patients will not reach the target dose.	No	78.42	86.32	7.91	No	<.01
6	Tolerance may be lost if patients discontinue the therapy.	Yes	97.86	98.50	0.64	Yes	Ceiling
7	OIT is considered by most to be a cure for food allergy.	Yes	87.61	92.52	4.91	No	<.05
8	No fatalities have been reported during OIT.	No	74.57	92.09	17.52	No	<.001
9	Adverse effects are uncommon during OIT.	No	85.47	93.59	8.12	No	<.001
10	EpiPen use during OIT has been reported in clinical trials and with our own clinic patients.	Yes	72.01	97.65	25.64	No	<.001
11	Eosinophilic esophagitis is very common during OIT.	No	57.48	78.42	20.94	No	<.001
12	Severe anaphylaxis is a possibility during OIT.	Yes	95.73	96.58	0.85	Yes/no	Ceiling, >.05 ^a
13	Medication, such as antihistamines, may be used during OIT.	No	85.68	92.95	7.26	No	<.001
14	Good asthma control is imperative during OIT and puffer use may be required.	No	96.37	97.86	1.50	Yes/no	Ceiling, >.05 ^a
15	Typical "buildup phase" lasts 2 to 3 months.	No	41.24	72.86	31.62	No	<.001
16	The "maintenance phase" of OIT may be lifelong.	Yes	97.01	97.44	0.43	Yes/no	Ceiling, >.05 ^a
17	Doses must be taken on a daily basis at home.	No	96.58	98.08	1.50	Yes/no	Ceiling, >.05 ^a
18	OIT food doses are increased during illness.	No	93.80	95.94	2.14	Yes/no	Ceiling, >.05 ^a
19	Exercise may contribute to an allergic reaction during OIT.	No	84.83	92.31	7.48	No	<.01
20	Avoidance strategies and EpiPen use are the standard of care for the management of food allergy.	Yes	94.23	97.86	3.63	No	<.01
21	At the end of therapy, we can get rid of our EpiPen.	Yes	97.65	98.08	0.43	Yes/no	Ceiling, >.05 ^a

Abbreviation: OIT, oral immunotherapy.

^aMaximum P-value when sum of discordant cells > 20.

of these questions was slightly higher than that from correct to incorrect, but statistical significance of this apparent improvement could not be obtained owing to the small number of discordant responses. Although the analysis of grouped low- and high-priority questions revealed mean (95% confidence interval) improvements of 9.73 (4.31–15.15) and 5.40 (–1.72 to 12.51), respectively, only the grouped low-priority questions revealed significant improvement ($P = .002$ vs $P = .12$) as a result of the aforementioned ceiling effect with very strong performance on pretests for high-priority questions (>94% correct for 5 of 8 questions).

Satisfaction was high among the 110 participants who voluntarily completed the exit questionnaire, and no patients requested to ask further questions (Fig 3). Although there were 80.1% of patients enrolled in OIT at our clinic, 13.1% declined OIT, 4.24% were subsequently determined to have no allergy, 1.27% were considered unsuitable for OIT because of other medical comorbidities, and 1.27% pursued OIT with another physician (Table 1).

The mean (SD) time of the face-to-face counseling discussion after the test and CVs was 61.1 (14.6) minutes.

A review of the completeness of discussion revealed that in all 221 patient CCDs, 100% of the necessary topics were discussed.

Discussion

Our retrospective analysis suggests that the use of a CV with pre- and posttesting during a structured, checklist-based consent discussion improves patient and parental knowledge about OIT in a very large, highly educated group. This improvement in knowledge was significant for all groups, including mothers, fathers, and

children. These results also suggest that a checklist may aid in ensuring completeness of discussion.

The use of a PPT/CV and checklist format may improve patient and caregiver knowledge by ensuring that participants actively and consistently encounter key topics of discussion fundamental to the understanding of OIT. The CV may also address different learning styles of participants, ensuring that visual learners encounter this information about OIT in a visual format as well. Finally, the repetition of information from the initial consultation may also contribute to the understanding of patients and caregivers.

Our study is consistent with previous literature, which suggests that a video presentation can favorably supplement a preprocedure consent discussion.²⁸ A systematic review reported that 73.7% of studies using multimedia programs as an adjunct to consent discussions before surgical procedures had significant improvement in patient comprehension.²⁰ This review also suggested high patient satisfaction with the use of multimedia. However, very few of the studies reviewed evaluated caregiver consent. Although there is a paucity of research regarding the use of adjunctive aids in informed consent in the field of pediatric allergy, 1 group evaluated a process to design multimedia resources for consent in a pediatric asthma trial; however, the practical application of this resource with patients was not evaluated.²⁹ Other studies of caregivers of a pediatric population suggest that multimedia presentations may improve parental understanding during consent discussions, although no change in the overall satisfaction was found.³⁰

To our knowledge, this study is the first to evaluate the differing experiences of mothers and fathers in the OIT counseling and consent process. The participation of both mothers and fathers is imperative in the SDM process for OIT because mothers tended to

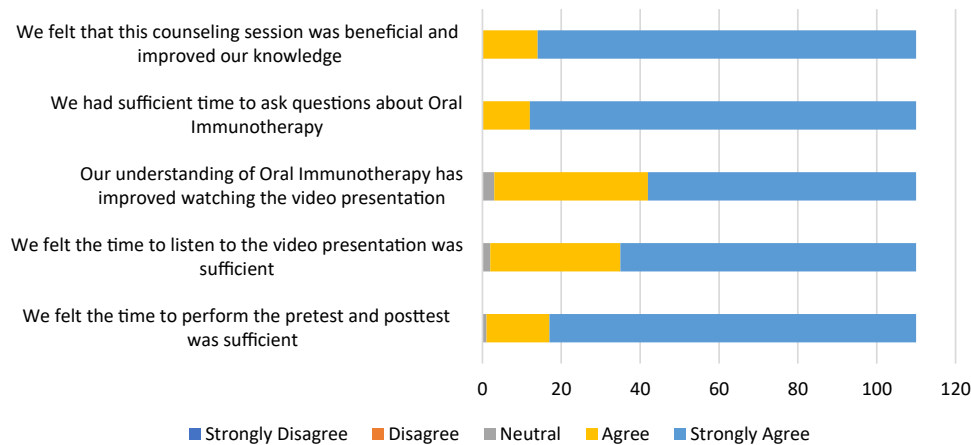


Figure 3. Representation of self-reported satisfaction on counseling feedback exit questionnaire.

perform better than fathers on the testing. These results suggest that fathers may not have the same depth of knowledge about OIT as mothers, and therefore, both parents should always be included in the counseling and consent process. A number of studies have revealed important differences in the quality of life and empowerment between mothers and fathers of patients with food allergy.^{7,8} The significant difference in performance between the parents in our study is consistent with the disproportionate burden of mothers found in the setting of food allergy. Despite the differences in understanding between these groups, it was encouraging to see that all the groups of participants improved after viewing our CV. Importantly, our PPT-CV experience revealed improved performance even among pediatric patients capable of giving informed consent. Not surprisingly, most patients in our study seemed to have less knowledge about OIT than the parents.

Although most patients incorrectly answered at least 1 question, a few answered predetermined high-priority questions incorrectly. It is important to note that these patients had already received much of this information verbally during the initial consultation, in written form in the information package, and with an online documentary before coming to the counseling session. Despite this previous information, approximately 20% of all questions were answered incorrectly at baseline. A pretest was not performed before the initial consultation; however, this step may be considered in the future to determine true baseline knowledge.

The questions that were answered incorrectly the most frequently dealt with the length of the buildup phase, the frequency of eosinophilic esophagitis, and availability of alternative therapies, such as epicutaneous immunotherapy. It is notable that even after initial consultation and review of educational materials at home, more than 10% of the participants initially felt the following at baseline: (1) OIT was a potential cure for food allergy, (2) OIT may be the standard of care, and (3) epinephrine use has not been reported during OIT. These high-priority misunderstandings improved after watching the CV. Other high-priority questions were answered correctly before the CV in nearly all patients, suggestive of a strong baseline understanding of key concepts about OIT. Among the 2 studies that looked at a qualitative analysis of parental expectations before peanut OIT, 1 study suggested that no caregivers expected OIT to be a cure, although the other study suggested that this was a common question asked by families.^{15,17} After our families watched the CV, no major deficiencies in knowledge were identified among key priority topics, and all but 1 priority question was correctly answered by more than 95% of the participants.

The importance of sufficient time allocation during the SDM process has been recently highlighted.³¹ We found that the average

time of face-to-face counseling for OIT in our practice was approximately 1 hour, which is consistent with previous reports.^{15,32} This length of time reflects the complexity of the OIT SDM process even amongst a highly educated population.

One concern identified in the informed consent research is the variability in topics discussed and inconsistency between informed consent discussions.²² The use of a checklist in our clinic resulted in 100% of key topics being addressed during the CCD with each patient. This finding is consistent with a recent pilot study of a checklist during a consent discussion in pediatric surgery.³³ Although we have no definitive comparison before our initiation of the checklist in our clinic, the surgical literature suggests significant gaps in key discussion topics.³³ Similarly, adequate informed consent for OIT has been previously found to occur in only two-thirds of allergists, even at academic centers.¹⁸ The use of a standardized checklist during an informed OIT consent discussion helps to ensure complete coverage of major topics.

Most patients expressed a high degree of satisfaction with this process and felt that the process was worthwhile. At the end of the OIT consent discussion, no patients requested to ask any further questions. This high degree of patient satisfaction is consistent with that of previous systematic reviews evaluating the use of multimedia aids during the informed consent process.

The weaknesses of this study include the fact that these results are retrospective and not randomized with no defined control group. The performance on these knowledge assessments may not represent an accurate portrayal of true participant understanding and may be reflective of the design of the questions because the questions were not previously validated. In addition, the primary intent of the PPT and CV was educational and not for research purposes. It is possible that simply taking a pretest quiz may have led to an improvement in the performance of the posttest; however, the only new or corrective information between each test was provided from the CV. We cannot rule out the possibility that the pretest itself led to an improvement in the posttest. It is also possible that the prompting of the knowledge of a posttest may have contributed as an incentive to families paying greater attention during the CV. Because this was a real-world experience, we were hopeful that families would have increased understanding about the pros and cons of OIT and so did not hide the fact that there would be a posttest after the CV. We have not repeated the administration of the PPT after families have initiated OIT, and it is possible that performance on this test may wane with time. Finally, although this is a highly educated population, the results of this intervention may not be representative among all populations.

There is a major mindset change for families and clinicians when undertaking OIT. The historical standard of care is avoidance of the allergen, and OIT shifts the “allergen to be avoided” to become the “medicine to be administered.” Unlike subcutaneous immunotherapy, OIT also comes with the expectation that families will bear the burden of risk because most reactions occur at home. In essence, families are expected to function as “amateur medical professionals,” and adequate education before, during, and after OIT is essential. This level of commitment may explain why many families interested in OIT at our clinic have a health care background.

The OIT is an elective, noncurative, and somewhat risky procedure.¹³ The SDM discussion must be inclusive of all the potential outcomes and needs to ensure that the expectations of the physician and the reality of OIT are aligned with the goals and expectations of the family. We believe that it is crucial for families and patients to be thoroughly informed about this potentially lifelong treatment. The counseling and consent process we used in our clinic is therefore deliberately comprehensive and structured to ensure thorough parent and patient education.

Our study is the first to evaluate the use of a pretest-counseling video-posttest and a checklist to educate families about the key principles of OIT during the informed consent process. Importantly, our study revealed no major deficiencies in the understanding of key principles of OIT at the end of the counseling session. Our findings also revealed that all major topics could be consistently addressed during a 1-hour CCD. Future research could explore the long-term retention of this information into the maintenance phase of OIT. We suggest that as part of extensive counseling for OIT, an educational video with pre- and posttesting is beneficial in a pediatric outpatient clinic.

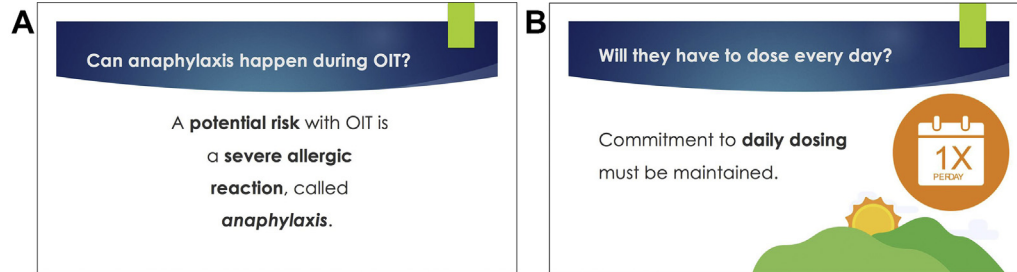
Supplementary Data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.anai.2020.06.044>.

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Supplementary Data



eFigure 1. Developed materials: examples of slides used in counseling video. Can anaphylaxis happen during OIT? OIT, oral immunotherapy (A) and (B) Developed materials: examples of slides used in the counseling video. Will they have to dose every day?



Halton Pediatric Allergy
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a A B C

Oral Immunotherapy PRE-TEST

Patient Name:

Date:

* 1. Oral immunotherapy is the standard of care in the management of food allergy.	TRUE	FALSE
2. OIT is currently being offered only in Canada.	TRUE	FALSE
3. Currently available alternatives to OIT include the peanut patch and homeopathy.	TRUE	FALSE
4. An oral challenge is mandatory prior to considering OIT.	TRUE	FALSE
5. Most patients will not reach the target dose.	TRUE	FALSE
* 6. Tolerance may be lost if patients discontinue the therapy.	TRUE	FALSE
* 7. OIT is considered by most to be a cure for food allergy.	TRUE	FALSE
8. No fatalities have been reported during OIT.	TRUE	FALSE
9. Side effects are uncommon during OIT.	TRUE	FALSE
* 10. EpiPen use during OIT has been reported in clinical trials and with our own clinic patients.	TRUE	FALSE
11. Eosinophilic esophagitis is very common during OIT.	TRUE	FALSE
* 12. Severe anaphylaxis is a possibility during OIT.	TRUE	FALSE
13. Medication such as antihistamines may be used during OIT.	TRUE	FALSE
14. Good asthma control is imperative during OIT and puffer use may be required.	TRUE	FALSE
15. Typical "buildup phase" lasts 2-3 months.	TRUE	FALSE
* 16. The "maintenance phase" of OIT may be lifelong.	TRUE	FALSE
17. Doses must be taken on a daily basis at home.	TRUE	FALSE
18. OIT food doses are increased during illness.	TRUE	FALSE
19. Exercise may contribute to an allergic reaction during OIT.	TRUE	FALSE
* 20. Avoidance strategies and EpiPen use are the standard of care for the management of food allergy.	TRUE	FALSE
* 21. At the end of therapy, we can get rid of our EpiPen.	TRUE	FALSE



Halton Pediatric Allergy
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a A B C

Oral Immunotherapy POST-TEST

Patient Name:

Date:

* 1. Oral immunotherapy is the standard of care in the management of food allergy.	TRUE	FALSE
2. OIT is currently being offered only in Canada.	TRUE	FALSE
3. Currently available alternatives to OIT include the peanut patch and homeopathy.	TRUE	FALSE
4. An oral challenge is mandatory prior to considering OIT.	TRUE	FALSE
5. Most patients will not reach the target dose.	TRUE	FALSE
* 6. Tolerance may be lost if patients discontinue the therapy.	TRUE	FALSE
* 7. OIT is considered by most to be a cure for food allergy.	TRUE	FALSE
8. No fatalities have been reported during OIT.	TRUE	FALSE
9. Side effects are uncommon during OIT.	TRUE	FALSE
* 10. EpiPen use during OIT has been reported in clinical trials and with our own clinic patients.	TRUE	FALSE
11. Eosinophilic esophagitis is very common during OIT.	TRUE	FALSE
* 12. Severe anaphylaxis is a possibility during OIT.	TRUE	FALSE
13. Medication such as antihistamines may be used during OIT.	TRUE	FALSE
14. Good asthma control is imperative during OIT and puffer use may be required.	TRUE	FALSE
15. Typical "buildup phase" lasts 2-3 months.	TRUE	FALSE
* 16. The "maintenance phase" of OIT may be lifelong.	TRUE	FALSE
17. Doses must be taken on a daily basis at home.	TRUE	FALSE
18. OIT food doses are increased during illness.	TRUE	FALSE
19. Exercise may contribute to an allergic reaction during OIT.	TRUE	FALSE
* 20. Avoidance strategies and EpiPen use are the standard of care for the management of food allergy.	TRUE	FALSE
* 21. At the end of therapy, we can get rid of our EpiPen.	TRUE	FALSE

Figure 2. A, Developed materials: pre-/posttest used to evaluate patient knowledge. The asterisk symbol represents predetermined "high-priority" question. Asterisk was added for reader reference but not included on the actual participant test. Pre- and posttests are identical apart from labeling. B, Developed materials: checklist used during counseling and consent discussion. ELORS, eosinophilic esophagitis like oral immunotherapy related syndrome; EoE, eosinophilic esophagitis; EPIT, epicutaneous immunotherapy, FEV1, forced expiratory volume in 1 second; GI, gastrointestinal; kU/L, kilo unit/liter; Mod, moderate; N/A, not applicable; OIT, oral immunotherapy; Rx, prescription; Sev, severe; SLIT, sublingual immunotherapy; SPT, skin prick test.



Halton Pediatric Allergy
Allergy • Asthma • Immunotherapy

Dr. Douglas Mack, MSc, MD, FRCPC
Dr. Mariam Hanna, MD, FRCPC

ORAL IMMUNOTHERAPY - PATIENT CHECKLIST

Patient Name:		Date:	
Date of Birth: _____		☐ Family Doctor/Pediatrician _____	
☐ Up-to-date contact information		☐ Halton Pediatric Allergy Online Support Group	
☐ Video Watched		☐ Preferred Pharmacy Information	
Known Food Allergies:			☐ Reviewed
☐ Milk	☐ Peanut	☐ Cashew	☐ Pistachio
☐ Walnut	☐ Pecan	☐ Hazelnut	☐ Almond
☐ Sesame	☐ Egg	☐ Pine Nut	☐ Pea
☐ Other: _____			
Food Allergy Evaluation:			☐ Reviewed
☐ SPT (mm in the past 12 months): _____			
☐ Bloodwork: _____			☐ >100 kU/L
☐ Oral Challenge: _____			☐ Declined ☐ Pending
Co-morbidities:			☐ Reviewed
☐ FEV1/Reversibility: _____		☐ N/A	☐ Asthma Signs/Symptoms
☐ Rx Puffers		☐ Asthma Action Plan	☐ Asthma Education
☐ GI/GERD: ☐ No ☐ Yes _____		☐ EoE/ELORS Reviewed	
OIT Knowledge Assessment:			☐ Reviewed
Pre-Test	A: _____	B: _____	C: _____
Post-Test	A: _____	B: _____	C: _____
Family Questions:			☐ Reviewed
Family Goals:			
Topics of Discussion:			☐ Reviewed
☐ Not Standard of Care	☐ Struggles/Distaste/Anxiety	☐ Epinephrine Use/Carriage	
☐ Long Term	☐ Exercise Restrictions	☐ IgE >100 kU/L	
☐ Tolerance Lost	☐ Illness Precautions	☐ Asthma	
☐ Not a Cure	☐ EoE/ELORS	☐ Voluntary/Free to Withdraw	
☐ Alternatives (EPIT, SLIT, Avoid)	☐ Mild-Mod-Sev Reactions	☐ Removal from Program	
☐ Daily Dosing	☐ Reaction Management	☐ Clinic Schedule	
OIT Status:			☐ Start ☐ Possible ☐ Declined

eFigure 2. (continued).

COUNSELLING FEEDBACK

1. We felt the time to perform the pre-test and post-test was sufficient:

☐ Strongly Agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly Disagree

2. We felt the time to listen to the video presentation was sufficient:

☐ Strongly Agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly Disagree

3. Our understanding of oral immunotherapy has improved watching the video presentation:

☐ Strongly Agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly Disagree

4. We had sufficient time to ask questions about oral immunotherapy:

☐ Strongly Agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly Disagree

5. We felt that this counselling session was beneficial and improved our knowledge:

☐ Strongly Agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly Disagree

6. Do you have any other comments to improve this session?

7. Would you like to speak with Dr. Hanna or Dr. Mack again before you leave?

☐ Yes ☐ No

eFigure 3. Developed materials: 5-point Likert-scale counseling feedback exit questionnaire to address patient satisfaction.