

REGULAR ARTICLE

Reintroduction failure is common among adolescents after double-blind placebo-controlled food challenges

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ABSTRACT

Aim: There has been a lack of research on adolescents who undergo double-blind placebo-controlled food challenges. The aim of this study was to investigate food allergic adolescents' experiences and consequences of double-blind placebo-controlled food challenges.

Methods: This qualitative, descriptive interview study included 17 adolescents aged 14–15 years with total elimination of cows' milk, hens' eggs or cod due to food allergies. The participants, who were initially identified from a large population-based cohort study, were interviewed 18 months after completing their challenges.

Results: The double-blind placebo-controlled food challenge proved to be a complex experience for the adolescents, involving fear of potential reactions and the hope that the food could be reintroduced. Experiences during the challenge were described in three themes: facing fears in a secure environment, being hesitant but curious about unknown tastes and waiting for unknown food reactions. Experiences after the challenge were described in two themes: gaining control and freedom and continuing old habits. A negative challenge was not consistently associated with the reintroduction of the challenged food.

Conclusion: This study highlighted the importance of considering the adolescents' expectations and experiences of the challenge and the reintroduction process to ensure desirable changes in their dietary habits. Follow-ups should be performed regardless of the outcome of challenges.

INTRODUCTION

It is common among school children to report symptoms after ingestion of various foods (1,2). However, the prevalence of self-reported food hypersensitivity is much higher than the prevalence of challenge-proven hypersensitivity (1,3). Eliminating foods, in particular essential foods, has a negative effect on nutrient intake and growth (4,5). In addition, the economic burden of food allergy on society and families is high (6) and a food allergy has a negative influence on the quality of life of those affected and their families (7,8). Living with a food allergy during adolescence means a balancing act between not allowing it to dominate their life and being sufficiently careful (9,10). This dual goal can be difficult to achieve. The majority of adolescents with diagnosed anaphylaxis cannot remember having a food reaction because it occurred in early childhood (11).

Because remission of food allergy in childhood is common (12,13), regular clinical follow-ups, including food challenges, are important to prevent unnecessary dietary restrictions. In general, tolerance to milk, eggs, wheat and soy are achieved during childhood, while allergies to peanuts, tree nuts and fish often persist (13). Studies have shown that children with mild symptoms from milk or eggs can tolerate heated forms of these foods in the diet and that

Abbreviation

DBPCFC, Double-blind placebo-controlled food challenges.

Key notes

- There has been a lack of research on adolescents' experiences of double-blind placebo-controlled food challenges, and we interviewed 17 adolescents aged 14–15 years after participating in food challenges.
- Reintroduction failure was associated with fear for reactions, not appreciating the taste of the food and having a normal life without the challenged food.
- Follow-ups should be performed after a double-blind food challenge, regardless of the outcome.

such incorporation may improve remission of the allergy (14,15).

Double-blind placebo-controlled food challenges (DBPCFCs) are considered the gold standard for diagnosing a food allergy (16). However, information about participants' experiences of such challenges, and the consequences, is limited. It has been shown that parental anxiety decreased after the child had performed DBPCFCs for peanuts and hazelnuts, irrespective of the outcome (17). However, reintroduction failure is common despite a negative challenge (18) and maternal fear during the child's DBPCFC has been shown to contribute to reintroduction failure (19). One study reported that health-related quality of life improved among children, regardless of the DBPCFC outcome, but it only improved among adolescents if the outcome was negative (20). This indicates that adolescents may have different experiences of DBPCFC than younger children. Furthermore, the reasons for reintroduction failure after a negative challenge are lacking. Therefore, we investigated the experiences and consequences of DBPCFC of adolescents with a food allergy.

METHODS

Study participants and procedure

The participants in this interview study were identified from a large paediatric cohort within the Obstructive Lung Disease in Northern Sweden (OLIN) studies. The cohort was recruited in 2006, when the parents of all 2704 children in grades one and two (age 7–8 years) in three municipalities in Norrbotten were invited to complete a questionnaire (2,21). The cohort was followed up when the children were 11–12 years of age, and a total of 2612 (96%) children participated (12). This study is based on that follow-up. The questionnaire that we used included the International Study of Allergy and Asthma in Childhood questionnaire (22), but was substantially expanded with additional questions about symptoms and physicians' diagnoses of allergic diseases and food hypersensitivity. Questions regarding food hypersensitivity included the type of offending food and the symptoms caused by the food (5,12,21). In the cohort, 5% ($n = 125$) of the children reported total elimination of cows' milk, hens' eggs, wheat and, or, cod because of food hypersensitivity. These children were invited to a clinical examination, including a structured interview and blood sampling for specific Immunoglobulin E to food, and 94 participated (3).

Based on the clinical examinations, 27 children were categorised as having a food allergy (3). Finally, 25 children were invited to participate in the DBPCFC, as two children were excluded, one because of a recent anaphylactic reaction and one because of a concomitant chronic disease that could influence the DBPCFC. Finally, 18 children with total elimination of cows' milk, hens' eggs and, or, cod agreed to participate in the DBPCFC procedures and a total of 20 challenge series were performed. Two children were challenged with two foods and the remaining participants with one food each. The DBPCFCs were performed at

hospitals with a paediatric clinic and adequate emergency equipment. The same experienced nurse (ÅS) and paediatric allergy specialist (AW) performed all of the challenges. The DBPCFC method has previously been described in detail (3). The result of the challenge was evaluated at a follow-up visit one week after the last challenge. Children with a negative outcome were advised to introduce the food, and children with mild symptoms were advised to partially introduce the food, namely in heated form.

The invitation to take part in the study was issued 18 months after the completed DBPCFCs, when the participants were adolescents aged 14–15 years, and 17 participated (Table 1). One adolescent could not be invited because he had moved outside the study area. Semi-structured interviews were performed at the adolescents' school. A written interview guide was used during the interviews, but it had a flexible structure that enabled the interviewer to ask follow-up questions to clarify points or to move the conversation forwards. The interviewer had not been involved in the DBPCFC. The interviews were digitally audio-recorded, transcribed verbatim and anonymised. The interview guide was tested in a pilot study, where children who had participated in open food challenges at a paediatric clinic participated.

The study was approved by the Regional Ethical Review Board in Umeå, Sweden. Informed written consent was obtained from the parents and the children.

Analyses

The transcribed interviews were analysed using qualitative content analysis (23), and the OpenCode 4.0 software (ICT

Table 1 Descriptive characteristics of the participants ($n = 17$), challenge outcome and achieved reintroduction of foods 18 months after the completed DBPCFCs

Sex	Challenge food	Age at onset (years)	Challenge outcome	Achieved reintroduction
Female	Milk	2–3	Negative	No
Female	Milk	2–3	Negative	Completely
Female	Milk	2–3	Negative	Partially
Female	Milk	<1	Mild	Partially
Female	Milk	<1	Mild	Partially
Female	Test 1	<1	Mild	Partially
Female	Test 2	<1	Severe	No
Female	Egg	4–5	Negative	Completely
Female	Egg	1	Mild	Partially
Female	Egg	5	Severe	No
Female	Cod	1	Mild	No
Female	Cod	1–2	Negative	No
Male	Milk	1	Negative	No
Male	Milk	5–7	Negative	Partially
Male	Egg	1–2	Negative	Partially
Male	Test 1	<1	Severe	No
Male	Test 2	1–2	Negative	No
Male	Cod	1	Negative	No
Male	Cod	5–6	Negative	No

Services and System Development and Division of Epidemiology and Global Health, Umeå University, Sweden) was used to code the interview data. The text was sorted into two domains corresponding to the aims of the study, namely, experience during and after the DBPCFC. Sentences were labelled with codes, compared regarding differences and similarities and collated into themes. To increase trustworthiness (23), several rounds of the process were completed. The interviews were conducted by a research nurse, who had not been involved in the challenges. Two of the authors (ÅS and VL) thoroughly read the interviews several times and discussed the analysis with the other authors.

RESULTS

All adolescents had experienced the onset of their food allergy symptoms in early childhood. Of 19 challenges, three resulted in severe reactions and five in mild reactions. The other 11 had a negative outcome, with no reactions. However, a negative outcome was not consistently associated with reintroduction of the food (Table 1). The qualitative analysis resulted in two domains and five themes (Table 2).

Experiences during the DBPCFC

Facing fears in a secure environment

The DBPCFC was described as a way to achieve knowledge about whether or not reactions would occur and about the severity of possible reactions. The symptoms were unknown, milder or more severe than the participants had expected. Some participants had no expectations that the challenge would lead to any changes in their lives and believed that their diets would remain the same. Fear was characterised by the uncertainty about whether a food reaction would occur during the DBPCFC. One participant said: *'I had to sit there and eat what I am not allowed to eat'*.

Fear was also described as the unwillingness to participate in the DBPCFC because of anxiety or that they had been forced to participate by their parents, who said that they would regret it if they did not. The magnitude of fear varied between the individuals and also within individuals during the challenge. In addition, positive feelings included excitement about participating, a desire for a changed life and the wish to find out whether or not they could reintroduce the eliminated food.

Table 2 Overview of the domains and themes

Domains	Themes
Experiences during the DBPCFC	Facing fear in a secure environment
	Being hesitant but also curious about unknown tastes
	Waiting for unknown food reactions
Experiences after the DBPCFC	Gaining control and freedom
	Continuing old habits

The participants said they felt secure if they believed that the researchers could handle allergic reactions, gave them sufficient information and were kind and cheerful. One participant said: *'I knew that they had everything needed, so if something would happen, something serious ... we were at the hospital, so I was not worried'*. They felt secure during a positive challenge if reactions disappeared quickly and spontaneously and if the allergic reaction did not cause breathing problems. Acceptable reactions were described as stomach problems, itching in the mouth or vomiting. The adolescents said they were afraid of having severe reactions, but they also said that it was positive for them to get information about the reactions in case they appeared again.

Being hesitant but also curious about unknown tastes

For most of the participants, the taste of the eliminated food was unfamiliar because it had been excluded from the diet for many years. Being hesitant about new tastes was explained as follows: *'It's so disgusting to drink milk, I'm not used to it'*. Participants also said that friends without food allergies were jealous of the food they ate at school because it looked more appetising. However, the participants were also curious about the taste of the challenged food and imagined that a nonelimination diet would be more flavourful.

The taste of the test samples was also new and unfamiliar. Opinions included that the test sample did not taste good, that it tasted good or that the taste was like vitamin tablets or blueberries. Although the majority of the study participants did not like the taste of the test sample, they said that they would do the DBPCFC again if needed.

Waiting for unknown food reactions

Each challenge lasted at least four hours, depending on whether or not reactions occurred. During this observation period, the adolescents passed the time by doing homework, watching movies, talking to others or reading books. Some described that there were advantages in spending time waiting, such as missing lessons at school. The waiting time was also described as boring, but acceptable: *'It was boring, but I have great patience'*. In addition, they felt that the challenge was time-consuming and it was not considered a high priority for them. Some adolescents with positive reactions expressed the view that the extended observation time after the challenge was unnecessary.

Experiences after the DBPCFC

Gaining control and freedom

The emotions were sometimes overwhelming following a negative food challenge:

'It was a huge relief; it was really nice'. If the offending food had been fully reintroduced, life had become easier for them as well as for their family. These adolescents described a new life with less control of their food intake and no need to read food labels. It was easier to socialise at parties, eat at

restaurants and spend time with friends: *'When you are somewhere you can just eat almost everything and it's really nice'*. Even if the adolescent had just chosen a partial reintroduction of the offending food, life was described as easier, with more freedom with regard to their food intake. Examples of partial reintroduction included eating eggs in baked products, but not a whole egg, or consuming baked product made with milk, but not drinking milk.

Others had severe reactions, and in these cases, the food was not reintroduced. The adolescents who chose to carry the prescribed epinephrine auto-injector reported that they were now prepared for accidental reactions because they knew about both the reactions and how to use the injector.

Continuing old habits

All participants had eliminated the offending food for many years before the DBPCFC and expressed that their friends and family accepted that they could not eat everything. Some study participants with a positive challenge said: *'It is sad, but that's the way it is'*. They described that they did not know any other way of life and accepted the situation: *'It is okay most of the time'*. Continuous food avoidance was described as less troublesome if other family members also eliminated the same food: *'It's no change in my life, because my father and brother also don't tolerate fish, so we can't cook fish at home'*. The adolescents who believed that the anaphylactic reaction that occurred during the challenge would not happen again chose not to carry the epinephrine auto-injector.

Even if the challenge was negative, some adolescents chose to continue eliminating the offending food. The reported reasons for continuing the elimination diet were that family members also eliminated the food or that they did not like the taste of the food: *'I can't stand the taste of milk. I can't get used to it'*. The adolescents also expressed fear of introducing the food because it had been eliminated for a long time and they believed that they still would have a reaction to the food: *'I know now that I can eat fish, but I don't. I believe that I imagine that I can't eat it, since I have been without it for 14 years, so I don't eat it'*.

DISCUSSION

This study describes adolescents' experiences of DBPCFC, collated into the following themes: facing fears in a secure environment, being curious but also hesitant about unknown tastes and waiting for unknown food reactions. The participants' experiences after the challenges were about gaining control and freedom and continuing old habits. Sometimes the challenged food was not reintroduced despite a negative challenge and the reasons varied: the participants did not like the taste of the offending food, it was normal to live life without the eliminated foods, or they were fearful of food reactions.

Living with a food allergy includes taking precautions to avoid foods that cause symptoms (9). During a challenge,

the children are exposed to this food, which may also induce anxiety and fear among the parents (19). In our study, the researchers' knowledge, skills and human presence were described as important factors for the participants as they made them feel secure during the challenge. These features have also been described in other studies as important factors in quality of care (24).

The study participants said that they accepted living with a restricted diet. On the other hand, these feelings of being accustomed to an elimination diet (9,20) seemed to be complex and contradictory. The adolescents expressed both the hope of a possible reintroduction of the eliminated food as well as the opposite, having no wish to reintroduce the food following the challenge. However, a correct diagnosis and knowledge of possible reactions may prevent hospitalisation (25) and have economic benefits for both society and the affected families (6).

Three of the adolescents had anaphylactic reactions during the challenge, and none of them had been prescribed an epinephrine auto-injector before the study. One explanation could be because the offended food had been eliminated for a long time and the family were unfamiliar with the reaction the food could cause. It was obvious that the experiences during the challenge were important for the family and the adolescent. This new knowledge increased their awareness of the need for more carefully controlled food intake (10,11) and also prepared them for possible reactions (11). Previous work has shown that a minority of children and adolescents use the auto-injector when it is clinically indicated (26). One study reported that most adolescents who reported severe symptoms from foods, such as swelling of the tongue or throat, loss of consciousness or troublesome breathing, did not know that these were symptoms of anaphylaxis (25). Thus, follow-ups are important after a severe food reaction.

The reintroduction of previously eliminated foods is worth striving for because it may result in improvements in quality of life (7,20). However, some of the study participants continued their old habits and did not reintroduce the food, despite a negative challenge outcome. This was particularly true for cod, as none of those who had experienced negative or mild reactions during the challenge introduced the food. The decision to reintroduce an unfamiliar food depends on the adolescent's motivation and willingness to taste the food (27). Parenting practices and family involvement may also influence whether that food is reintroduced or not (18). Lifestyle changes are a complex process for adolescents as well as parents. This process involves feeling that it is safe to give up old habits, feelings of discomfort with the present situation and a decision to enter the uncertainty of learning something new (28). Our findings indicated that the participants strived for what they felt was a normal life, independent of the outcome of the challenge. A review article describing important coping strategies among adolescents living with chronic illness noted that the most important aspect was being accepted by friends, getting on with life and being normal (29). Sometimes the food was not reintroduced after

a negative challenge because of fear, which has also been shown in other studies (18). In these cases, follow-ups are equally important. The fear could be avoided by serving a normal portion size of the challenged food under observation at the clinic after a negative DBPCFC (30). In this way, the fear about late-onset symptoms could be reduced. As this was not done in our study, the effect of such an intervention could not be evaluated.

The interviews in our study were performed about 18 months after the DBPCFC, because we considered that if a reintroduction was possible it would take some time before the tested food was fully reintroduced in the diet. However, the 18-month follow-up time may have introduced recall bias, which could be a weakness of our study. The strength of our study was the population-based design, with a representative population sample with total elimination of cows' milk, hens' eggs or cod and diagnosed as having a food allergy after clinical examinations (3). Furthermore, the participation rate was very high, as only one child did not participate in the interview. Qualitative studies involve small sample sizes compared to quantitative studies. Despite the large cohort, and the high participation rate, we could only identify 27 children with a food allergy, which is why stratified analyses, such as by sex or the offending food, could not be performed (3). Although some adolescents were not very talkative during the interview, they provided a wide range of experiences and, taken together, the interviews resulted in rich and varied stories. Furthermore, we performed 17 interviews which are considered sufficient to obtain valid results.

CONCLUSION

Double-blind placebo-controlled food challenges was a complex experience for adolescents, involving both fear of potential reactions and the hope that the food could be reintroduced. Sometimes the food was not reintroduced despite a negative challenge, because they did not like the taste, they experienced a normal life without the challenged food or they still feared food reactions. This study highlights the importance of considering adolescents' expectations and experiences of the challenge and the reintroduction process to ensure desirable changes in their dietary habits. Follow-ups should be performed regardless of the outcome of the challenge.

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CONFLICT OF INTEREST

None of the authors declare any conflict of interest.

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