

Does providing written dietary advice improve the ingestion of non-allergic nuts in children with existing nut allergies? – A randomized controlled trial

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Summary

Background Allergy to one or more nuts is common in children and often complete nut avoidance is advised. More recently, introduction of non-allergic nuts into the diet is advised by some allergists.

Objective This study aims to determine whether the provision of additional written dietary advice increases the ingestion of non-allergic nuts by children with nut allergy. Secondary aims include determining which factors facilitate or prevent successful inclusion of non-allergic nuts in the diet, and how inclusion influences quality of life, sensitization and the rate of nut reactions.

Methods This is a randomized, double-blinded, controlled trial of children with nut allergy who were asked to ingest one or more non-allergic nuts. Participants were 75 children aged 2–16 years (Intervention=36, Control=39), recruited in Adelaide, Australia. Randomized participants were supplied with the intervention (recipe booklet and monthly reminder text messages) or provided standard verbal dietary advice. After 6 months participants were assessed by a blinded investigator with regard to nut ingestion, quality of life, sensitization and nut reactions.

Results The intervention did not increase the ingestion of non-allergic nuts. A negative hospital challenge was a predictor of successful introduction. Parental report of child concern about a reaction was the greatest barrier. Ingestion of non-allergic nuts did not improve quality of life or change nut sensitization. Few nut reactions occurred during the study.

Conclusions and Clinical Relevance Ingestion of non-allergic nuts by children with nut allergy was not improved by additional dietary intervention. Selective introduction of non-allergic nuts is difficult to achieve when the child is anxious about introduction and challenges cannot be done in a medically supervised setting.

Capsule Summary This dietary intervention did not improve non-allergic nut ingestion by nut allergic children. Hospital challenge increased introduction rates, whilst parentally reported child concern about a reaction reduced success. Non-allergic nut ingestion did not change quality of life or sensitization.

Keywords child, diet, food allergy, non-allergic, nut, parental burden, quality of life

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Introduction

Food allergies are common in both adults and children and cause significant societal anxiety. IgE mediated food allergy is most prevalent in early childhood and

infancy, with food challenge proven allergy rates in one study as high as 10% [1]. While allergies to foods such as cow's milk and egg may be outgrown, allergy to peanuts and tree nuts are more likely to persist. Peanut and/or tree nut allergy affects 0.2–1.7% of the

population [2]. Only 20–25% of children with peanut allergy and 10% of those allergic to tree nuts will develop tolerance over time [3–5].

The relationship between peanut and tree nut allergy and the development of tolerance is complex and poorly understood. Peanut and tree nut allergy commonly co-exist, with 19% of 2 year olds with nut allergy demonstrating multi-sensitization, increasing to 86% of nut allergic 5–14 year olds [6]. Patterns of allergy and tolerance to different nuts vary between individuals and tolerance may develop to one nut while allergy develops to another [7].

Previously, a nut free diet was advised for children with nut allergy, largely due to concerns about accidental ingestion. Confusion with visual identification of whole nuts, 'hidden' ingredients in food and cross contamination in products all provide risk of exposure [8,9]. The estimated annual reaction rate due to accidental exposure has previously been reported to be as high as 50% [10], with more recent estimates of 3–12% [11, 12].

There is now increasing evidence that blanket avoidance may not be beneficial. It has been shown that strict avoidance of a known allergen does not increase the acquisition of tolerance, and that accidental ingestion or exposure does not prevent the development of oral tolerance [13]. Once tolerance is acquired, allergy can recur, and this occurs at higher rates in those who avoid the food, or eat it infrequently as seen in multiple case reports [14–16]. This raises an argument for both the selective introduction of non-allergic nuts into the diet and the maintenance of nut ingestion.

The need to avoid allergic foods places significant psychological burden on the child and their family. When assessed with formal quality of life (QOL) scales, children with food allergy have reduced general health and overall physical functioning and have high levels of stress, worry and anxiety [17, 18]. This is worse when multiple foods must be avoided, suggesting that reducing avoidance may be beneficial.

Anecdotally, families find it difficult to introduce non-allergic nuts, and home challenge has been reported to have limited success [19, 20]. There is currently no published data evaluating the success of introduction after hospital challenges, or how the child's allergic history influences nut introduction. It is also unclear whether ingestion of non-allergic nuts can alter the sensitization and tolerance profile of the nut allergic child or lead to changes in QOL.

Aims

The primary aim of this study was to determine whether the provision of additional written dietary advice in the form of a recipe booklet and reminder text messages, to

parents of children with nut allergy, would lead to increased ingestion of non-allergic nuts, when compared to current practice.

The secondary aims included; firstly to determine which factors facilitate or prevent successful inclusion non-allergic nuts in the diet, secondly to determine the effects of non-allergic nut inclusion on QOL, thirdly to monitor sensitization in those who include non-allergic nuts in the diet and finally to monitor adverse events occurring when non-allergic nut introduction is advised.

Methods

Study population and inclusion criteria

Eligible subjects were recruited from Allergy and Immunology clinics at the Women's and Children's Hospital, and from private Allergist's clinics in Adelaide by their treating allergist. Children 12 months to 17 years of age were included if they had confirmed or suspected nut allergy and had been asked to introduce one or more nut into their diet after completion of oral food challenge(s).

Confirmed nut allergy was defined by any previous typical IgE mediated symptoms of reaction on exposure, either in a hospital based oral food challenge, or in the community. Suspected nut allergy was defined by sensitization, (positive skin prick test (SPT)) with weal diameter ≥ 3 mm to a particular nut. This indicates the presence of allergen specific IgE to the nut allergen and the possibility of a clinical reaction on exposure [19]. A nut was defined as non-allergic after passing a hospital or home based oral food challenge, following graded challenge protocols already used as standard practice. Whether to perform a challenge and if this should be performed in hospital or at home was decided by the child's treating allergist, guided by the size of the weal, reaction history, and the social context. Challenge was only offered if the family wanted to include the nut regularly in the diet.

All parents were given standard advice during routine clinical contact to eat one serve (Table 1), of non-allergic nut(s) at least once per week after the challenge. There were no restrictions on the type of food or environment in which the nuts were consumed. It was explained that following this recommendation should allow the nut to remain in the diet in the future, but no specific advice was given if the recommendations were not met. Parents were reminded to strictly avoid confirmed or suspected allergic nuts, although they may consume food with 'may contain traces' on the label. Families were then invited to participate in the study, either in person or by follow-up phone call.

Table 1. Definition of 'one serve of nuts' by age

Age (years)	Weight (grams)	Volume whole nuts (cups)	Volume nut paste (tablespoons)	Range nut protein* (grams per serve)
1–6	10 g	1/8 cup	½ Tbs	0.98–2.47 g
7–12	20 g	1/4 cup	1 Tbs	1.52–4.98 g
13–18	30 g	1/3 cup	1 ½ Tbs	2.28–7.41 g

*From NUTTAB 2010, Food Standards Australia and New Zealand [24].

Data collection and questionnaire:

Once consented, parents were asked a series of questions about nut intake, previous reactions and atopic history. This was verified through the patient's medical record to account for recall bias. Most recent SPT data to nuts was collected from the medical notes.

The child's parents were also asked to complete the Food Allergy Quality of Life – Parental Burden (FAQL-PB) survey [21]. The FAQL-PB is a validated, food allergy specific, health related QOL questionnaire. This evaluates the parental burden associated with having a child with food allergy. It consists of 17 questions answered on a 7-point Likert scale, with a higher score indicating worse QOL.

Randomization

Consented participants were randomized into intervention and control groups with an allocation ratio of 1:1 by a third party using a random number generator. Siblings were randomized together due to the nature of the intervention. Parents were posted the 'Go Nuts!' booklet and their phone number was entered into an automated text message service.

Intervention group

The 'Go Nuts!' booklet was developed by the Nutrition Department at the Women's and Children's Hospital, Adelaide. It is 18 pages and includes a serving size guide, tick box of nuts to be included, a 'Quick Guide' of nut containing meals and snacks and a 2 page list of commercial foods containing specific nuts. The remainder of the booklet contains 26 recipes, 6 general nut recipes, 10 main meals and 10 snacks/desserts for specific nuts. On the cover and within the booklets are safety reminders only to include non-allergic nuts in the diet.

The parents in the intervention group also received monthly text messages for 6 months (5 messages), which read, 'Go Nuts! Remember to include NON-ALLERGIC nuts in your child's diet' and provided contact details of a blinded dietician.

Control group

After baseline data collection, there was no further contact with the control group until they were contacted for follow-up.

Follow-up and classification of nut ingestion

Six months after randomization, all participants were asked via email or phone call to complete an online survey on recall over the last month. Nut ingestion was classified; 'as recommended' if one serve was eaten weekly, 'in the diet' if any amount was eaten monthly or more frequently (includes 'as recommended'), 'eaten infrequently' if eaten more than once since the challenge, but not in the last month, 'not introduced' if eaten only once or not at all since the challenge.

At follow-up, parents were also asked to repeat the FAQL-PB and to report any adverse events experienced by the child or anyone at home with nut allergy. All participants were invited to attend the Women's and Children's Hospital, Adelaide, to have repeat SPT which was performed by a blinded investigator. This was done in accordance with the ASCIA skin prick testing manual[22] using commercially available nut extracts.

Statistical analysis

The sample size was determined by the number required to detect 50% of children including non-allergic nuts 'as recommended' with a power of 80%. This was an increase from the pilot baseline rate of 15% which was calculated from 20 controls as no published comparison rate was available. Comparison between the intervention and control and between subgroups was made with the Chi Squared Approximation. All significant results are quoted with a probability of 95%. Mean and individual question scores from the FAQL-PB were compared for statistical significance with the Mann–Whitney U Test. Once found to be statistically significant, a difference of 0.5 was considered the minimal clinically important difference (MCID) as previously demonstrated by Jaeschke et al [23].

Study drop outs

All participants were analysed on an intention to treat basis. Any participant who did not complete the survey was contacted to ensure that no adverse events experienced by the child or any family member were un-accounted for.

Results

Baseline characteristics

Seventy-five children were enrolled (Fig. 1) from December 2013 to November 2014 in the 12 month

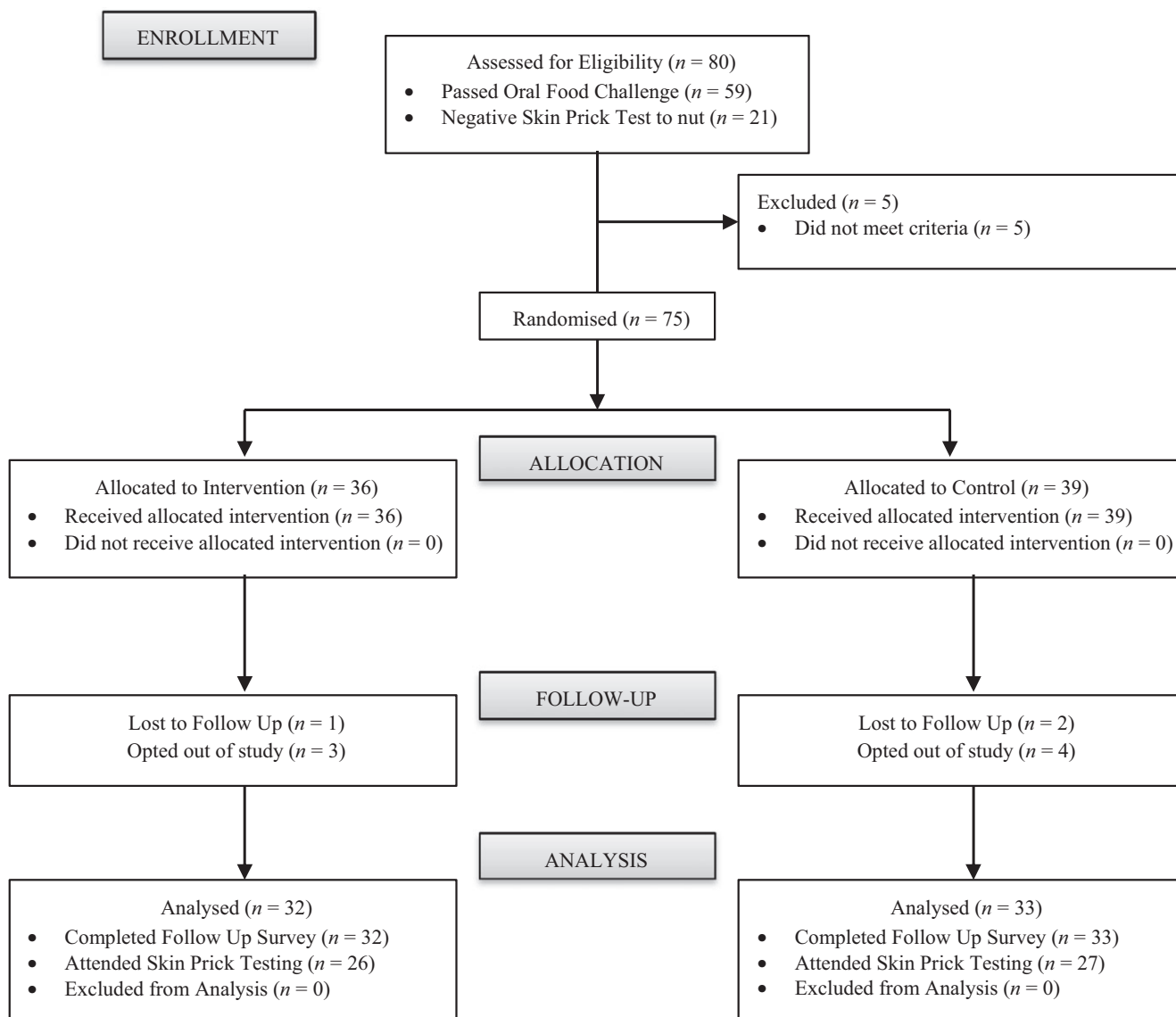


Fig. 1. Study participant flow diagram.

recruitment period, 36 in the intervention and 39 in the control group. There were no significant differences between the groups (Table 2). The age range was 2–16 years with a mean age of 8.5 years old. Children were asked to ingest 1–6 nuts by their treating allergist, the mean was 2.6 nuts.

Efficacy of the intervention

The rate and frequency of ingestion of non-allergic nuts as per our definitions is summarized below (Table 3). Only 9 (14%) of children included one or more non-allergic nuts as recommended (one serve per week), but 49 (75%) included any amount in the diet. There was no statistically significant difference between the intervention and control groups in the proportion of

children who succeeded in introducing non-allergic nuts as recommended, included them in the diet, ate them infrequently or did not introduce them.

Factors affecting success of introduction

Children who introduced non-allergic nuts into the diet were compared to those who did not (not introduced or eaten infrequently) and factors which could influence this outcome are summarized below (Table 4). Children who were avoiding more than one allergic nut had a significantly higher rate of successful inclusion of non-allergic nuts in the diet than those who were only avoiding a single allergic nut. Those who underwent a hospital challenge had a significantly higher rate of including nuts in the diet (44/54, 81%) than those who

Table 2. Baseline characteristics of nut allergic children

		Total <i>n</i> = 75 (%)	Control <i>n</i> = 39 (%)	Intervention <i>n</i> = 36 (%)	<i>P</i> value
Gender	Boys	49 (65)	27 (69)	23 (64)	NS
	Girls	26 (35)	12 (31)	13 (36)	NS
Age (years)	<5yo	12 (16)	8 (21)	4 (11)	NS
	5–12	52 (69)	27 (69)	25 (69)	NS
	>12	11 (15)	3 (8)	7 (19)	NS
Atopy (current or previous)	Asthma	44 (59)	24 (62)	20 (56)	NS
	Eczema	60 (80)	31 (79)	29 (81)	NS
	Allergic Rhinitis	50 (67)	23 (59)	27 (75)	NS
	Other Food Allergy	35 (47)	17 (44)	18 (50)	NS
	Family member with nut allergy	14 (18)	10 (26)	4 (11)	NS
	Nuts already in the diet	33 (44)	18 (46)	16 (44)	NS
Reaction and Exposure	Nut free diet prior to study	39 (52)	21 (54)	20 (56)	NS
	Any previous allergic reaction to nuts	57 (76)	28 (72)	29 (81)	NS
	Previous nut anaphylaxis	30 (40)	16 (41)	14 (39)	NS
	Only sensitized to nuts	18 (24)	11 (28)	7 (19)	NS
	Single nut introduction	19 (25)	12 (31)	7 (19)	NS
Advice from Allergist	Multiple nut introduction	56 (75)	27 (69)	29 (81)	NS
	Single nut avoidance	16 (21)	11 (28)	5 (14)	NS
	Multiple nut avoidance	59 (79)	28 (72)	31 (86)	NS
	Mean FAQL-PB* Score	1.8	1.8	1.7	NS

*Food Allergy Quality of Life- Parental Burden.

NS, Not statistically significant.

Table 3. Comparison of number of children who introduced non-allergic nuts in the intervention and control groups (*n* = 65)

Ingestion of non-allergic nuts	Total <i>n</i> = 65 (%)	Control <i>n</i> = 33 (%)	Intervention <i>n</i> = 32 (%)	<i>P</i> value
As recommended*	9 (14)	3 (9)	6 (19)	NS
In the diet†	49 (75)	24 (73)	25 (78)	NS
Only eaten infrequently‡	2 (3)	1 (3)	1 (3)	NS
All nuts not introduced§	14 (22)	8 (24)	6 (19)	NS

*One or more nuts eaten at an amount of one serve weekly.

†One or more nuts eaten of any amount, monthly or more frequently (includes 'as recommended').

‡One or more nuts eaten more than once since introduction, but no nuts eaten in the last month.

§All nuts only eaten once or not at all.

NS, Not statistically significant.

challenged at home (5/13, 38%). The child's concern over having a reaction was significantly associated with a lower chance of including non-allergic nuts in the diet. Whether a child had a history of any reaction, anaphylaxis or only sensitization was not associated with the rate of success. The mean number of nuts included in the diet was 1.4.

Quality of life

There was no significant change in FAQL-PB scores over the entire cohort over the 6 month follow-up per-

iod. Both the intervention and control group reported no change in QOL and there was no significant difference between the groups. In subgroup analysis, those who included non-allergic nuts in the diet reported a significantly higher score, (+0.9) indicating worse QOL, for 'participating in social activities involving food.'

Sensitization

Fifty-three children returned for follow-up SPT. In 5 of the 256 individual nut SPT performed, there was a positive test at follow-up (mean = 4.2 mm) which had been negative at enrolment. In all cases the nut had never been eaten by the child. There were nine SPT which had been positive at enrolment (mean = 6.6 mm), avoided, and were then negative at follow-up. The rate of becoming sensitized or becoming negative on SPT across the course of the study, was not significantly associated with whether non-allergic nuts were included in the diet or not. There were two children who ate nuts infrequently, neither of whom had positive a SPT at follow-up.

Adverse events

There were five reported adverse events in four (5%) children during the study (Table 5). One child was accidentally given muesli bar labelled to contain a known allergic nut which the child was avoiding. This resulted in a reaction consistent with anaphylaxis. The other

Table 4. Factors affecting the number of children who introduced non-allergic nuts in the diet ($n = 65$)

		Nuts in the diet (≥ 1 nut) $n = 49$ (%)	Nuts not introduced or eaten infrequently $n = 16$ (%)	<i>P</i> Value
Reaction history	Previous reaction to any nut	36 (73)	14 (88)	NS
	Previous anaphylaxis to any nut	19 (39)	7 (44)	NS
	No nut reaction	13 (27)	2 (13)	NS
Nut ingestion prior to study	Eating nuts	23 (47)	6 (38)	NS
	Nut free diet	26 (53)	10 (63)	NS
Number of nuts to introduce	Introduce single nut	14 (28)	3 (19)	NS
	Introduce >1 nut	35 (71)	13 (81)	NS
Number of allergic nuts	Single allergic nut to avoid	7 (14)	6 (38)	$P < 0.01^*$
	Avoiding >1 allergic nut	42 (86)	10 (62)	$P < 0.01^*$
Method of Introduction	Hospital challenge	44 (90)	8 (50)	$P < 0.01^*$
	Home challenge	5 (10)	8 (50)	$P < 0.01^*$
Child's Perception	Child worried about reaction	9 (18)	9 (56)	$P < 0.01^*$
	Child didn't like taste of nut	25 (51)	7 (44)	NS

*Statistically significant.

NS, Not statistically significant.

Table 5. Adverse events during study

	Event 1	Event 2	Event 3	Event 4	Event 5
Nut	Cashew	Hazelnut	Macadamia	Hazelnut	Almond
Previous Reaction?	Yes	No	No	No	No
Sensitized	Yes - currently	Yes - previously	Never	Never	Never
Allergist advice	Avoid	Introduce - hospital challenge	Introduce - hospital challenge	Introduce - home challenge	Introduce - home challenge
Reaction to	Muesli bar	Nut	Nut different brand	Nut (Tolerating Nutella)	Nut
Symptoms	Urticaria, lip swelling, wheeze	Vomited, first home exposure	Urticaria, lip swelling	Urticaria, lip swelling	Vomited, previously tolerated
Action after event	Continue to avoid	Avoided	Tolerated initial brand	Tolerated Nutella	Tolerated nut
Follow-up SPT* (mm)	6	2	0	0	4
Conclusion	Accidental exposure	Non-specific Inconclusive	Contamination	Contamination OR Dose related	Non-specific Unlikely allergy

*Skin Prick Test.

four events occurred when ingesting nuts they had been advised to introduce. In three cases the parent re-introduced the nut which was subsequently tolerated, and SPT was negative which raises the possibility of contamination or a non-allergic cause. There were no adverse events experienced by children who did not complete the study, or by others in the house with nut allergy.

Generalizability and limitations:

These results can be generalized to paediatric populations presenting to tertiary allergy services in Australia. Information gathered about nut intake was limited by parental recall and by the options provided in the survey, this applied to both groups. The FAQL-PB measures the parent's QOL and does not capture the child's perspective or how this may vary with age.

Our population of nut allergic children was not confirmed by oral food challenge to allergic nuts, and therefore children without clinical nut allergy may have been included. These children, which exist in the community, must also avoid nuts and behave as if they are nut allergic, regardless of the true allergic status. As behavioural and psychological factors are the focus of this study, we felt that true allergic status did not need to be clarified to obtain results relevant to this population.

Discussion

This study evaluated whether written dietary advice could aid families of children with nut allergy in the process of non-allergic nut introduction. We did not find this to be the case, and very few families followed our recommended amount and frequency of one

serve weekly. Non-allergic nuts were included of varying amount at least once a month by 75% of families which was sustained for 6 months. This indicates that 'one serve weekly' may be difficult to achieve, even for families who were willing to ingest non-allergic nuts. The mean number of nuts included in the diet was 1.4 despite allergist instruction to introduce a mean of 2.6 nuts (maximum 6). This indicates that perhaps fewer nuts should be the focus of targeted introduction.

The most important factor in predicting the success of inclusion of non-allergic nuts in the diet was passing a hospital oral food challenge. This overcomes anxiety about the first exposure and also provides a defined time and environment to perform the challenge. Parents have anecdotally reported that they can find it difficult to perform home challenges, and that they and their children are anxious about the introduction process. Our study supports previous observations that home challenge led to a low rate of successful introduction. Interestingly, children avoiding more than one allergic nut were more successful in including non-allergic nuts in the diet than those only avoiding a single nut. Perhaps the prospect of single nut avoidance long-term is less concerning for families and those with multiple allergic nuts are more motivated to reduce the number of nuts which must be avoided.

The most frequently identified barrier to including non-allergic nuts in the diet was the child's concern about a reaction on parental report. This was independent of their reaction history, with rates of nut inclusion the same for those with previous anaphylaxis, a milder reaction, or only sensitization. This indicates that many children who are avoiding nuts are likely to be experiencing significant anxiety about eating nuts even in the absence of proven nut allergy.

It may be postulated that including non-allergic nuts in the diet would lead to a better family QOL as less foods must be avoided. Our study did not support this and found that those who included non-allergic nuts in the diet had no change in mean score, but a worse score for participation in social activities involving food. This suggests that some families may benefit from selectively eating non-allergic nuts at home but remaining on a nut free diet in public.

Little is known about the effects of eating non-allergic nuts on the sensitization and tolerance profile of other nuts. We did not identify any cases where infrequent ingestion or failed introduction after passing a challenge led to sensitization to a non-allergic nut. There were five cases of sensitization at follow-up

which was not present at enrolment to nuts which had never been eaten, however this was not followed by formal challenge so the true allergic status is not known. This may represent a missed window of opportunity where the nut could have been introduced. We also found that eating non-allergic nuts did not influence the rate of becoming sensitized or becoming negative on SPT to other nuts. This was not confirmed with oral food challenge, but suggests that eating non-allergic nuts does not prevent the acquisition of tolerance.

There has been concern that if a nut allergic child eats any nuts, there may be an increased rate of accidental exposure and reaction. We did observe possible reactions caused by contamination but these were very mild and the families successfully re-introduced the nuts without further reactions. There was one accidental exposure leading to anaphylaxis to a muesli bar which was labelled as containing the offending nut which the child was supposed to be avoiding. It could be argued that this reaction would have occurred even if the child was on a nut free diet. Although there was no published comparison rate of children avoiding all nuts, the conservative reaction rate in this study was low at 5% which is well within reported ranges in nut allergic children.

Ingestion of non-allergic nuts by nut allergic children continues to have a theoretical benefit for improving QOL by reducing dietary restriction. Intervening when sensitization is low or absent and eating the nut in childhood, may prevent long-term dietary exclusion into adulthood. Although no benefits in regard to QOL or tolerance acquisition have been demonstrated, this study captured only a short time interval and focussed on the experience of the parents of a child with nut allergy. Further studies tracking the paediatric population into adulthood will be important in this expanding population. Longitudinal examination of the individual's experience of nut allergy and their sensitization and tolerance profile is necessary to better understand this area to give families the best advice in childhood.

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Conflict of interests

The authors declare no conflict of interests.

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