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Dietary counselling of children with food allergy

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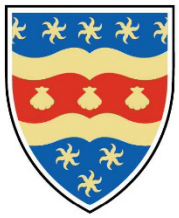

UNIVERSITY OF PLYMOUTH

DIETARY COUNSELLING OF CHILDREN WITH FOOD ALLERGY

by

JULIA EISENBLAETTER

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Dedication

I dedicate this work to my father, who passed on his love of research to me and who unfortunately can no longer witness his daughter following in his footsteps.

Author's declaration

At no time during the registration for the degree of Doctor of Philosophy has the author been registered for any other University award without prior agreement of the Doctoral College Quality Sub-Committee.

Work submitted for this research degree at the University of Plymouth has not formed part of any other degree either at the University of Plymouth or at another establishment.

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Statement of candidate's contribution to co-authored papers

There is one paper in this thesis that has been published and one unpublished manuscript. The candidate made the substantial contribution to these co-authored papers as described below. Chapters 5 & 6 contain these manuscripts.

Manuscript 1: Chapter 5

Eisenblaetter, J., Bürklin, S., Gschwend, A., Relats, C., Roduit, C., Stalder, K., Fischer, I., Hofmann, D., Schütt, G., Herzog, R., Gianelli, D., Mura, M., Martel, P., Werder, A., Martin, L., Hickson, M., Skypala, I., & Payne, A. (2020). Development of a practice guideline for dietary counselling of children with IgE-mediated food allergy. Allergo Journal International, 29(5), 42–51. https://doi.org/10.1007/s15007-020-2568-4

The first manuscript was submitted to *Allergo Journal International* in March 2020. The candidate contributed by writing the first draft of this manuscript and conducting the literature research together with Claudia Relats. The first three steps of the guideline development process were conducted in form of a Bachelor thesis by Selina Buerklin supervised by the candidate. The other steps including the Delphi survey were performed by the candidate. All authors commented on other versions of the manuscript.

Manuscript 2: Chapter 6

Eisenblätter, J. Walther, K.; Bigler, V.C., Zbären, E.; Tedde, G., Skypala, I, Payne, A., van der Horst, K., Hickson, M. German translation, cultural adaption, and initial validation of the Food Allergy Quality of Life Questionnaire – Parent Form. [Unpublished Manuscript]

The candidate contributed by writing the first draft of the manuscript together with Giulia Tedde. Material preparation and data collection were performed in form of a Bachleor thesis by Kerstin Walther supervised by the candidate. For this manuscript, the candidate performed a new data analysis with statistical support provided by Vidushi Bigler. All authors commented on other versions of the manuscript.

Abstract

DIETARY COUNSELLING OF CHILDREN WITH FOOD ALLERGY

JULIA EISENBLAETTER

Background The management of food allergy is challenging for children and their families. Several international guidelines recommend involving dietitians in the management; however, their tasks remain uncertain, and the effectiveness of dietary counselling has rarely been investigated. Therefore, the aim of this project was to evaluate the effectiveness of dietary counselling in children with food allergy regarding food allergy related quality of life (QoL), number of allergic reactions, and growth as indicator of nutritional status and diet diversity.

Methods The project was guided by the Complex Intervention Model by the Medical Research Council. To reach the overall aim there needed to be a common understanding of how to counsel this patient group. Therefore, the first step was to develop a practice guideline for dietary counselling in collaboration with dietitians and other stakeholders. Furthermore, a valid instrument to measure QoL was required. For this purpose, a previously validated English questionnaire, the Food Allergy Quality of Life Questionnaire – Parent Form (FAQLQ-PF), was translated into German, adapted culturally, and validated. For the final evaluation study, a multi-centre non-randomised controlled study was conducted, in which children with food allergies were followed up from diagnosis over one year, comparing children who received dietary counselling (intervention) with those that did not (control). Outcomes were measured at baseline, after three, six and twelve months, with online questionnaires. In this thesis, only six months data is presented due to delay in recruitment and consequent follow up data collection.

Results Results of this project include the practice guideline consisting of 25 recommendations for dietitians based on the Nutrition Care Process. A further result is a validated German version of the FAQLQ-PF. In the comparative study, 48 children were included, 29 with counselling and 19 without counselling. The most important finding was that children without counselling had a 2.65-fold higher risk of experiencing an allergic reaction in the first three months after diagnosis (Incident Rate Ratio=2.65 (unadjusted model), 95% CI: 1.12; 6.25. p = 0.026). The only other outcomes to differ were the number of allergic reactions after three and six months in the model adjusted to age, sex, and multiple food allergies. However, the median number of consultations with the dietitian was two and the guideline was incompletely implemented by the dietitians, thus, the full impact of dietary counselling may not be evident.

Conclusion This data suggests that dietary counselling is an important element of the routine management of children with food allergy because it has the potential to reduce allergic reactions. Further evidence needs to underpin this preliminary finding and cost-effectiveness needs to be evaluated. The German version of the FAQLQ-PF tool was successfully used to assess QoL in this study (acceptable to participants and feasible in the study context) but lack sensitivity at already high QoL. The implementation of the practice guideline developed in this project needs to be further evaluated, and reasons for the failure to fully implement it into the work of dietitians identified.

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Abbreviations

ANOVA ..... Analysis of variance
BMI ..... Body Mass Index
CARE-study ..... Childhood, Allergy, Nutrition and Environment study
CI ..... Confidence Interval
CMA ..... cow's milk allergy
EAACI ..... European Academy of Asthma and Clinical Immunology
ECTS ..... European Credit Transfer System
EFAD ..... European Federation of the Associations of Dietitians
FAIM ..... Food Allergy Independent Measure
FAIM-G ..... German version of FAIM
FAO ..... Food and Agriculture Organization
FAQL-PB ..... Food Allergy Quality of Life-Parental Burden Questionnaire
FAQLQ ..... Food Allergy Quality of Life Questionnaire
FAQLQ-PF ..... Food Allergy Quality of Life Questionnaire - Parent Form
FAQLQ-PF-G ..... German version of FAQLQ-PF
IgE ..... Immunoglobulin E
IL ..... Interleukin
IQR ..... Interquartile range
IR ..... Incidence rate
IRR ..... Incidence rate ratio
MRC ..... Medical Research Council
NCP ..... Nutrition Care Process
QoL ..... Quality of life
SDS ..... Standard Deviation Score
SVDE ASDD ..... Swiss Association of Registered Dietitians
T_H2 ..... T helper 2 cells
TSLP ..... Thymic stromal lymphopoitin
WHO ..... World Health Organization

1 Background

Food allergy is an immune mediated hypersensitivity reaction to food (Johansson et al., 2001). The management of food allergy is challenging for children and their families. International guidelines recommend involving dietitians in the management of children with food allergy, but this recommendation is often not followed (Muraro, Werfel, et al., 2014; Worm et al., 2015). This may be because not much is known about the influence of dietary counselling on food allergy outcomes. My work focusses on evaluating the influence of dietary counselling of children with food allergies on food allergy related quality of life (QoL), number of allergic reactions, nutritional status, and diet diversity.

1.1 Brief overview

A background on food allergy, its mechanisms, prevalence, symptoms, diagnosis and management is described in sections 1.3, 1.4, 1.5, 1.6, and 1.7. The role of dietitians in the management and diagnosis of food allergies and the competencies necessary to fulfil this are discussed in sections 1.8, 1.9 and 1.10. It becomes obvious that the role varies from country to country and that there is a need for a clearer definition, especially in Switzerland. Thus, this chapter concludes with the aim of this thesis and the resulting research questions and hypotheses.

The Medical Research Council's (MRC) complex intervention model was used as a framework for this project. Chapter 2 describes how this model guided this project in the definition of the 'intervention', the selection of outcomes and the evaluation of the effectiveness of dietary counselling. Moreover, it clarifies the theoretical positioning from which this thesis is written.

There is a lack of studies investigating the effectiveness of dietary counselling on diverse outcomes. However, it has been suggested that children with food allergies and their caregivers face diverse challenges after diagnosis. This includes a reduced QoL, fear of allergic reactions, a reduced nutritional status and a less diverse diet. Chapter 3 reviews the literature on studies investigating these outcomes.

A practice guideline was developed to define dietary counselling for this project. Furthermore, it should help to establish a common understanding of dietary counselling. Chapter 4 describes its development process.

No instrument measuring food allergy related QoL in children 0-10 years was available in German. Therefore, it was necessary for this project to translate, culturally adapt and validate an English questionnaire for its use in German. Chapter 5 describes this subproject.

A non-randomised controlled study was performed to evaluate the effectiveness of dietary counselling in children with food allergy on allergy related QoL, number of allergic reactions, nutritional status, and diet diversity. In chapter 6 six months data of this study is presented. 12 months analysis will be published after the finalisation of the PhD since the recruitment was delayed and follow-up data was not yet available for all participants at the time of data analysis.

Chapter 7 discusses the overall findings of this project and provides an outlook on further research needed on the topic. Strength and limitations are reflected upon, and an overall conclusion is drawn.

1.2 Definitions

The following statements define the general terminology used in this thesis:

This thesis focuses on *IgE-mediated food allergies*. These are hypersensitivity reactions to food initiated by an immunological mechanism involving antibodies of the Immunoglobulin E (IgE) isotype (Johansson et al., 2001).

Several definitions of the term *children* exist. The United Nations General Assembly defines a child as every human being below the age of eighteen (United Nations General Assembly, 1989). This includes the World Health Organization's (WHO) definition of adolescents aged 10-18 years (World Health Organisation [WHO], 2014). In this thesis, the term '*children'* refers to humans from birth to adolescence, which means up to 10 years of age.

*Dietitian*s (in Swiss German 'Ernährungsberater/innen') are defined as those that are legally recognised under the Health Insurance Ordinance (KVV, Art. 46 and 50a) to provide services in accordance with the health care system (KLV, Art. 9b). They need to have completed a bachelor's degree in Nutrition and Dietetics at a recognised University of Applied Sciences and bear the official academic title 'BSc in Nutrition and Dietetics' or in the case of an old-law degree at the level of 'higher technical college': dipl. Ernährungsberater/in HF (SVDE ASDD, 2022).

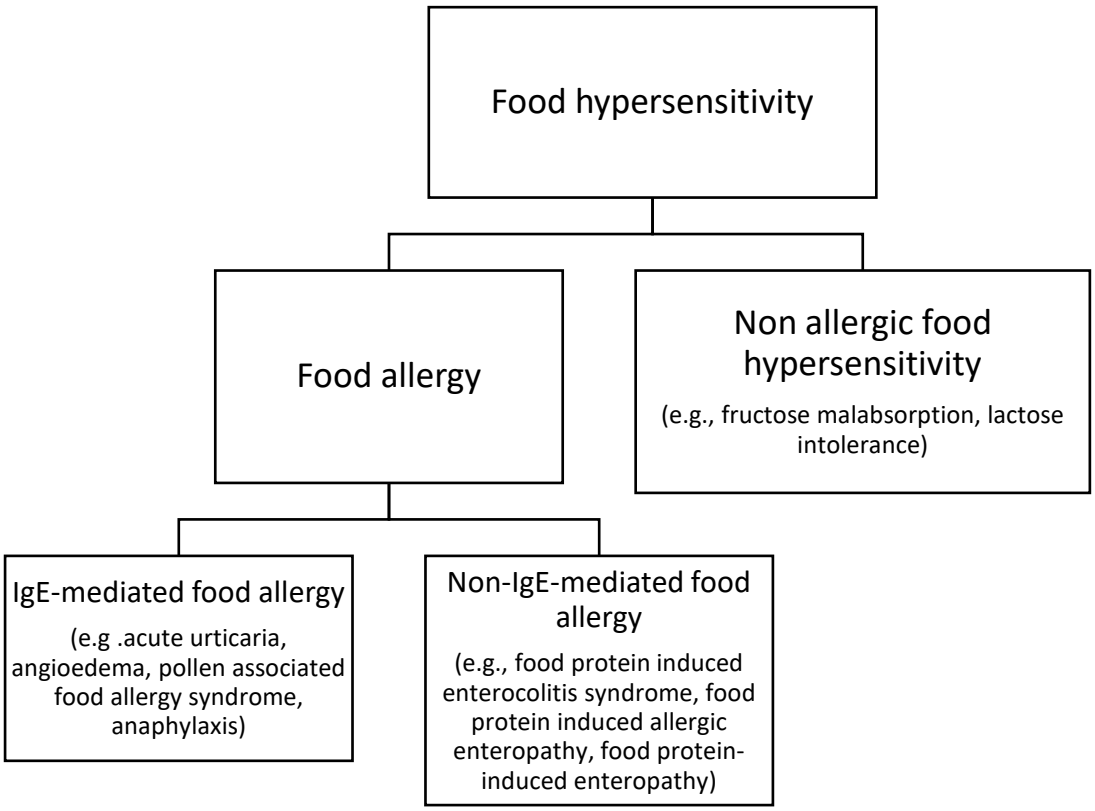
The service dietitians provide is named *dietary counselling*. It is defined by the Swiss Association of Registered Dietitians (SVDE ASDD) using the definition by Silvia Honigmann, as 'a person-centred, professional counselling that relates to dietary topics and problems with the aim to promote health through changes in dietary behaviour, to prevent disease, and to facilitate the management of a disease or living with a disease in a positive way' (SVDE ASDD, 2020). For children with food allergy facilitating the

management and living with the disease is therefore the main goal of dietary counselling in this thesis.

1.3 Mechanisms of food allergy

According to the nomenclature of the European Academy of Asthma and Clinical Immunology (EAACI), allergy is a hypersensitivity reaction initiated by immunologic mechanisms (Johansson et al., 2001). This definition excludes non-immunologic food intolerances such as lactose intolerance or fructose malabsorption. Allergies are known as either IgE-mediated, when IgE is involved, or non-IgE-mediated allergy, if not (Johansson et al., 2001). The American nomenclature further introduces a mixed IgE- and non-IgE-mediated category of food allergy (Boyce et al., 2010). However, this thesis refers to the European nomenclature. Non-IgE-mediated food allergies include food protein-induced proctocolitis, food protein-induced enterocolitis syndrome, food protein-induced enteropathy and eosinophilic gastrointestinal disorders (Ruffner & Spergel, 2016). Diagnosis of these food allergies is especially challenging because of the lack of non-invasive confirmatory testing of these disorders (Ruffner & Spergel, 2016). Therefore, the present study focuses on examining children with IgE-mediated food allergies, which can be more easily diagnosed. Examples for IgE-mediated food allergic disorders are urticaria, angioedema, pollen associated food allergy syndrome or anaphylaxis (Sicherer & Sampson, 2018). Figure 1 visualises the types of food hypersensitivities and gives examples of corresponding allergic diseases for each category.

Figure 1 Classification of food hypersensitivities adapted from Boyce et al., 2010; Johansson et al., 2001; Sicherer & Sampson, 2018



Note. IgE = Immunoglobulin E

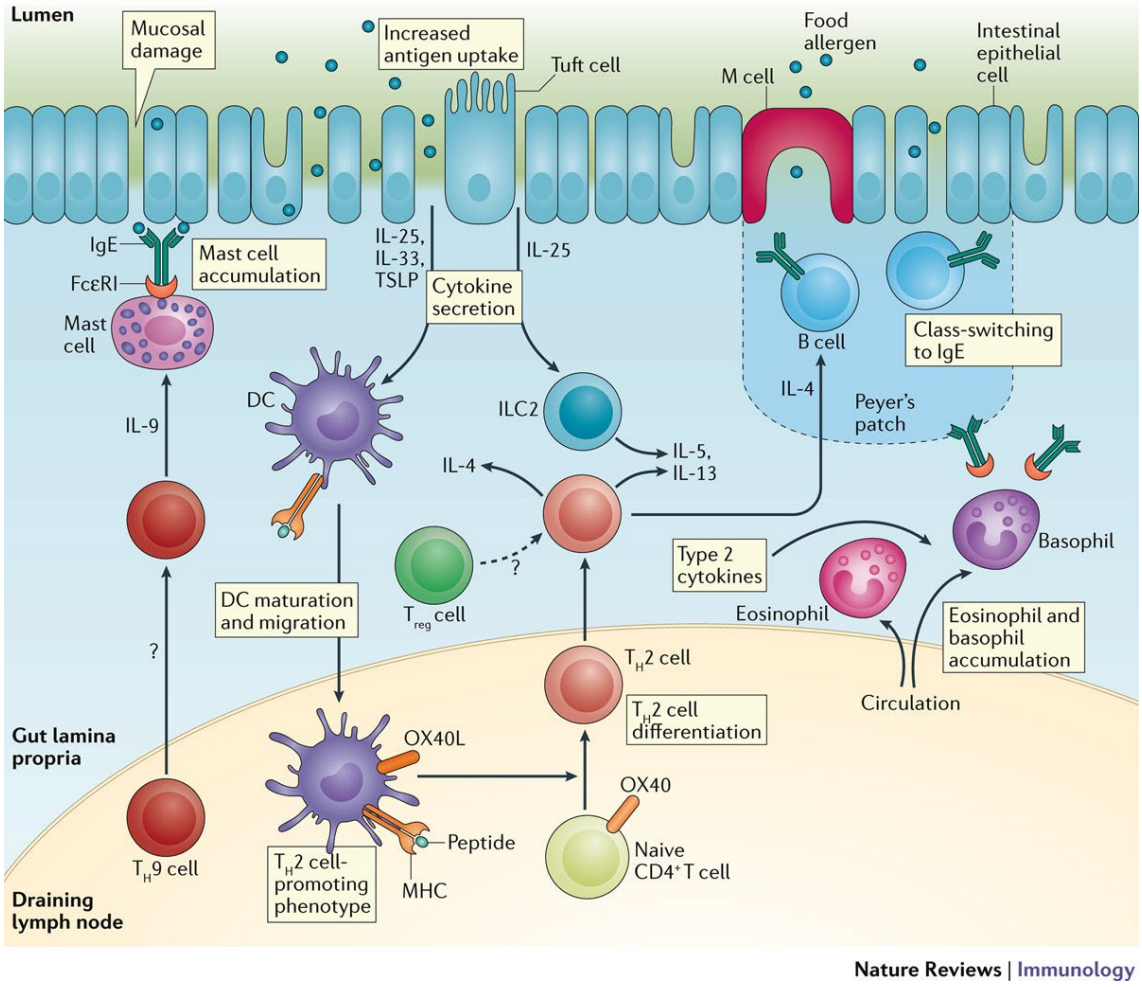
A food allergy is a breakdown of oral tolerance, which is the normal physiologic response to an ingested food protein, and leads to a sensitisation to the food (Sampson et al., 2018). Sensitisation can take place in the gastrointestinal tract, skin or, less commonly, in the respiratory tract (Sampson et al., 2018).

Figure 2 visualises the mechanism of sensitisation to food proteins, which are then also referred to as allergens, using the gastrointestinal tract as an example. It is assumed that epithelial damage or inflammation of these organs leads to an increased uptake of the food allergen, which (in the presence of a genetic predisposition) promotes the secretion of the epithelium derived cytokines interleukin (IL)-25, IL-33 and thymic stromal lymphopoietin (TSLP) (Divekar & Kita, 2015). These inflammatory cytokines trigger a cascade leading to allergen specific IgE synthesis by initiating a T helper 2 (T_H2)-type immune response. However, this pathway remains incompletely understood so far. But it is assumed that these mediators act on dendritic and innate lymphoid cells. In particular, TSLP seems to stimulate the maturation of dendritic cells towards a T_H2 cell promoting phenotype by upregulating the expression of the surface protein OX40L (Siracusa et al., 2013). These dendritic cells migrate to the lymph node where they present the allergen to the naïve $CD4^+$ T-cells which differentiate in the presence of OX40L into T_H2 cells (Blázquez & Berin, 2008). In addition, IL-25 secreted by epithelial cells may stimulate the development of type 2 innate lymphoid cells (Klose & Artis, 2016). They potentially secrete together with T_H2 cells cytokines including IL-4 that promote the T_H2 type immune response including class swift of B-cells into IgE expressing cells and the accumulation of eosinophils and basophils in the tissues (Mirchandani et al., 2014). Moreover, T helper 9 cells promote the accumulation of mast cells, which fungate together with basophils as effector cells in allergic reactions (Sehra et al., 2015). IgE binds on the high-affinity IgE receptor FcεR1 on mast cells and basophils.

Now it is perceived that initial sensitisation to a food allergen frequently takes place in the skin and that oral exposure induces tolerance (Sampson et al., 2018; W. Yu et al., 2016). This dual exposition hypothesis is supported by studies showing that the

early consumption to potentially allergenic food such as peanut, fish or wheat leads to a reduced incidence of allergy to these foods (Du Toit et al., 2008; Kull et al., 2006; Poole et al., 2006).

Figure 2 Mechanism of food allergy sensitisation in the gastrointestinal tract. Reprint from W. Yu et al., 2016 with permission.



Note. DC = Dendritic cell; FcεR1 = high-affinity IgE receptor; IL= Interleukin; ILC = Innate lymphoid Cell; TSLP = Thymic Stromal Lymphopoietin; T_H2 = T helper 2 cell; T_H9 = T helper 9 cells; IgE = Immunoglobulin E

After sensitisation to a specific food, re-exposure to the allergen of that specific food can lead to an allergic reaction. Thereby, allergen-induced cross-linking of IgE bound to FcεRIs on the surface of mast cells or basophils induce degranulation releasing mediators, such as histamine, prostaglandins, leukotrienes and proteases within minutes after exposure (Sampson et al., 2018). The vasoactive and proinflammatory

effects of these mediators result in the allergic symptoms described in section 1.5 (Valent et al., 2019). However, not every sensitisation leads to an allergic reaction.

An IgE-mediated food allergy involves reactions due to antibodies against foods or aeroallergens. When aeroallergens are involved, reactions occur due to similarities between aeroallergen proteins and food proteins (Werfel et al., 2015). Cross-reactions can also occur in someone sensitised to one food but reacting to another (Sicherer & Sampson, 2018).

1.4 Prevalence of IgE-mediated food allergy in children

The prevalence of IgE-mediated food allergy is difficult to determine, because a reliable diagnosis involves a multi-step approach including patient history, skin and/or blood tests and the gold standard, the double-blind placebo-controlled food challenge, and this is not possible to conduct on whole populations (Muraro, Werfel, et al., 2014). On the one hand, food challenges are costly and challenging, as well as risky for the patient and are therefore often not performed at a population level (Warren et al., 2020). On the other hand, self-reporting instruments have been shown to overestimate the true prevalence (Woods et al., 2002). This may be partly due to the misinterpretation of lactose intolerance symptoms. Consequently, a variety of different methods ranging from self-report to oral food challenge are used in studies to estimate the prevalence of food allergy in populations. This leads to a wide variation of estimated prevalence, according to the method used. Nevertheless, there appears to be a variation between countries, as well as age groups, and the prevalence seems to increase (Prescott et al., 2013).

For Switzerland the current best available prevalence data comes from the EuroPrevall study, a multi-centre cross-sectional study investigating children aged 7 to

10 years from the general population in eight European countries (Lyons et al., 2020). They reported a prevalence of probable food allergy, defined as self-reported food allergy plus blood test showing sensitisation, ranging from 1.9% to 5.6% across countries. For Zurich a prevalence of 2.3% was observed. Only three children performed an oral food challenge in Zurich, making it impossible to calculate the prevalence rate based on confirmed food allergy.

For younger children (< 7 years) no recent data is available from Switzerland. In other countries the prevalence appears to be higher in this age group as food allergy may resolve, as will be explained in section 1.5. The HealthNuts study, a birth cohort study including 5'276 children from Australia, estimated the prevalence of challenge proven food allergy in one-year-old children as high as 11.0%, but for four-year-old children reducing to 3.8% (Peters et al., 2017). In the US, Gupta et al. (2018) conducted a survey on a representative sample of 38,408 children from 0 to 17 years in which caregivers reported on the food allergy of their children. They suggested the prevalence of children with at least one food allergy to be 7.6%. The peak was observed at the age of two years with 10% prevalence, but in the primary-school-age group (6-10 years) the estimated prevalence was still 8%.

To conclude, only cautious estimations of the prevalence of food allergy in Swiss children are possible. Taking the above-mentioned considerations and studies into account, food allergy in Swiss children might vary somewhere between 2% and 11%, with a higher prevalence in infants (< 1 year) and toddlers (1-3 years) (Gupta et al., 2018; Lyons et al., 2020; Peters et al., 2017).

1.5 Symptoms and foods involved in childhood food allergy

A variety of foods can trigger allergic reactions, however, only a limited number are responsible for most reactions, but these differ between age groups. According to a Swiss cross-sectional study including 151 children with food allergy, cow's milk is with 37.9% the most common elicitor of IgE-mediated food allergy in infancy (< 1 year), followed by hen's egg (31.0%) and wheat (10.3%) (Ferrari & Eng, 2011). In the age group between one and three years, hen's egg became the most common food allergen (27.9%), followed by cow's milk (20.5%) and Hazelnut (13.1%). Above three years of age peanut became the most prevalent (21.4%), followed by hen's egg (14.3%) and fish (10.2%) in second and third position respectively. Interestingly, data from the EuroPrevall project showed, for Swiss children aged seven to ten, hazelnut as the most common food allergen, followed by carrot and apple for the centre in Zurich, suggesting that pollen related food allergies are already the predominant form of allergy in this age range (Lyons et al., 2020).

The natural history of food allergy depends on the particular food and individual factors. Epidemiological studies suggest that milk, egg, wheat, and soy allergy are more likely to resolve than peanut or tree nuts allergy. Savage et al. (2016) narratively reviewed the literature on the natural history of food allergy. They showed resolution rates for milk allergy ranging from 43%-57% until early to late childhood (2-10 years) (Elizur et al., 2012; Santos et al., 2010; Schoemaker et al., 2015; Skripak et al., 2007; Wood et al., 2013). 47%-50% of the children outgrew egg allergy by a similar age (2-9 years) (Peters et al., 2014; Savage et al., 2007; Sicherer et al., 2014). The resolution of soy and wheat allergy was 45% and 50% by the age of six and seven years respectively (Keet et al., 2009; Savage et al., 2010). However, only 22% of children outgrew peanut

allergy until the age of 4 years (Peters et al., 2015) and tree nuts allergy resolved only in 10% of the cases (Fleischer et al., 2005). Newer studies have similar results. For example Xepapadaki et al. (2016) reported 49% resolution of egg allergy by two years from the EuroPrevall project. These studies show that tolerance can be developed spontaneously. An increase of allergen specific IgG4 level and a decrease of allergen specific IgE-level have been observed in children outgrowing food allergy (Savilahti et al., 2010; Sommanus et al., 2014), but mechanisms behind natural tolerance induction remain incompletely understood (Hamad & Burks, 2017).

Symptoms of IgE-mediated food allergy range from mild reactions on the skin to potentially life-threatening anaphylaxis (Muraro, Werfel, et al., 2014). Table 1 summarises clinical presentations of food allergy. Prevalence studies report cutaneous manifestations such as urticaria, flush or angioedema being the most common, ranging from 44% to 81% from study to study and between age groups (Ferrari & Eng, 2011; Lyons et al., 2020; Schoemaker et al., 2015). Gastrointestinal manifestations, including vomiting and diarrhoea, or respiratory manifestations seem to be less frequent. In the above-mentioned studies, gastrointestinal symptoms account for 21% to 36% and respiratory symptoms for 10% to 21% of clinical manifestations. Cardiovascular symptoms are perceived to be seldom. Lyons et al. (2020) reported that around 5% of the investigated children (7-10 years) of the EuroPrevall study with probable food allergy developed cardiovascular symptoms. Ferrari & Eng (2011) did not mention isolated cardiovascular symptoms, but anaphylaxis, defined by a Grade III or IV allergic reaction affecting the respiratory tract and/or cardiovascular symptoms according to the criteria of Mueller (1966). According to these criteria they found anaphylaxis on average in 5% of clinical manifestations, which is comparable to the results of the EuroPrevall study for cardiovascular symptoms. Cardiovascular symptoms and anaphylaxis are severe but rare

events of IgE-mediated food allergy in children. Even though, food is the most common trigger according to the European Anaphylaxis Registry (Grabenhenrich et al., 2016). Whereas in the first two years of life cow's milk and hen's egg often trigger anaphylaxis, it is hazelnut and cashew in preschool children and peanut in all age groups.

Table 1 Clinical manifestation of food allergy adapted from Pajno et al. (2018)

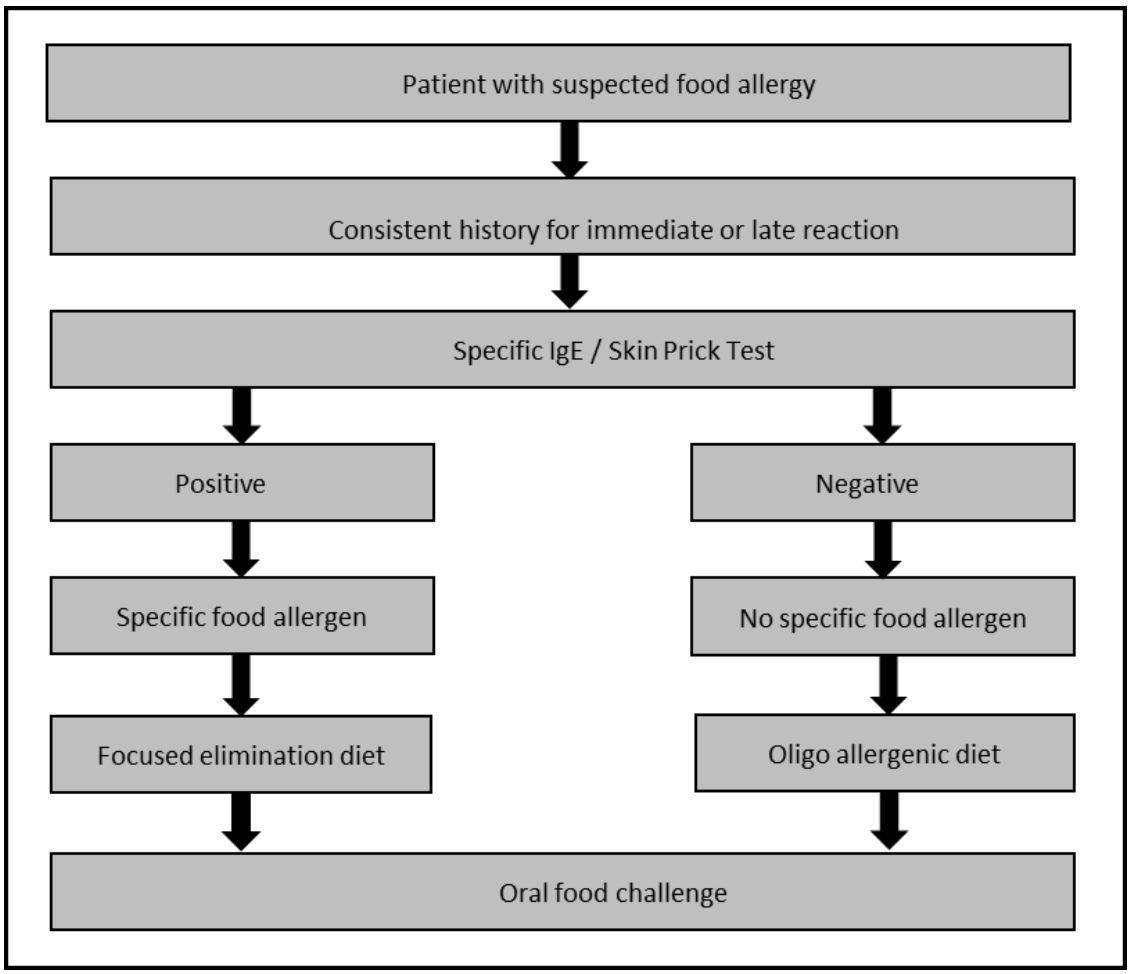
System	Symptoms
Cutaneous	Pruritus, erythema/flushing, urticaria, angioedema, urticaria
Ocular	Itching, redness, tearing, periorbital oedema
Oropharynx	Itching, dryness/discomfort, swelling of the oral cavity, lips, tongue and/or pharynx
Respiratory tract	Nasal congestion, nasal pruritus, rhinorrhoea, sneezing, hoarseness, laryngeal oedema, dysphonia, shortness of breath, cough, wheezing, chest tightness/pain
Gastrointestinal	Abdominal pain, nausea, emesis, diarrhoea
Cardiovascular/Neurological	Tachycardia, hypotension, dizziness, loss of consciousness/fainting, seizures, incontinence
Multi-organ	Anaphylaxis
Miscellaneous	Sense of impending doom, uterine cramping/contractions

1.6 Diagnosis of food allergy

As already mentioned, diagnosis of food allergy is a multi-step approach as illustrated in Figure 3 (Boyce et al., 2010; Ebisawa et al., 2017; Muraro, Werfel, et al., 2014). The first step is taking a medical history. If the medical history indicates an IgE-mediated food allergy, a skin and/or blood test is indicated. When these tests are positive, a focused elimination diet can be performed, followed by a food challenge to

prove clinical manifestation of the sensitisation. The gold standard is the double-blind placebo-controlled food challenge.

Figure 3 Diagnostic algorithm for food allergy adapted from Muraro et al. (2014)



Note. IgE = Immunoglobulin E

Sicherer & Sampson (2018) describe patient history as the most important single test for food allergy. They further state that patient history should be reviewed in the context of knowledge about clinical manifestations as well as epidemiology of food allergy and with an understanding of disorders with similar clinical manifestations that might be misinterpreted as food allergies. Also, EAACI emphasised the importance of patient history in their guidelines for diagnosis and management of food allergy (Muraro, Werfel, et al., 2014). Based on this awareness, an Allergy-focussed Diet History Task Force developed a standardised diet history tool for a diagnosis (Skypala et al., 2015). Due to the lack of evidence, they based the tool on expert opinion only. Six years

later high-quality evidence on the topic is still missing. An attempt was made by evaluating data from the EuroPrevall project (Lyons et al., 2021). However, no food challenge outcomes were available, making it impossible to calculate reliable predictive values for patient history. Still, they found reporting oral allergy symptoms and allergic rhinitis comorbidity to be the strongest predictors of probable food allergy in children. Despite the lack of good evidence, it can be assumed based on expert opinion that patient history is a very important, if not the most important step of the process of food allergy diagnosis, suggesting that it should be performed at the beginning of every food allergy diagnosis.

In case of a consistent history for food allergy, the next step is to perform diagnostic skin and/or blood tests (Muraro, Werfel, et al., 2014). Traditionally, skin prick tests and specific IgE to allergen extracts have been used to detect the presence of IgE-antibodies to the food. Using the conventional cut-off points of a wheal size ≥3mm compared to negative control for the skin-prick test, and ≥ 0.35 kU/l for the specific IgE, both tests show a high sensitivity and negative predictive value, but low specificity and positive predictive value (Foong et al., 2021; Soares-Weiser et al., 2014). This indicates that negative test results reliably rule out diagnosis of IgE-mediated food allergy. Positive test results, however, show sensitisation, but not true clinical reactivity. Attempts with other cut-offs have been made leading to an increase of specificity but lowering sensitivity. Compared to specific IgE-test to extract, component-resolved diagnostics measures IgE to specific proteins in a food and not to the whole food extract (Treudler & Simon, 2013). This method allows the identification of a specific sensitisation profile to better determine clinical relevance of the sensitisation. This is especially valuable for peanut and hazelnut allergy, where the risk profile varies immensely depending on the protein family the allergen comes from (Kleine-Tebbe et

al., 2016; Knol & Wickman, 2016). The clinical relevance for other food allergies is less evident and component resolved diagnostics is more expensive compared to standard specific IgE determination. Therefore, the use of component-based diagnostics should be decided on an individual basis, as these tests do not always add diagnostic value (Foong et al., 2021). Further tests include specific IgE to allergen peptides, basophil activation test and mast cell activation test, which could add additional diagnostic information in future, but are currently not routinely used in clinical practice (Foong et al., 2021). Other tests such as IgG testing, provocation and neutralization, electrodermal testing, cytotoxic testing, and applied kinesiology are unproven and currently unaccepted methods to diagnose food allergy (Hammond & Lieberman, 2018). To conclude, diagnostic tests are an important part of diagnosis, but are not sufficient alone to diagnose a food allergy and should therefore always be interpreted in a clinical context.

The gold standard of food allergy diagnosis remains the double-blind placebo-controlled food challenge (Muraro, Werfel, et al., 2014). Oral food challenges are used to diagnose, but also to determine tolerance or resolution of allergy to a food that is already avoided. However, as mentioned before, food challenges are time-consuming, costly, and bear the risk of severe systemic reactions. This is why, in practice, oral food challenges are unlikely to be recommended, if a positive result is highly probable (Cox & Nowak-Wegrzyn, 2018). Before challenging to a food, the suspected food needs to be eliminated or, in the rare event of no specific food being suspected, an oligo allergenic diet is performed, in which only foods with a low certainty of triggering a food allergy are provided (Muraro, Werfel, et al., 2014). The food challenge usually takes place in a hospital setting under continuous medical supervision (Ballmer-Weber & Beyer, 2018). Practical allergy (PRACTALL) consensus recommends giving the food protein titrated,

starting with a low dose to avoid symptoms, and increasing the amount until reaching an age-appropriate serving size as cumulative dose (Sampson et al., 2012). To rule out titration effects Niggemann et al. (2012) suggest giving the full cumulative dose again on another day in case of a negative result. Food challenges can be given open, single-, or double-blinded. The latter are predominantly used in research, but also in clinical practice to avoid placebo effects. Ahrens et al. (2014) retrospectively analysed 740 double-blind placebo-controlled food challenges in children and found 2.8% positive placebo challenges. Younger children showed higher rates, especially those with skin symptoms and worsening of atopic dermatitis. This shows the necessity of blinding food challenges when reliable diagnosis is of specific importance. To conclude, oral food challenges represent the gold standard in the diagnosis of food allergy, however, benefits and potential harms should be weighed up carefully against each other on an individual basis.

In summary, there is no single test for the diagnosis of food allergy. In practice, diagnosis of food allergy is often based on patient history in combination with diagnostic tests as it is used as inclusion criterium in this project. Nevertheless, the double-blind placebo-controlled food challenge remains the gold standard and is commonly used in research, but also in clinical practice.

1.7 Management of IgE-mediated food allergy

Once a person has been diagnosed with a food allergy, the most important long-term therapy remains the avoidance of the culprit food (Muraro, Werfel, et al., 2014). However, in case of an accidental allergic reaction, acute management becomes necessary. In recent years, promising results with various forms of immunotherapy to

induce tolerance have been achieved, which could change the future management of food allergy.

In case of an accidental allergic reaction, acute management is essential and can save lives. In their meta-analysis Umasunthar et al. (2015) calculated an incidence of anaphylaxis on food of 0.2 per 100 person years in the age group 0-19 years and 7 in children 0-4 years. Even though food-related anaphylaxis is relatively common, fatal reactions to food represent very rare events. Turner et al. (2017) estimated fatalities ranging between 0.03 and 0.3 death per million person years. According to the severity of symptoms the physician prescribes an emergency medication for the patient. Intramuscular administration of adrenaline with an auto-injector is regarded as first-line treatment in the event of an accidental allergic reaction (Muraro, Roberts, et al., 2014). EAACI guidelines further recommend equipping the patient with a management plan covering avoidance advice, contact details for advice as well as an anaphylaxis emergency action plan including possible symptoms and how to respond to each (Muraro, Roberts, et al., 2014). Furthermore, training on allergen avoidance, symptoms of allergic reactions, and when and how to use an adrenaline auto-injector should be provided to the patient and caregivers. These measures are taken to empower the person concerned to respond adequately in the event of an accidental adverse reaction.

Avoidance of the culprit food is the central intervention in food allergy management and is leading to a resolution of symptoms, even though this effect cannot be studied in randomised controlled trials due to ethical reasons (Muraro, Werfel, et al., 2014). Empowering the affected children and their caregivers in avoidance diet is an essential element of the therapy. This includes education on products containing the specific allergen and those that normally do not, food label reading, and training on how to react in case of an accidental reaction (Muraro, Werfel, et al., 2014). This training of

allergen avoidance is a central component of dietary counselling for children with food allergy, which will be further described in section 1.8.

Newer forms of avoidance tailor the diet to the individual tolerance of the child with the aim to induce earlier tolerance. This strategy dates from 2008 with two studies on baked milk and baked egg, respectively, in which they observed that around 70% of the children with egg or milk allergy tolerated an extensively heated form of the corresponding food (Nowak-Wegrzyn et al., 2008; Lemon-Mulé et al., 2008). This initiated a debate, which is still ongoing, on whether eating accelerates tolerance development or whether children tolerating this form are those more likely to outgrow the allergy (Dang et al., 2016; Leonard, 2016). In recent years some allergy centres have moved to using the milk ladder invented for non-IgE-mediated milk allergy by Venter et al. (2017) also for children with IgE-mediated food allergy as a kind of immunotherapy (Ball & Luyt, 2019). This stepwise approach involves a gradual introduction of milk in the form of an extremely processed food until tolerating natural unprocessed milk. Similar attempts with egg have been made in Swiss allergy centres (Felicitas Bellutti Enders, personal communication).

Allergen immunotherapy is the repeated allergen exposure at regular intervals to modulate the immune response in order to reduce symptoms and the need of medication (Pajno et al., 2018). The underlying principle is to gradually increase the dose of the specific food allergen with the intention of inducing the development of tolerance, so the affected person can safely consume the food in question (Jones et al., 2014). Oral, sublingual and epicutaneous routes of administration have been tested, whereby so far the oral route has provided the most promising results (Keet et al., 2012; Narisety et al., 2015; Pajno et al., 2018). Nurmatov et al. (2017) performed a systematic review and meta-analysis to inform the immunotherapy guideline development of

EAACI. They included 31 studies with 1259 patients and concluded that allergen immunotherapy may be effective in raising the threshold of reactivity to various food allergens in children whilst receiving immunotherapy, but also post-discontinuation. However, the therapy also modestly increases the risk of severe systemic reactions and substantially increases the risk of local allergic reactions. EAACI therefore recommends to individually consider the initiation of allergen immunotherapy based on the persistence of food allergy and/or the likelihood of a spontaneous resolution as observed for hen's egg or cow's milk (Pajno et al., 2018). Moreover, the motivation of the child and its family as well as the expertise of the clinical centre should be considered. Even though many studies have been conducted on allergen immunotherapy in people with food allergy, it has thus far not become routine management of food allergy.

To conclude, as there is currently no cure for food allergy, the management consist of an individually tailored elimination diet for the long-term management and a management plan for the acute management of accidental reactions. Both should be carefully accompanied with training of the children and their caregivers, which is often the task of dietitians. Allergen immunotherapy might be an option for a selected patient group but is still not the standard therapy.

1.8 Role of dietitians in diagnosis and management of food allergies

The European Federation of the Associations of Dietitians (EFAD) states that dietitians are 'recognised healthcare professionals, educated to at least Bachelor level. Using evidence-based approaches, dietitians work autonomously to empower or support individuals, families, groups, and populations to provide or select food, which is nutritionally adequate, safe, tasty, and sustainable.' In Switzerland dietitians are legally recognised under the Health Insurance Ordinance (KVV, Art. 46 and 50a) to provide services in accordance with the Health Care Services Ordinance (KLV, Art. 9b). Medically indicated services of dietitians include providing dietary counselling for patients with food allergies. Data suggests, however, that less than 50% of children with food allergies in the German-speaking part of Switzerland are actually referred to dietitians for dietary counselling (Beck & Stadelmann, 2017).

The role of dietitians working in the field of food allergy is currently not clearly defined in international guidelines and is influenced by the perspective of the group writing the guideline. Guidelines are predominantly developed by allergists. It is noticeable that all of them recommend involving dietitians somehow in the management of patients with food allergy (Table 2). However, only the German and the British guideline mention dietitians in connection with diagnosis. In all guidelines the clearest attribution is in connection to nutritional status (Muraro, Werfel, et al., 2014; Worm et al., 2021), but even in this case, the Japanese guideline only recommends involving dietitians, if the physician cannot provide the service alone (Ebisawa et al., 2020). Other management topics such as education on avoidance diet, alternative products or label reading are not clearly attributed to a specific profession (National Institute for Health and Care Excellence [NICE], 2011; Worm et al., 2015; Worm et al.,

2021). It seems that newer guidelines address the dietitian's role more specifically than earlier guidelines do. Efforts should be made by dietitians to resolve these shortcomings in future versions of these guidelines and support their implementation.

Table 2 Tasks of dietitians according to international guidelines on diagnosis and management of food allergies

Autor, year, country, 0rganisation	Type of guideline	Role of dietitian in diagnosis	Role of dietitian in management	Comments, limitations, bias
Worm et al., 2021, Germany DGAKI	Update Consensus - based guideline	Dietitians are specifically mentioned in connection with the evaluation of the dietary and symptom diary. The role in taking medical history and performing food challenges is not specified.	It is strongly recommended that specialist dietitians counsel in case of long-term elimination diet. Tasks in the long-term management are not clearly attributed to specific health professionals.	The role of dietitians is not clearly defined, even though this part of the guideline was written by dietitians.
Ebiswada et al., 2020, Japan	Evidence- and consent-based guideline	Dietitians are not mentioned in connection with food allergy diagnosis.	Where sufficient nutritional management cannot be provided by a physician alone, instructions are provided in cooperation with a registered dietitian. When a nutritional deficiency is suspected, a prompt and accurate nutrient evaluation is conducted in cooperation with the dietitian.	The role of dietitians is defined, but the dietitian has not many responsibilities according to this guideline.
NICE, 2011. Update 2018, UK	Not mentioned	Healthcare professionals with the appropriate competencies should take an allergy-focused clinical history. Diagnostic tests should be undertaken by healthcare professionals with the appropriate competencies.	Topics to discuss with parents or caregivers are listed. It is stated to seek advice from a dietitian with appropriate competencies.	The role of dietitians not clearly defined. Unclear, wether dietitians are meant to undertake diagnostic tests
Muraro et al. 2014, Europe, EAACI	Evidence- and consent-based guideline	Dietitians are not mentioned in connection with food allergy diagnosis.	Patients with food allergy who are on long-term elimination diets should have access to appropriate dietetic counselling, ideally by a dietitian with competencies in food allergy.	Dietitians are involved in long term management.
Boyce et al., 2010, USA	Evidence and consent-based guideline	Dietitians not mentioned in connection with food allergy diagnosis.	Dietary counselling and regular growth monitoring are recommended for all children with food allergy. Education on avoidance diet and label reading is mentioned but not specially attributed to dietitians.	Dietitians are not explicitly named.

Note. DGAKI = Deutsche Gesellschaft für Allergologie und Klinische Immunologie [German Society for Allergology and Clinical Immunology], EAACI = European Academy of Allergy and Clinical Immunology, NICE = The National Institute for Health and Care Excellence,

Some efforts have been made to define the dietitian's role by dietitians themselves (Table 3). Dietitians Australia provides a clear definition of the role of Accredited Practicing Dietitians in the field of adverse food reactions (Dietitians Australia, 2019). They further distinguish between what can be expected by a newly qualified dietitian compared to a food allergy specialist dietitian. They also describe what the role of a dietitian in the multi-professional team is. However, they failed to involve other professions in the development of the definition. The practice paper of the American Academy of Nutrition and Dietetics also describes the role of dietitians in diagnosis and management based on the Nutrition Care Process (NCP) (Collins, 2016). However, the boundaries of their tasks with those of other professions remain unclear. The Italian Society of Paediatric Nutrition and the Italian Society of Paediatric Allergy and Immunology consider in their position statement both nutritionists and dieticians as part of the multidisciplinary team (Giovannini et al., 2014). The role of dietitians in this team is not further specified. Only nutritionists are mentioned in regards to nutritional needs of children with multiple food allergies. This may be due to the different roles dietitians and nutritionists have in Italy compared to Switzerland and to other countries. Also, the International Network for Diet and Nutrition in Allergy attempted to define the dietitian's role, but concluded that the role differs between countries 'depending on the extend of the physician's role in dietary management' (Venter et al., 2012). As to be expected, the dietitians' view on their role is more precise, but it can only be considered in the context of the role of the other professions and varies between countries.

Table 3 Roles in diagnosis and management defined by dietitians and nutrition societies

Autor, year, country	Type	Role of dietitian in diagnosis	Role of dietitian in management	Comments, limitations, bias
Dietitians Australia, 2019, Australia	Role statement	Taking and interpreting clinical history, determine the likelihood of a food triggering food related symptoms. Dietitians usually do not undertake diagnosis of immune mediated adverse food reactions or conduct supervised food allergen challenges.	Implementation of nutritionally sound individualised exclusion diet, education on label reading and food substitutions, age and stage appropriate nutrition advice for paediatric patients, maternal diet manipulation, infant formulae, milk substitutes for infants and children. Dietitians do not provide medical management.	Distinction between entry and higher level of dietetic practice, provides only dietitian's views.
Collins, 2016, USA	Practice paper of the Academy of Nutrition and Dietetics	Taking and interpreting a clinical history, dietitians should never perform food challenges in isolation.	NCP including nutrition assessment, nutrition diagnosis, nutrition interventions and nutrition monitoring. Nutrition interventions include safe and nutritious alternatives and substitutes, label reading, dining in restaurants, managing food allergy in schools.	The document is written by a single dietitian. Unclear, whether this is the view of the academy.
Giovannini et al., 2014, Italy	Position statement	Diagnosis is not part of this position statement	Dietitians and nutritionists are mentioned as part of the multidisciplinary team in the management of children with food allergies to ensure growth and health of allergic children and to help family members to deal with the daily challenges. Only nutritionists are specifically mentioned in relation to the nutritional needs of children with multiple food allergies.	The distribution of roles among nutritionists and dietitians seems to be different in Italy than in Switzerland and in other countries.
Venter et al. 2012, International	Article by the International Network of Diet and Nutrition in Allergy	Allergy focussed diet history	Advice on avoidance diet, education on label reading, safe eating at restaurants, risk of cross contamination, information on support groups, dietary assessment to ensure adequate energy and nutrient intake.	Conclusion that the role differs from country to country.

Note. NCP = Nutrition Care Process

For Switzerland, no specific definition of the dietitian's role in diagnosis and management of food allergy exists. Ruch (2017) interviewed five dietitians specialising in food allergy in the German-speaking part of Switzerland. The results showed that dietitians' involvement in diagnosis varies greatly. Some of them have extensive roles, taking an allergy-focussed diet history, contributing to oral food challenges, interpreting food-symptom protocols and diagnostic tests in close collaboration with allergists, whilst others have no role in diagnosis and are only involved in management. In the latter case they predominantly educate patients and caregivers on several topics of allergen avoidance and alternative food choices, but also label reading. This shows that even within Switzerland activities of dietitians vary widely. It gives the impression that their role is dependent on the attitudes of the allergist and the competencies of the dietitian.

Only one study looked at the patient's expectations of dietitians (Mackenzie et al., 2015). This qualitative study found that mothers of children with food allergies value dietitians monitoring their child's health, providing information, practical advice, and support, but also giving emotional support. They would like to understand how to provide a nutritionally adequate, allergen-safe diet while maintaining a normal life. It would be valuable to know more about the role of the dietitian from the patient's perspective and to include this perspective in guidelines and role definitions to provide patient-centred support.

To conclude, the role of dietitians in diagnosis and management is defined very differently throughout the literature. A discrepancy exists between their role in guidelines, the views of the dietitians, the parents' expectations, as well as the implementation in practice. It would be beneficial to develop a mutual understanding of the dietitian's role in the diagnosis and management of food allergy in Switzerland,

but also in other countries. This could lead to a better inter-professional cooperation. The guideline developed as part of this thesis should lead to clarification of roles in Switzerland, which can serve as an example for other countries (Eisenblaetter et al., 2020).

1.9 Competencies of dietitians

There are many definitions for the term competencies. In connection with health care, the definition by Frank et al. (2010) is often cited. He defines competencies as 'observable ability of a health professional, integrating multiple components such as knowledge, skills, values, and attitudes'. The level of competencies differs between newly graduated and allergy experienced dietitians. Based on the Dreyfus model (Dreyfus & Dreyfus, 1986) the Academy of Nutrition and Dietetics developed a level of education and practice model ranging from novice to expert (Academy of Nutrition and Dietetics, 2017). With registration, dietitians are at competent level developing to proficiency and expert level during their professional career.

Some guidelines summarised in section 3.1 recommend involving competent or specialised dietitians in diagnosis or management of food allergy (Muraro et al., 2014; Margitta Worm et al., 2015). However, the terms specialised or competent remain undefined. The Academy of Nutrition and Dietetics defines specialists as practitioners 'who demonstrate a minimum of proficient level of knowledge, skills and experiences in a focus area of dietetic practice by the attainment of a credential'. Until now, such a specialised role for food allergy is only defined for dietitians in Australia (Dietitians Australia, 2019).

A European task force (EAACI) developed a set of competencies which health professionals including dietitians should attain when working in a clinical allergy setting

(Skypala et al., 2018). These include symptoms and features of allergic and non-immune mediated disease, diagnosis of allergic disease, management of allergic disease and wider health care issues such as evidence base and ethical issues. It is suggested that these competencies are verified through annual appraisal or examination. A national or international recognised certification for allied health professionals showing allergy competencies comparable to those for allergists would make competencies of dietitians in Europe more comparable and visible for other health professions and allergists.

Also, studies suggest that further training of dietitians in food allergy is needed to gain the required knowledge and competencies (Table 4). Ginis et al. (2016)detected relevant knowledge gaps, even though the majority of respondents self-rated their knowledge as moderate or good. Another study found that dietitians self-rate their competencies in developing food challenge protocols and managing feeding problems as low (Maslin et al., 2014). The study also showed that whereas many dietitians in the UK (58%) and Australia (77%) received allergy training during undergraduate dietetic education, only 31% received such education in the US. Their allergy training was predominantly provided in post-registration courses. Even though this is only data from self-evaluation studies, they suggest that without any further specialist training dietitians may not have the competencies to counsel children with food allergy.

Table 4 Key studies on food allergy competencies of dietitians

Author, year, country	Study design and aim	Subjects	Results	Comments, limitations, bias
Ginis et al. 2016, Turkey	Cross-sectional survey aimed to investigate dietitian's knowledge on food allergy management.	Dietitians and dietetic students in Turkey (N = 122)	They found that 8% of the 86 participating dietitians self-assessed their knowledge about food allergies as inadequate. Knowledge gaps that were identified included insufficient knowledge about hidden allergens, measures to avoid cross contamination and cow's milk substitutes.	Knowledge was self-rated and does not necessarily reflect their real knowledge.
Maslin et al. 2014, UK, Australia, USA	Cross-sectional survey aimed to compare self-reported food allergy competencies of dietitians.	Dietitians in UK, Australia, and USA (N = 797)	Dietitians self-rated their competencies in understanding food allergy and intolerance, diagnosis, recognition of signs and symptoms, development of food challenge protocols, educate patients on avoidance, development of elimination diet, management of multiple food allergy and managing feeding problems. Length of practice as a dietitian, caseload and food allergy training was positively associated with a higher rating of competencies.	Competencies were self-rated and do not necessary reflect their real competencies. This study was based on the survey of Groetch et al. and used data from this study for the USA.
Steer et al. 2011, South Africa	Cross sectional survey aimed to determine aspects of food-allergy-related knowledge and current approaches of medical practitioners and dietitians managing children with food allergy.	General practitioners (n = 47), dietitians (n = 25), medical specialists (n = 42) in South Africa	Limited knowledge existed regarding appropriate diagnosis, dietary intervention, and allergy prevention strategies across all professional groups.	Very low response rate and therefore small sample size.
Groetch et al. 2010	Cross sectional survey aimed to measure self-reported proficiency and educational needs and preferences of paediatric dietitians.	Dietitians in USA (N = 311)	Dietitians rated themselves 'moderate' for educating families, creating diets, and evaluating safe food items, and 'low' for creating diagnostic food challenges.	Competencies were self-rated and do not necessarily reflect their real competencies.

A bachelor's programme is a generalist education, comparable to general medical education, which cannot teach all diseases in depth. Therefore, it needs post graduate training and specialisation in specific topics such as food allergy. Since 2017 a Certificate of Advanced Studies (12 European Credit Transfer System (ECTS)-Points) on food allergy and intolerances can be obtained from Bern University of Applied Sciences (Bern University of Applied Sciences [BFH], 2021). Furthermore, a special interest group in food allergy and intolerances of the SVDE ASDD meets at least four times annually facilitating peer exchange of specialist dietitians (SVDE ASDD, n.d.). Although there are some food allergy specialist dietitians in Switzerland, no official creditation is available, which makes it difficult for other health professionals to differentiate and refer to competent dietitians.

To conclude, food allergy is a broad and complex topic which cannot be sufficiently taught in the bachelor's programme. Post graduate education and specialisation is important to gain the necessary competencies to be able to adequately counsel children with food allergy. Even though there are specialised dietitians, they are not officially recognised by national or international bodies, which reduces their visibility, and makes it difficult for third parties to distinguish between competent and non-competent dietitians in the field. Dietitians who supported this research, work in collaboration with allergists in specialised departments of children's hospitals in Switzerland can all be regarded as specialists in food allergy.

1.10 Effectiveness of dietary counselling

In the European Food and Nutrition Action Plan, the WHO recommends to 'monitor and evaluate diet-related activities, interventions and policies in different contexts in order to determine their effectiveness and to disseminate good practice'

(World Health Organization [WHO], 2014). Until now, very little is known about the effectiveness of dietary counselling on children with food allergy. The available studies are summarised in Table 5. There is only one prospective cohort study which showed a significant effect of dietary counselling on nutritional status (Berni Canani et al., 2014). However, this study lacked an appropriate control group without dietary counselling. Another study found that a lack of consultation with a dietitian was associated with a 1.89-fold increase in the risk of accidental reaction to egg (Bégin et al., 2017). The retrospective design of this study, however, may have led to recall bias and thus, over- or underestimated the number of allergic reactions. Moreover, the amount or content of consultations were not documented, which makes a definition of dietary counselling difficult. Other studies looking at the impact of dietary counselling on nutritional status are summarised in section 3.3., and it was concluded that the benefits of dietary counselling could not be definitively proved.

In conclusion, no prospective study has looked at the impact of dietetic counselling on QoL or diet diversity and there is only low-level evidence on the impact of dietary counselling on nutritional status or accidental reaction. Therefore, this thesis aims to investigate the effectiveness of dietary counselling on QoL, the frequency of allergic reactions, nutritional status, and diet diversity.

Table 5 Key studies on effectiveness of dietary counselling

Autor, year, country	Study design	Subjects	Results	Comments, limitations, bias
Begin et al., 2017, Canada	Cross-sectional study aimed to test the hypothesis if real-life professional dietary advice is associated with a decrease in accidental reactions to egg in allergic children.	Egg allergic children in an egg allergy influenza vaccination cohort (n = 397)	Lack of consultation with a dietitian was associated with a 1.89 (CI 1.47-2.42) fold increase in the risk of accidental reactions to egg.	Retrospective study design potentially leading to a recall bias of the number of allergic reactions. No further information on dietetic consultation available.
Berni Canani, 2014, Italy	Prospective cohort study aimed to investigate the effects of dietary counselling on children with food allergy using anthropometric data and laboratory biomarkers for nutritional status as outcomes.	Children with food allergy (n = 91) Control group without food allergy (n = 66)	At six months following dietary counselling, the total energy intake of children with food allergy was the same as the baseline values of control children. A significant improvement of anthropometric and laboratory biomarkers of nutritional status was observed.	Lack of control group of children with food allergy without dietary counselling.
Kapoor et al., 2004, UK	Prospective cohort study aimed to assess the impact of a multidisciplinary paediatric allergy clinic consultation on parenteral knowledge of food allergy and to determine the rate of subsequent allergic reactions after one year.	Children < 17 years with food allergy (N = 62)	A multidisciplinary paediatric allergy clinic visit (paediatric allergist, nurse specialist, dietitian) significantly improved parental knowledge of allergen avoidance (26.9% $p = 0.001$), managing allergic reactions (184.4%, $p < 0.0001$) and EpiPen usage (83.3 times per person, $p < 0.001$). Data before the visit is compared to data after the visit. Children with egg, milk or multiple food allergies were more likely to suffer subsequent reactions than those with other food allergies.	Before and after study Lack of control group without dietary counselling. Individual impact of dietary counselling not quantified.

Note. CI = Confidence Interval

1.11 Research questions and aims

This review of the literature led to the following research questions that will be answered in this thesis:

i. How does dietary counselling of children with food allergy influence food allergy related QoL?
ii. Do children who receive dietary counselling have allergic reactions less often than children who do not receive dietary counselling?
iii. How does dietary counselling influence growth in children with food allergy?
iv. How does dietary counselling influence the diversity of food eaten by children with food allergy?

The final goal is that children with food allergy and their families benefit from receiving an acceptable therapy.

1.12 Hypothesis

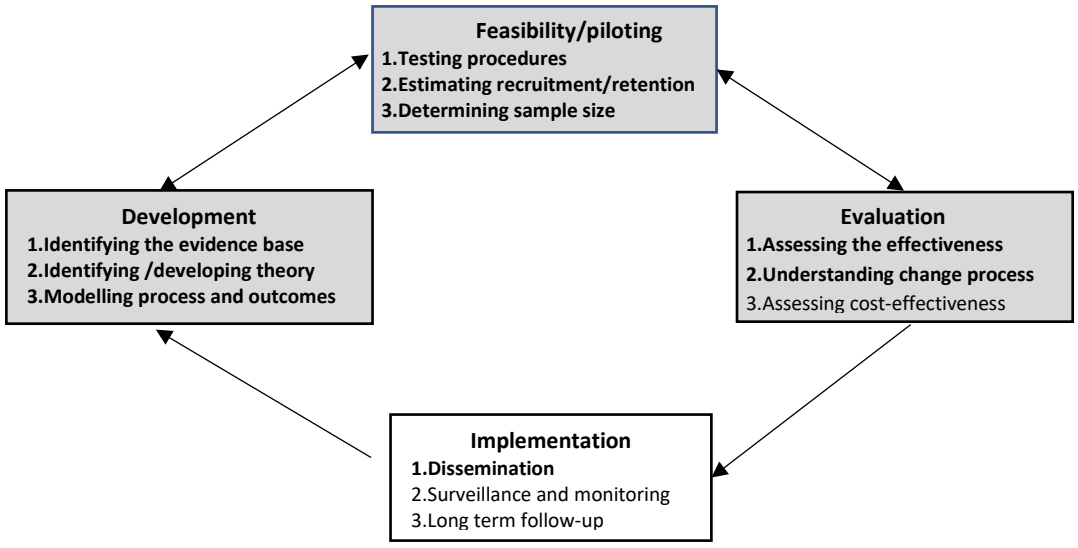
Children with food allergy who receive dietary counselling have a better food allergy related QoL, show fewer symptoms of allergic reactions, have a better nutritional status, and eat more diverse foods compared to those who do not receive dietary counselling.

2 Methodological framework and theoretical positioning

Dietary counselling of children with food allergy can be seen as a complex intervention, as it includes several interacting components such as the complexity in the design due to the different foods that may cause the allergy as well as staffing issues due to the diverse personalities and competencies of the dietitians but also patient issues like prior knowledge and skills (Craig et al., 2008; Richards & Hallberg, 2015).

Therefore, the MRC guidance of developing and evaluating complex interventions can be used as a framework for this research project, even though dietary counselling of children with food allergy is not a new intervention. The new framework published after the study was conducted explicitly takes the aspect of choosing interventions that already exists into account (Skivington et al., 2021). In this sense it is an identification rather than a development of the intervention. The classic framework consists of four main stages, of which three are included in this project. These are highlighted grey in Figure 4, whereas the key functions and activities at each stage considered in the project are in bold.

Figure 4 The steps of the complex intervention model and their use in this project.



Note. Steps included in this project are highlighted in grey. Key functions and activities involved at each stage are in bold

2.1 Development of a complex intervention

The next three sections describe the design of the project including three steps of the complex intervention model: 1. Identification of the evidence 2. Identifying/developing theory, and 3. Modelling the process and outcome. Much of this preliminary work took the form of guideline development, which is described in chapter 4. For a better understanding, the components are assigned to the individual process steps of the model.

2.1.1 Identifying the evidence base

The first step of the development phase is the identification of the evidence base (Craig et al., 2008). As a starting point in this project, the literature on studies evaluating the effectiveness of dietary counselling in children with food allergies was reviewed. A literature search on Medline® via PubMed® was performed using a predefined search term (Appendix A). Reference lists were screened to find additional studies. Only two studies were identified looking specifically on dietary counselling on food allergy related outcomes, of which only one was prospective (Bégin et al., 2017; Berni Canani et al., 2014). One more study investigated dietary counselling by dietitians as part of a multidisciplinary team (Kapoor et al., 2004). These studies are presented in section 1.10. Appendix A presents the documentation of the search. As concluded in chapter 1 there seems to be a lack of knowledge on the influence of dietary counselling in children with food allergy, which underpins the need for a prospective study evaluating the effectiveness of dietary counselling. The most extensive part of identifying the evidence was performed as a step in the development of the practice guideline described below, including a systematic review on three predefined research questions.

2.1.2 Identifying / developing theory

'The question of mechanisms of action is also addressed through the identification and development of the theory that underpins the proposed intervention' (Richards & Hallberg, 2015). Therefore, guidelines and position statement were searched describing dietary counselling for food allergy. These are summarised in section 1.8. However, as stated in this chapter, dietary counselling is poorly defined in the context of food allergy. Consequently, it became obvious that standards for dietary counselling must be preliminary developed to make this intervention comparable and measurable. Literature was searched to investigate methods for the development and implementation of standards of dietary counselling. The prospective study by Berni Canani (2014), evaluating dietary counselling in children with food allergy, does not describe the process of developing the intervention, but only its content. When looking at studies evaluating dietary counselling in other diseases diverse methods were identified. In these studies often only one research dietitian provided the service (Poulsen et al., 2014; Ravasco et al., 2012; Uster et al., 2013). However, this raises the question of whether the results can be generalised or whether they depend strongly on the personality of the counsellor. Bounoure et al. (2016) used a guideline approach for modelling the dietary intervention, which we felt would be reasonable for this present study, because guideline recommendations are flexible enough to realise a patient-centred approach and specific enough to be replicable by diverse dietitians. Therefore, literature on guideline development was searched. The most used method identified was AGREE II: Advancing guideline development, reporting and evaluation in healthcare (Brouwers et al., 2010). However, as dietitians in Switzerland work with the NCP, an adaption of the AGREE process by the Academy of Nutrition and Dietetic structuring the

guideline by the steps of the NCP was considered to be the best choice (Papoutsakis et al., 2017).

2.1.3 Modelling processes and outcomes

Modelling the complex intervention should bring together all active components that are known to have an effect based on empirical evidence or theory (Sermeus, 2015). One challenge of modelling dietary counselling is, as already mentioned, the patient-centred and therefore very individual approach, which is based on the needs of the specific patient (SVDE ASDD, 2020). Furthermore, food allergy is also diverse, as various foods can trigger an allergy, one or more foods can be involved, and the allergy can generate mild or severe symptoms. This implies standards of dietary counselling need a degree of flexibility in their implementation, but also must be specific so that if the intervention works, we know how to replicate it. That is also why it was decided to create a practice guideline for dietitians that can guide them through the counselling process. Chapter 4 describes the steps involved in developing the practice guideline in detail. Briefly, this included recruiting and involving stakeholders (paediatric allergists, dietitians etc) at an early stage in the project to gain a mutual understanding of the intervention. Relevant practice questions were developed in cooperation with the stakeholders and literature systematically searched for those questions where it was expected to find primary studies. These studies as well as international guidelines and position papers were used to evidence the recommendations. The draft recommendations were discussed with stakeholders and a consensus was found using the Delphi-method. Most dietitians working in hospitals with food allergic children in the German-speaking part of Switzerland were involved in the development process

which will facilitate the implementation into practice, which is important to be considered in the development phase (Richards & Hallberg, 2015).

The evaluation of complex interventions requires the definition of indicators to reflect both intervention processes and their outcomes (Buhse & Mühlhauser, 2015). To evaluate the intervention process, a tool was developed for dietitians to document the implementation of practice guideline recommendations for each patient (Appendix B). Outcome measures for the evaluation were defined by clinical experience and previous studies (Bégin et al., 2017; Berni Canani et al., 2014). These comprise health related QoL, number of allergic reactions, nutritional status, and diet diversity. These parameters have been considered to be relevant for the patients (Buhse & Mühlhauser, 2015) and might be influenced by dietary counselling. The proposed parameters were discussed with supervisors, allergists and Swiss dietitians working in the field of food allergy.

Literature was searched on studies investigating these outcomes in children with food allergy to detect potential influences besides dietary counselling. A narrative review was conducted, because such reviews are better suited to addressing a topic in wider ways than systematic reviews (Baethge et al., 2019). Literature was searched on Medline® via PubMed® using predefined keywords including all types of studies (Appendix C). Reference lists were screened for additional literature. Only literature in English and German was included. Strength and weakness of the literature were identified, but no standardised critical appraisal tool was used and no second researcher reviewed the literature as foreseen in a systematic review (Page et al., 2021). When writing this thesis, an update of the literature was performed. Chapter 3 summarises these literature reviews.

The next step was to operationalise these outcomes, based on literature reviews. A validated instrument to measure food allergy related QoL was researched and the

guideline for QoL measured by EAACI was chosen. This recommends using Food Allergy Quality of Life Questionnaire - Parent Form (FAQLQ-PF) for young children (0-12 years), a questionnaire answered by the care givers as proxies on behalf of their child. Even though it was mentioned in this guideline that there would be a validated German version, no publication of this validation existed, and the German version was not published on the Food Allergy Quality of Life Questionnaire (FAQLQ)-website nor was it available from the author of this questionnaire. Therefore, it was decided to translate, culturally adapt, and validate this questionnaire in agreement with the author (A. Dunn Galvin, personal communication, July 2, 2017) as part of this project. The process of translation and validation is described in chapter 5 and the final questionnaire can be found in Appendix D of this thesis. An alternative would have been not to measure the QoL of the child and instead measure the burden of the parents with Food Allergy Quality of Life-Parental Burden Questionnaire (FAQL-PB) (Cohen et al., 2004). In retrospect, this might have been better, as it turned out later that it was difficult for the parents to imagine oneself in the children's perspective. However, the focus would have been different with this questionnaire, and it was suggested that answering both questionnaires would have been a too high burden for the participants.

For the measurement of allergic symptoms, a literature-based questionnaire was used. Initially, however, it was planned to measure the allergic symptoms with the help of the ‘e-symptoms’ app. This app was developed by the Swiss allergy centre ‘aha!’ together with Christine Kuehne – Center for Allergy Research and Education (CK-CARE), a foundation based in Munich and Davos. It included an electronic diary for the documentation of symptoms and additional functions. Requirements of symptom measurement found in other studies using allergic symptoms as outcome (Boyano-Martinez et al., 2009; Boyano-Martinez et al., 2012; Ewan & Clark, 2005; Fleischer et al.,

2012; J. W. Yu et al., 2006) were compared with possibilities of symptom measurement in ‘e-symptoms’. Moreover, a qualitative evaluation study was performed as a bachelor thesis to compare the application of e-symptoms with the use of a standardised questionnaire in this project (see section 2.2.1). This questionnaire was based on the above-named literature, the study from Kelleher et al. (2013) and questions from the questionnaire on anaphylaxis from the German Allergy and Asthma Association [Deutscher Allergie und Asthma Bund] (DAAB, n.d.).

The final questionnaire can be found in Appendix E. It consists of 13 questions including those on the number of allergic symptoms, the date, which food had been eaten before the reaction, which food is suspected to have elicited the allergic reaction, the time until the reaction was observed, the location, whether this reaction happened and extensive information on the symptoms. This included the organ and the severity of the symptoms. One challenge was to translate the name of the symptom into the language of the patients, so that they were able to correctly answer the questions. These questions were answered for each allergic reaction independently.

Standard Deviation Scores (SDSs, z-scores) for length/height-for-age, weight-for-age, weight-for-length/height and body mass index (BMI)-for-age are parameters for growth in children (WHO & United Nations Children's Fund [UNICEF], 2009). According to WHO child growth is an important indicator of nutritional status (WHO, n.d.–b). Table 6 summarises growth problems as indicated by z-scores defined by WHO. For the calculation of z-scores the child’s weight and length or height must be collected. The best way would have been to have extra appointments in the hospital on specific time points. However, this would not have been possible due to personal and financial resources. Therefore, parents reported the weight and length or height of their child in the questionnaire at the defined time points, and the data collected in the hospital at

routine appointments was additionally collected. The hospitals were asked to use WHO criteria for their measurements (WHO, 2008).

Table 6 Growth problems as indicated by z-scores of length/height/length-for-age, weight for age, weight for length/height and BMI for age adapted from WHO (2008)

Z-score	Length / height-for-age	Weight-for-age	Weight-for-length / height	BMI-for-age
> 3	-	-	Obesity	Obesity
> 2	-	-	Overweight	Overweight
<-2	Stunting	Underweight	Wasting	Wasting
<-3	Severe stunting	Severely underweight	Severe wating	Severe wasting

Note. BMI = Body mass Index

To measure diet diversity, a comparison of various questionnaires used in the literature was made (Appendix F). The questionnaire should not be too long, in order to minimise the effort for the participants, but still cover all important food groups. Finally, it was decided to base the questionnaire on the food frequency questionnaire used in the Childhood, Allergy, Nutrition and Environment (CARE)-study, because it was already used for measuring diet diversity of children in the context of allergy in Switzerland (C. Roduit, personal communication, June 2018). Furthermore, the questionnaire was not too long and included specific foods known to often induce food allergy. The questionnaire of the CARE-study is based on the food groups defined as indicators for diet diversity by the WHO and Food and Agriculture Organization (FAO) (Food and Agriculture Organization [FAO], 2010; WHO, 2010). The final version consists of four questions on breast feeding and allergen avoidance. Then caregivers answer which of the 31 food(groups) the child ate in the last months. The selection of these food(groups) were oriented on the WHO groups (WHO, 2010). A longer recall period of four weeks was chosen to gain a more general impression of the diet diversity of the child. The final version of the diet diversity questionnaire can be found in Appendix G. Based on the

results of this questionnaire the WHO seven food group score was calculated (WHO, 2010).. The calculation of the diet diversity score is explained in section 6.2.4.

Baseline characteristics included information on the date of birth, the nationalities, income and education of the parents, the number of family members in the household, the food allergy diagnosed in hospital, information on the type of symptoms of the food allergy. When possible, questions already tested in previous studies were used for baseline characteristics. This Questionnaire can be found in German in Appendix H.

2.2 Assessing feasibility and piloting methods

This section describes the assessment of the feasibility of the evaluation study. According to Craig et al. (2019) this 'includes testing procedures for their acceptability, estimating likely rates of recruitment and retention of subjects and the calculation of appropriate sample size'.

2.2.1 Testing procedures

All questionnaires were tested before their use in the evaluation study. The translation, cultural adaption and validation of FAQLQ-PF is described in chapter 5. It demonstrates that the German version of FAQLQ-PF provides valid data on food allergy related QoL. Only sub-scores of children 0-3 should be interpreted with caution. These were therefore excluded from analysis of the evaluation study (see chapter 6).

For the measurement of allergic reactions, a student at Bern University of Applied Sciences compared in her bachelor thesis the use of the 'e-symptoms' app with the literature-based questionnaire for this project (Linder, 2018). Six parents of children with food allergies tested both instruments simultaneously and documented the allergic reactions of their children. After that the student conducted a telephone interview in

which she evaluated the usability and other advantages and disadvantages of the two instruments. The most important findings are summarised in Therefore, an app for the measurement of symptoms of food allergy would be desirable, however, the ‘e-symptoms’ app did not meet the requirements for this project and has since been withdrawn from the market. Within the project, it would have been too costly and time consuming to develop an applicable app, but it may be a subsequent project as described in section 7.3.

Table 7. Finally, it was decided to use the questionnaire in this project. The most important arguments for this decision were the additional possibilities to document the foods eaten before the allergic reaction and the more detailed information on the symptoms. Moreover, according to the developers it was uncertain how long the ‘e-symptoms’ app would be available for use and whether data protection can be guaranteed. However, the constant availability of the app in the smart phone and the direct transmission of the data would have been an advantage of using the app. Therefore, an app for the measurement of symptoms of food allergy would be desirable, however, the ‘e-symptoms’ app did not meet the requirements for this project and has since been withdrawn from the market. Within the project, it would have been too costly and time consuming to develop an applicable app, but it may be a subsequent project as described in section 7.3.

Table 7 Positive and negative aspects of the 'e-symptoms' app and the questionnaire for the use in this project based on Linder (2018)

	e-symptoms	**questionnaire**
Positive	- always available - easy saving and transmission of the data	-more detailed information on symptoms -information on foods eaten can be included - the questions are more clearly arranged
Negative	- data protection - more suitable for people with a pollen allergy	-no immediate data transfer -no pictures of symptoms

The understandability and acceptability of the diet diversity questionnaire was required to be tested in a small sample. Therefore, a link to an online version of the questionnaire in SurveyMonkey® (SVMK Inc., San Mateo, Canada) was sent to parents with children with food allergy via food allergy specific Facebook® (Facebook Inc., Menlo Park, USA) groups. Parents could comment on each question. Seven parents answered the questionnaire and commented on the questions. The questionnaire was slightly adapted according to this feedback.

2.2.2 Estimating recruitment/retention

More than half of the studies fail to recruit the expected sample size (Walters et al., 2017). Therefore, recruitment was assessed by discussions with allergists and dietitians working in children's hospitals. All hospitals in the German-speaking part of Switzerland were contacted. Dietitians and allergists were asked, if they were willing to take part in the study, how many children they diagnosed on average per week and how many they suggested – based on their experience from previous studies – could be recruited for the study. From this information it was estimated that 30-43 children are diagnosed per month in the centres willing to take part. In the absence of available recruitment rates, it was estimated that 40% would participate in the study.

Table 8 Recruitment of hospitals and estimation of newly diagnosed children with food allergy per week

Hospital	Profession	Willing to take part	Participating	Children diagnosed per week
Inselspital Berne	Allergist	no	no	2-3
	Dietitian	yes		
Children's hospital Zurich	Allergist	yes	yes	4-5
	Dietitian	yes		
Children's hospital St. Gallen	Allergist	yes	yes	1
	Dietitian	Yes		
Children's hospital Basel	Allergist	yes	yes	1-2
	Dietitian	yes		
Cantonal hospital Chur	Allergist	NF	no	-
	Dietitian	yes		
Cantonal hospital Aarau	Allergist	yes	yes	1
	Dietitian	yes		
Cantonal hospital Luzern	Allergist	NF	no	-
	Dietitian[s]	-		

Note. NF no feedback. [a] At the time of recruitment, there was no specialist dietitian available in this hospital.

2.2.3 Determining sample size

To determine the sample size needed for a significant result a power calculation was performed. At first, allergic reaction was chosen as primary outcome as it was suggested that a clinical outcome such as allergic reaction is most relevant for the children and their caregivers. However, as the literature suggests few allergic reactions happen (Boyano-Martinez et al., 2009; Boyano-Martinez et al., 2012; Fleischer et al., 2012) a sample size of 130-1228 participants would have been needed to show a reduction of 30%-50% of allergic reactions, which did not seem to be feasible for this project (Appendix I). Therefore, food allergy related QoL assessed by the FAQLQ-PF was defined as primary outcome. The sample size calculation based on food allergy related QoL is presented in chapter 6. According to this calculation a sample size of 55 participants per group would have been needed to detect a 30% difference between groups, when accounting for 20% drop-out.

2.3 Evaluating a complex intervention

The next section describes considerations regarding study design for the evaluation of the effectiveness of dietary counselling for food allergies. Then the evaluation of the process of dietary counselling is described. This is followed by first thoughts on assessing cost effectiveness in subsequent projects.

2.3.1 Assessing the effectiveness

The goal of this research project was to evaluate the effectiveness of dietary counselling of children with food allergy. Randomisation should be always considered when assessing the effectiveness of complex interventions, because it is the most robust method of preventing selection bias, which happens when those that receive an intervention systematically differ from those that do not (Craig et al., 2019). However, there are also situations in which an experimental design is infeasible or inacceptable, for example, when an intervention is already in widespread use as it is the case with dietary counselling for children with food allergy (Craig et al., 2019). Moreover, the additional cost of experimental studies should be considered when choosing the design for an evaluation study.

Since dietary counselling as an intervention for children with food allergy is already in widespread use and recommended by several guidelines (see Table 2), it would have been difficult to persuade allergists to accept an experimental design. This issue was also discussed with two allergists working in hospitals in Switzerland (A. Helbling & C Roduit, personal communications, 2016). Both confirmed that, in their opinion, it would not be possible to randomise the children to groups, as it would be unethical to deny one group dietary counselling and that Swiss allergists would therefore not be willing to randomise children to these groups. Even though the

effectiveness of dietary counselling in the field of food allergy was not proven, it would have been difficult to find allergists in Switzerland supporting such a study, which was a prerequisite.

Furthermore, the costs would have been much higher for a randomised controlled trial because a monitoring institution must be commissioned and counselling sessions and travelling costs must be paid. This would not have been possible within this PhD project with limited funding. In addition, an observational design may better reflect real-world conditions and thus, have a higher external validity than randomised trials under highly controlled conditions, which are difficult to transfer into daily practice (Singal et al., 2014).

Based on the above-mentioned consideration non-randomised design was chosen. Conducted for a Bachelor thesis, a small survey of 21 allergists in the German-speaking part of Switzerland showed that only a minority of children with food allergy receive dietary counselling (Beck & Stadelmann, 2017). This gave the opportunity to observe two groups without intervening. Children that do not receive dietary counselling receive the usual care that they would receive independent from this study. According to the above-named survey, usual care means receiving nutrition information and/or leaflets by the allergist. In case of severe reactions, an emergency kit is prescribed by the allergist independent from this project.

Another important aspect of the evaluation is the choice of outcome measures (Craig et al., 2019). As described in section 2.1.3 the outcomes defined in consultation with stakeholders are food allergy related QoL, number of allergic reactions, growth parameters as indicators of nutritional status, and diet diversity. Based on the considerations of the sample size, food allergy related QoL was chosen as primary

outcome, whereas the other three outcomes were defined as secondary outcomes in section 2.2.3.

A multi-centre approach was chosen to include a sufficient number of children, but also to include a range of dietitians to minimise the influence of the dietitian's personality. It was decided to follow the participants for a period of one year after diagnosis, so that the observation period was long enough to see the potential influences of dietary counselling. Caregivers should receive an online questionnaire at baseline, after three months, after six months and after one year. The idea behind these timepoints was that it would be beneficial to follow up more closely directly after diagnosis because it was assumed that more changes happen in this period than after half a year.

Table 9 shows which questionnaires were sent at which time point to the participants. At each time point it was asked whether the participants received counselling and how many sessions they had. Furthermore, QoL with FAQLQ-PF and diet diversity were asked at every time point. After three months parents reported the number of allergic reactions from diagnosis up to this time point. On basis of the study by Cherkaoui et al. (2015) we assumed that longer disease duration reduces the number of allergic reactions. That is why follow-up started directly after three months. Weight and height were asked at baseline, six and twelve months, because this frequency was deemed sufficient for the assessment of the development. Questions on baseline characteristics were per definition only sent at baseline.

Table 9 Questionnaires send to the participants on the four timepoints

Questionnaire	Baseline	3-months	6-months	12-months
Baseline characteristics	x			
Dietary counselling	x	x	x	x
FAQLQ-PF	x	x	x	x
Allergic reactions		x	x	x
Weight/height self -reported	x		x	x
Diet diversity	x	x	x	x

Note. FAQLQ-PF = Food Allergy related Quality of Life Questionnaire – Parent Form

Inclusion and exclusion criteria were based on pragmatic considerations. The age range of children included was set to 0-10 years. The range was chosen rather broad to avoid excluding any children because of their age, although it was suggested, based on other studies, that most children are diagnosed in the first years of life (Ferrari & Eng, 2011; Savage et al., 2016). Moreover, it was decided to focus on children with IgE-mediated food allergies. This aspect was discussed with two allergists. Arguments for this decision were that nutritional status and follow-up are rather different between IgE-mediated and non-IgE-mediated food allergies. Moreover, diagnosis is easier in IgE-mediated food allergy (P. Eigenmann, personal communication, 14. Dec 2016; A. Helbling, Personal communication, n.d.). Diagnosis should be based at least on patient history in combination with sensitisation shown by specific IgE or positive prick test (see section 1.6). Even though double-blind placebo-controlled food challenges are the gold standard, they are not routinely performed for the diagnosis in Swiss hospitals and would have therefore excluded too many children. Another criterion for inclusion was that the participants were able to answer the questionnaire in German. Retrospectively,

this criterion excluded many participants, as especially in the centres of Basel and Zurich many parents had insufficient German knowledge to fulfil this criterion. An additional English questionnaire might have led to more participants. Excluded were also children additionally suffering any intolerances or other chronic diseases influencing nutritional status, so that the outcome is not influenced by these other diseases. A list of all inclusion and exclusion criteria can be found in chapter 6.

Recruitment duration was based on a consideration of recruitment and sample size calculations in section 2.2.2 & 2.2.3. A recruitment duration of 6 to 9 months was calculated. In retrospect, these considerations were too optimistic in two respects. The number of children diagnosed in the centres and the recruitment rate were much lower than expected. However, the retention rate was lower than the 20% assumed for the sample size calculation.

2.3.2 Understanding the change process

According to the MRC model, evaluation of the change process can provide insights on the reasons why interventions fail or succeed and how they can be optimised (Craig et al., 2019). For the evaluation of the process, dietitians documented which recommendations of the guideline they implemented for each child. A further qualitative approach like interviewing dietitians and parents on how they experienced the intervention could be a subsequent project to gain deeper insights into the change process but was beyond the scope of this project.

2.3.3 Assessing cost effectiveness

The MRC model suggests including an economic evaluation, as it makes the results more useful for decision makers (Craig et al., 2019). Such an economic evaluation of dietary counselling would be helpful to justify the work of the dietitians. However, this was beyond the scope of this project. Considerations for a subsequent project on cost effectiveness are described in the last chapter of this thesis when outlining further research in section 7.3.

2.4 Implementation

Even though implementation is not explicitly part of this project, it should be considered at an early stage, as it increases the potential to be widely adopted and maintained in real life (Skivington et al., 2021). In this project, the intervention was already in widespread use. However, by publishing the practice guideline a clearer definition and a greater recognition of dietary counselling in the field of food allergy might result. Moreover, involving stakeholders such as dietitians, allergists and the Swiss patient organisation might have increased implementation of the guideline. The publication of the results of the evaluation study has the potential to further increase the involvement of dietitians in the field of food allergy. A subsequent project could be established to gain long-term data for relevant outcomes.

2.5 Theoretical positioning

The direction for this project comes from concrete problems in society, which is the unknowingness of the effectiveness of dietary counselling on children with food allergy, which could lead to an inadequate health service for this patient group. Another problem is the lack of recommendations for dietary counselling, which could result in variability of the quality of counselling among dietitians.

Therefore, a pragmatist point of view is presumed, which postulates that the goal of research is not to generate knowledge that reflects correct reality, but that knowledge is a tool to help act purposively (Cornish & Gillespie, 2009). Pragmatism adopts a position on the understanding of reality that falls between qualitative and quantitative paradigm (Bortz & Döring, 2016) and the idea is that these approaches are not in competition with each other, but each serve different purposes (Cornish & Gillespie, 2009). Therefore, it is acceptable to mix qualitative and quantitative methods, as in this research project, when it serves the main goal.

The research project incorporates quantitative and qualitative elements and can therefore be considered as mixed-method approach. Especially in applied research it is common to mix qualitative and quantitative methods. However, different views exist how these different approaches of data collection can be integrated into an overall research process (Bortz & Döring, 2016; Greene, 2008). In this project qualitative elements have mainly been included in the guideline-development process and the pre-tests of questionnaires. Quantitative data was collected in the Delphi survey of the guideline development process, the validation of the FAQLQ-PF and the evaluation study.

3 Review of the literature

This chapter narratively reviews the literature investigating the influence of food allergy on QoL, accidental reactions, nutritional status, and diet diversity. A narrative review was chosen because of the wide range of topics (Baethge et al., 2019). As described in section 2.1.3 literature was searched on Medline® via PubMed® using predefined search terms (Appendix C). Relevant literature was identified by screening title and abstract based on inclusion and exclusion criteria. Moreover, reference lists

were screened for additional literature. Strengths and weaknesses of the studies were assessed without using a standardised critical appraisal tool. Key studies in terms of their relevance for this thesis were qualitatively summarised by extracting author's name, year of publication, country of orgin, study design, subjects and controls, main results as well as comments, limitations, and bias. The first search was conducted in 2016 and 2017 and an update was performed, when writing up this thesis in 2021 and 2022. Further literature was used in this review to define terms and concepts.

3.1 QoL in children with food allergy

The WHO defines QoL as 'an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment' (WHO, 1997).

'Health related QoL is a multi-dimensional construct, consisting of physical, psychological and social components' (Dunn Galvin et al., 2008). It is commonly estimated using either generic or disease specific questionnaires. Generic health related QoL questionnaires can be used to evaluate and compare different diseases, whereas disease specific ones evaluate differences between individuals with the disease or changes in health related QoL over time (Guyatt et al., 1993).

Several studies have investigated the impact of food allergy on QoL (Table 10). A study by Protudjer et al. (2015) reported that the QoL of children aged 0-12 with staple food allergies was significantly worse when compared with healthy controls, measured using a generic health related QoL questionnaire. In another study the generic health

related QoL scores of food allergic individuals were compared with scores from the general population, and also patients with asthma, irritable bowel disease, diabetes mellitus and rheumatoid arthritis (Flokstra-de Blok, B., Dubois, et al., 2010). The health related QoL of food allergic individuals was poorer than those with diabetes mellitus, but better when compared with those who had rheumatoid arthritis, asthma, or irritable bowel disease. The same result was shown by Avery et al. (2003) whose study on children aged 9 to 10 years found that the health related QoL of children with peanut allergy was more impaired than that of children with insulin dependent diabetes mellitus. This seemed to be closely related to disease related anxiety, especially in eating situations outside familiar environments. A potential bias of this study may be the fact, that they used a self-developed QoL questionnaire for children with peanut allergy.

Table 10 Overview on key studies reporting on factors influencing health related QoL of children with food allergy

Autor, year, country	Study design	Subjects	Comparison	Results	Comments, limitations, bias
Saleh-Langenberg et al., 2015, Europe	Cross-sectional	648 food allergic patients (404 adults, 244 children)	n/a	The prediction model for food allergic children accounted for 28% of the variance of health-related QoL score. Variables significantly influencing to this variance were: perceived disease severity, having a peanut or soy allergy and country of origin. Neither experiencing anaphylaxis nor being prescribed an epinephrine auto-injector contributed to impairment of health-related QoL.	+ validated health related QoL questionnaire (FAQLQ-CF) + large sample size - diagnosis was self-reported - no long-term data
Kelleher et al, 2012, Ireland	Randomised controlled trial	Children < 16 years with food allergy (n = 52)	Randomised control group	Scores gradually improved in the group having access to a 24-hour helpline, with a significant difference seen at six months ($p < 0.005$). QoL scores remained static in the control group.	+ study design + validated QoL questionnaires (FAQLQ-PF, CF; TF) + adequately powered - external validity
Protudjer et al., 2015	Cross sectional	Children with allergy to staple foods (n= 85)	Age and sex matched children (n = 94)	Parent-reported respiratory and cardiovascular symptoms were associated with decreased health related QoL. Previous anaphylaxis and epinephrine autoinjector prescription was negatively associated with health-related QoL ($p < 0.001$ and $p < 0.003$, respectively). Children with food allergy had lower generic QoL compared to health controls ($p < 0.01$).	+ validated health related QoL questionnaires (generic EQ 5-D; disease related FAQLQ-PF) + reliable diagnosis
Flokstra-de Blok et al, 2010, the Netherlands	Cross sectional	79 children, 74 adolescents and 73 adults with food allergy	Scores of published studies on the general population, patients with asthma, irritable bowel syndrome, diabetes mellitus and rheumatoid arthritis	Food allergic patients reported lower generic health related QoL than patients with diabetes mellitus, but higher on compared to rheumatoid arthritis and irritable bowel disease. Children with food allergy reported fewer limitations in school due to behavioural problems ($p \leq 0.013$).	+ validated questionnaire (CHQ-CF87) - lack of control group

Autor, year, country	Study design	Subjects	Comparison	Results	Comments, limitations, bias
Avery et al, 2003, UK	Cross-sectional	Children with peanut allergy (n = 20)	Children with insulin dependent Diabetes mellitus (n = 20)	Children with peanut allergy reported more anxiety about eating, especially when eating out of home compared to those with diabetes mellitus. Moreover, they felt more threatened by potential hazard in their environment and felt more restricted by their peanut allergy regarding physical activities and worried about being away from home. However, they felt save when carrying epinephrine kids and were positive about eating at familiar restaurants.	+ additional qualitative measure with camara - non validated QoL questionnaire

Note. FAQLQ = Food allergy related quality of life questionnaire; PF = Parent form; CF = Child form, TF = Teenage form; CHQ = Child Health Questionnaire™ EQ 5- D European QoL-5 Dimensions; QoL = Quality of Life

Different factors have been described that may modify health related QoL in food allergic children. A study by Saleh-Langenberg et al. (2015) investigating factors predicting health related QoL in food allergic patients was conducted as part of the EuroPrevall project in multiple centres across Europe. Besides 404 adults, 244 children (8-12 years) from the Netherlands, Spain, Ireland, and Poland were included. Perceived disease severity, having peanut or soy allergy and country of origin were identified to predict health related QoL in children. However, these factors only accounted for 28% of the variance in health related QoL in children. Neither experienced anaphylaxis nor being prescribed an epinephrine auto-injector contributed to impairment of health-related QoL in this patient group. However, perceived disease severity significantly influenced the variance. A Swedish study by Protudjer et al. (2015) of children diagnosed with staple food allergy found that previous anaphylaxis and epinephrine autoinjector prescription was negatively associated with health-related QoL. Moreover, respiratory, and cardiovascular symptoms were associated with worse health related QoL. It appears as if perceived disease severity and anxiety have more impact on health related QoL than objective disease severity demonstrated by previous anaphylaxis or the prescription of an epinephrine autoinjector. Further studies are needed to be able to clearly identify factors contributing to the impairment of QoL in children with food allergy.

Although there are currently no studies investigating the effect of dietary counselling on QoL, Kelleher et al (2013) did investigate the influence of a 24-hour helpline for access to expert management on QoL, which is also an accompaniment to food allergy management. They randomised children with food allergy carrying an adrenaline autoinjector to a group with access to a 24-hour helpline or a control group receiving usual care. Whereas QoL scores in the control group remained stable, scores

gradually improved in the intervention group, with a significant difference seen at 6 months.

To conclude, health related QoL of children with food allergies appears to be worse compared to healthy children, or those with as diabetes mellitus. Psychological factors in particular (perceived disease severity and anxiety) seem to have the greatest impact. However, an appropriate level of anxiety may be needed to maintain appropriate vigilance and take necessary precautions (Polloni & Muraro, 2020). The challenge for dietitians supporting these children is to establish the right level of caution to avoid accidental reactions without unnecessary impairment of QoL.

3.2 Accidental allergic reactions after the diagnosis of food allergy

One of the most important goals in the treatment of children with food allergies is to avoid further allergic reactions. Several studies investigated the frequency of allergic reactions after the diagnosis is established (Table 11). Annual accidental reaction rates reported in these studies range from 0.12 to 0.81 reactions per child and year (Boyano-Martinez et al., 2012; Cherkaoui et al., 2015; Fleischer et al., 2012; Kansen et al., 2020; Segal et al., 2017). Postulated causes of accidental exposure are unintentional ingestion, label reading errors, and cross contact (Fierstein et al., 2021), and instances were more common when food was not prepared by the parents. Factors which reduced accidental exposure include a longer disease duration, recruitment through patients' association, and having other food allergies (Cherkaoui et al., 2015), which allows the conclusion that caution, and experience, are important prerequisites for avoiding reactions. Only one retrospective study investigated the influence of dietary counselling on accidental reactions in children with egg allergy (Bégin et al., 2017). This study found a 1.89-fold increase in the risk of allergic reaction to egg, when dietary counselling was

lacking. However, the analysis by Fierstein et al. (2021) shows that not all exposure is unintended.

One limitation of studies on accidental allergic reactions is their high risk of recall bias. Accidental exposure and consequent allergic reactions to a trigger food normally occur outside of a healthcare setting and must therefore be reported retrospectively by parents. Only the study by Fleischer et al. (2012) tried to minimise this potential bias by advising parents to immediately contact the study site in case of an allergic reaction. Recall bias might lead to under- or overestimation of the rate of accidental allergic reactions. Underreporting may occur because of parents not remembering all reactions or forgetting to inform the study site. Overreporting might happen if parents have incorrectly classified a symptom as an allergic reaction. Moreover, findings might be influenced by different treatment methods or allergen declaration regulations varying by time and country.

Data on intervention to prevent accidental allergic reactions is limited; only one study is identified, testing the use of a written management plan to prevent nut exposure (Ewan & Clark, 2005).The use of the plan reduced the frequency and severity of allergic reactions. However, the study used a before and after design with no control group, which means that inclusion in the study and extra attention received could have produced the results.

Table 11 Overview on key studies on accidental allergic reaction after the diagnosis of food allergy

Autor, year, country	Study design	Subjects	Results	Comments, limitations, bias
Fierstein et al. 2020, USA	Retrospective Analysis of data from the national patient registry	4075 respondents of which 2679 were parent of a food allergic child	Half of the respondents had one or more than one food allergic reaction per year. Nearly 10% of the allergen exposure was classified as intentional, 82% unintentional and 4.8% medically related. The main reason for intended allergen exposure of children was that the child never had severe reaction. Cross contamination was the most reported reason for unintended exposure.	+ large sample size + standardised questionnaire -retrospective design - respondents might overestimate the average number of allergic reactions per year
Kansen et al., 2019, Netherlands	Cross sectional study three years after diagnosis	Children with peanut allergy (n = 41?) Mean age: 11.5 years	Seventeen of 41 children with peanut allergy had 68 accidental reactions to peanut during three years of follow up. This results in an annual reaction rate of 68/123 = 0.55. Five children had mild or moderate symptoms, 12 reported severe symptoms.	+all children were diagnosed by DBPCFC - relatively small sample size - only vague information on treatment - potential recall bias (reporting data for a three-year period) - no data on dietary counselling or general treatment
Begin et al., 2017, Canada	Cross-sectional study.	Egg allergic children in an egg allergy influenza vaccination cohort (n=397)	Lack of consultation with a dietitian was associated with a 1.89 (CI 1.47-2.42) fold increase in the risk of accidental reactions to egg.	+ large sample size - retrospective study design - no further information on dietetic consultation available.
Segal et al, 2017, Canada	Cross-sectional study	Children with sesame allergy (n = 115) Mean age: 2.4 years	Sixteen accidental allergic reactions occurred within 100.4 patient years, resulting in 0.16 reactions per year. Five of these reactions were mild, 9 moderate and 2 were severe. Fifty percent occurred at home, two in schools, 2 in restaurants, one each in a sports venue, a friend's house, a vehicle, and an unknown location.	+ adequate sample size for sesame allergy - potential recall bias (reporting for a 12-month period) - no data which product was responsible - no data on dietary counselling or general treatment

Autor, year, country	Study design	Subjects	Results	Comments, limitations, bias
Cherkaoui et al. 2015, Canada	Cohort study	1941 children with peanut allergy Mean age: 6.9	Five hundred and sixty- seven accidental allergic reactions occurred in 429 children over 4589 patient years, resulting in 0.12 reactions per year. Thirty-seven percent of accidental reactions occurred at home, 9.3% in restaurants, 4.9% at relatives/ friends' home 3% at schools/day care, and 31.6% at others not further specified locations. Longer disease duration, recruitment through allergy advocacy association, and having other food allergies decreased the likelihood of accidental exposure and age at entry of the study ≥ 13 years as well as living with a single parent increased the risk.	+ diagnosis based on positive food challenge + large sample size + long term data - recall of a period of one year (potential recall bias) - no data on dietary counselling or general treatment
Boyano-Martinez, 2012, Spain	cross sectional study	Children with egg allergy (< 24 months) (n = 92)	Nineteen children had 24 reactions in the previous year (annual reaction rate: 0.2). Of these 16 had one reaction, two reactions, one four reactions. Ten had mild, 12 moderate and 2 severe reactions. Twelve reactions took place at home, four in a restaurant, three at school and one at a neighbour's house and two at other places. In 13 cases the causative food were candies, cakes, or cookies, in two cases fried foods coated in egg, ice cream (1 case), mayonnaise (1 case) and frozen potatoes (1 case) In two cases egg was labelled.	+ reliable diagnosis + well described criteria for allergic reactions - Recall of a period of one year (potential recall bias)
Fleischer et al., 2012, USA	Cohort study	Children with milk or egg allergy (n = 512) Median age 35.5 months	A total 1171 reactions were reported in 367 of 512 subjects over a median period of 36 months. This corresponds to an annual reaction rate of 0.81. Accidental exposure was attributed to unintentional ingestion, label-reading errors, and cross contact. In 50.6% of the reaction's food was not prepared by the parents. A higher number of food allergies (p = < 0.0001) and a higher food specific IgE (p = < 0.0001) was associated with reactions.	+ prospective cohort study + large sample size + patient contacted study site at time of reaction (minimises recall bias) - 173 children had no confirmed baseline food allergy - only vague information on treatment (written information for management)

To conclude, even when the diagnosis of food allergy is established, allergic reactions happen relatively frequently, mostly due to unintended but also intended allergen exposure. The factors associated with accidental allergic reactions (unintended ingestion, label reading errors and cross-contamination) are typical topics discussed in dietary counselling of children with food allergy. Therefore, dietary counselling might reduce the frequency of accidental allergic reactions, but this has been only investigated in one retrospective study in children with egg allergy. This thesis therefore presents a study designed to test whether dietary counselling can reduce accidental allergic reactions and improve child health outcomes.

3.3 Nutritional status of children with food allergy

The FAO defines nutritional status as the physiological state of an individual, which results from the relationship between nutrient intake and requirements and from the body's ability to digest, absorb and use these nutrients (FAO, 2007). Indicators to identify malnutrition in children proposed by the WHO and the Academy of Nutrition and Dietetics together with the American Society of Parenteral and Enteral Nutrition include z-scores for weight-for-height or length, body mass index or weight-for-age and height or length for age (Becker et al., 2014; WHO, n.d.–a). Z-scores also named SDS are used to describe how far a measurement is from the median and thus enable a comparison of growth in children (WHO, 2008).WHO defines indicators for malnutrition as weight-for-age (underweight), height-for-age (stunting) and height-for-weight (wasting) of between -2 and -3 z-scores for moderate malnutrition and ≤ -3 z-scores as severe malnutrition (WHO, 2008). Whereas overweight is defined as weight-for-age > 2 z-scores (see also section 2.1.3). Whereas wasting is a symptom of acute undernutrition, stunting is a result of long term nutritional deprivation, which can result in delayed

mental development, poor school performance and reduced intellectual capacity (WHO, n.d.–b).

Numerous studies have investigated the impact of food allergy on growth and nutritional status. Table 13 summarises key studies on the topic. Most studies reporting growth and nutritional status are however cross-sectional studies, so that growth development cannot be observed. It is also often unclear how long after diagnosis data was collected. Some of the studies use healthy matched controls for comparison (Berni Canani et al., 2014; Boaventura et al., 2019; Christie et al., 2002; D'Auria et al., 2019; Dong et al., 2018; Isolauri et al., 1998; Mehta et al., 2014; Tuokkola et al., 2017), others use national or international reference standards (Chong et al., 2018; Meyer et al., 2014; Meyer et al., 2019). It remains uncertain whether a reference standard better reflects the general population of the children than a small comparison group.

The study results are conflicting. Some observed a negative impact of food allergy on nutritional status when comparing them to healthy controls (Boaventura et al., 2019; Flammarion et al., 2011; Isolauri et al., 1998) whereas one study cannot find any influence (D'Auria et al., 2019). Nevertheless, a tendency can be seen that children with food allergies are smaller and more at risk of being underweight than their healthy age mates (Berni Canani et al., 2014; Flammarion et al., 2011). Stunting seems to be more prevalent than underweight or wasting, but overweight has also been observed (Chong et al., 2018; Meyer et al., 2014; Meyer et al., 2019). Only Thomassen et al. (2017) found higher rates for underweight and wasting than for stunting. Elimination diet and nutrient intake cannot fully explain this observation, because Flammarion et al. (2011) found that children were smaller for their age even when they received similar nutrient intake. Therefore, other factors, such as persistent inflammation and/or abnormal

intestinal permeability, but also adverse feeding behaviours are considered as influencing factor (Meyer et al., 2014).

Various studies reported z-scores for the relevant growth indices using WHO standards as reference. In these studies underweight ranged from 1.0%-10.5%, stunting from 5.3%-11.1% and wasting from 1.4% to 1.5% (Table 12) (Chong et al., 2018; Flammarion et al., 2011; Meyer et al., 2014; Meyer et al., 2019; Thomassen et al., 2017). WHO defined cut-off values for public health significance for these indicators based on the data from Onis et al. (2019) (WHO, n.d.–b). Appling these cut-off values to the results of above-mentioned studies most prevalences can be regarded as low or very low (Table 12). Only the values highlighted in bold are classified as medium according to these criteria. Uncertain is how much this prevalence reflects the distribution in the general population in these countries or is specific for the group of children with food allergy.

Table 12 Comparison of rates of underweight, stunting, wasting and overweight between studies reporting nutritional indicators in children with food allergy

Nutritional status	**Meyer et al., 2019, N=430**	**Meyer et al., 2014, N = 97**	**Thomassen et al., 2017, N =57**	**Chong et al., 2018, N = 74**
	%	%	%	%
Underweight	6.0	8.5	10.5	1.0
Stunting	9.0	**11.1**	5.3	5.4
Wasting	**5.0**	3.7	**10.5**	1.4
Overweight	**8.0**	**7.5**	NR	1.4

Note. frequencies of underweight (weight-for-age z-score < -2), stunted (Height-for-age z-scores < -2), wasted (weight-for-length/height< -2) and overweight (weight-for-length/height z-score > +2). NR = not reported

Table 13 Overview on key studies reporting nutritional status of children with food allergy

Autor, year, country	Study design	Subjects	Comparison	Results	Comments, limitations, bias
Boaventura et al. 2019, Brazil	Cross-sectional study	Children with IgE-mediated CMA (n= 27) Age: mean age 4 years (+/- 1.9)	Age- and gender matched healthy children (n = 30)	The mean height-for-age z-score was lower in those with CMA compared to healthy controls-(-0.24 vs 0.19) (p = 0.004); Children with CMA had a lower calcium (p = 0.0033) and lipid (p = 0.0043) intake.	- five children received fruit juice as cow's milk substitute. - small sample size - not clear how long the elimination diet has been in place
D'Auria et al 2019, Italy	Cross sectional, case control study	Children with IgE-mediated food allergy (n = 30)	Sex and age matched controls (n = 31)	No differences between children with food allergy and healthy controls were found regarding resting energy expenditure, anthropometric indicators, or dietary intake.	+ no external funding + elimination diet for at least 6-month + data on dietary counselling - cut-off points for BMI z-scores not reported - other growth parameters not reported -small sample size
Chong et al. 2018, Singapore	Cross sectional study	Children with IgE- and non-IgE-mediated food allergy (N = 74) Age: median age 25 month	WHO-Growth Data	Of the children with food allergies 1% were underweight (weight-for-age ≤ -2 z-scores), 5.4 % stunted (height-for-age ≤ -2 z-scores) and 1.4% undernourished (weight-for-height≤ -2 z-scores), but 1.4% was overweight (weight-for-height≥+2 z-scores) Weight-for-age was significantly lower for those referred to the dietitian (p= 0.027). Eczema, IgE-mediated and mixed type allergies were associated with poorer growth rates. No correlation for number of foods avoided or type of food elimination and reduced growth was found.	- no information on funding - lack of control group - no data on duration of elimination diet - no data on assessment method -numbers reported in the abstract are inconsistent to those in the result section
Meyer et al. 2018, international	Cross sectional survey	Children with IgE and non-IgE-mediated food allergy (N = 430)	WHO-Growth Data	Of the children with food allergy 6% were underweight (weight-for-age ≤ -2 z-scores), 9% stunted (height-for-age ≤ -2 z-scores) and 5% undernourished (weight-for-height≤ -2 z-scores). Growth parameters were significantly higher for weight-for-height, height-	+ large sample size + reliable analysis - data collection not comprehensible - lack of control group

Autor, year, country	Study design	Subjects	Comparison	Results	Comments, limitations, bias
		Median age: 23 months		for-age, and BMI where nutritional input was available; milk exclusion diet significantly impacted all growth parameters.	- no data on duration of elimination diet - no long-term data
Dong et al., 2018, China	Cohort study (24 months)	Children with milk allergy (n=60) Age: mean age 3 ± 0.9 months at enrolment	Age matched healthy children (n=60) Age: Mean age 2.8 ± 1.2 months at enrolment	Weight-for-age z-scores were significant lower in the milk allergy group at 6, 9, 12 and 18 months, but not at 24 months; No significant difference in length for age z-score. Weight-for-length z-score was significantly lower in the milk allergy group.at 9 and 12 months	+ control group + long term data - relatively high dropout rate (18% in the milk allergy group and 21% in the control group)
Thomassen & Kvammen et al. 2017, 2018, Finland	Cross sectional study	Children on a milk elimination diet (n = 57) Age: 0 to 2 years	National reference standards	Underweight (weight-for-age z-score ≤ -2) was 10.5%; stunting (length for age z-score ≤ -2) 5.3 % and BMI-for-age z-score ≤ -2 = 10.5 %	+ data on dietary counselling - lack of control group - Breast milk was not included in the calculation of nutrient intake
Tuokkola et al. 2017, Finland	Retrospective Case control study of a birth cohort study	Children with cow's milk and /or wheat, barley, or rye allergy (n = 295)	Matched controls (n = 265)	Children with milk elimination grew slower than healthy controls ($p = 0.009$). The growth of children with both milk and wheat, barley or rye elimination diets followed similar pattern to those with only a milk allergy. Protein and calcium intake were lower in children with milk elimination compared to controls ($p < 0.5$). Children on elimination diet consumed less saturated fat and sugar as well as more vitamin C and ion than controls.	+ large sample size + long term data + standardised measurements - parentally reported food allergies - retrospective design - only infants carrying human leucocyte antigen genotypes were included

Autor, year, country	Study design	Subjects	Comparison	Results	Comments, limitations, bias
Berry et al. 2015, Finland	Prospective cohort study	Children with milk allergy (n = 18)	Children with milk and wheat allergy (n = 28)	The markers of nutritional status, nutrient intake or height-for-age, and weight-for-age were comparable between the group with milk allergy and the group with milk and wheat allergy in the follow up at the age of 12, 21 and 28 months. The means for anthropometric measures were below the average for age in both groups.	+ long term data + data on duration of food allergy + data on dietary counselling - small sample size - they compare only milk allergy with milk and wheat allergy, even though some children seem to have more allergies
Berni Canani, 2014, Italy	Prospective cohort study	Children with food allergy (n = 91)	Children without food allergy providing baseline values only (n = 66)	Children with food allergy had a lower energy and protein intake at enrolment than healthy controls (p = < 0.001) and a weight to length ratio < -2 z-scores was more frequent in children with food allergy (p = < 0.001). After six-month, energy intake was similar to the baseline values of healthy children. Also, nutritional status improved.	+ long term data + data on dietary counselling + data of the duration of food allergy (start with diagnosis) - lack of control group with children not receiving dietary counselling
Meyer et al. 2014, UK	Cross sectional study	Children with IgE or non-Ige-mediated food allergy (n = 97)	WHO-data	Of the children with food allergy 8.5 % were underweight (z-score ≤ -2), but on the opposite site 8.5% were overweight (z-score ≥ +2 z-scores). Stunting (weight-for-length/height z-score ≤ -2) was present in 11.1%.	+ data on dietary counselling - no data on dietary advice - no data on the duration of food allergy - lack of control group
Metha et al., 2014, USA	Retrospective chart review	439 children with food allergies	9938 non-food allergic children	In the group of children with commercial health insurance children with food allergy were significantly shorter (mean height z-score 0.06 versus 0.42, p = 0.01) and weighted less (mean weight z-score -0.1 versus 0.07, p = 0.006) compared to the children without food allergy. Children with state insurance were not smaller in weight or height. Children with CMA weighted significantly less than children without milk allergy (p = 0.0006). No association was found between multiple food allergies and poor growth.	+ large sample - retrospective design

Autor, year, country	Study design	Subjects	Comparison	Results	Comments, limitations, bias
Flammarion et al., 2011, Belgium	Cross sectional study	96 children with food allergy Mean age 4.7 ± 2.5 years	95 paired controls Mean age 4.7 ± 2.7 years	Children with food allergies had lower weight -for-age and height-for-age than controls (0.1 vs 0.6 and 0.2 vs 0.8). Children ≥ 3 food allergies were significantly smaller than those with ≤ 2 food allergies ($p = 0.04$). Children were smaller for their age even when they received similar nutrient intake.	+ control group + sample size + data on dietary counselling + elimination diet at least 4 months -no long-term data Treatments might have changed since 2011
Christie et al., 2002, USA	Cross sectional study	98 children with food allergy Mean age 3.7 ±2.3 years	99 age-matched controls Mean age 4.1 ± 2.4 years	More children with food allergy were below the 25th percentile for height-for-age compared to the control group; however, this was not significant. Children ≥ 2 food allergies were shorter based on height-for-age percentile than those with one food allergy ($p = 0.05$). Children not receiving dietary counselling were more likely to have an intake of vitamin D and calcium below 67% of the dietary reference intake ($p < 0.05$).	+ control group + data on dietary counselling - no data on duration of elimination diet Treatments might have changed since 2002
Isolauri et al., 1998, Finland	Cohort study	100 children with atopic dermatitis and CMA Mean age 7 months	60 age-matched controls	The mean length SDS and weight-for-length index of children with food allergy decreased compared to controls ($p < 0.0001$ and $p = 0.03$). The relative weight continued to fall compared to the control group ($p = 0.03$). Impaired growth was more pronounced in children with early onset than in those with later onset of symptoms ($p < 0.0001$). No catch-up growth at the age of 24 months.	+ long-term data (13 months) +sample size +data on dietary advice (not clear if given by a dietitian) Treatments might have changed since 1998.

Note. CMA = Cow's milk allergy

The relationship between specific food allergens, growth and nutritional status has also been investigated. The focus is particularly on cow's milk allergy (CMA), as cow's milk is one of the most common food allergens in infants and toddlers and a supplier of important nutrients and energy at this age. Isolauri et al. (1998) found that mean length z-score and weight-for-length index of children with CMA decreased significantly compared to healthy controls. A more recent cohort study from China by Dong et al. (2018) could not confirm the observation that children with CMA are shorter for their age, but found significant lower weight-for-age z-scores at six, nine, twelve and 18 months, though not at the age of 24 months. Furthermore, the weight-for-lengths z-scores were lower at 9 and 12 months. A limitation of this study is the relatively high dropout rate (> 18%), which can only partly be explained by the long observation time. It is also questionable to what extent these results from China can be transferred to the situation in Switzerland. Another recent but rather small cross-sectional study by Boaventura et al. (2019) compared children with IgE-mediated CMA with age and gender matched healthy controls and found that mean height-for-age z-score was lower in those with CMA. Furthermore, children with CMA had significantly lower calcium and lipid intake.

Tuokkola et al. (2017) compared 295 children with milk and/or wheat, barley, or rye allergy with 295 matched controls and found that children on milk elimination diet grew significantly slower than controls, but wheat, barley or rye elimination was not associated with growth. Other studies are consistent with these findings. Thus, Mehta et al. (2014) found that children with CMA were significantly shorter and weighed less than controls, whereas no difference was found for children having peanut, tree nut, egg, fish, shell fish or wheat allergy. Also, the international survey by Meyer et al. (2019) detected a significant negative impact of CMA on growth, which was in contrast to a

former survey by Meyer at al. (2014) conducted in the UK in which they did not find an impact of specific food elimination on the level of malnutrition.

Findings on the impact of the number of food allergy on growth are conflicting and study designs of the described studies are limited, so that to date no conclusion on the impact of the number of food allergies can be drawn. A systematic review by Sova et al. (2013) including six studies with children suffering from two or more food allergies concluded that children with multiple food allergies have a higher risk of impaired growth and may have a higher risk of inadequate nutrient intake than children without food allergy. Moreover, data from the above-mentioned survey by Meyer et al. (2014) supports this hypothesis by observing that children with three or more food allergies are significantly more often underweight. A study by Berry et al. (2015), however, could not confirm this observation. They compared children with CMA with children with cow's milk and wheat allergy and found comparable results for height-for-age and weight-for-age between these groups suggesting that the extent of food elimination diet has no influence, when diet is adequately supervised. A limitation of this study is the small sample size and missing data on how many foods were eliminated besides milk and wheat. Also, Metha et al. (2014) could not find an association between multiple food allergies and poor growth. In addition, the international survey of Meyer et al. (2019) does also not support the hypothesis that the number of food allergies has an impact on growth. They speculate that this might be due to children with multiple food allergies receiving more support and nutritional input.

The influence of dietary counselling on growth and nutritional status has been observed in some, but not all studies. Christie et al. (2002) found that children not receiving dietary counselling were more likely to have an intake of vitamin D and calcium below 67% of the dietary reference intake. A prospective cohort study by Berni Canani

(2014) specifically investigated the impact of dietary counselling on nutritional status of 91 children with food allergy. At diagnosis children with food allergy had significantly lower energy intake than the 66 healthy controls and a weight-to-length ratio below -2 z-scores was significantly more frequent in the children with food allergy. After six months, energy intake was similar to the baseline values of healthy children and nutritional status improved. However, due to the lack of a control group of children with food allergy not receiving dietary counselling, it is difficult to clearly attribute this improvement to the effect of dietary counselling.

To conclude, nutritional status of children with food allergies may be influenced by a variety of factors. Besides the elimination diet as most obvious one, especially, when staple foods are involved, further potentially influencing factors are discussed, as elimination diet alone cannot explain impaired growth of children with dietary unimportant foods such as peanuts (Meyer et al., 2014). Children with CMA seem to be at higher risk for impaired growth, but the influence of the number of food allergies is still uncertain. Finally, the impact of dietary counselling on nutritional status and growth needs to be further investigated. This thesis presents work which investigates growth of children with food allergy receiving dietary counselling compared to those not receiving such treatment.

3.4 Diet diversity in children with food allergy

Numerous definitions of diet or food or dietary diversity exist. The EAACI position paper on diet diversity in pregnancy, infancy and childhood uses the definition by Ruel (2003), who defined diet diversity as the number of different foods or food groups over a given period (Venter et al., 2020). This recently published position paper provides a

comprehensive overview of the topic, which is why only the most important aspects in connection with this thesis are presented here.

Diet diversity of children with food allergy might be impacted by the elimination diet, as well as the anxiety of parents introducing new foods in their child's diet when they have previously experienced an allergic reaction to a food. Diet diversity has been positively associated with nutritional status independent of socioeconomic factors, and it may also reflect diet quality (Arimond & Ruel, 2004). Moreover, a diverse diet might prevent food allergy and food allergy sensitization (Roduit et al., 2014). This might also be important for the prevention of additional food allergies in those children already allergic to some foods. Data from the Learning Early about Peanut Allergy (LEAP), Enquiring About Tolerance (EAT) and other related studies suggests that early introduction of a specific food prevents allergy to this food (Du Toit et al., 2008; Perkin et al., 2016; Silva et al., 2021). Thus, a diverse diet might prevent diverse food allergies by early exposure to these foods, which is why, diet diversity may also be important for secondary prevention of food allergy. Moreover, diet diversity might influence further allergy development by modifying the child's microbiota (Bisgaard et al., 2011; Savage et al., 2018).

Whilst diet diversity can be argued to be an important outcome as it might be adversely affected by the existing food allergy, be associated with nutritional status and prevent additional food allergies, to date only one study investigated diet diversity in children with established food allergy. Maslin et al. (2016) conducted a cross-sectional study in children with CMA aged 8 to 27 months and controls. They found that children on a milk exclusion diet had a significant lower overall diet diversity, including a less varied consumption of meat and sweet foods, but more ready-made baby foods. Even though evidence on diet diversity in children with established food allergy is very limited,

it is reasonable that a diverse diet is an aim of dietary counselling and was therefore be investigated in this study.

Table 14 summarises the above-named studies on diet diversity for food allergy prevention and in children with established food allergy.

Table 14 Studies reporting on diet diversity in relation to food allergy and food allergy prevention in children

Autor, year, country	Study design	Subjects	Comparison	Results	Comments, limitations, bias
Maslin et al., 2016, UK	Cross sectional study	66 children consuming a milk exclusion diet Mean age 13 month	60 children with unrestricted diet	The children on cow's milk exclusion diet had a significant lower overall dietary diversity ($p < 0.05$). They consumed less variety of meat and sweet foods and more ready-made baby food. There was greater concern with healthy eating in the group of children on cow's milk exclusion diet ($p < 0.05$).	- no validated diet diversity index - no long-term data
Roduit et al., 2014, Europe	Prospective cohort study (Birth cohort)	856 new-borns	n/a	An increased diversity of complementary food introduced in the first year of life was inversely associated with food allergy and food sensitization.	+ large sample size + long term data -no validated diet diversity index

Note. n/a = not applicable

4 Practice guideline development

This chapter describes the process of the development of the practice guideline as a tool to standardise and document dietary counselling of children with food allergy as introduced in section 2.1.3. The article on the development process was published in Allergo Journal International in 2020. The permission to reprint the article in this thesis can be found in Appendix J. The following section is a reprint of this article. The full version of the practice guideline can be accessed online in German on the website of Bern University of Applied Sciences https://www.bfh.ch/dam/jcr:34f97a5a-0065-45ba-8340-fc37e0f62abe/ERNA.pdf.

4.1 Development of a practice guideline for dietary counselling of children with IgE-mediated food allergy

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4.1.1 Abstract

Purpose

The incidence of food allergy is increasing globally and whilst there is consensus that dietitians should be involved in its management, the roles that dietitians should fulfil differ between different guidelines and the description of tasks remains unclear. Currently, no Swiss guideline exists to assist dietitians in counselling children with food allergies. There is a need for recommendations that will guide dietitians through the counselling process. The aim of this project was to create a practice guideline for dietary counselling of children with food allergy.

Methods

Practice guidelines were developed following the Academy of Nutrition and Dietetics stepwise approach. The process consisted of six steps: 1. Determine the scope of the guideline. 2. Conduct a systematic review. 3. Draft the guideline recommendations using the NCP as a framework. 4. Finalise the guideline during a face-to face meeting. 5. Conduct internal and external review and revise accordingly. 6. Publish guideline.

Results

The process resulted in 25 recommendations for dietary counselling. Most recommendations are based on expert opinion only, due to the lack of studies in this field and showed similar levels of consensus between the expert group and external review by allergists. However, there were nine recommendations where the consensus differed.

Conclusion

This guideline provides a comprehensive guide to dietary counselling for food allergy by dietitians in Switzerland. It will inform best practice and improve patient-centred care and encourage a consistent approach, but it will need to be reviewed and updated as more robust evidence is produced.

Keywords

dietary counselling, food allergy, practice guidelines, children, dietitians

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4.1.2 Background

An allergy is a hypersensitivity reaction initiated by immunologic mechanisms (Johansson et al., 2001); the World Allergy Organisation estimates the incidence of food allergy in toddlers at five to eight percent (Fiocchi et al., 2013) and it appears to be increasing globally (Prescott et al., 2013). In this age group, staple foods including cow's milk, hen's egg, wheat, and foods that are difficult to avoid, such as peanuts and hazelnuts, often cause allergic reactions (Ferrari & Eng, 2011). Food allergies are commonly managed by the avoidance of allergy-inducing substances (Worm et al., 2015). However, long-term elimination diets without supervision can lead to nutrient deficiency, poor nutritional status (Flammarion et al., 2011) and a less varied diet (Maslin, Dean, et al., 2016). Moreover, the elimination and replacement of problem foods can lead to increased strain on families and is associated with fear of accidental contamination, especially if multiple or difficult to avoid foods are involved [8]. All of these factors can result in a significantly lower QoL for the person concerned and his/her family (Flokstra-de Blok, B., van der Velde, J. L., et al., 2010).

Patients with confirmed food allergy need clear recommendations and guidance from a qualified health professional to implement the elimination diet into daily life. European and international guidelines recommend involving dietitians with competencies in food allergy, including diagnosis and management (Fiocchi et al., 2010; Muraro, Werfel, et al., 2014; NICE, 2011; Worm et al., 2015). The roles that dietitians should fulfil in the management of children with food allergy differs between different guidelines and the description of tasks remains unclear. The European guideline and the German guideline list topics which should be covered in dietary counselling of patients with food allergy (Muraro, Werfel, et al., 2014; Worm et al., 2021) and the European

Academy of Allergy and Clinical Immunology recently published competencies for healthcare professionals working in allergy (Skypala et al., 2018). The guideline by the Australasian Society of Clinical Immunology and Allergy is the only one that clearly defines the role of a dietitian in the diagnosis and management process and gives concrete recommendations for dietitians working with patients with food allergy (ASCIA, 2017). Other professional societies including the Academy of Nutrition and Dietetics and the International Network for Diet and Nutrition in Allergy, have published position papers on the role of a dietitian in the diagnosis and management of patients with food allergy (Collins, 2016; Venter et al., 2012). However, these documents are mainly based on expert opinions and their development was not structured nor was their influence evaluated.

Guidelines provide a standardised approach to practice and are able to optimise patient care by providing consistency across healthcare settings (Hollon et al., 2014; Melnyk, 2012). They also improve the effectiveness of practice by reducing risk of harm and ineffective variations in care (Hollon et al., 2014; Kredo et al., 2016). However, it is widely acknowledged that clinical guidelines should be adapted to meet individual needs and preferences where possible (van Dulmen et al., 2015).

Therefore, the aim of this project was to develop a guideline for dietitians counselling children with diagnosed IgE-mediated food allergy. A special focus was placed on children with CMA as they are particularly affected by nutrient deficiencies (Lifschitz & Szajewska, 2015; Luyt et al., 2014).

The guideline can be used by dietitians working in private practice and in hospitals in Switzerland. Moreover, this approach can be transferred to inform guideline development in other countries. The goals of this guideline are to improve patient QoL, to avoid unnecessary food restrictions, to enable adequate nutrient intakes, to provide

strategies on avoiding accidental allergen uptake, and to facilitate general allergen avoidance in the daily lives of children with IgE-mediated food allergy and their families.

4.1.3 Methods

This guideline is based on the stepwise approach for development of evidence-based nutrition practice guidelines by the Academy of Nutrition and Dietetics, with slight modification (Papoutsakis et al., 2017). Table 15 outlines the implementation process. This method was chosen as it structures the guideline according to the NCP which is a standardised framework for dietetic practice that is recommended to be used by the SVDE ASDD. The NCP is composed of four steps of patient care; nutrition assessment, nutrition diagnosis, nutrition intervention, plus nutrition monitoring and evaluation (American Dietetic Association, 2008).

Table 15 Implementation of guideline development process by the Academy of Nutrition and Dietetics for the practice guideline of children with IgE-mediated food allergy (Papoutsakis et al., 2017)

Steps		Implementation
1. Determine the scope of the guideline		a. The goal of the guideline was defined by SB and JE, and practice questions developed based on existing guidelines, position papers and review papers.
		b. Experts judged the relevance of the questions on a five-point scale on a SharePoint® workspace.
2. Conduct Systematic Review		A Systematic review was conducted by CR and JE on three topics following the stepwise approach of the Academy of Nutrition and Dietetics (Handu et al., 2016).
3. Draft guideline recommendations using the NCP model as a framework		a. A draft of the guideline with the recommendations, background information and advantages and disadvantages of each recommendation was developed by SB and reviewed by JE.
		b. The experts commented on the draft guideline on a SharePoint® workspace.
4. Finalise guideline during a face-to face meeting		Open questions were discussed in a face-to-face meeting with experts. The discussion was prepared by SR and moderated by JE.
5. Conduct internal/external review and revise		a. Internal Review: Two rounds of an online Delphi Survey were sent to the experts. Recommendations receiving less than 70% full agreement in the second round were excluded from the guideline
		b. External Review: The adapted online survey was sent to allergists working in the German speaking part of

		Switzerland for external review. Sixteen paediatric allergists answered to what extent they agreed that dietitians should fulfil these tasks.
6. Publish guideline; Evaluate for Revision		The full guideline is published on the website of Bern University of Applied Sciences. It is planned to evaluate the guideline. The revision will be in 5 years.

A guideline development group was convened and comprised JE, SB, CR and an expert group of health professionals, selected according to their knowledge, competency, and expertise in food allergies. The experts included ten dietitians from all areas of the German-speaking part of Switzerland working in the field of food allergy, as dietary counsellors for hospitals or in private practice. The expert group also included a representative of the national patient organisation aha! Swiss Allergy Centre and one paediatric allergist. The group undertook a stepwise approach to the development of the guideline.

Step 1: Scope of the guideline: This step involved developing a goal for the guideline and relevant practice questions formatted by the PICO structure (Patient, Intervention(s) or Exposure(s), Comparison and Outcome) (Speckman & Friedly, 2019). The expert group evaluated these questions using a 5-point scale regarding their relevance for practice (0 not relevant to 5 very relevant) (Appendix K).

Step 2: Systematic review: In undertaking step 1, by screening guidelines, expert reviews, and position papers, three topics were identified which were expected to be found in primary literature. These were ‘formula for infants with CMA’, ‘dietary advice for patients with food allergy’ and ‘growth, nutrient intake and food allergy’. Systematic reviews were conducted on these three topics using the five-step approach recommended by the Academy of Nutrition and Dietetics (Handu et al., 2016). CR and JE searched for articles in Medline®, Embase® and Cochrane® and included relevant studies regarding predefined inclusion and exclusion criteria. Two authors (CR and JE)

critically appraised these studies. CR and JE summarised the evidence (Appendix L) and wrote a conclusion statement (Table 16). Those statements informed the recommendations to be included in this guideline.

Table 16 Summary of the systematic literature search using the method of the Academy of Nutrition and Dietetics (Handu et al., 2016)

Topic	Nutrient intake	Infant formula	Dietary advice
PICO Questions	P: Children with IgE-mediated food allergy I: Dietary avoidance C: n/a O: Nutrient intake, height/length, weight, growth	P: Infants with CMA I: infant formula C: Other formula O: Symptoms, growth, nutrient intake	P: Children with IgE-mediated food allergy I: Dietary advice C: n/a O: Tolerance, growth, nutrient intake, quality of life
Search term	(children OR child OR paediatric OR infant) AND ((food OR milk OR egg OR peanut OR wheat OR soy OR fish) allergy) AND (((nutrient (intake OR deficiency)) OR weight OR growth))	(Infant OR baby) AND (milk allergy OR CMA) AND ((extensively OR partially) hydrolysed OR hypoallergenic OR amino acid formula) (symptoms OR nutrient intake OR growth OR weight)	(dietary OR nutritional OR nutrition (advice OR counselling OR counselling OR information)) and ((food OR egg OR nut OR peanut OR soy OR milk) allergy) and (tolerance OR growth OR nutrient intake OR quality of life)
Limits	5 years, English	5 years, English	5 years, English
Number of included studies	3 Cohort studies 2 Case control studies 5 Cross sectional Study	7 Randomised controlled trials 1 Cohort Study 5 Noncontrolled Trials	3 Randomised controlled trials 2 Noncontrolled Trials
Conclusion statements	- Children with food allergy may be smaller and lighter than healthy children. - Children with CMA and multiple food allergies may show more micro-nutrient deficiencies. - More studies are needed to further investigate the effect of food allergy on growth and nutrient intake.	- Normal growth can be archived with Amino Acid formula. - Hints that probiotics might have a positive effect on tolerance development.	- More studies are needed to be able to give evidence based dietary advice for children with food allergy. - Hints that eating baked milk products of children tolerating these products might have a positive effect on tolerance development in children with CMA.

Step 3 Draft the guideline: Two authors drafted the guideline (SB and JE) using the NCP structure for guidance based on the results of the systematic reviews conducted in step 2, existing guidelines, position papers, expert reviews and a qualitative study based on interviews with Swiss dietitians (Ruch, 2017) (Appendix M). The expert group commented on this draft using an online SharePoint® (Microsoft Corporation, Redmond, USA). Table 17 shows a summarised version of the Academy of Nutrition and Dietetics rating scheme and grading system. Evidence is based on the elements of quality, consistency, quantity, clinical impact, and generalisability.

Table 17 The rating scheme for the strength of the recommendations adapted from the Academy of Nutrition and Dietetics (Papoutsakis et al., 2017)

Statement rating	Definition
Strong (I)	The benefits of the recommendation clearly exceed the harms and the quality of the evidence is good (grade I or II).
Fair (II)	The benefits of the recommendation exceed the harms, but the quality of the evidence is not as strong (grade II or III).
Weak (III)	The quality of the evidence is suspect or that well-done studies (grade I, II or III) show little clear advantage.
Consensus (IV)	Expert opinion (grade IV) supports the recommendation even though the evidence does not support consistent results, or controlled trials are lacking.
Insufficient Evidence (V)	A lack of pertinent evidence (grade V) and/or an unclear balance between benefits or harms.

Step 4 Face-to-face meeting: The agenda for the face-to-face meeting to finalise the guideline was based on the remaining draft comments. The guideline was adapted according to the results of the meeting.

Step 5 Review and revise the guideline: Internal Review: Two rounds of an online Delphi Survey were sent to the experts (Keeney et al., 2011). Recommendations receiving less than 70% full agreement in the second round were excluded from the guideline. An online questionnaire was sent to the experts of the guideline development group using SurveyMonkey®(SVMK Inc., San Mateo, Canada). For each recommendation respondents registered their agreement using a 5-point Likert scale (1 fully agree to 5

strongly disagree). Furthermore, they had the option to add comments. The Delphi process reduced recommendations from 31 to 25. Additionally, these 25 recommendations were sent to allergists working in the German speaking part of Switzerland for external review. Sixteen paediatric allergists answered to what extent they agreed that dietitians should fulfil these tasks on a Likert scale (1 fully agree to 5 strongly disagree). Internal and external review were analysed using Excel® (Microsoft Corporation, Redmond, USA). The frequency of the answers 'fully agree' and 'considerably agree' of the internal and external review is reported in tables 4 to 6.

Ethics

Participants of the expert group signed an informed consent form. The project was ethically approved by the Research Ethics Committee for the Faculty of Health & Human Sciences and Peninsula Schools of Medicine & Dentistry, Plymouth University. A jurisdictional inquiry was submitted to the Ethics Committee Bern, who advised that it did not require their approval, because no generalisable and health related data was obtained in this research project.

4.1.4 Results

The final version of the practice guideline consists of 25 practice recommendations. Nine recommendations for the nutrition assessment of children with diagnosed IgE-mediated food allergy (Table 18). Thirteen recommendations for nutrition intervention (Table 19) and three for nutrition monitoring (Table 20). The recommendation to define nutrition diagnoses was excluded as a consequence of the Delphi rounds it did not reach the required consensus level, leaving recommendations for three of the NCP steps.

There are only three recommendations that are based on published research evidence in addition to expert opinion. These are recommendation 10 on substitutes for children with CMA, recommendation 12c on supplementation for 'prevention and therapy of nutrition deficiencies' and recommendation 14e on 'when indicated discuss oral challenges with allergist' for QoL promotion. All other recommendations are based on expert opinion of guidelines, position papers, expert reviews, interviews with dietitians and the opinion of the expert group.

The majority of the recommendations showed similar levels of consensus between the expert group and allergists. However, there were nine recommendations where the results differed by 20% or more; 9c, 11b, 11c, 11d, 11e, 15c, 17, 24 and 25 (Table 18-Table 20)

Table 18 Evidence and consensus level for the recommendations relating to the nutrition assessment process

Recommendations: Nutrition Assessment	EL[a]	CL E [b] (%)	CL A[c] (%)
Food/Nutrition Related History			
1. Diet history The dietitian should obtain a diet history	IV	91	100
2. Content of diet history The diet history should include the following: a) Intake of foods and beverages b) Tolerated foods c) Avoided food(group)s and reasons therefore d) Use of substitute products and/or supplements	IV	100	100
3. Suitable assessment methods The dietary intake of the child with diagnosed food allergy can be obtained via diet history, 24 h recall or a dietary record. In case of risk of nutrient deficiency, a three-day food diary should be taken.	IV	89	92
4. Evaluation of assessment Depending on the allergy the intake of specific nutrients will be evaluated.	IV	100	88
Anthropometric Measurements			
5. Weight and height The dietitian should consider height and weight in the assessment and compare it to growth charts with children of the same age and gender.	IV	91	94
Biochemical Data, Medical Tests and Procedures			
6. Diagnostic tests and diet specific laboratory parameters The dietitian considers results of allergy specific diagnostic tests (specific IgE, skin prick tests and food challenges) in the assessment. If they are not available, they should be requested. If available, the dietitian includes diet specific laboratory parameters in the assessment.	IV	100	81
Nutrition-Focused Physical Findings			
7. Overall impression of the child The dietitian should consider the overall impression of the child in the assessment. Moreover, allergy-specific co-morbidities should be documented. This requires close collaboration with the allergist.	IV	100	100
Client History			
8. Content of client history The client-assessment for children with food allergy should include:			
a) Medical situation	IV	100	100
b) Language requirements	IV	91	100
9. Allergy specific medical history The dietitian should assess the following aspects, if not present in the medical records:			
a) Known allergies and other atopic diseases and other medical diagnoses	IV	89	81
b) Symptoms of food allergy	IV	100	100
c) Atopic diseases in the family	IV	89	69

Note. [a] EL evidence Level, [b] CL E (%) consensus level expert group, [c] CL A (%) consensus level allergists

Table 19 Evidence and consensus level for the recommendations relating to the nutrition intervention process

Recommendations: Nutrition Intervention	EL[a]	CL E [b] (%)	CL A[c] (%)
Food and/or Nutrient Delivery			
10. Substitutes for children with CMA The selection of an adequate infant formula for children with CMA should be in consultation with the responsible allergist. The allergist will prescribe the formula. For the selection, various individual factors should be considered such as nutrient content, cost, and flavour. The nutrient intake of the child should be regularly monitored. A stepwise approach is recommended: 1. First choice: breast milk, eventually avoidance of the culprit food 2. Formula with extensively hydrolysed cow's milk protein (EHF) 3. Amino Acid Formula (AAF) *(comment: In Switzerland costs are covered by medical insurance, if EHF is not effective)*	II	100	100
11. Unsuitable substitutes for CMA For CMA, the following products are *not* suitable as breast milk substitute and therefore *cannot* be recommended:			
a) Infant formula comprising of soy or rice (rice formula not available in Switzerland), depending on the age of the child [d]	IV	89	77
b) Partly hydrolysed infant formula	IV	90	62
c) Lactose free milk and milk drinks	IV	100	80
d) Cereal or nut drinks are not recommended as milk substitutes but can be used for meal preparation	IV	100	80
e) Milk and infant formula of other mammals, such as goat or sheep, in most cases [d]	IV	100	69
f) Self-made infant formula	IV	100	82
12. Prevention and treatment of nutrient deficiency Careful support and monitoring of the diet by an experienced dietitian are important to avoid or treat nutrient deficiencies. Therefore, the following interventions are recommended:			
a) Education on alternative products with adequate nutrient coverage I. Alternative products to replace avoided food(s) II. Use of substituted products	IV	100	100
b) Alternative products for meal preparation	IV	90	100
c) Where appropriate discuss supplementation	III	100	100
Nutrition Education			
13. Training in allergen avoidance The dietitian should empower the child with food allergy and the parents to avoid the allergy-eliciting food in daily life without being too restricted. Therefore, the following topics should be discussed in dietary counselling:			
a) How to avoid the allergen uptake: Which products may contain the allergy-eliciting food and respectively, which foods should be avoided	IV	100	100
b) Meal preparation safety and techniques	IV	90	100
c) Discussion of unnecessary restrictions	IV	100	93
d) Effects of the disease on nutrition	IV	100	93
14. quality of life promotion To improve the quality of life of the child and their parents, the dietitian should discuss the following topics:			
a) Recommendation to assure a clear diagnosis	IV	100	93
b) Consider individual tolerance	IV	100	93
c) Consider personal preferences	IV	100	100

Recommendations: Nutrition Intervention	EL[a]	CL E [b] (%)	CL A[c] (%)
d) Handling of out of home consumption	IV	100	100
e) When indicated discuss oral food challenges with allergist	III	100	93
15. Food law The legal basis of allergen information on prepacked and non-prepacked food should be communicated in an understandable way. This should contain:			
a) General information on food laws	IV	100	87
b) Reading and interpreting ingredient lists	IV	100	93
c) Handling precautionary labelling	IV	100	73
16. Risk situations The dietitian should sensitise children and their parents to situations with risk without unnecessarily alarming them. Therefore, the following topics should be discussed:			
a) Out of home consumption I. Restaurants II. Traveling with food allergy III. Third-party care (e.g., school, nursery, grandparents)	IV	100	100
b) Contaminations	IV	100	93
17. New situations Children develop and grow constantly, therefore, new situations arise, which should be discussed in dietary counselling. Ideally, dietary counselling should happen before foreseeable changes. For example, the implementation of solid foods to prevent additional allergies according to current guidelines.	IV	100	80
Nutrition Counselling			
18. Counselling aids It can be helpful to use counselling aids for counselling of children with food allergies and their parents. For example: a) Fact sheets with written information b) Lists with pictures c) Food replicas d) Printed ingredient lists e) Product examples from the internet f) Lists with pictures of foods g) Positive-negative lists h) Foods that parents bring i) Links, e.g., of self-help groups	IV	100	85
19. Accidental reactions Instructions on how to act in case of an accidental reaction (including anaphylaxis) is generally the duty of the physician. The dietitian can play a supporting role by double checking if the emergency plan and drugs are available, and that the patient knows how to use them. The dietitian can recommend anaphylaxis-training and consult the physician if no emergency plan exists but is necessary.	IV	100	100
20. Counselling style and language The counselling style and the language used should be adequate for the age of the child, be clear and understandable to both the parents and child, and their socioeconomic status should be considered. In case of language difficulties an interpreter should be utilised.	IV	100	100
21. Target group Dietary counselling should address the child depending on his/her age as well as the parents. As required, relatives, friends, teachers, and further persons that look after the child can be included. Alternatively, parents may be empowered to inform others.	IV	100	93
Coordination of Care			
22. Interprofessional cooperation	IV	100	100

Recommendations: Nutrition Intervention	EL[a]	CL E [b] (%)	CL A[c] (%)
The optimal management of children with food allergy should use a multidisciplinary approach. The dietitian will work closely with the allergist and other health professionals and refers to further contacts when required.			

Note. [a] EL evidence Level, [b] CL E (%) consensus level expert group, [c] CL A (%) consensus level allergists, [d] see full guideline for further detail

Table 20 Evidence and consensus level for the recommendations relating to the nutrition monitoring and evaluation process

Recommendations: Nutrition Monitoring and Evaluation	EL[a]	CL E [b] (%)	CL A[c] (%)
Anthropometric Measurements			
23. Monitoring of weight and height Weight and height as well as the development along the centile curve should be assessed on a regular basis.	IV	90	100
Biochemical Data, Medical Tests and Procedures			
24. Monitoring of natural course and laboratory parameters To be controlled on a regular basis if the allergy persists. This is generally the duty of the allergist. However, the dietitian can consult the allergist and request to undertake a food challenge. If malnutrition is suspected, it is reasonable to evaluate relevant laboratory parameters.	IV	100	67
Nutrition-Focused Physical Findings			
25. Monitoring of symptoms The dietitian should ask, if an accidental allergic reaction occurred (symptoms, anaphylaxis). The development of physical findings (e.g., change of eczema) should be considered in monitoring.	IV	100	80

Note. [a] EL evidence Level, [b] CL E (%) consensus level expert group, [c] CL A (%) consensus level allergists

The full guideline with background information including the references on which the recommendation is based, and advantages and disadvantages of its implementation can be downloaded in German on the Bern University of Applied Sciences website https://www.bfh.ch/dam/jcr:34f97a5a-0065-45ba-8340-fc37e0f62abe/ERNA.pdf. An update of the guideline will be provided in five years.

4.1.5 Discussion

This project has produced a guideline to assist dietitians in counselling children with food allergies, based on all available evidence. It is focussed on the management of food allergy, as this is the usual role of dietitians in Switzerland, even though we would appreciate them being more involved in diagnosis. At present this largely remains

the domain and responsibility of allergists in Switzerland. Consensus levels of the expert group and allergists were used in combination with the NCP to form the recommendations and provide a more targeted approach to the development of the guideline. The majority of the recommendations showed similar levels of consensus between the two groups. However, there were a small number of recommendations where the results differed, as outlined in Table 18-Table 20. This difference highlights the importance of interprofessional collaboration in the treatment and management of food allergy. With greater interprofessional working and more effective communication between different health professionals, such as dietitians and allergists, fewer discrepancies in opinion may occur resulting in more efficient patient care.

Recommendation 11b states partially hydrolysed infant formula is not recommended as a breast milk substitute, but the experts and allergists did not agree with a difference in the consensus level of 28%. While it is recognised a small number of infants may tolerate partially hydrolysed infant formula, expert guidelines on management of CMA do not recommend its use (Egan et al., 2017; Lifschitz & Szajewska, 2015; Luyt et al., 2014). Similarly, there was a 20% difference in consensus levels on recommendation 11c and 11d; lactose free milk and milk drinks, and cereal or nut drinks, should not be recommended as a breastmilk substitute. Nut and cereal drinks are not nutritionally adequate, often low in energy, protein, and many vitamins and minerals, which is why they should not be recommended (Luyt et al., 2014). Lactose free formula is also not recommended due to the content of intact cow's milk protein which can cause an allergic reaction (Luyt et al., 2014). Recommendation 11e, with a 31% discrepancy, concerns infant formula of other mammalian milks, which also potentially contain proteins which could cause an allergic reaction (Luyt et al., 2014). However, the DRACMA guidelines of the World Allergy Organisation from 2010 recommend milk of

other mammalians for individual patients when diagnostic indicates that they are tolerated (Fiocchi et al., 2010). Moreover, recent research has found camel's milk to be safe and well tolerated in patients with CMA over one year of age (Navarrete-Rodríguez et al., 2018). Both may explain the difference in opinion. For a revision of the guideline, it may be beneficial to separate products that are unsuitable due to allergological concerns from those being nutritionally inadequate as breastmilk substitute. This may lead to a clearer distinction and prevention of any misunderstanding.

Considerable disagreement was also seen for recommendation 15c: Communicating information about handling precautionary labelling (Food law), where there was a 27% difference in consensus levels. It is obviously in the best interest of the patient to educate them on identification of the allergen, so it can be avoided (Collins, 2016). Correct label identification has been shown to be associated with prior instruction by a dietitian (Joshi et al., 2002). According to a survey in the UK however, dietitians seem to be more cautious in recommending eating foods with precautionary labelling than allergists (Turner et al., 2014). Even though legislation on precautionary labelling is slightly different in Switzerland, in the way that it is mandatory, if a certain amount of the allergenic ingredient is or may be exceeded, the question remains who should avoid products labelled this way. A common agreement between allergist and dietitians regarding labelling and who would discuss this with the patient would be in the best interest of the patient to avoid confusion. This is especially necessary as questions on precautionary labelling are frequently raises in dietary counselling of patients with food allergies.

The evidence levels for most recommendations in this guideline are low with most being expert opinion. Food allergy is a broad topic involving a vast number of different foods and mechanisms and the literature can often be conflicting on what

advice should be provided to patients. Limited studies are available on dietary advice for food allergy which is partly due to ethical issues with performing randomised controlled trials with allergic individuals (Silva et al., 2014). Most studies focus on diagnosis of food allergy rather than management. Working collaboratively using a multidisciplinary approach to food allergy is important both in practice and in research settings to provide effective patient-centred care.

The guideline is structured according to the NCP resulting in a series of recommendations designed for clinical practice. However, some clinicians may find the length and detail of the guideline unacceptable, meaning the guideline is not implemented. It is also recognised that implementation of the guidelines by dietitians, to standardise care and patient management with the goal of improving care, may be difficult and challenging due to limited time resources and daily routine. As dietitians in Switzerland are used to working with the NCP and know its structure, it might be easier to extract the relevant information and use the full guideline as a lookup document. We will evaluate the implementation the guideline when we revise it and will shorten it, if necessary. Lastly, counselling strategies vary between different allergies, which make it difficult to define specific recommendations for each different allergy. For example, in children with CMA it is important to find alternative calcium sources, whereas in peanut allergic children nutrient deficiencies are not relevant. In these children it is more important to empower patients and their families to detect hidden peanut protein.

The next step is to evaluate the effectiveness of dietary counselling defined by this project. A cohort study is being undertaken in several hospitals across the German speaking part of Switzerland. Dietitians will be asked to document the process of using the guideline and this will be evaluated by asking patients about the impact of the counselling on their QoL, frequency of allergic symptoms, growth, and diet diversity.

This newly developed guideline provides a clearer view of the role of a dietitian in supporting the patient-focussed management of food allergy. The recommendations will guide dietitians through the process of counselling and can be used as a tool to document progress with patients. It can be used by dietitians in private practice and in hospitals and is especially relevant for dietitians new to the field of food allergies. Furthermore, the discussions and written exchanges within the guideline development group offered the possibility to adopt a common understanding on dietary counselling of children with food allergy.

In conclusion, we have developed a comprehensive guideline, based on the best available evidence and expert opinion, to support dietary counselling for food allergy. It will help ensure consistency of care between experienced and less experienced specialist paediatric allergy dietitians to improve the QoL of food allergic children and their families and reduce the burden of food exclusion.

4.2 Overall conclusion of this chapter

The practice guideline serves as a guidance for dietitians in the evaluation study. Out of the guideline an instrument to document the counselling process was developed (Appendix B). With this document dietitians can easily document which recommendations they implemented, which they have not implemented and which they considered not to be relevant for this specific patient. Besides these outcomes this intensive process has strengthened the understanding of dietary counselling for food allergies and the trust among the dietitians and other stakeholders.

5 Translation and cultural adaption of the QoL questionnaire

This chapter presents the process of translating, culturally adapting and validating the QoL questionnaire for its use in the evaluation study. This was necessary as no German instrument was available to measure allergy related QoL in children aged 0-10 in the evaluation study. In the first sections, the translation and cultural adaption is described. The subsequent sections consist of the previously unpublished manuscript of the validation study.

5.1 Background

Health related QoL was defined as primary outcome in the evaluation study of this project. In the respective age group, it is especially challenging to measure QoL because of the limited ways infants and toddlers can express their emotions. One questionnaire, developed by Cohen et al., (2004) for the American environment, measures the parental burden of the child's food allergy. Another questionnaire, FAQLQ-PF was developed and validated as part of the EuroPrevall project and, measures parental perception of children's QoL (Dunn Galvin et al., 2008). It was decided to use the latter questionnaire, as it better represents the European culture and was already used in relevant other studies (see section 3.1). Until then, this questionnaire was only available in English, French, Spanish, Japanese and Portuguese (Couto et al., 2015; Dunn Galvin et al., 2008; Manso et al., 2017; Mizuno et al., 2016; Wassenberg et al., 2012). However, as the language of the participants in this research project is German, one aim of this project was to translate the questionnaire into German and culturally adapt it to the local habits.

5.2 Methodology of translation and cultural adaption

FAQLQ-PF was translated and adapted following the WHO process (WHO, n.d.–c).

1. English to German translation (forward translation)

Forward translation was done by the author who is a health professional and German native speaker. Recommendations by WHO to emphasise a conceptual rather than literal translation were followed. The target population was kept in mind and lay language was used.

2. Expert panel discussion and back-translation into English

The draft version was discussed in an internal expert panel at Bern University of Applied Sciences and the back-translation was done by an English native speaker. The back-translation was sent to the author of FAQLQ-PF for feedback, but no reply was received, so the translation was carefully compared to the original.

3. Pre-testing and cognitive interviewing in a group of parents of children with food allergy

First pre-tests and cognitive interviews were performed with parents of children with food allergy recruited in two children's hospitals in the German-speaking part of Switzerland. For the pre-test an interview questionnaire was developed. The interviews were performed by an internship student at Bern University of Applied Sciences after thorough briefing by the author. During pre-tests, notes were filled into the document with the interview questions. Furthermore, all interviews were recorded, using a smartphone app as a back-up in case of any questions.

4. Final version

The German version of FAQLQ-PF was finalised and further analysed with respect to content and discriminant validity within a Bachelor thesis in 137 parents of children

with food allergy supervised by the author (Walther, 2019). A second analysis of the raw data was conducted by the author and outlined in the manuscript in section 5.4.

Ethical considerations

Each participant of the pre-test signed an informed consent form. This part of the research project was ethically approved as part of the overall research project by the Research Ethics Committee for the Faculty of Health & Human Sciences and Peninsula Schools of Medicine & Dentistry, Plymouth University.

5.3 Results of the pre-tests

In the first step a draft of a German version of FAQLQ-PF was generated. For most questions more than one possible translation was made. The expert panel discussion, which is part of the second step, took two hours of intensive discussion. The panel consisted of four health professionals working in the field of food allergy or intolerances. For each question they decided on the best version of the translation. For some questions, new versions were created (Appendix N). The comparison of the back-translation with the original version, showed similarity with no need to change any items. Ten pre-tests have been performed with parents of children with food allergy. Participants of the pre-test needed approximately 20 minutes to fill in the questionnaire. The interviews lasted between 30 and 60 minutes. All participants brought in new aspects on the wording, the formulation of the questions and the construction of the questionnaire. Parents of young children (0-3) mentioned that it was in parts difficult to answer the questions from the perspective of their child. This particularly concerned the items of the Food Allergy Independent Measure (FAIM). As a result of the pre-test wording and formulation, the German version of FAQLQ-PF was slightly adapted. Appendix O summarises the results of the pre-tests in more detail.

5.4 German translation, cultural adaption, and initial validation of the Food Allergy Quality of Life Questionnaire – Parent Form

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5.4.1 Abstract

Purpose

This project aimed to translate, culturally adapt, and validate the Food Allergy Quality of Life Questionnaire Parent Form (FAQLQ-PF) for the use in German-speaking countries.

Methods

The original questionnaire was translated and culturally adapted using the three-step process of the WHO (WHO, n.d.–c). To evaluate internal consistency, floor/ceiling effect, convergent and discriminant construct validity, the German version of FAQLQ-PF(-G) was shared online with parents of children (0-12 years) with at least one food allergy in German-speaking countries. SPSS® (IBM, Armonk, NY, USA) was used for statistical analysis.

Results

In total, 148 respondents were considered for the statistical analysis. Cronbach α was ranging from 0.73 to 0.95 indicating a good internal consistency of FAQLQ-PF-G. A floor effect was detected for the subscale 'Food Anxiety' in the age group 0-3. The total score of FAQLQ-PF-G correlated significantly with all categories of the FAIM and all but one subcategory of the KINDL® demonstrating construct validity. In addition, the instrument was able to discriminate between number of organs and foods involved in allergic reaction as well as age groups.

Conclusion

The German online version of FAQLQ-PF showed a good construct and discriminant validity as well as internal consistency and can therefore be used to measure food allergy related QoL of children with IgE-mediated food allergy in German-

speaking countries. Nevertheless, subscales of the youngest age group should be interpreted cautiously, and further studies should investigate retest reliability as well as the paper-based version of the questionnaire.

Keywords:

cultural adaption, food allergy, FAQLQ-PF, quality of life, translation, validation

5.4.2 Introduction

Health related QoL is an important outcome measure of interventions in food allergy because studies show that food allergy impacts on the QoL of patients and their relatives (Antolin-Amerigo et al., 2016; Lange, 2014; Walkner et al., 2015). In particular, food allergy can result in lifestyle restrictions regarding food, social events and worrying about eating away from home, which can lead to frustration, stress and isolation (Dunngalvin et al., 2020). Various questionnaires are available to evaluate QoL, but disease specific tools are more sensitive than generic ones (Antolin-Amerigo et al., 2016). The validated FAQLQs, developed for the EuroPrevall project, are some of the most well used food-allergy-related QoL- questionnaires. They have been found to be excellent tools for group comparison studies and for monitoring individual patients (van der Velde, J. L. et al., 2009).

Altogether, five different forms of the FAQLQ have been developed. Three self-administered forms to be completed by the patients themselves (Child Form, FAQLQ-CF; Teenager Form, FAQLQ-TF; and Adult Form, FAQLQ-AF), and two forms to be completed by parents as proxies for their food-allergic children (Parent Form; FAQLQ-PF) and teenagers (Parent Form Teenager; FAQLQ-PFT) (Dunn Galvin et al., 2008; FAQLQ, 2011; Flokstra-de Blok, B. et al., 2008; Flokstra-de Blok, B. et al., 2009; Muraro, Dubois, et al., 2014). The FAQLQ were developed in English or Dutch and have been translated into many different languages and adapted to different cultures (FAQLQ, 2011). The parent form (for children aged 0-12 years), which allows parents to report children's health-related QoL from the parent's perspective, has been translated into French (Wassenberg et al., 2012), Japanese (Mizuno et al., 2016), Spanish (Manso et al., 2017), Portuguese (Couto et al., 2015; Mendonça et al., 2020) and Thai (Limpitikul et al., 2020),

but no German version exists. A German version of FAQLQ-PF would enable studies to measure QoL in small children in German-speaking countries and help health workers to provide patients with individualised treatments.

Questionnaires should always be translated and culturally adapted before using them in other settings (Guyatt et al., 1993). Therefore, the aim of this project was to translate, culturally adapt and initially validate a German version of the FAQLQ-PF.

5.4.3 Method

Questionnaire

The FAQLQ-PF consists of 14 items which parents of all children aged 0-12 answer, 12 additional items for children of 4-12 years old, and again 4 additional items for parents of children 7-12 years old (Dunn Galvin et al., 2008). Parents of children 7-12 years old answer all 30-items. The scale utilises a seven-point Likert-scale ranging from 0 (not at all) to 6 (extreme) covering three domains: 1. Emotional Impact, 2. Food Anxiety and 3. Social and Dietary Limitations. Scores are calculated by building the mean of each domain and then merging them to a total score. For this calculation items should be recoded to scores ranging from 1 (no impairment) to 7 (maximal impairment) (FAQLQ, 2011).

Translation and cultural adaptation

The FAQLQ-PF was translated and culturally adapted following the three-steps process of the WHO (WHO, n.d.–c). First, a native speaker translated the questionnaire into German (forward translation). Second, an expert panel discussed the translation, and a native English-speaking health professional translated the German version into English without reference to the original English version (back translation). This version was carefully compared to the original English version to identify differences which were

then resolved in discussion between the forward-translator and back-translator. Third, a pre-test with the questionnaire was carried out for which ten parents of children with food allergies were recruited in two children's hospitals in the German-speaking part of Switzerland. After completing the questionnaire parents were asked whetherquestions were relevant and comprehensible, not offensive, or inappropriate as well as whether the questionnaire included any unknown words. Subsequently, the questionnaire was adapted accordingly. This version has been named the FAQLQ-PF-G and can be found in a supplement to this publication (Appendix D).

Validation of the Food Allergy Quality of Life Questionnaire Parent Form German

In line with other translations, internal consistency, floor/ceiling effect, convergent and discriminant construct validity of the FAQLQ-PF-G were examined (Limpitikul et al., 2020; Manso et al., 2017; Mizuno et al., 2016). Internal consistency measures to which extend items of a questionnaire are corelated with each other and measuring the same concept accordingly (Terwee et al., 2007). A questionnaire is considered to have good internal consistency when the corresponding reliability coefficient Cronbach's α is greater than 0.70 (Terwee et al., 2007). However, very high values of alpha (>0.95) could be an indication of redundancy (Terwee et al., 2007). A floor or ceiling effect is considered when more than 15% of the respondents achieve the minimal or maximal score respectively (Terwee et al., 2007). This indicates that extreme items are missing on the lower respectively upper end of the scale (Terwee et al., 2007). Convergent construct validity tests the relationship of a particular questionnaire to an instrument measuring similar concepts (Ginty, 2013). For this evaluation German version of the FAIM (FAIM-G) (van der Velde, J. L. et al., 2012)(children's and parents' view) scale score and KINDL® were chosen as comparators (Ravens-Sieberer & Bullinger, 1998; van der Velde, J. L. et al., 2010). FAIM contains four questions about the subjective

expectations of food allergy outcome for both children and parents and is generally used in connection with FAQLQ (Dunn Galvin et al., 2008). Parents rate these questions on a six-point Likert scale. KINDL® is a widely used generic health-related QoL questionnaire developed in German consisting of 24 Likert-scaled items which can be assigned to six domains: 1. Physical wellbeing, 2. Emotional wellbeing, 3. Self-esteem, 4. Family, 5. Friends and 6 School. The subscales of the six dimensions can be merged to a total score. A high score indicates a high QoL. A comparison of FAQLQ-PF with FAIM and KINDL® allows to prove the hypothesis that FAQLQ-PF is measuring the construct of food allergy related QoL. Discriminant construct validity evaluates the ability of a questionnaire to discriminate between objective impact variables (Ginty, 2013). For this study, the number and type of organs involved in allergic reactions, age groups, and the number and type of food allergies were chosen as objective impact variables because they impact allergy related QoL (Saleh-Langenberg et al., 2015; Sicherer et al., 2001; Wassenberg et al., 2012). The online-approach was chosen because the questionnaire was intended to be used in a web-based version.

Parents of children (0-12 years) with at least one food allergy diagnosed by a physician were invited to fill in an online version of all three questionnaires (FAQLQ-PF-G, FAIM-G, KINDL®(Ravens-Sieberer & Bullinger, 1998)) on SurveyMonkey® (SVMK Inc., San Mateo, Canada). Parents were recruited via patient organisations and Facebook® (Facebook Inc., Menlo Park, USA) groups.

Statistical analysis

The scores of FAQLQ-PF-G and KINDL® were recoded and scores calculated according to manual instructions (FAQLQ, 2011; Ravens-Sieberer & Bullinger, 2000). Statistical analyses were performed using SPSS Statistics® version 24 (IBM, Armonk, NY, USA). The percentage of respondents completing the questionnaire was evaluated.

Internal consistency was assessed by calculating Cronbach's α. Convergent construct validity was analysed using Spearman correlation coefficient between FAQLQ-PF-G and FAIM-G and the age-appropriate proxy-versions of the KINDL®. The ability of FAQLQ-PF-G to discriminate between the objective impact variables was examined using a one-way ANOVA, with Bonferroni post hoc tests, in the case of more than two categories in the predictor variable, otherwise independent t-test was used.

Ethical considerations

A jurisdictional inquiry was submitted to the Ethics Committee Bern for the pre-test of the questionnaire, but the Committee advised that their approval was not required as no generalisable data was obtained. All parents were informed about the purpose of the pre-test and signed an informed consent. Data collection for the validation study was anonymous, therefore EU General Data Protection Regulation did not apply (Art. 4, Para.1, GDPR). Information on the study was given at the beginning of the survey and parents had to press a button to confirm their informed consent before the start of the survey.

5.4.4 Results

Characteristics of Participants

In total, 164 parents of children answered the online questionnaire. One case was excluded, because diagnosis had not been made by a physician. Another 15 cases were excluded, because the respondents answered less than 80% of FAQLQ-PF-G. This leaves 148 analysable datasets. Characteristics of the children of the respondents are summarised in Table 21, which shows the sample mainly resided in Germany, had a higher proportion of boys, was relatively evenly distributed by age group, and suffered a wide range of symptoms and allergies.

Table 21 Sociodemographic and clinical characteristics of children of the participants

Variable		n	(%)
Country	Germany	121	81.8
	Switzerland	20	13.5
	Austria	5	3.4
	others	2	1.4
Child's Gender	Male	111	75.7
	Female	37	25.0
Age groups (years)	0-3	41	27.7
	4-6	44	29.7
	7-12	63	42.6
Emergency kit prescribed	Yes	140	94.6
Symptoms [a]	Cutaneous	145	98.0
	Respiratory	108	73.0
	Gastrointestinal	95	64.2
	Cardiovascular	80	54.1
Number of foods allergies	1-2	91	61.5
	3-4	36	24.3
	≥5	21	14.5
Allergenic foods [a]	Peanut	99	66.9
	Tree nuts	69	46.6
	Hen's egg	49	33.1
	Cow's milk	38	25.7
	others	60	40.5

Note. N = 148. Children had mean age 6.0 years (SD = 2.97)

[a] Multiple answer possible

Table 22 shows the mean values of FAQLQ-Scores and sub-scores per age group. Total scores ranged from 3.1 (SD 1.1) in the age group 0-3 to 4.2 (SD 1.0) in the age group 7-12, indicating a lower QoL when children get older.

Table 22 Comparison of FAQLQ-PF-G scores between age groups

Age group (y)	FAQLQ-PF-G	Mean score (SD)
0 - 3	Total Score	3.1 (1.1)
	Subscale Scores	
	Emotional Impact	2.8 (1.2)
	Food Anxiety	2.4 (1.2)
	Social Dietary Limitation	4.0 (1.4)
4 - 6	Total Score	3.4 (1.1)
	Subscale Scores	
	Emotional Impact	3.2 (1.2)
	Food Anxiety	3.3 (1.3)
	Social Dietary Limitation	3.8 (1.3)
7 - 12	Total Score	4.2 (1.0)
	Subscale Scores	
	Emotional Impact	4.0 (1.0)
	Food Anxiety	4.0 (1.2)
	Social Dietary Limitation	4.4 (1.2)

Note. FAQLQ-PF scores and subscale scores range from 1 ‘no impairment’ to 7 ‘maximal impairment’.

Completion of the questionnaires

Completion of FAQLQ-PF-G was evaluated. From 163 questionnaires, 142 participants (87.1%) completed 100%., 15 (9.2%) completed < 80% and 6 (3.7%) completed between 80% and 100% of the questions which indicates that it is possible and acceptable for the parents to complete the questionnaire

Internal consistency and floor/ceiling effect

Table 23 shows the results of Cronbach’s α for the FAQLQ-PF-G indicating that there was a good internal consistency for all subscale scores. The lowest Cronbach’s α was observed for ‘food anxiety’ (0.727) and ‘social and dietary limitations’ (0.787) in the 0-3 years age group but these are still above the 0.7 cut off. The total score for the 4-6 years age group was 0.954 suggesting there may be evidence of redundancy. This is the

case when questions are voiced differently, but practically measure the same thing. This is underpinned by the fact that Cronbach's α remains relatively constant when single items are removed (data not shown).

Table 23 Internal consistency and floor and ceiling effect of FAQLQ-PF-G total score and subscales in children with food allergy.

FAQLQ-PF-G	Age Group (years)	Items	Cronbach's alpha	% min (floor)	% max (ceiling)
Total score	0-3	14	0.898	4.9	0
	4-6	26	0.954	0	0
	7-12	30	0.946	0	0
Subscales					
Emotional impact	0-3	6	0.872	7.3	0
	4-6	10	0.896	0	0
	7-12	13	0.876	0	0
Food anxiety	0-3	3	0.727	**19.5**	0
	4-6	7	0.883	0	0
	7-12	8	0.869	0	0
Social and dietary limitation	0-3	5	0.787	4.9	0
	4-6	9	0.891	0	0
	7-12	9	0.891	0	1.6

For the subscale 'Food Anxiety' 19.5% of respondents in the age group 0-3 gave the lowest possible score, indicating a floor effect. This shows that this proportion of parents felt that their child had no distress or anxiety related to symptoms of their food allergy. No ceiling or floor effects were seen for the other dimensions and age groups.

Construct Validity

The correlations between FAQLQ-PF-G, FAIM-G and KINDL are summarized in Table 24. The total and all three subscale scores of the FAQLQ-PF-G correlated significantly with the FAIM-G, suggesting both questionnaires elicit similar responses in the various domains and overall. All scores and subscale scores of the KINDL® except the ones for 'family' correlated significantly with the scales and subscales of FAQLQ-PF-G, indicating FAQLQ-PF-G measures a similar concept.

Table 24 Spearman's and Kendall's correlation between FAQLQ-PF-G total score, subscales and KINDL® subscales as well as FAIM total score

FAQLQ-PF-G	**KINDL (N=101)**							**FAIM-G (N=140) [CI 95%]**
	Physical wellbeing [CI 95%]	Emotional wellbeing [CI 95%]	Self esteem [CI 95%]	Family [CI 95%]	Friends [CI 95%]	School [CI 95%]	KINDL total [CI 95%]	
Total score								
Spearman rho	-0.448** [-0.596, -0.269]	-0. 498** [-0.630, -0. 316]	-0. 364** [-0.516, -0. 191]	-0.163 [-0.353, 0.029]	-0.490** [-0.651, -0.305]	-0.366** [-0.541, -0.169]	-0.567** [-0.691, -0.416]	0.336** [0.181, 0.476]
Kendall's tau	-0.321** [-0.435, -0.193]	-0. 355** [-0.465, -0.227]	-0.260** [-0.379, -0.139]	-0.114 [-0.254, -0.022]	-0.364** [-0.488, -0.231]	-0.262** [-0.397, -0.121]	-0.395** [-0.504, -0.285]	0.229** [0.120, 0.329]
Subscales								
EI-Score								
Spearman rho	-0.446** [-0.588, -0.274]	-0. 505** [-0.639, -0.340]	-0.390** [-0.537, -0.212]	-0.154 [-0.338, 0.039]	-0.488** [-0.650, -0.321]	-0.381** [-0.548, -0.197]	-0. 566** [-0.680, -0.420]	0.294** [0.147, 0.438]
Kendall's tau	-0.323** [-0.432, -0.200]	-0. 363** [-0. 474, -0. 245]	-0.279** [-0.393, -0.148]	-0.109 [-0.245, 0.033]	-0.359** [-0.488, -0.232]	-0.275** [-0.408, 0.143]	0.395** [-0.489, -0.287]	0.201** [0.097, 0.309]
FA-Score								
Spearman rho	-0.377** [-0.533, 0. 204]	-0. 405** [-0. 559, -0. 235]	-0.234* [-0. 401, -0.053]	-0.056 [-0.258, 0.127]	-0.332** [-0.504, -0.134]	-0.264** [-0.435, -0.070]	-0.447** [-0.585, -0.287]	0.307** [0.147, 0.458]
Kendall's tau	-0. 274** [-0.394, 0.149]	-0. 285** [-0. 409, -0.162]	-0.166* [-0.288, -0.042]	-0.038 [-0.186, -0. 092]	-0.263** [-0.394, -0.032]	-0.182* [-0.308, -0.046]	-0.300** [-0.405, -0.188]	0.209** [0.94, 0.325]
SDL-Score								
Spearman rho	-0. 360** [-0. 517, -0. 178]	-0. 395** [-0. 557, -0. 207]	-0.326** [-0.495, -0.132]	-0.197 [-0.382, 0.003]	-0.468** [-0.641, -0.271]	-0.297** [-0.479, -0.089]	-0.478** [-0.621, -0.307]	0.283** [0.137, 0.433]
Kendall's tau	-0. 258** [-0. 381, -0. 127]	-0.291** [-0. 420, -0. 148]	-0.241** [-0.373, -0.102]	-0.140 [-0.280, -0.003]	-0.355** [-0.493, -0.209]	-0.213** [-0.356, -0.063]	-0.338** [-0.455, -0.214]	0.202** [0.096, 0.304]

Note. EI-Score = Emotional Impact Score; FA-Score = Food Anxiety Score SDL-Score= Social and Dietary Limitations Score CI =Confidence Interval. * $p < 0.05$. **$p < 0.01$.

Discriminant construct validity

There was a significant effect of the type of symptoms (cutaneous, respiratory, gastrointestinal & cardiovascular) on FAQLQ-PF-G total score, $F (3, 139) = 6.89$, $p < 0.001$, $\omega 2 = 0.110$. Post hoc comparisons using Bonferroni correction revealed that the mean score (M) for one organ system involved ($M = 2.77$, $SD = 1.09$) was significantly different to three organ systems ($M = 3.66$, $SD = 1.09$) ($p = 0.02$) and four organ systems ($M = 3.01$, $SD = 1.13$) ($p < 0.001$). No significant difference was found between one and two organ systems being involved. Parents reporting cardiovascular symptoms had higher total FAQLQ-PF-G scores ($M = 3.99$, $SD = 1.12$) indicating a lower QoL, compared to those not having cardiovascular symptoms ($M = 3.23$, $SD = 1.09$). This difference was significant ($t (142) = -4.11$, $p < 0.001$) and represents an effect of $d = 0.688$, indicating a medium effect of having cardiovascular symptoms on allergy-related QoL. A similar effect was observed for respiratory symptoms, where those with these symptoms ($M = 3.83$, $SD = 1.12$) had higher scores than those without ($M = 3.14$, $SD = 1.16$, $t (142) = -3.31$, $p = 0.001$. $d = 0.616$. No such significant differences were observed for skin or gastrointestinal symptoms.

In addition, a significant effect was observed between age groups on FAQLQ-PF-G total score, $F (2, 141) = 13.36$, $p < 0.001$, $\omega 2 = 0.147$. Post hoc comparisons indicated the mean scores for the age group 0-3 ($M = 3.08$, $SD = 1.07$) and 4-6 ($M = 3.45$, $SD = 1.15$) were significantly lower than the score for 7-12 years ($M = 4.17$, SD 1.03) ($p < 0.001$ and $p = 0.003$ respectively). No significant difference was found between age groups 0-3 and 4-6 years.

For the number of food allergies there was a significant effect observed between the three subgroups (1-2 food allergies, 3-4 food allergies and ≥ 5 food allergies) $F (2, 141) = 3.74$, $p = 0.03$, $\omega 2 = 0.037$. Post hoc comparisons indicated the mean FAQLQ-PF-

G score for 3-4 food allergies (M = 3.34, SD = 1.21) to be significantly lower than in this with ≥ 5 food allergies (M = 4.22, SD = 1.31) (p = 0.02). No significant differences were detected for specific foods, such as peanut, wheat or milk.

5.4.5 Discussion

The aim of this study was to translate, culturally adapt and validate the FAQLQ-PF for German-speaking countries. We successfully created the FAQLQ-PF-G and demonstrated good completion rate by respondents, and good internal consistency, construct, and discriminant validity. This provides a new tool now available for use within German-speaking countries.

Mean FAQLQ-PF-G-Scores are comparable with the original validation study and the Japanese as well as the Thai validation studies ranging from 2.0 to 4.7 indicating a low to moderate impairment of allergy-related QoL (Appendix P). The French, Spanish and Portuguese validation studies reported lower mean values ranging from 1.2 to 3.4.

Internal consistency values are comparable with the original validation and validation studies of other translations (Dunn Galvin et al., 2008; Limpitikul et al., 2020; Manso et al., 2017; Mizuno et al., 2016). Through all studies Cronbach's α varies from 0.73 to 0.97, indicating that FAQLQ-PF has a good internal consistency regardless of the translation and cultural adaption (Appendix P). Cronbach's α for 'Food Anxiety' and 'Social and Dietary Limitations' in this study was relatively low in the age group 0-3. This is likely due to Cronbach's α dependency on the number of items in a scale, as these domains contain three and five items respectively (Terwee et al., 2007). 'Food Anxiety' includes only three and 'Social and Dietary Limitations' only five items for this age group compared to seven/eight and 9 respectively in the older age groups. This might be the reason why the original validation study did not report Cronbach's α for the subscales in

this age group (Loh & Tang, 2018; Mizuno et al., 2016). The Japanese translation also observed relatively low Cronbach's α values (Mizuno et al., 2016). Only the Thai translation reported high values in this age group (Limpitikul et al., 2020).

The floor effect for the subscale 'Food Anxiety' in the age-group 0-3 might indicate that extreme items are missing, and responsiveness may be limited as changes cannot be measured (Terwee et al., 2007). This is reasonable as this subscale includes only three questions for the youngest age group. However, it could also mean that most of the children in the younger age group are not distressed and do not exhibit anxiety regarding their allergy. It could also indicate that parents have difficulties observing or recognizing food anxiety in their children. Maybe because they think they are too small to be aware of the food allergy. The validation study of the Spanish questionnaire also reported a floor effect for 'Food Anxiety', in addition to one for 'Emotional Impact' both in the age group 0-3 (Appendix P) (Manso et al., 2017). DunnGalvin et al. (2008) found no floor or ceiling effects in the initial validation study for FAQLQ-PF (Dunn Galvin et al., 2008). However, they did not report any results for the subscales of age group 0-3 years, which makes a direct comparison impossible. Other validation studies did not evaluate floor or ceiling effects (Appendix P) (Epstein-Rigbi et al., 2020; Limpitikul et al., 2020; Mendonça et al., 2020; Mizuno et al., 2016)

FAQLQ-PF-G showed a good construct validity with significant correlations of all scales and subscales of the FAIM-G. However, these relationships were less strong than in the original validation study and some translations, which detected stronger correlations between FAQLQ-PF and FAIM ranging from 0.393 to 0.614 (Appendix P) (Dunn Galvin et al., 2008). Only the Spanish translation reported less strong correlations for Food Anxiety in the age group 0-3 (Manso et al., 2017). This difference in our results might be explained by the difficulties parents reported in answering questions of the

FAIM-questionnaire from the perspective of their child, which might be culturally driven. When comparing FAQLQ-PF with KINDL®, there were significant correlations on all scales and subscales, except the subscale 'Family'. This subscale includes questions on how the child feels and behaves at home, which might be less impacted by food allergy and thus not relevant for explaining the construct. Interestingly, the validation of the Spanish version of FAQLQ-PF, using the Spanish version of the KINDL®, found contrary results (Manso et al., 2017). In this study only the 'Emotional Impact' and the 'Family' subscales showed statistically significant correlations with FAQLQ-PF. This may be explained by the low sample size (n = 31) of children in the relevant age group in this study.

FAQLQ-PF-G showed a good discriminating ability between the number of organ systems involved in the symptoms, age groups and the number of food allergies, but specific foods had no significant influence on the total FAQLQ-PF-G score. Maybe the food eliciting the allergy did not influence the parent's perception of allergy severity and thus not affect allergy-related QoL scores. However, the original FAQLQ study found a significantly higher score for children allergic to peanut (as a single food) compared to children allergic to any another single food (Dunn Galvin et al., 2008). This may be due to the increased awareness in the Irish and US society of the severity of peanut allergy, which would explain why the study carried out in the French-speaking part of Switzerland did not find a significant impact of peanut allergy on FAQLQ-PF scores either (Wassenberg et al., 2012). A reason for this might be the higher prevalence of peanut allergy in the US paediatric population, estimated to be 2.0 % compared to 0.4% in the Swiss population (Dyer et al., 2015; Lyons et al., 2020). Nevertheless, the European Anaphylaxis Register shows similar frequencies of anaphylaxis elicited by peanuts in children and adolescents between Germany (18%), Ireland (17%), Switzerland (15%) and Austria (14%) (Maris et al., 2021). Also, differences in awareness campaigns might play

a role. The observed difference between age groups were also found in other translations (Limpitikul et al., 2020; Manso et al., 2017; Mizuno et al., 2016; Wassenberg et al., 2012) where older age groups (7-12 years) had significant higher total FAQLQ-PF scores and Emotional Impact scores compared to younger age groups. Difficulties in living with food allergies seem to increase with age, when the child's becomes more independent, and parents have less control over what their child eats. It would be interesting to investigate how a change in life circumstances, such as starting kindergarten, impacts on allergy-related QoL.

The FAQLQ-PF-G elicits the parents' responses as a proxy for the child. However, the proxy responses do not always correspond to the children's responses in such questionnaires (Guyatt et al., 1993). Evidence from a comparison between FAQLQ-PF and FAQLQ-CF with children aged 8-12 suggests that the agreement of health-related QoL in food allergic children between child and parent reporting is influenced by the child's age (2011). The difference between parents and children was greater when the children were younger (8-10 years versus 10-12 years), suggesting a parental positive bias while estimating the QoL of their children (Theunissen et al., 1998; van der Velde, J. L. et al., 2011). Especially in younger children, the assessment of the health-related QoL could be influenced by the lack of ability of the child to express itself (Eiser & Varni, 2013). The youngest group in this study was 0-3 years old, and clearly the answers in this age group will be strongly influenced by the parent's opinion and their own anxiety, and not necessarily representative of the child's experience. Nevertheless, this is the only possible measure to collect data on QoL for the youngest age group.

Due to the anonymous online study design, it was possible to reach a high number of respondents, however, this has also caused some limitations. Firstly, diagnosis was self-reported as confirmed by a physician, therefore it is possible parents

felt the allergy was confirmed even without a physician confirmation. Secondly, test-retest reliability could not be evaluated and must be investigated in a subsequent study. However, the test-retest reliability of the FAQLQ-PF has been established in the English version and tested in the Thai, Portuguese and Japanese versions (Dunn Galvin et al., 2008; Limpitikul et al., 2020; Mendonça et al., 2020; Mizuno et al., 2016) . Thirdly, the mode of administration (online) may have influenced the results in an unforeseen way. Reassuringly, another study with an online version of the FAQLQ-AF showed comparable measurement properties to the paper-based version (Goossens et al., 2011). Lastly, it was not possible to calculate response rate as it was not comprehensible how many potential participants received the questionnaire.

5.4.6 Conclusion

Food allergy related QoL is an important outcome measure in children with food allergies and the use of validated instruments is essential. This study showed good construct and discriminant validity as well as internal consistency of the German online-version of FAQLQ-PF, which indicates that the questionnaire can be used to measure food allergy related QoL in children (0-12 years) in German-speaking countries. However, in the age-group 0-3 years subscales must be interpreted with caution and subsequent studies are needed to investigate the validity of the paper-based version in addition to test-retest reliability as well as potential further improvements of the 0-3 years subscales with additional items.

5.5 Overall discussion and conclusion of this chapter

This part of the project produced a German version of FAQLQ-PF, which can be used to evaluate dietary counselling in this project. Some parents of children in the youngest age group (0-3 years) mentioned difficulties with answering specific questions for their child. This might be especially difficult in domains the proxy cannot observe (Guyatt et al., 1993). This phenomenon was not mentioned in other publications about this questionnaire (Couto et al., 2015; Dunn Galvin et al., 2008; Manso et al., 2017; Mizuno et al., 2016). However, these publications did not focus on parent feedback during pretesting. Nevertheless, this aspect might represent a serious limitation of the questionnaire, but cannot be avoided in this age group, as it is not possible to interview the children themselves.

The German version of FAQLQ-PF has been adapted for the use in the Swiss-German population. Changes have been made according to uncertainties and suggestions of the participants of the expert panel as well as parents in the pre-test. A further validation is necessary as, cultural differences can have an inappropriate influence on the measuring properties even if translations are adequate (Guyatt et al., 1993).

6 Effectiveness of dietary counselling of children with food allergy

This chapter describes the evaluation study investigating the effectiveness of dietary counselling in children with food allergies, which was the main goal of this project. It starts with a brief overview of the literature giving some background information, the research questions and hypothesis. The methods, results and discussion are then presented, finishing with conclusions. Due to severe delays in the recruitment of participants, only data up to six-months measurement are presented in this chapter. It is foreseen that twelve months data will be published after the completion of the PhD degree.

6.1 Background

As described in section 1.10, so far there has been only one prospective study evaluating the influence of dietary counselling on nutrient intake and nutritional status (Berni Canani et al., 2014). The main conclusion of this study was that children receiving dietary counselling significantly improved their anthropometric and laboratory biomarkers of nutritional status. Furthermore, their total energy intake was similar to the baseline values of healthy controls six months after dietary counselling. However, the main issue with this study is that there was no control group of children with food allergy not receiving dietary counselling. Therefore, these results should be taken with caution and be replicated with a study including a control group. A retrospective study investigated the effect of dietary counselling on the frequency of allergic reactions in children with egg allergy (Bégin et al., 2017). However, the retrospective design makes the study vulnerable to recall bias. The available evidence for the effectiveness of dietary counselling is therefore extremely limited. Also, there are currently no published studies investigating the effect of dietary counselling on QoL in children. Therefore, a study was

designed to evaluate the effectiveness of dietary counselling of children with food allergy. This study aimed to answer the following questions:

i. How does dietary counselling influence the food allergy related QoL of children with food allergy?
ii. Do children who receive dietary counselling have less frequent allergic reactions compared to children who do not receive dietary counselling?
iii. How does dietary counselling influence nutritional status as indicated by growth in children with food allergy?
iv. How does dietary counselling influence the diversity of the food eaten in children with food allergy?

From this, the following hypothesis was derived:

Children with food allergy who receive dietary counselling have a significantly better score of food allergy related QoL, show fewer symptoms of allergic episodes after consumption, have a better nutritional status as indicated by growth (weight and Length/height-for-age, weight-for-height, and BMI-for-age) and eat a more diverse diet compared to those who do not receive dietary counselling.

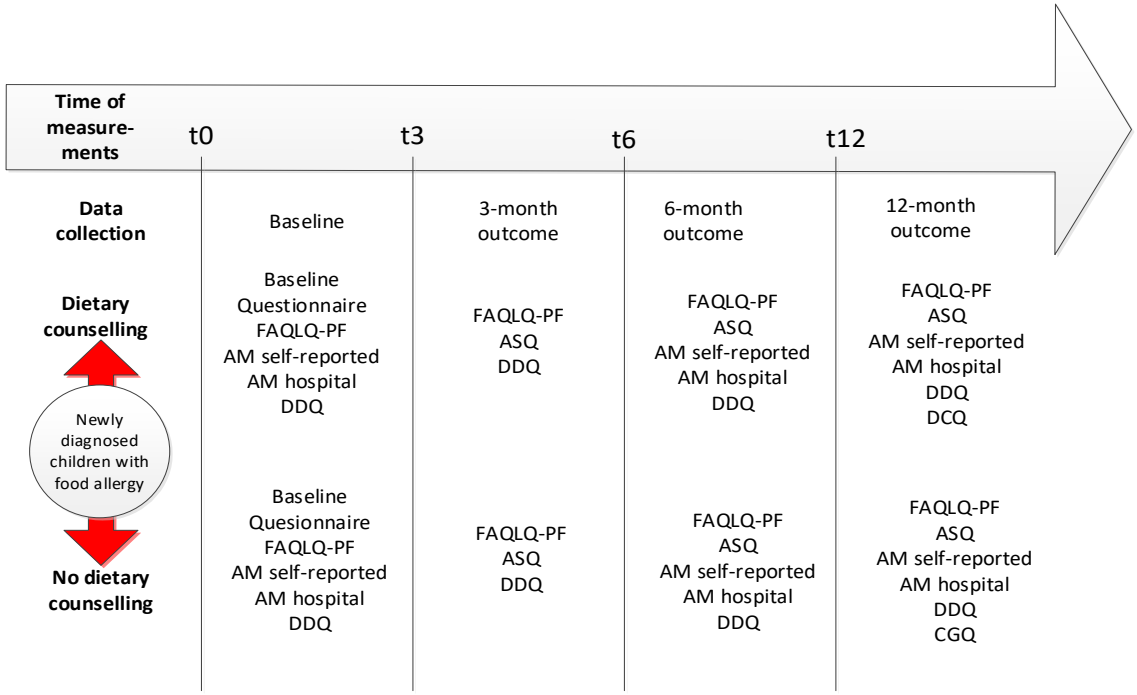
6.2 Methodology

6.2.1 Study design

A multicentre non-randomised controlled study with newly diagnosed food allergic children and their caregivers was conducted. Children were not randomised to one group as this was not possible as explained in chapter 2. Caregivers were asked if they received dietary counselling at each time point and were referred to the group with no dietary counselling, when they never had dietary counselling. Dietitians confirmed the allocation with their documentation. Online Questionnaires were sent to the

caregivers at baseline, after three, six and twelve months (see Figure 5). Data on weight and height were self-reported by the caregivers in the questionnaire and furthermore measured in hospital and submitted by the responsible person to the research team. A multicentre approach was chosen to account for the potential confounding factor of the personality and skills of the counselling dietitian and also to reach a sufficiently large number of potential participants.

Figure 5 Study design including dates and instruments



Note. AM = Anthropometric Measures; FDQ = Diet Diversity Questionnaire; ASQ = Allergic Symptom Questionnaire; DCQ = Dietary Counselling Questionnaire; CGQ = Control Group Questionnaire

6.2.2 Participants

Recruitment took place in four hospitals in the German-speaking part of Switzerland: (University-) Children's hospital Zurich, Children's hospital Basel, Chidren's hospital of Eastern Switzerland (St Gallen) and Cantonal hospital Aarau. In this part of Switzerland there are six children's hospitals that diagnose and treat children with food allergy and employ a registered dietitian. All of them were contacted; two of them declined to take part in the study due to lack of resources. In three of the hospitals the

allergist informed parents of children meeting the inclusion criteria (Table 25) about the project and handed out a folder with information material including an invitation to take part, the researchers contact details and the informed consent form. Parents were then asked to contact the researcher directly if they were interested in taking part. If the parents agreed, the allergist transmitted the phone number and we called them for follow-up. In the last hospital the recruitment was done by the main researcher by on-site visits when children with a suspected food allergy were registered for an appointment with the allergist. The researcher orally explained the study to the parents and delivered them the information material including the informed consent form. When the parents returned the informed consent form by mail and it was confirmed that the child met the inclusion criteria (summarised in Table 25), the child was included in the study.

Table 25 Inclusion and exclusion criteria of study participants

Inclusion criteria	**Exclusion criteria**
• Aged 0-10 years • Newly diagnosed food allergy • IgE-mediated food allergy • Diagnosis based on history and evaluation of sensitivity • Sufficient knowledge of German to follow the counselling sessions and to read instructions • Willing and able to give written informed consent	• Dietary counselling on food allergy before entering the study • Other food intolerances e.g., lactose tolerance, fructose malabsorption • Other chronic diseases that influence nutritional status e.g., Cystic Fibrosis, Morbus Crohn, Coeliac disease, cancer, HIV. • Inability to follow dietary counselling due to language problems, psychological disorders, or dementia.

Note. IgE = Immunglobulin E

6.2.3 Dietary counselling

In the baseline questionnaire, parents were asked for reasons why they decided to consult the dietitian or not. They had the option to decide on the predefined reasons or answer in an open text field.

Registered dietitians in the corresponding study centre performed dietary counselling with the parents of the children. Before starting the study, a guideline for the counselling process was developed and agreed upon (see chapter 4). During the study, the dietitians documented the implementation of the recommendations made in the guideline with the help of a monitoring instrument created for the study (Appendix Q). The dietitians indicated whether the recommendations had been implemented, not implemented or was not relevant for the specific child. The dietitians were free to decide how many consultations were necessary, to reflect routine clinical practice as closely as possible.

6.2.4 Primary and secondary outcomes

As defined in chapter 2, the primary outcome was the mean difference in food allergy related QoL (measured with FAQLQ-PF score) after six months compared between children with and without dietary counselling. This outcome was chosen because food allergy related QoL is a patient relevant outcome. Moreover, we assumed based on previous studies measuring accidental allergic reactions (Boyano-Martinez et al., 2009; Boyano-Martinez et al., 2012; Ewan & Clark, 2005; J. W. Yu et al., 2006) and experience of an allergist (C. Roduit, personal communication, 2 May 2017) that too few allergic reactions occur to find a significant difference between groups in a realistic sample size. Secondary outcomes were the change in FAQLQ-PF over time, difference in

the number of allergic reactions, difference in indicators of nutritional status and the difference in diet diversity score between the two groups.

For measuring food allergy related QoL, the FAQLQ-PF questionnaire by Dunn Galvin et al. (2008) was translated and validated (see chapter 5). FAQLQ-PF scores and sub-scores were calculated according to FAQLQ manual (FAQLQ, 2011). Scores range from 1 (no impairment) to 7 (maximal impairment).

Parents reported allergic reactions at three and six months after diagnosis. Beside the number and timepoints of the allergic reaction, they gave details of symptoms and the foods they suspected had elicited triggered the allergic reaction. In this thesis only the number of allergic reactions after three and six months are evaluated.

Weight and height or length were reported by parents via an online questionnaire at baseline, after six and twelve months. In addition, the responsible persons in the hospital transmitted routinely measured data on weight and height or length for the study. Only questionnaire data for baseline and six months is shown in this chapter, as the 12 month follow ups were not completed at the time of the data analysis for this thesis (see section 6.3.1). Standard Deviation Scores (SDS, Z-Scores) for weight-for-age, height-for-age, weight-for-height, and BMI-for-age were calculated using WHO Anthro® version 3.2.2 (WHO, Geneva, Switzerland) for children under 5 years of age, and WHO AnthroPlus® version 1.0.4 (WHO, Geneva, Switzerland) for children over 5 years of age. According to user instructions, extreme and potentially incorrect z-score values were excluded from analysis (WHO, 2009, 2011).

Foods eaten were assessed with an adapted version of the food frequency questionnaire developed for the CARE-study (Appendix G). As an indicator of diet

diversity, the WHO seven food group score was calculated on this basis (WHO, 2010). The score includes the following seven food groups:

1. Grains, roots and tubers
2. Legumes and nuts
3. Dairy products (milk, yoghurt, cheese, infant formula, or breastmilk)
4. Flesh foods (meat, fish, poultry, and liver/organ meats)
5. Eggs
6. Vitamin-A rich fruits and vegetables and
7. Other fruits and vegetables.

As a minor change to the WHO-score, infant formula and breast milk were added to the dairy products group. This is similar to the updated version of the WHO-score, in which Infant formula is also included in the diary group (WHO, 2021). A point was added for each of the 7 food groups, if any food of this group was eaten according to the food frequency questionnaire resulting in a range of 0-7 food groups.

6.2.5 Statistics

Sample size was calculated using G*Power 3.1.9.2 (Heinrich Heine University, Düsseldorf, Germany) (Faul et al., 2009) based on the primary outcome defined in section 2.3.1. Using a two-sided T-Test with significance level 0.05 and power 80%, a sample size of 45 per group was needed to detect a mean difference of 30% between groups. This takes into consideration the minimal important difference of 0.45 score points detected by Dunn Galvin et al. (2010). To account for dropouts estimated to be 20% over the one-year period based on clinical experiences due to the lack of similar studies, 55 patients per group would have to be enrolled in the study.

SPSS® version 24 (IBM, Armonk, NY, USA) was used for statistical analysis. Descriptive statistics of continuous variables are presented as means and standard deviation in case of normal distribution and median (Mdn) and interquartile range (IQR) when the assumption of normal distribution was violated. Normal distribution was assessed visually interpreting Quantile-Quantile Plots and using Shapiro Wilk test (Kirkwood & Sterne, 2003). Few outliers were tolerated for considering the variable as normal distributed. Categorical variables are presented in absolute and relative frequencies. For allergic reactions, incidence rates (IR), incidence rate ratios (IRR) their confidence intervals (CI) are presented (Schober & Vetter, 2021).

To test for differences in categorical variables, a Chi-square test was used. In case the expected frequency in one cell of the contingency table was less than 5, a Fischer's exact test was used instead (Field, 2017).

For normal distributed continuous variables an independent Student's T-test was performed to test for differences between the group with and without counselling. Normal distribution was assessed as described for descriptive statistics and variance homogeneity tested with the Levene's test. In case of non-normally distributed data a Mann-Whitney-U-Test was performed.

A repeated measure ANOVA was performed to analyse the development of continuous data over time between children with and without counselling when assumptions were met. The absence of sphericity was tested using Mauchly's test (Field, 2017). When the assumptions of the repeated measure ANOVA were violated, a Friedmann Test was performed. However, a Friedman test only allows to compare development over time, but no simultaneous comparison between two groups. Therefore, groups had to be compared separately using a T-test or Mann Whitney U Test.

Count data like the number of allergic reactions often assumes a Poisson or negative binominal distribution (Green, 2021). Therefore, a Poisson or in case of overdispersion (variance unequal to mean) a negative binominal regression model was used to analyse this data (A. Limacher, personal communication, 11 March 2022).

6.2.6 Ethical considerations

The project was ethically approved by the Ethics Committee Bern (ID 2018-01216) and the Research Ethics Committee for the Faculty of Health & Human Sciences and Peninsula Schools of Medicine & Dentistry, Plymouth University. Caregivers of children signed an informed consent form prior to entering the study. They had the option to terminate their participation in the study at any time without giving a reason.

6.3 Results

6.3.1 Characteristics of participants

Recruitment of participants turned out to be extremely challenging. Even though much effort was put into recruitment, the targeted number of 110 could not be reached. One problem was that fewer children than expected were diagnosed and many caregivers did not return the informed consent form. Therefore, follow-up calls were introduced, if parents agreed to their telephone number being shared with the research team. After an extended recruitment phase of two years from January 2019 to February 2021, 49 parents of children with food allergy consented to participate in the evaluation study. Despite the slow recruitment the numbers of patients were reasonably similar, enabling comparative statistical analysis. Details of dropouts and data completion is shown in Figure 6. The characteristics of the children are displayed in Table 26. The groups were not equal – counselling was larger than no counselling. Moreover, children who received counselling were younger than those who did not by a median of 9

months. The proportions of allergic triggers were different but there were also similarities (in both groups tree nuts were the most common allergy, followed by egg) and there were more children with multiple allergies (≥ 3) in the counselling group. Proportions of male and female were similar in both groups. The level of education and income was high in both groups.

Table 26 Sociodemographic and clinical characteristics of children of the participants

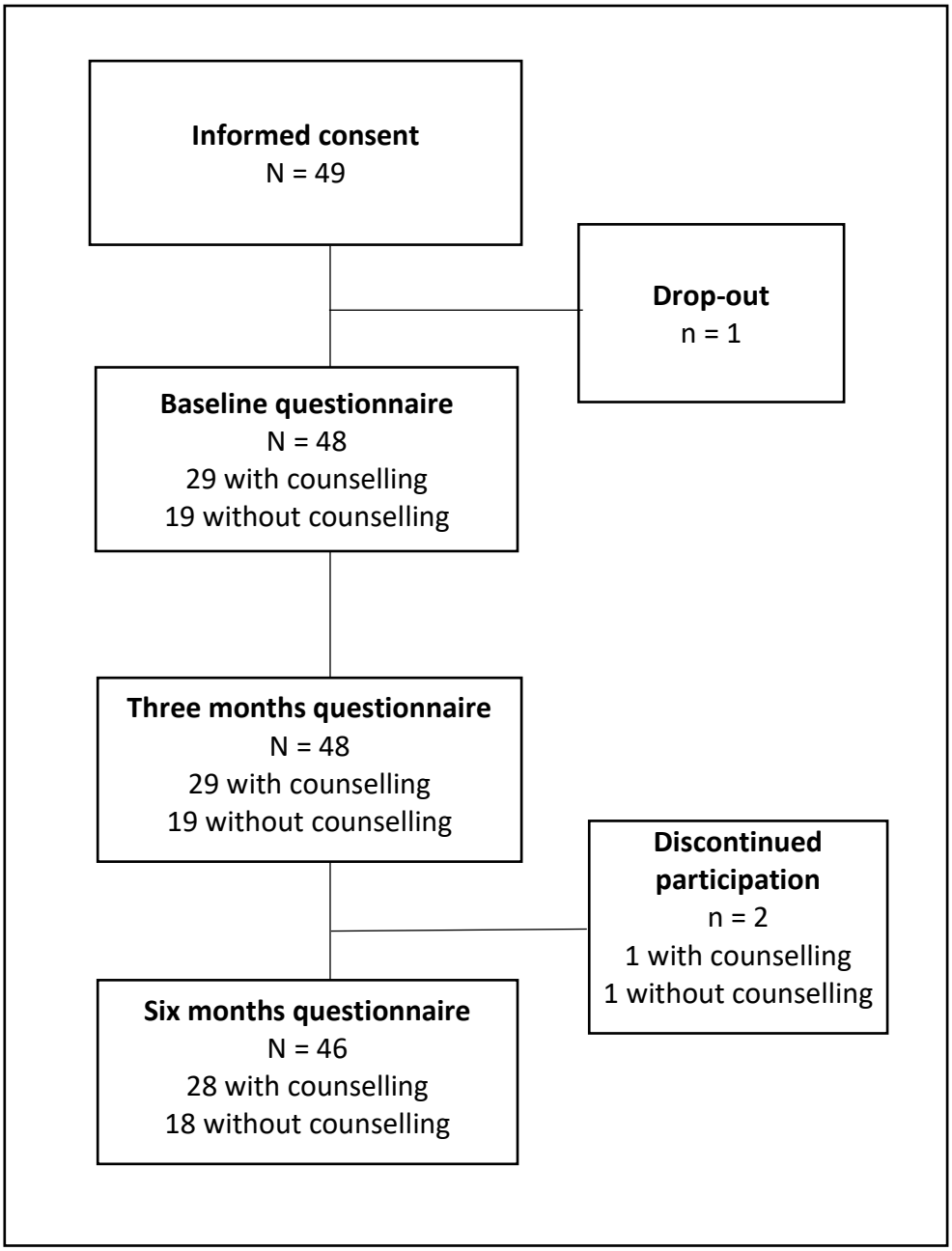
Variable		with counselling		without counselling		Total		P Two-tailed
		n	%	n	%	n	%	
Total		29	100.0	19	100.0	48	100.0	
Study site	Zurich	18	62.1	8	42.1	26	54.2	0.397c
	Basel	7	24.1	7	36.8	14	29.2	
	St Gallen	3	10.4	4	21.1	7	14.6	
	Aarau	1	3.4	0	0.0	1	2.1	
Gender	Male	19	65.5	12	63.2	31	64.6	1.000b
	Female	10	34.5	7	36.8	17	35.4	
Age groups (years)	0-3	27	93.1	15	78.9	42	87.5	0.110[c]
	4-6	2	6.9	1	5.3	3	6.3	
	7-10	0	0.0	3	15.8	3	6.3	
Emergency kit	Yes	24	82.8	16	84.2	40	83.3	1.000[c]
Symptoms [a]	Cutaneous	28	96.6	17	89.5	44	91.7	0.554[c]
	Gastrointestinal	16	55.2	5	26.3	20	41.7	0.075[b]
	Respiratory	9	31.0	6	31.6	13	27.1	1.000[b]
	Cardiovascular	3	10.3	0	0.0	3	6.3	0.267[c]
Number of foods allergies	1-2	18	62.1	17	89.5	35	72.9	0.049[b]
	≥3	11	37.9	2	10.5	13	27.1	
Allergenic foods [a]	Tree nuts	17	58.6	10	52.6	27	56.3	0.770[b]
	Hen's egg	15	51.7	8	42.1	23	47.9	0.566[b]
	Cow's milk	12	41.4	1	5.3	13	27.1	0.007[b]
	Peanut	6	20.7	6	31.6	12	25.0	0.501[c]
	Soy	5	17.2	0	0.0	5	10.4	0.142[b]
	Others	8	27.6	2	10.5	10	20.8	0.276[c]
Education level	Primary	0	0.0	0	0.0	0	0.0	0.366[b]
	Secondary	8	27.6	8	42.1	16	33.3	
	Tertiary	20	69.0	11	57.9	31	64.6	
	No indication	1	3.5	0	0.0	1	2.1	
Income (CHF per year)	< 50.000	0	0.0	0	0.0	0	0.0	0.227[c]
	50.000-100.000	8	27.6	3	15.8	11	22.9	
	100.000-200.000	13	44.8	15	78.9	28	58.3	
	> 200.000	4	13.8	1	5.3	5	10.4	
	No indication	4	13.8	0	0.0	4	8.3	

Note. IQR = Interquartile range, median age of children was 15.5 months (IQR =22), median age with dietary counselling was 14.0 (IQR = 9), median age without dietary counselling was 23.0 (IQR = 16) [a] multiple answers possible [b] chi square test [c] Fischer's exact test with counselling versus without counselling

Figure 6 presents a flow chart of the number of completed questionnaires at different points in time and of the participants dropping out. In the first 6 months, 6.1%

of participants dropped out of the study. Attrition was similar between groups. Reasons for discontinuation could not be evaluated, because participants could not be reached despite several attempts via mail and telephone. Moreover, due to the study design it was not possible to assess the number of children assessed for eligibility.

Figure 6. Flow chart on number of completed questionnaires per time point



6.3.2 Dietary counselling

The majority of children (60.4%) in this sample received dietary counselling. Reasons parents named for and against choosing dietary counselling are listed in Table 27. Most frequently reported reasons for choosing dietary counselling was the recommendation by the physician and the difficulty of implementing an avoidance diet in daily life. The reasons for not choosing dietary counselling were more diverse. Costs, however, were not mentioned as a reason for not choosing dietary counselling.

Table 27 Reasons parents reported for or against choosing dietary counselling.

For what reasons do you attend dietary counselling?	**n**
because my physician recommended it [a]	17
to get tips on how to implement allergen avoidance in everyday life [a]	17
to learn what my child can eat [a]	12
to assure my child has a balanced diet [a]	12
the dietitian was present at the allergist's consultation [b]	2
introduction and extension of complementary feeding without cow's milk [b]	1
to learn how to replace food [b]	1
For what reasons do you not attend dietary counselling?	**n**
my physician did not recommend it a	4
I can get information in another way a	4
allergen restriction can be easily implemented a	4
costs are too high a, c	0
until now, we did not have any problems b	1
no demand b	1
I am not aware, that this is recommended b	1
I went to bioresonance with my child b	1
we are in the peanut allergy association, there is also a lot of information b	1

Note. [a] Closed question. Multiple answers were possible. [b] Answer from textbox. [c] In Switzerland dietary counselling for food allergy is reimbursed by health insurance, but patients must pay a gap retention.

The number of counselling sessions varied from one to seven with a median of two sessions (IQR = 2). Nearly half (48.3%) had only one consultation. After three months, only three of 46 children had continued consultations. Table 28 shows the median percentage (IQR) of recommendations implemented by the dietitians while counselling sessions as well the median percentage of those they considered as relevant

of the specific child. More recommendations for the intervention and assessment were realised than for monitoring. This is understandable as 48.3 % had only one consultation with the dietitian. Only a part of the recommendations for interventions was considered as relevant for the specific child. This is partly because some recommendations are only relevant for specific food allergies, such as recommendation 10 on milk substitutes being only relevant for children with CMA (see chapter 4). In Appendix Q the numbers of each realised recommendations are shown.

Table 28 Median and interquartile range (IQR) of practice guideline recommendations realisation by dietitians.

Recommendations		**Overall realisation of recommendations**		**Realisation of relevant recommendations**	
	n	Median (%)	IQR	Median (%)	IQR
All recommendations incl. subrecommendations	43	56.5	22.1	87.0	20.4
Assessment	15	73.3	33.3	86.7	15.2
Intervention	25	56.0	30.0	91.7	21.9
Monitoring	3	33.3	50.0	66.7	66.7

6.3.3 Primary outcome: Food allergy related QoL

Table 29 shows median FAQLQ-PF-G scores and subscale scores in the overall sample and for the three age groups and time points. A score of one indicates ‘no impairment’ and a score of seven ‘maximal impairment’. The median FAQLQ-PF total score decelerates from Mnd = 1.33 (IQR = 0.89) at baseline to 1.62 six months after diagnosis. The median food allergy related QoL scores in youngest age group (0-3 years) were generally low ranging from 1.32 to 1.48 indicating only minor impairment of food allergy related QoL in this age group. Both groups of children aged 4-6 years and aged 7-10 years include only three children. Median QoL scores were higher in these groups indicating lower QoL ranging from 1.53 to 5.29. However, due to the small number of children in these age groups no conclusion can be drawn. The following statistics of

FAQLQ-PF only included the overall sample and the age group of 0-3 years, because the other age groups are too small for any separate analysis.

Table 29 Median scores and Interquartile range (IQR) of FAQLQ-PF-G scores per age group and timepoint

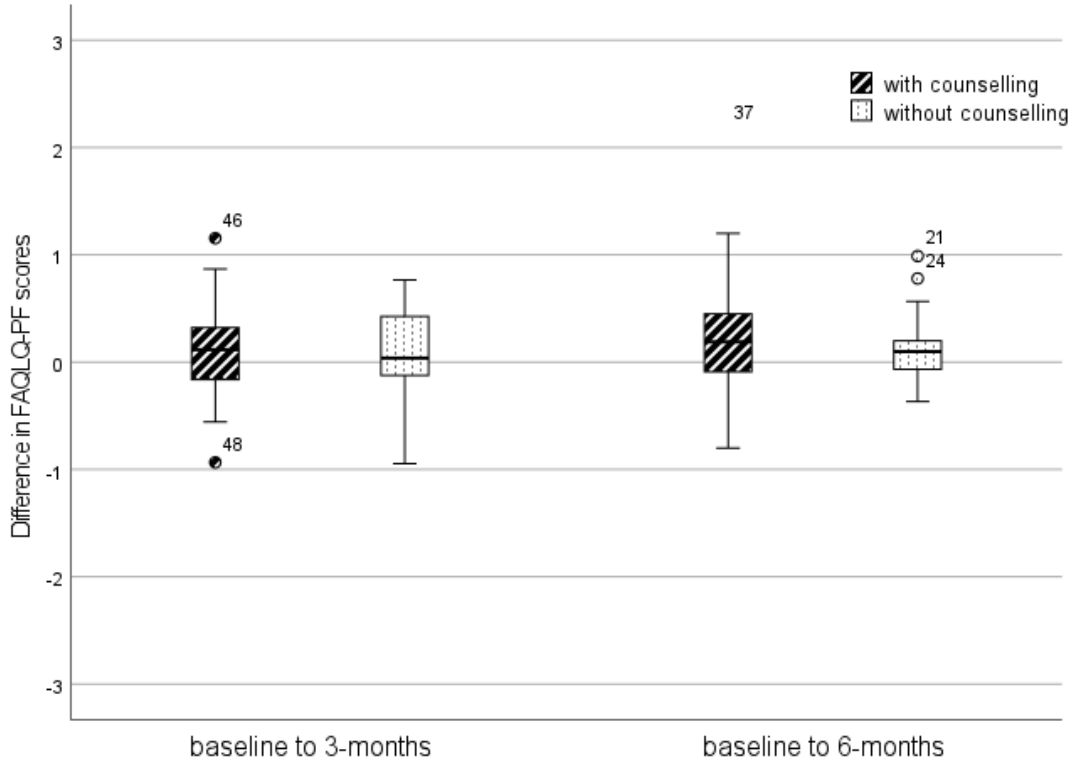
Sample	FAQLQ-PF-G	N	Median score (IQR) baseline	N	Median score (IQR) 3-months	N	Median score (IQR) 6-months
Overall	Total Score	48	1.33 (0.89)	48	1.54 (0.66)	46	1.62 (1.16)
	Subscale Scores						
	Emotional Impact		1.17 (0.83)		1.33 (0.83)		1.42 (1.00)
	Food Anxiety		1.00 (0.94)		1.33 (0.67)		1.00 (1.00)
	Social Dietary Limitation		1.60 (1.15)		1.60 (1.35)		1.80 (1.42)
0 - 3 years	Total Score	42	1.32 (0.69)	42	1.43 (0.67)	40	1.48 (0.92)
	Subscale Scores						
	Emotional Impact		1.00 (0.67)		1.17 (0.71)		1.33 (0.83)
	Food Anxiety		1.00 (0.67)		1.33 (0.33)		1.00 (0.58)
	Social Dietary Limitation		1.60 (0.90)		1.60 (0.95)		1.60 (0.95)

Note. FAQLQ-PF scores and subscale scores range from 1 'no impairment' to 7 'maximal impairment'.

The median change in total FAQLQ-PF-G scores of all age groups between baseline and after six months was 0.131 (IQR = 0.46) This is less than the minimal important difference of 0.45 score points detected by Dunn Galvin et al. (2010), indicating that these differences are not clinically relevant. A Mann Whitney-U-Test was conducted to compare this change between children with and without dietary counselling after six months, because change in scores between baseline and six months in the dietary counselling group were not normally distributed. The change in FAQLQ-PF scores did not significantly differ between children with counselling (Mdn = 0.189, IQR = 0.59) to children without counselling (Mdn = 0.100, IQR = 0.33); U = 221.0, z = -0.698, p=0.485, r = -0.10. The change between baseline and three months was also not significantly different between the children with counselling (Mdn = 0.117, IQR = 0.49) and the children without counselling (Mdn = 0.039, 0.57); U = 244.5, z = -0.169, p = 0.866,

r = 0.02. This indicates that dietary counselling in this sample did not appear to influence a change in allergy related QoL. Figure 7 shows boxplots of the difference in FAQLQ-PF scores between baseline and three six months respectively.

Figure 7 Difference in total FAQLQ-PF-G-scores in all age groups between baseline and 3 and 6 -months respectively with and without counselling



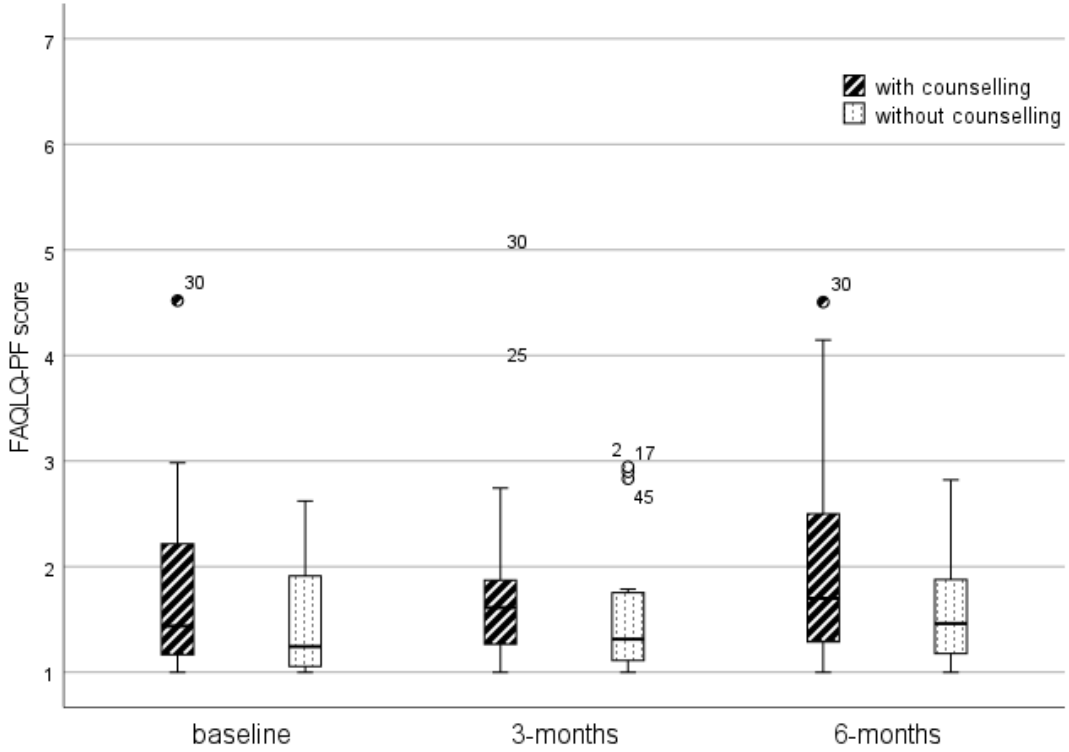
Note. A positive score represents a worsening in quality of life, whereas a negative score an improvement. Zero represents no change. N = 48 (29 with counselling, 19 without counselling) between baseline and 3-months. N = 46 (28 with counselling, 18 without counselling) between baseline and 6-months.

A Friedman Test was performed to compare the effect of dietary counselling on allergy related QoL. It showed a statistically significant difference of the total FAQLQ-PF-G score over the three time points for both samples. Test statistics for the overall sample was $\chi2(2) = 9.112$, $p = 0.011$. and for the age group 0-3 years $\chi2(2) = 9.130$, $p = 0.010$. Dunn-Bonferroni post-hoc tests were carried out and detected significant differences between baseline and 6-months in both groups ($Z = -0.609$, $p = 0.011$and $Z = -0.650$, $p = 0.011$ respectively). There was no statistical difference between the other time points.

This indicates that the food allergy related QoL of the children deteriorate over this first half year after diagnosis in this sample.

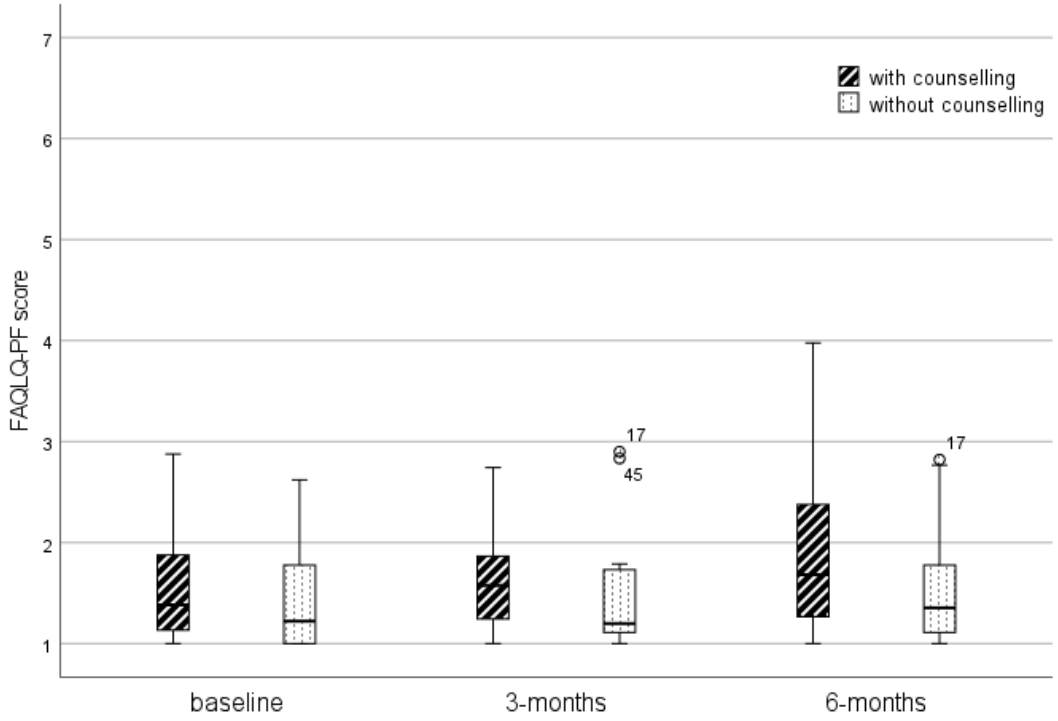
Figure 8 and Figure 9 illustrate the development of FAQLQ-PF-G scores distribution in all children and in children 0-3 years, with and without counselling at baseline, after three and six months.

Figure 8 Boxplots of FAQLQ-PF-G score distribution of all children at baseline, after three and six months with and without counselling



Note. Total N = 46, with counselling (n = 28), without counselling (n = 18).

Figure 9 Boxplots of FAQLQ-PF-G score distribution of children 0-3 years at baseline, after three and six months with and without counselling



Note. Total (N = 40), with counselling (n = 26), without counselling (n = 14).

A Mann Whitney-U-Test was conducted to compare differences in FAQLQ-PF-G score in the overall sample and in children 0-3 years with and without dietary counselling at baseline, after three and six months (Table 30). FAQLQ-PF-G scores did not differ significantly between these groups at any time point.

Table 30 Comparison of FAQLQ-PF-G scores between food allergic children with and without counselling at the time points in the overall sample and in the age group 0-3 years

Sample	**Time**	**Median Score (IQR) With counselling**	**Median Score (IQR) Without counselling**	**U**	**Z**	**p**
Overall	baseline	1.44 (1.13)	1.24 (0.91)	219.5	-1.182	0.237
N = 46	3 -months	1.61 (0.62)	1.31 (0.65)	210.5	-1.371	0.170
	6-months	1.70 (1.23)	1.46 (0.74)	208.0	-0.991	0.322
0-3 years	baseline	1.38 (1.00)	1.22 (1.00)	149.5	-1.394	0.163
N = 40	3-months	1.58 (1.00)	1.20 (1.00)	138.5	-1.682	0.093
	6-months	1.68 (1.16)	1.36 (0.70)	141.0	-1.163	0.254

Note. IQR = Interquartile range.

6.3.4 Allergic reactions

Table 31 presents the food allergic reactions the children experienced between baseline and three months, and three to six months, as well as all reactions from baseline to six months reported by the parents. In the first 6 months after diagnosis more parents reported at least one allergic reaction for more than half of the children (57.8%). This percentage was higher in children not receiving dietary counselling (66.1%) compared to the children with counselling (50%). This trend was more pronounced in the first three months, when overall more children experienced allergic reactions 41 compared to 24 between three and six months. Between three and six months more children in the dietary counselling group had allergic reactions.

Table 31 Number and frequency of food allergic reactions in children with counselling versus without counselling at each measuring time and in total.

Measuring time	Number of allergic reactions	with counselling N=28*		without counselling N=19*	
		N	%	n	%
0-3-months	0	19	67.9	9	47.4
	≥ 1	9	32.1	10	52.6
	1	7	24.1	4	21.1
	2	1	3.4	2	10.5
	3	2	6.9	1	5.3
	4	0	0.0	1	5.3
	5	0	0.0	1	5.3
	6	0	0.0	1	5.3
3-6-months*	0	19	66.7	15	83.3
	≥ 1	9	33.3	3	16.7
	1	4	14.8	2	11.1
	2	4	14.8	0	0.0
	5	1	3.7	1	5.6
0-6 months*	0	14	50.0	7	38.9
	≥ 1	14	50.0	11	61.1
	1	7	25.0	3	16.7
	2	2	7.1	3	16.7
	3	3	10.7	0	0.0
	4	1	3.6	2	11.1
	5	0	0.0	2	11.1
	6	0	0.0	1	5.6
	8	1	3.6	0	0.0

Note. One Person in the group with counselling answered that he/she does not know if his/her child had an allergic reaction to food at three months. *One child dropped out in each group after 3 months.

The overall IR was 1.413 allergic reactions per child in the first six months after diagnosis. This rate was numerically lower in children with counselling (1.143 reactions per child) compared to children without counselling (1.833 reactions per child) resulting in an IRR of 1.604. This difference was more pronounced in the first three months after diagnosis when IR was 0.854 in all children and 0.517 in those with counselling and 1.368 in children without counselling and IRR was 2.646. However, between 3 and 6 months, more children experienced food allergic reactions in the group with counselling. During

this time, there were fewer allergic reactions overall with IR being 0.521 allergic reaction per child, 0.607 in children with counselling and 0.389 in the group without counselling and an IRR of 0.641.

A Negative Binominal Regression Model was performed to predict the number of food allergic reactions based on dietary counselling, as a Poisson model was not suitable due to overdispersion recognised by a variance that is not equal to the mean. Table 32 presents the unadjusted model, a model adjusted to age, sex, and multiple food allergy (≥ 3 foods) (adjusted model 1) and a model adjusted to cow's milk, tree nut and peanut allergy (adjusted model 2). A significant difference was detected between baseline and three months in the unadjusted as well as the adjusted model, and between baseline and six months only in the adjusted model, indicating that children without counselling had more food allergic reactions at this time point. Having multiple food allergies (≥ 3 foods) significantly ($p = 0.019$) influenced the model between baseline and three months and between baseline and six months. Sex significantly influenced the model between 3 and 6 months. Having cow's milk, tree nut or peanut allergy did not influence the number of allergic reactions at any time.

Table 32 Unadjusted and adjusted negative binominal models predicting the number of food allergic reactions in children with food allergy

Measuring time	**0-3 months N = 48**			**3-6 months [b] N = 46**			**0-6 months [c] N=46**		
Parameter	IRR	95% CI	p	IRR	95% CI	p	IRR	95% CI	p
Unadjusted Model									
Intercept	0.517	0.277-0.965	0.038	0.389	0.162-0.931	0.034	1.833	1.032-3.256	0.039
Without counselling	2.646	1.120-6.248	**0.026**	1.561	0.540-4.510	0.410	1.604	0.746-3.451	0.227
Adjusted model 1[a]									
Intercept	1.304	0.507-3.353	0.582	0.114	0.007-1.750	0.119	3.055	1.325-7.045	0.009
Without counselling	6.036	1.852-19.675	**0.003**	1.284	0.219-2.770	0.700	3.653	1.370-9.741	**0.010**
Age in months	0.979	0.957-1.001	0.067	0.969	0.930-1.009	0.130	0.977	0.957-0.998	**0.031**
Male sex	0.821	0.307-2.197	0.695	4.481	1.106-18.154	**0.036**	1.423	0.584-3.469	0.438
Multiple food allergies [a]	4.210	1.261-14.056	**0.019**	2.720	0.808-9.156	0.106	3.186	1.209-8.391	**0.019**
Adjusted model 2									
Intercept	0.569	0.211-1.530	0.264	0.563	0.181-1.752	0.321	1.079	0.444-2.625	0.866
Without counselling	2.517	0.984-6.437	0.054	0.597	0.179-1.989	0.400	1.587	0.669-3.762	0.295
Cow's milk allergy	0.907	0.293-2.805	0.865	0.573	0.157-2.088	0.398	0.760	0.282-2.053	0.589
Tree nut allergy	0.850	0.351-2.061	0.719	1.183	0.374-3.741	0.775	1.092	0.474-2.513	0.836
Peanut allergy	1.162	0.430-3.137	0.768	1.541	0.485-4.896	0.464	1.314	0.535-3.224	0.551

Note. IRR = incidence rate ratio [a] multiple food allergy was defined by allergies to ≥ 3 foods. P-values < 0.05 are in bold [b] Omnibus test was not significant for the 3-6 months data indicating that the model is not better than the zero model. [c] Omnibus Test for the unadjusted model was not significant for 0-6 months data.

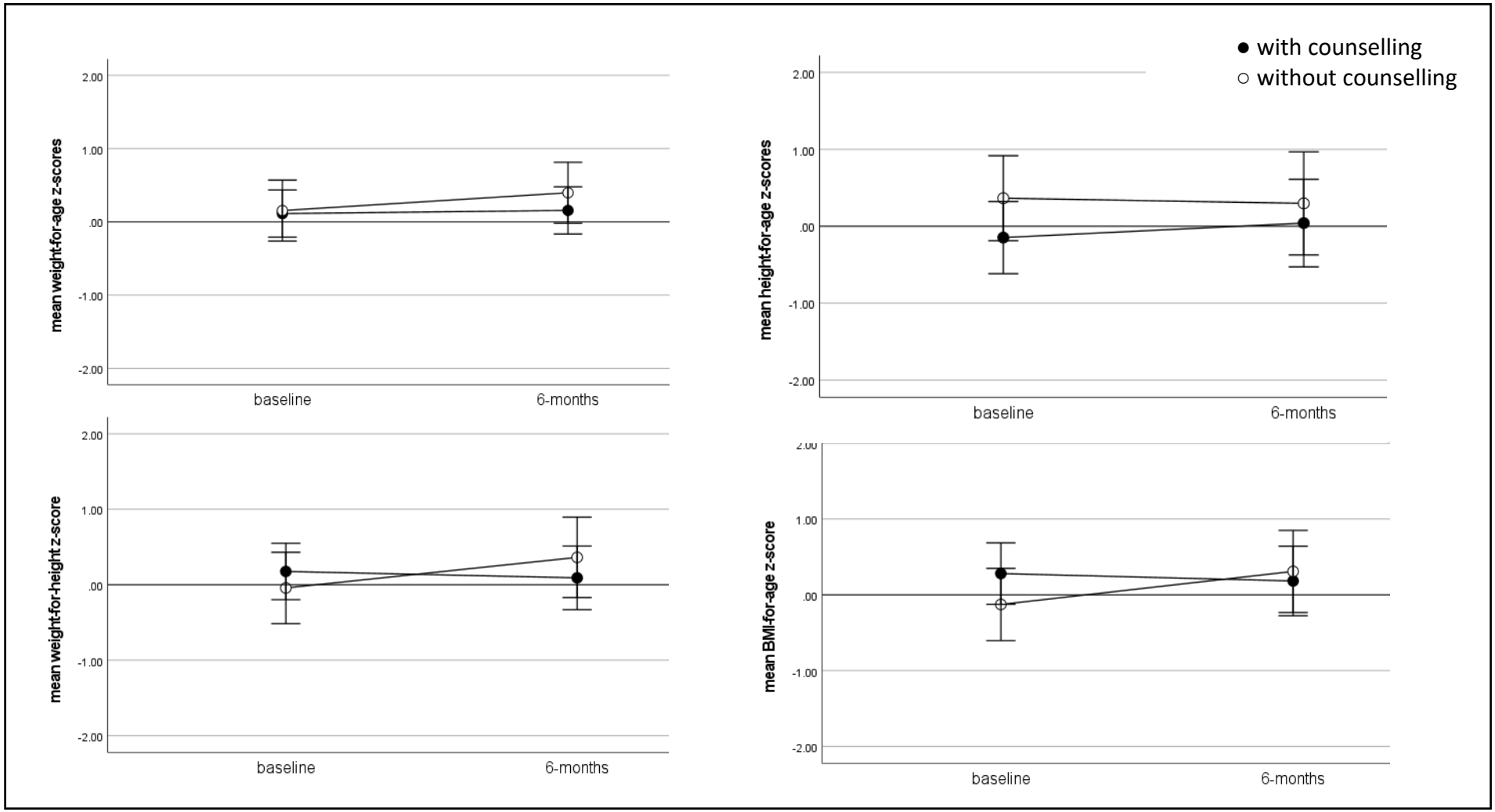
6.3.5 Nutritional status

Figure 10 presents the growths z-scores as indicators for nutritional status at baseline and after six months. According to the instruction of Anthro®, data from three children were excluded from analysis due to extreme and potential incorrect z-score values. For children over the age of five no height-for-weight and for children over 10 years no weight-for-age z-scores were calculated. Leaving 39 children for weight-for-length/height, 43 for length/height-for-age, 40 for weight-for-age and 43 for BMI-for-weight analysis (WHO, 2009, 2011).

Mixed repeated measure ANOVA showed no significant effects for any of these indicators regarding time or group affiliation. Figure 10 visualises the changes in z-score values over time and between groups

.

Figure 10 Change in mean z-scores between baseline and six months after diagnosis



Note. Weight-for age z-scores N = 40; length/height-for-age z-scores N = 43; weight-for-length/height z-scores N = 39; BMI-for-age z-scores N = 43; error bars: 95% CI

Children of this study were overall well-nourished. Only few children were identified as underweight, stunted, wasted or overweight according to WHO-criteria (s. Table 33). No significant differences between the group with dietary counselling and the one without could be detected.

Table 33 Numbers, frequencies, and Fischer's exact test results for underweight, stunting, wasting and overweight per time and group

Measuring time	Indicator	with counselling			without counselling			Two tailed
		N	n	%	N	n	%	p
baseline	underweight	27	0	0.0	19	1	5.3	0.413
	stunting	27	1	3.7	19	0	2.2	1.000
	wasting	27	0	0.0	16	2	4.7	0.133
	overweight	27	1	3.7	16	1	6.3	1.000
6-months	underweight	26	0	0.0	15	0	0.0	-
	stunting	26	2	7.7	18	1	5.6	1.000
	wasting	25	1	4.0	15	0	0.0	1.000
	overweight	25	1	4.0	15	0	0.0	1.000

Note. Number, frequencies, and Fischer's exact test results between dietary counselling and no dietary counselling group of children being underweight (weight-for-age z-score < -2), stunted (height/length for age z-score < -2), wasted (Weight-for-length/height z-score < -2) and overweight (Weight-for-length/height z-score > +2). Data from three children were excluded from analysis due to extreme and potential incorrect z-score values. For children over the age of five no height-for-weight and for children over 10 years no weight-for-age z-scores were calculated. Leaving 39 children for weight-for-height, 43 for height-for-age, 40 for weight-for-age and 43 for BMI-for-weight analysis (WHO, 2009, 2011).

6.3.6 Diet diversity

Table 34 presents the food groups of which the children ate at least one food at the different measurement times. This shows which foods groups count for the diversity score and which foods are avoided by the parents. Only 11 children did not eat foods from all defined food groups after six months. The children ate the least foods from the groups 'eggs', 'legumes and nuts'. This was mainly due to the allergy of the respective child. At baseline 16.7% of the parents (17.2% in the counselling group and 15.8% in the group without counselling) reported that they avoid introducing new foods in the child's diet due to the food allergy. This number dropped to 14.6% after three and 15.2% after six months, with 20.7% and 21.4% in the group with counselling, and 5.3% and 5.6% in

the group without counselling. This indicates that parents in the counselling group are more cautious to introduce new foods in the diet of their children.

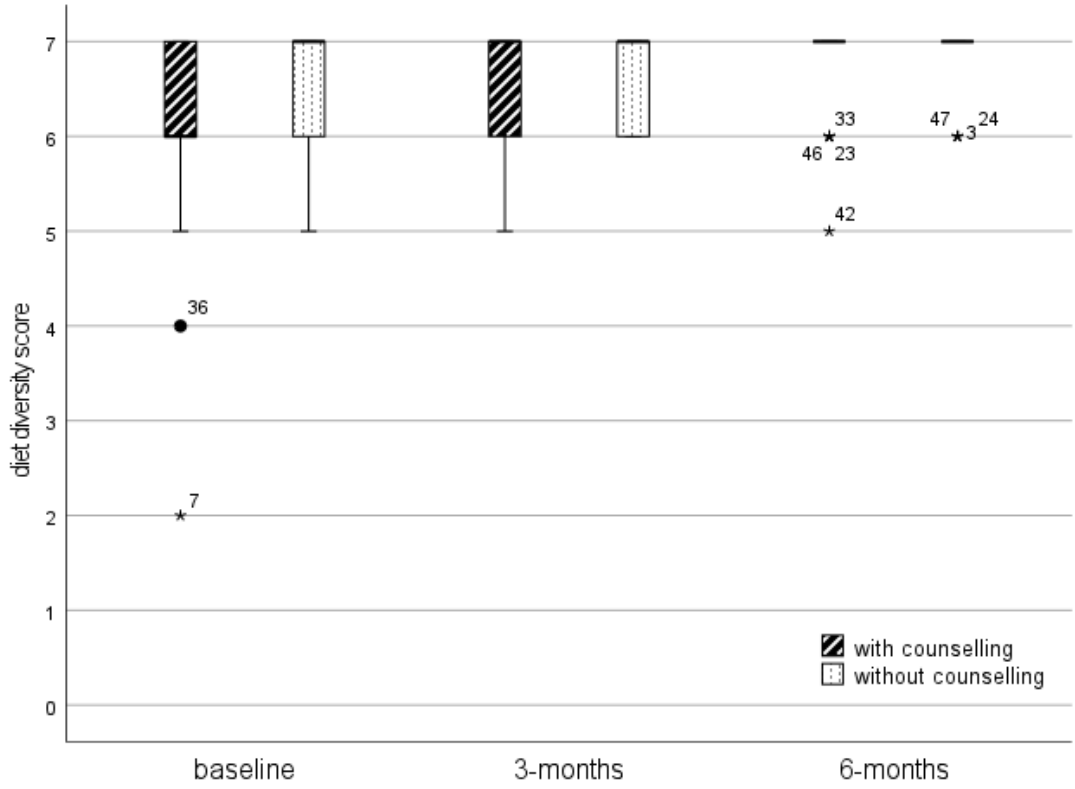
Table 34 Numbers, frequencies, and Chi-square or Fischer's exact test results for food groups eaten by the child in the last four weeks before measurement

Food groups	**with counselling** N = 29*		**without counselling** N = 19*		**Two tailored** p
	n	%	N	%	
baseline					
Grains, roots, and tubers	28	96.6	19	100.0	1.000[a]
Legumes and nuts	23	79.3	17	89.5	0.451[a]
Dairy products	29	100.0	19	100.0	-
Flesh foods	27	93.1	19	100.0	0.512[a]
Eggs	14	48.3	12	63.2	0.312[b]
Vitamin-A rich fruits and vegetables	29	100.0	19	100.0	-
Other fruits and vegetables	28	96.6	19	100.0	1.000[a]
3-months					
Grains, roots, and tubers	29	100.0	19	100.0	-
Legumes and nuts	27	93.1	18	94.7	1.000[a]
Dairy products	27	95.8	19	100.0	0.512[a]
Flesh foods	29	100.0	18	94.7	0.396[a]
Eggs	19	65.5	14	73.7	0.551[b]
Vitamin-A rich fruits and vegetables	29	100.0	19	100.0	-
Other fruits and vegetables	29	100.0	19	100.0	-
6-months					
Grains, roots, and tubers	28	100.0	18	100.0	-
Legumes and nuts	28	100.0	17	94.4	0.391[a]
Dairy products	27	96.4	18	100.0	1.000[a]
Flesh foods	28	100.0	18	100.0	-
Eggs	22	78.6	16	88.9	0.453[a]
Vitamin-A rich fruits and vegetables	28	100.0	18	100.0	-
Other fruits and vegetables	28	100.0	18	100.0	-

Note. Number, frequencies, and chi-square results between dietary counselling and no dietary counselling of food groups eaten by children with food allergy. [a] Fischer's exact test [b] Chi-square test * One dropped out at six months in each group

Median diet diversity score was 6.5 (IQR = 2) at baseline, and 7.0 (IQR = 1) three months and 7.0 (IQR = 0) six-months after diagnosis in the overall sample. The Friedman Test showed a statistically significant difference of the score over the three time points, $\chi2(2) = 14.324$, $p < 0.001$. Dunn-Bonferroni post-hoc tests were carried out and there were significant differences between baseline and six months ($Z = -0.478$, $p = 0.022$). There was no statistical difference between the other time points. This indicates that the diet of the children became more diverse in this first half year after diagnosis.

Figure 11 Boxplot of diet diversity scores at baseline, after three and six months after diagnosis by dietary counselling.



Note. N = 46. Diet diversity score is the sum of food groups from which at least one food was eaten.

Figure 11 visualises diet diversity distribution by dietary counselling versus no dietary counselling. A Mann Whitney-U-Test was conducted to compare differences in diet diversity score in children with and without dietary counselling at baseline, after three and six months. The change in diet diversity scores did not differ significantly between these groups at any time point (Table 35). This indicates that diet diversity did not influence the decision to seek dietary counselling and dietary counselling did not influence diet diversity as defined by WHO.

Table 35 Comparison of diet diversity scores between food allergic children with and without counselling at the time points in the overall sample and in the age group 0-3 years

Time	Median Score (IQR) With counselling	Median Score (IQR) Without counselling	U	z	p
Baseline	6.0 (1.0)	7.0 (1.0)	226.5	-1.139	0.255
3 -months	7.0 (1.0)	7.0 (1.0)	256.0	-0.479	0.632
6-months	7.0 (0.0)	7.0 (0.0)	238.5	-0.441	0.659

Note. IQR = Interquartile range.

6.4 Discussion

This is the first study in Switzerland observing children with food allergies with and without dietary counselling over a six-month period, the longest follow-up to date. Even though it is not a randomised controlled trial it shows real-life data from clinical practice. The most important result was that children who did not receive dietary counselling had a 2.65-fold higher risk of experiencing an allergic reaction in the first three months after diagnosis. Even though this was not the primary outcome, it is probably a more relevant result than QoL, as one of the main goals in the dietary management of patients with food allergies is to avoid allergic reactions (Muraro, Werfel, et al., 2014; Worm et al., 2015; Worm et al., 2021). It was not planned to be the primary outcome because available evidence suggested it would be unlikely to observe many allergic reactions during the time period of the study. Therefore, having accidental allergic reactions as the primary outcome would have required a much larger and unrealistic sample size of 130-1228 children (section 2.2.3). The other two outcomes, nutritional status, and, diet diversity, did not show significant differences between those children with and without counselling.

Although the results of the study demonstrate that, overall, the number of allergic reactions was less in the group with dietary counselling, this difference was only significant three months after diagnosis in the unadjusted model. In the following three months, no differences were observed. The first three months was also the period when

most of the consultations took place and most of the allergic reactions happened. Other researchers have shown that in children with peanut allergy a longer disease duration decreases the risk of allergic reactions (Cherkaoui et al., 2015), suggesting that learning to avoid allergenic foods needs time. This study suggests that this learning can be accelerated through dietary counselling. However, it remains uncertain if continued counselling sessions would help to further reduce allergic reactions. In the model adjusted to age, sex, and multiple food allergies the influence of dietary counselling was also significant when investigating the whole period from baseline to six months. This was mainly influenced by the children with multiple food allergy (≥ 3 foods) having more allergic reactions and were more present in the group with dietary counselling. It seems as if children with multiple food allergies would especially benefit from counselling, and thus, should be given special consideration for referral to a dietitian. However, the type of food provoking the allergic reactions does not seem to influence the number of allergic reactions.

The rate of children experiencing *at least one allergic reaction* after 6 months was 54.3%, and this was higher compared to other studies. Fierstein et al. (2021) found that 50.5% of respondents of the US patient registry reported one or more food allergic reaction per year. It is uncertain from the publication to which period this frequency refers with regard to the diagnosis. Cross sectional studies found that 41% of children with peanut allergy and 20% children with egg allergy experienced at least one allergic reaction to the respective food in a three year and one year period respectively (Boyano-Martinez et al., 2012; Kansen et al., 2020). Also, for these studies it is unclear if they started data collection with diagnosis. In addition, all these studies collected data retrospectively, as opposed to prospectively in our study, and over longer periods of time, which may have led to underreporting. From our study we learn that most

accidental allergic reactions seem to happen in the first three months after diagnosis. This should be considered in future studies.

QoL (as measured by the FAQLQ-PF) was not much impaired, especially in the youngest age group, and no significant differences between the group with and without dietary counselling could be detected. The lack of impairment in the youngest children was also seen in our validation study and other validation studies of FAQLQ-PF; scores ranged from 1.7 to 3.6 (maximum possible score = 7) (Dunn Galvin et al., 2008; Limpitikul et al., 2020; Manso et al., 2017; Mendonça et al., 2020; Mizuno et al., 2016). The mean score of our study population was even lower at baseline (1.52) and after three months (1.57), but had reached 1.73 after six months (Appendix R). This steady deterioration in QoL over six months corresponds with the other cross-sectional studies suggesting that the allergy-related QoL deteriorates with the age of the children. This may be explained by the greater challenges the children and their family face in avoiding allergens when the child gets older. Therefore, it will be interesting to evaluate one year data of FAQLQ-PF to see if this trend continues to increase. Longer observation periods could provide important clues as to which life events and interventions influence allergy-related QoL.

The overall very good QoL (low FAQLQ-PF scores) in this cohort might be one reason why dietary counselling did not influence this outcome; an already good QoL is potentially harder to improve. Nevertheless, dietary counselling did not prevent QoL from worsening within the first six months after diagnosis. In fact, QoL has deteriorated slightly more in the group with dietary counselling with a greater inter-individual range (Figure 7). This may be due to the greater risk perception in this group but might also depend on the individual dietitian and how well the dietitian alleviates the patients' fears and supports them in their everyday life. Maybe more emphasis should be placed

on promoting QoL in dietary consultations, which was only a minor issue according to the process documentation of the counselling sessions (Appendix Q).

Overall nutritional status was good in our sample, with few children being underweight (0.0%), stunted (6.8%), wasted (2.5%) or overweight (2.5%) six months after diagnosis. These rates can be regarded as low for stunting, wasting and overweight when using the WHO cut-off values based on the study of Onis et al. (2019). No cut-off value for underweight exists, but as the rate for underweight is zero in this cohort, no such value is needed to describe this rate as very low. Most other studies investigating growth parameters in children with food allergy also found height-for-age (stunting) most impaired (Chong et al., 2018; Meyer et al., 2014; Meyer et al., 2019) (Table 36). Flammarion et al (2011) observed that children with food allergy are stunted despite receiving similar energy intake to healthy controls, suggesting that other factors (such as inflammation) play an important role. Our study found lower overall rates of underweight, stunting and wasting compared to all other studies (Meyer et al., 2014; Meyer et al., 2019; Thomassen et al., 2017) reporting nutritional indicators except one (Chong, 2018) (Table 36). This is maybe due to the higher rates of CMA in the study of Meyer et al. (2019) (64%) and Thomassen (2017) (100%) compared to the study of Chong et al. (2018) (38%) and our study (27.1%). Meyer at al. (2014) did not report the frequency of CMA, but stated that CMA was the most common allergy in this sample. Moreover, our study only included children with IgE-mediated food allergy, whereas the other studies included children with IgE- and non-IgE-mediated food allergies. Meyer et al. (2019) suggested that growth parameters for weight-for-height, height-for-age and BMI were higher when nutritional input was available, but our study did not confirm this as dietary counselling did not influence any of these parameters. This result might be different in a cohort including more children with CMA. To conclude, nutritional status

of Swiss children with food allergy does not seem to be much impaired, however, the risk for stunting remains, and weight and height should be monitored in dietary counselling.

Table 36 Comparison of rates of underweight, stunting, wasting and overweight between our study at baseline and 6-months and other studies reporting nutritional indicators in children with food allergy

Nutritional status	**Baseline N = 46**	**6-months N =44**	**Meyer et al., 2019, N=430**	**Meyer et al., 2014, N = 97**	**Thomassen et al., 2017, N =57**	**Chong et al., 2018, N = 74**
	%	%	%	%	%	%
Underweight	2.1	0.0	6.0	8.5	10.5	1.0
Stunting	2.1	6.8	9.0	11.1	5.3	5.4
Wasting	4.7	2.5	5.0	3.7	10.5	1.4
Overweight	4.7	2.5	8.0	7.5	NR	1.4

Note. frequencies of underweight (weight-for-age z-score < -2), stunted (Height-for-age z-scores < -2), wasted (weight-for-length/height< -2) and overweight (weight-for-length/height z-score > +2). NR = not reported

Children in this study, in both the active and control groups already ate a diverse diet (diversity score = 6.5 at baseline). All children ate foods from more than five food groups six months after diagnosis. Diet diversity was mainly influenced by age, which is understandable as many children in this sample were in the process of complementary feeding. Only 16.7% of caregivers reported delaying the introduction of any complementary food due to food allergy or avoiding specific foods at baseline, which was less than we would have expected based on other study results (Lai & Sicherer, 2019). Furthermore, no differences were observed between children with or without dietary counselling. Only one other study investigated diet diversity in children with existing food allergies (Maslin, Dean, et al., 2016). This study found that children with milk allergy had an overall less diverse diet, including a less varied consumption of meat and sweet foods. However, they used a more detailed food frequency questionnaire and different diversity score method. Maybe a more sensitive instrument is needed to detect

differences in diet diversity in this patient group, especially when measured in countries with a high socioeconomic status, where alternative products are available and affordable for the majority of the society. Until now, there has been no consensus on which instrument should be used to measure diet diversity in children with food allergy (Venter et al., 2020). Efforts should be made to validate and establish appropriate questionnaires and diversity scores.

The number of *counselling sessions* was small (Mdn=2) and most of the counselling sessions took place in the first three months. Only three children consulted the dietitian over a longer period. This is surprising because health insurance finances up to seven dietary counselling sessions per diagnosis, and when using the NCP (which is a standard for the Swiss Dietetic Association) monitoring of patients is an essential stage. Monitoring cannot be performed adequately when only one or two sessions are conducted (Swan et al., 2017). Moreover, especially for children, circumstances constantly change (for example when they enter kindergarten or school) and it is recommended that dietitians support parents and the child throughout this journey (Eisenblaetter et al., 2020). It could be that there are differences between dietitians working in hospitals and those working in private practices, where dietitians may be able to have longer counselling sessions with their patients. It would be interesting to know more about the reasons why only limited numbers of counselling sessions were performed. This could be investigated by interviewing participating dietitians in a qualitative follow-up of this study.

The studied cohort is representative of children diagnosed with food allergies in most, but not all characteristics. The young age at diagnosis (Mnd = 15.5 months) at the beginning of the study is typical for the onset of IgE-mediated food allergy, and was also seen in another Swiss study where the median age of diagnosis was 22.8 months (Ferrari

& Eng, 2011). The fact that more males than females were diagnosed in this age group was also observed in other studies (Ferrari & Eng, 2011; Sicherer et al., 2020). Unusually, however, is the relatively high rate of children diagnosed with a tree nut allergy in this young cohort. In another Swiss child cohort, nut allergies accounted for only around 11% of the allergic reactions after egg and milk (Ferrari & Eng, 2011). The higher prevalence of nut allergy in young children may be driven by the paradigm shift in allergy prevention recommendations (Halken et al., 2021). These have changed from strict avoidance to early introduction in the last decades. This results in an earlier contact to nuts and thus may also lead to an earlier diagnosis of nut allergy. Another reason might be that nuts are now believed to be healthy and so introduced into Swiss children's diet earlier.

The focus of the counselling sessions was on allergen avoidance rather than on topics in the field of QoL promotion, as defined in the practice guideline (Appendix Q). Those QoL topics were often rated as not relevant by the dietitian. Some of these aspects may not be seen as dietitians' responsibility and others might come later in the life of the child (such as friends, birthday parties or eating out of home). Interestingly, precautionary labelling was an issue covered in most consultations. This contrasted with allergist opinion in the Delphi survey of the guideline development process, which indicated that this is not an issue that should be addressed by dietitians (see chapter 4). Fortunately, interprofessional cooperation seems to be practised in most hospitals with only few exceptions, and so dietitians did tend to discuss labelling with patients. It should be further investigated in a qualitative study what information best supports children with food allergies and their caregivers and enables them to better cope with the food allergy.

This study has some limitations. As a randomised controlled trial was not possible as described in chapter 2, the study cannot prove causality of dietary counselling on the

measured outcomes. There may be unknown differences between the counselled and non-counselled groups which explain the differences found. For example, it cannot be ruled out that more cautious parents may have chosen the option of dietary counselling and thus may have been more careful with allergen avoidance leading to fewer allergic reactions. Nevertheless, the advantage of this study design was that it was possible to provide prospective long-term data on management of children food allergy after diagnosis under real-life conditions. It gives the first insight into potential influences of dietary counselling on food allergy outcomes, which must be further investigated in larger and eventually randomised controlled trials.

Another important limitation of the study is that it was not possible to reach the calculated sample size. Maybe the relatively long duration of the study and the associated effort has deterred patients from participating. Therefore, it is possible that we failed to find statistically significant results for the primary outcome because analysis is underpowered. However, the small differences between groups do not indicate that larger sample sizes would have had significant results for QoL. Maybe a larger sample would have shown the influence of dietary counselling on allergic reactions more clearly and it would have been possible to stratify dietary diversity scores by smaller age groups, which would have made results more comparable.

Moreover, results may be influenced by the COVID-19 pandemic. While this study was conducted Switzerland, as did many other countries, experienced three periods of lockdowns. This influenced recruitment on the one hand but may have also influenced study results. For example, during lockdowns restaurants were closed for a longer period. Consequently, people could not go to restaurants regardless of food allergy status. This may have made parents of children with food allergies feel less affected by the food allergy. However, it is impossible to estimate the influence of the

pandemic on the measured outcomes any further than postulating these and other possible effects.

For this report parents answered the questionnaires as proxies for their children, which can lead to a proxy bias; we cannot know the true feelings and experience of the children themselves. However, in this very young age group QoL, accidental reaction and diet diversity cannot be reported in any other way without enormous effort. For this analysis only parent reported data is included due to time constraints. The planned publication of the twelve months data will also include growth data measured in the hospitals.

As in other studies, our study included participants with a high socioeconomic status, which could have led to a selection bias and might have influenced the results. In particular, QoL may have been influenced by the high economic status of our cohort, because it appears to be more reduced in those who are socioeconomically disadvantaged (Didsbury et al., 2016).

6.5 Conclusion

Dietary counselling seems to help reduce the frequency of allergic reaction in the first three months after diagnosis, and so this period may be the most important time to ensure dietary counselling is delivered, particularly for those children with multiple food allergies. The lack of attendance at counselling sessions after this time may have influenced the frequency in reactions during the next three months. Thus, more counselling sessions may further reduce allergic reactions. Supporting the children and their parents for a longer period could promote compliance and thus further reduce allergic reactions. Furthermore, understanding the reasons for the lack of counselling after three months is required.

In very young children allergy related QoL seems not to be relevantly impaired but supporting the patient for a longer period may decelerate impairment of QoL by preparing families for challenges such as entering school. Maybe also more emphasis should be put on promoting QoL which might also help to prevent its deterioration, and further research is needed to understand why QoL seems to deteriorate over time in these children. No differences in diet diversity were found in the counselled group but this may be due to the insensitivity of the instrument. Further research is required to develop a more sensitive tool that can be specifically used in children with food allergies.

7 Overall discussion and further research

This chapter presents an overall discussion of the findings of this thesis. It begins with a summary of the aims and findings of this project, then discusses its contribution to the research field, its implications for further research and practice, defines outcomes for further studies and ends with drawing final conclusions of this project.

7.1 Aim and findings

This PhD-thesis aimed to investigate the influence of dietary counselling on allergy related QoL, number of accidental reactions, nutritional status, and dietary diversity. Therefore, standard dietary counselling had to be defined prior the project. This took the form of a guideline development in cooperation with dietitians from the practice, an allergist, and a patient representative (see chapter 4). In order to be able to measure allergy related QoL as primary outcome of the study, FAQLQ-PF was translated into German, culturally adapted and validated within this project (see chapter 5). Finally, a multi-centre non-randomised controlled study was conducted to evaluate the impact of dietary counselling on the above-named outcomes. The whole process was guided by MRC complex intervention model (see chapter2).

The most important finding of the evaluation study was that children with dietary counselling experienced significantly fewer allergic reactions in the first three months after diagnosis. However, no other significant differences were observed between the two groups in the evaluation study. Another interesting finding was, that QoL, nutritional status and diet diversity of children with food allergy in this very young age group do not seem to be much impaired, but QoL decreases significantly over the first half year after diagnosis. Evaluating dietary counselling, it was surprising that only a few counselling sessions were conducted, and guidance of patient treatment as outlined by

the developed guideline, was incompletely implemented. The external validity of these findings is limited as this was not a randomised controlled trial and thus, cannot prove causality. However, these are the first prospective long-time observations comparing children with food allergy receiving dietary counselling with those without counselling.

To conclude, this project showed that dietary counselling as it was performed in this study may influence the number of allergic reactions, but not QoL, nutritional indicators or diet diversity. Out of this project a guideline for dietary counselling of children with food allergy and a validated German instrument for food allergy related QoL were generated and are available for further use.

7.2 Contribution to research in the field

This project gave first insights into dietary counselling of children with food allergy in Switzerland, providing initial evidence that dietetic input at diagnosis provides important potential advantages for the child and their family. Allergic reactions are distressing and carry significant health risks, so the reduction in frequency post dietetic counselling is an important finding. This data may influence service design and encourage the inclusion of dietitians in the allergy teams who diagnose children. There is only one prospective study from other countries investigating the influence of dietary counselling on food allergy related outcomes showing a positive influence of dietary counselling on nutritional status (Berni Canani et al., 2014). A recent scoping review on dietary counselling of children with CMA also found little information on nutritional management strategies (Zamanillo-Campos et al., 2022). Thus, these results may also support practice more widely in Europe and other developed countries. In general, there are insufficient studies looking at the management of food allergies beyond desensitization. Most of them have only a pre-post design looking at surrogate parameters such as knowledge (Muraro & Mendoza Hernandez, 2020). Only two

prospective long-term studies could be found. One randomised controlled trial found that a 24 hours helpline improved food allergy related QoL over a period of six months (Kelleher et al., 2013). A long term case control study lasting 36 months in median found that a management plan reduced the severity and frequency of allergic reactions in children with peanut or nut allergy (Ewan & Clark, 2005). What happens to children with food allergies after diagnosis is virtually unknown in the research literature. This study is an important contribution providing initial insights to evaluate the impact of health services and to provide a basis for improvement. This will become more important especially in Switzerland, where the demonstration of effectiveness, expediency and economic efficiency is part of the 2020-2030 strategic plan to reduce health economic costs (The Federal Council of the Swiss Confederation, 2019). Therefore, it will become more important to evaluate health services in future and randomised controlled trials cannot always be performed.

The guideline development and the documentation tool developed from it has proven helpful to define the dietary counselling process and document it in a simple way. This can be transferred to evaluate dietary counselling for other diseases such as food intolerances, Irritable Bowel Disease or Cystic Fibrosis. However, more emphasis should be placed on the implementation of the guideline in practice. Also, the instruments used to measure the outcomes of dietary counselling in children with food allergy have proven to be useful. Though, some adaptions especially in the diet diversity food frequency questionnaire and the scoring system are needed. There seems to be too little differentiation to detect differences especially when the child gets older. However, it is challenging to define what constitutes good diet diversity in terms of secondary food allergy prevention, nutritional adequacy of the diet and QoL and how it can be best measured. The position paper published by an EACCI task force is a first step

in this direction (Venter et al., 2020). However, it focuses mainly on primary allergy prevention and not on diet diversity as an outcome in food allergy management. This aspect should be further considered. Beside this, this set of outcome measures has turned out to be useful to evaluate dietary counselling and can be recommended to future researchers and clinicians.

7.3 Implications for research and practice

A next subsequent project would be interviewing a subset of parents and older children to get a deeper insight into the impact of dietary counselling and the challenges parents and children face in this time after diagnosis. Moreover, interviews with dietitians participating in this project could enlighten why only a limited number of dietary counselling sessions were conducted and what would be needed to further guide children with food allergies and their caregivers through the developmental steps. Qualitative methods like interviews are more useful for the study of contextual issues such as the experiences of the parents, their thoughts and attitudes or the view of dietitians regarding the number of counselling sessions than quantitative methods used in the evaluation study of this project (Malterud, 2001). Both projects can be easily implemented in form of Bachelor or Master theses by students at Bern University of Applied Sciences in the next two years.

The further evaluation of dietary counselling in children with food allergy will be to agree a core outcome set for dietitians to use routinely in practice and trials, and thus evaluate their service. A core outcome set is a standardised collection of outcomes that should be measured and reported in a specific area (Williamson et al., 2017). One important advantage of a core outcome set is that it makes outcomes comparable, as they use the same parameters and measured in the same way. A European Cooperation in Science & Technology (COST) Action project is currently working on a core outcome

set for food allergy (COMFA, n.d.). In their preliminary publication they propose eleven outcomes including patient and caregiver-reported symptoms and QoL as measured in this project (Sim et al., 2020). This will form a good basis for a specific core outcome set for dietitians, however, some outcomes relevant for the evaluation of dietary counselling are missing. For example, no outcome is defined measuring the adequacy of the diet or growth in children. Therefore, it is necessary that dietitians develop an adapted core outcome set to be able to evaluate their service. To ensure these outcomes are patient relevant, it will be necessary to include parents and older children with food allergies into this development process; preferably, they should take a role as a participant in the advisory board or even co-researcher (Clearfield et al., 2021). The development process should be guided by the steps of the Core Outcome Measures in Effectiveness Trials (COMET) Handbook (Williamson et al., 2017). From the experience of this project, it is suggested considering the frequency and severity of allergic reactions, but also food allergy related QoL, growth and diet diversity as core outcomes for dietitians. With the German version of FAQLQ-PF a validated instrument exists to monitor food allergy related QoL in children 0-12 years in German-speaking countries. Other instruments are also available on the FAQLQ website (FAQLQ, n.d.).

A standardised tool to document allergic reactions would be helpful. As mentioned in section 2.1.3 there are several tools used in the literature to measure food allergic reactions (Boyano-Martinez et al., 2009; Boyano-Martinez et al., 2012; Ewan & Clark, 2005); however, no instrument for standardised measurement has yet become established in practice in Switzerland. Ideally, such a tool would be available as smartphone application, so that children with food allergy or their caregivers can easily document allergic reactions including pictures of the symptoms and the food eaten before the reaction. Though, such applications are expensive to develop and difficult to

keep updated, so that a conventional questionnaire may first be developed. Our questionnaire may form a basis for this but could be further developed for its use in routine practice. For this, the questionnaire must be shortened and easier to fill out.

As already mentioned, a more sensitive instrument to measure diet diversity should be developed and evaluated. To date a variety of data collection instruments and scoring systems have been used in studies to measure diet variety (Venter et al., 2020). It would be important to agree on one validated instrument used for children with food allergy to be able to compare diet diversity between centres and countries. Therefore, it is important to investigate and agree on what makes a good diet diversity in terms of secondary allergy prevention, nutritional adequacy and QoL.

Ideally, a central database or register would be initiated to collect these outcomes anonymously from all allergy service providers. This would establish benchmarks on diverse outcomes and a 'learning from the best' system, where dietitians with good results on one outcome help dietitians with poorer results in improving their performance. Benchmarking is a method originally developed in economic science to continuously measure products, services and practices against the toughest competitors or those companies recognized as industry leaders and was then applied to health care (Camp, 1989; Camp & Tweet, 1994). Willmington et al. (2022) found in their systematic review that benchmarking has been established in several fields of health services including oncological and surgical care as well as cardiovascular and chronic illnesses (Willmington et al., 2022). They conclude that it may foster quality improvement and that complementary interventions, such as meetings as well as audit and feedback, can further contribute to quality improvement. Therefore, benchmarking may also help to further improve the quality of dietary counselling. However, such systems require a mutual trust and open culture of failure, where failure is seen as an opportunity to learn.

This must be established before introducing benchmarking and should be maintained during the process. Moreover, establishing such a benchmarking system, would need a complex infrastructure, so that dietitians can easily and safely document the outcomes of their patients, which is very cost and time intensive.

Moreover, intervention studies need to be established to prove the effectiveness of specific dietetic interventions in children with food allergy. For example, above mentioned methods appearing to improve outcomes recognised in the benchmarking may be further investigated. Small intervention studies testing these interventions would help to further improve dietary counselling in this field and set an evidence base for these interventions. This would help dietitians to know which interventions help their patients and therefore form a basis for an evidence-based practice. Randomised controlled trials would be the gold standard for such studies. However, as for this study, it might be ethically difficult to deny one group of children an intervention that is expected to be helpful. Nevertheless, it could be argued that these interventions have never been proven to be effective. But, as for all studies in the dietetic field not involving industry products, it will be challenging to find financial support for these studies.

A more comprehensive intervention study would be a randomised controlled trial testing a stage-based intervention compared with standard care. The stages could include three dietetic consultations in the first three months, two before kindergarten and one before school, because with these stages the burden of responsibility moves from the parents to external caregivers and the independence of the child increases (Rubeiz & Ernst, 2021). Preparing these situations carefully might influence relevant outcomes such as QoL or accidental allergic reactions. It would also be of potential value to offer two consultations in adolescence, if allergy still exists, because this phase is characterised by the increased transfer of responsibility to the adolescent, risk taking

behaviour and most anaphylactic reactions occur in this age group (Rubeiz & Ernst, 2021). Although such a trial could further guide the optimal dietetic intervention it would be a challenging and costly study to establish. In addition, it would be vital to involve patients and families in the design of such a study to ensure the intervention is acceptable.

As mentioned before cost effectiveness will become more important in future as the costs of national health care systems increase and financial resources are limited (The Federal Council of the Swiss Confederation, 2019). As a result, only interventions that have been proven to be cost effective will be reimbursed by health insurance providers in future. Therefore, another important field of research are cost effectiveness analyses (Federal Office for Health, 2022). It would therefore be important to evaluate whether dietary counselling is cost effective. Cost effectiveness analysis is the characterisation of the costs of an intervention relatively to the clinical benefits of the outcome, measured in nonmonetary values (Shi & Nambudiri, 2017). For such a comprehensive cost calculation not only the cost of the counselling session itself must be considered, but also associated cost such as for the facility and loss of productivity of the parents (Sanders et al., 2016). The effects in cost effectiveness analysis are health outcomes rather than monetary measures like in cost benefit analysis (Sanders et al., 2016). In the case of food allergies these effects might be the prevention of allergic reactions, but also quality adjusted life years due to dietary counselling. These cost and effects should be compared to at least one alternative programme, which could be no counselling or counselling by allergists (Sanders et al., 2016). Before being able to conduct such cost effectiveness analysis more studies on the effectiveness of dietary counselling in the field of food allergy are needed. Therefore, such cost effectiveness analyses are a project for the future.

In conclusion, there is little evidence to inform how dietitians can best support children with food allergy and their parents. Consequently, there are many research gaps to fill, but it is challenging to conduct such studies and financial support is limited.

7.4 Strengths and limitations

The strengths of this thesis are that it is the first study that produced prospective long-term data on food allergy related QoL, accidental reactions and diet diversity on dietary counselling of children with food allergy. Only 6% of participants dropped out and all participant completed the questionnaires fully. Stakeholders as allergists and dietitians working in clinical practice and the patient organisation were involved in the project at an early stage. Moreover, within this project a guideline for dietary counselling was developed, which can be used by dietitians to guide the counselling process, especially when they are new in the field. The implementation of the recommendations of the guideline should be promoted through their use in education and training. The guideline also forms a basis for further quality development of dietary counselling. It is already the second most often cited guideline used by dietitians for the management of CMA in Switzerland (Martel, 2022). Regular updates will help to implement new evidence and developments. These will be organised in five-year intervals as Bachelor or Master theses. Particular attention should be paid to the topic of promoting QoL in the guideline update, as dietary counselling as it was performed in this study could not counteract the deterioration of QoL over time. Another strength is that the food allergy related QoL questionnaire was translated and validated in a relatively large sample before its use and is now available for other studies and practice in German. Finally, it was a strength that four hospitals in the German-speaking part of Switzerland were willing to take part in this project. These are spread over the German-speaking part of Switzerland so that a broad regional diversity was reached.

The most obvious limitation is that a randomised controlled trial was not possible due to ethical and feasibility reasons (see section 2.3.1). Therefore, causality between dietary counselling and the outcomes cannot be proven as unknown group differences cannot be ruled out (Sibbald & Roland, 1998). Nevertheless, the presented data is currently the best available evidence and shows associations between dietary counselling and the number of allergic reactions. Another limitation is that the targeted number of 110 participants was not reached, even though efforts were made to improve the recruitment process and the recruitment phase was prolonged. A pilot study of the whole project and not only parts might have shown these recruitment problems before starting the full trial. This was not carried out due to lack of financial and time resources. However, the recruitment problems regarding the COVID-19 pandemic could not have been foreseen even with a full pilot study. Nevertheless, if I conducted such a study again, I would probably try to do a full pilot study. Other limitations of the evaluation study are already discussed in section 6.4. For the overall project it might have been beneficial to add a qualitative element, to gain a greater understanding of the child and parent perspectives. Interviewing a subset of parents and older children could have given deeper insights into the impact of dietary counselling and the challenges parents face in this time after diagnosis. It might also have been helpful to involve parents of children with food allergy at an early stage in the project. This might have helped with recruitment, ensuring that the outcomes are patient relevant and developing patient relevant recommendations.

7.5 Overall conclusions

Our data provides first evidence that children with food allergy may benefit from reduced allergic reactions by receiving dietary counselling. Therefore, dietary counselling should be a routine part in the management of children with food allergy,

not only in children with CMA, but also in children with other allergies, especially those with multiple food allergies. However this should be further substantiated with evidence before this can become an evidence-based guideline. Dietitians should routinely evaluate their work and constantly improve the quality of their counselling. New forms of quality assurance instruments, such as a benchmarking system, should be implemented for this purpose. As a basis for this, a core outcome set should be defined and routinely applied in dietary counselling of children with food allergy. More robust data is needed on the impact of dietary counselling in general, but also on influence of specific dietary interventions on relevant health outcomes. A continuous review of the data and the regular adjustments to guidelines and its implementation into practice should promote the quality of the counselling provided. This would enable evidence based dietary counselling of children with food allergy and thus help children and their families to live a good life despite the food allergy.

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Appendices

Appendix A Literature review on the effectiveness of dietary counselling

Table A1 Inclusion and exclusion criteria for the literature research on the effectiveness of dietary counselling of children with IgE-mediated food allergy

Inclusion criteria	**Exclusion criteria**
Individual dietary counselling Outcome: nutritional status, Quality of life, allergic reaction	Educational program Multidisciplinary programs

Table A2 Literature research for studies on the effectiveness of dietary counselling of children with food allergy

P	**I**	**C**	**O**	**S**	
Children with food allergy	Individual dietary counselling by a dietitian	Standard care	Effectiveness	Randomized or non-randomized controlled studies, cohort studies	
Food allergy AND (Children OR Infants OR toddlers)	(dietary counselling OR nutritional therapy OR dietitian OR diet therapy) AND dietitian		(efficacy OR effectiveness OR quality of life OR food intake OR food diary OR nutritional status OR weight OR growth OR allergic reaction*)		
Search term				limits	hits
(Dietary counselling OR nutritional therapy OR dietitian OR diet therapy) AND (Efficacy OR effect OR Quality of life OR food intake OR food diary OR nutritional status OR Weight OR Growth OR allergic reactions) AND (Children OR Infants OR toddlers) AND food allergy AND dietitian				10 years	39

Appendix B Monitoring instrument for the implementation of guideline recommendations

Table B1 Instrument to document the implementation of guideline recommendations by dietitians

Patient ID I__I__I I__I__I Admission to study I__I__I I__I__I I__I__I

Total number of counselling sessions I__I__I

Recommendation	**implemented**	**Not implemented**	**Not relevant**
1. Diet history	☐	☐	☐
2. Content of diet history			
a Intake of foods and beverages	☐	☐	☐
b Intake of foods and beverages	☐	☐	☐
c Avoided food(group)s and reasons therefore	☐	☐	☐
d Use of substitute products and/or supplements	☐	☐	☐
3. Suitable assessment methods (Diet history, 24 h recall or a dietary record. In case of risk of nutrient deficiency, a three-day food diary should be taken)	☐	☐	☐
4. Evaluation of Assessment	☐	☐	☐

5. Height/length and weight	☐	☐	☐
6. Diagnostic tests and diet specific laboratory parameters	☐	☐	☐
7. Overall impression of the child (incl. allergy associated comorbidities)	☐	☐	☐
8. Content of client history			
a. Medical situation	☐	☐	☐
b. Language requirement	☐	☐	☐
9. Allergy specific client history			
a. Known allergies and other atopic diseases and other medical diagnoses	☐	☐	☐
b. Symptoms of food allergy	☐	☐	☐
c. Atopic diseases in the family	☐	☐	☐
10. Substitutes for infants with CMA 1. First choice: breast milk, eventually avoidance of the culprit food	☐	☐	☐

2. Formula with extensively hydrolysed cow's milk protein (EHF) 3. Amino Acid Formula (AAF)			
11. Unsuitable substitutes for CMA	☐	☐	☐
12. Prevention and treatment of nutrient deficiencies			
a. Education on alternative products with adequate nutrient coverage … i. Alternative products to replace avoided products … ii. Use of substituted products	☐	☐	☐
b. Alternative products for meal preparation	☐	☐	☐
c. Where appropriate discuss supplementation	☐	☐	☐
13. Training in allergen avoidance			
a. Identification of allergens in products and strategies for their avoidance	☐	☐	☐
…b. Meal preparation safety and techniques	☐	☐	☐
c. Discussion of unnecessary restrictions	☐	☐	☐
d. Effects of the disease on nutrition	☐	☐	☐
14. Quality of life promotion			

a. Recommendation to assure a clear diagnosis	☐	☐	☐
b. Consider individual tolerance	☐	☐	☐
c. Consider personal preferences	☐	☐	☐
d. Handling out of home consumption	☐	☐	☐
e. When indicated discuss oral food challenge with allergist	☐	☐	☐
15. Food law			
a. General information on food laws	☐	☐	☐
b. Reading and interpreting ingredient lists	☐	☐	☐
c. Handling precautionary labelling	☐	☐	☐
16. Discuss risk situations			
a. Out of home consumption i. Restaurants ii. Travelling iii. Third party care (e.g., school, nursery, grandparents)	☐	☐	☐
b. Contaminations	☐	☐	☐

17. New situations (e.g., complementary feeding)	☐	☐	☐
18. Counselling aids	☐	☐	☐
19. Accidental reactions	☐	☐	☐
20 Counselling style and language (Possibly with interpreter)	☐	☐	☐
21. Target groups Dietary counselling should address the child depending on his/her age as well as the parents. As required, relatives, friends, teachers, and further persons that look after the child can be included. Alternatively, parents may be empowered to inform others.	☐	☐	☐
22. Interprofessional cooperation	☐	☐	☐
23. Monitoring of weight and height	☐	☐	☐
24. Monitoring of the natural course and laboratory parameters	☐	☐	☐
25. Monitoring of Symptoms	☐	☐	☐

Note. This instrument was originally used in German. This translation was made for this thesis only.

Appendix C Literature researches on study outcomes

Table C1 Inclusion and exclusion criteria for studies on QoL

Inclusion criteria	**Exclusion criteria**
Children (0-10 years) IgE-mediated food allergy QoL	immunotherapy

Table C2 Creation of the search strategy for studies on QoL based on the PICO principle

P	**I**	**C**	**O**	**S**
Children with diagnosed food allergy	n/a	n/a	Quality of life	RCT, Retrospective and prospective observational studies, systematic reviews, and Meta-analysis.
(children OR child OR paediatric OR infant) AND Food allerg*	n/a	n/a	Quality of life OR QoL	

Search term	limits	hits
(children OR child OR paediatric OR infant) AND Food allerg* AND (quality of life or QoL)	10 years, clinical trial, RCTs, Systematic review, Meta-Analysis	115

Note. n/a = not applicable

Table C3 Inclusion and exclusion criteria for studies on allergic reactions

Inclusion criteria	**Exclusion criteria**
Age 0-16 years Diagnosis of food allergy IgE-mediated food allergy (?) Accidental reactions Anaphylaxis and other Symptoms	Reaction before diagnosis Reaction while diagnosis only Anaphylaxis

Table C4 Creation of the search strategy for studies on allergic reactions based on the PICO principle

P	I	C	O	S
Children with diagnosed food allergy		-	frequency of Allergic reaction	Retrospective and prospective observational studies
(children OR child OR pediatric OR infant) AND Food allerg*			(Reaction* OR symptom*OR anaphylaxis OR anaphylactic OR accidental OR exposure OR ingestion) (frequency OR Incidence OR occurrence)	Cross sectional studies

Search term	limits	hits
(children OR child OR pediatric OR infant) AND food allerg* AND (reaction* OR symptoms*) AND (incidence OR frequency)	10 years	516

Table C5 Inclusion and exclusion criteria for studies on nutritional status and growth

Inclusion criteria	Exclusion criteria
Children (0-16 years) IgE-mediated food allergy Nutritional status / Growth parameters	

Table C6 Creation of the search strategy for studies on nutritional status and growth based on the PICO principle

P	I	C	O	S
Children with diagnosed food allergy	n/a	n/a	Nutritional status	RCT, Retrospective and prospective observational studies
(children OR child OR paediatric OR infant) AND Food allerg*	n/a	n/a	Growth OR nutritional status OR height OR weight OR	

Search term	limits	hits
(children OR child OR paediatric OR infant) AND Food allerg* AND (growth OR nutritional status OR height OR weight OR nutritional intake)	10 years	242

Table C7 Inclusion and exclusion criteria for studies on diet diversity

Inclusion criteria	**Exclusion criteria**
Children (0-16 years) IgE-mediated food allergy Diet diversity as outcome	Allergy prevention

Table C8 Creation of the search strategy for studies on diet diversity based on the PICO principle

P	**I**	**C**	**O**	**S**	
Children with diagnosed food allergy	n/a	n/a	Diet diversity	RCT, Retrospective and prospective observational studies	
(children OR child OR paediatric OR infant) AND Food allerg*	n/a	n/a	(Diet OR Dietary OR food) diversity		
Search term				limits	hits
(children OR child OR paediatric OR infant) AND Food allerg* AND (diet OR dietary OR food) diversity				10 years	449

Appendix D German version of FAQLQ-PF

Fragebogen zu Nahrungsmittelallergie und Lebensqualität -Elternversion (FAQLQ-PF-G) Kinder zwischen 0-12 J

Anleitung für die Eltern

Eltern haben uns erzählt, dass die Lebensqualität ihrer Kinder wegen der Nahrungsmittelallergie durch die folgenden Aspekte beeinflusst wird.
Bitte geben Sie an, welchen Einfluss jedes Szenario auf die Lebensqualität Ihres Kindes hat, indem Sie ein Kästchen zwischen 0 und 6 ankreuzen.

Antwortmöglichkeiten
0 = überhaupt nicht
1= kaum
2 = etwas
3 = mittelmäßig
4 = ziemlich
5 = sehr
6 = extrem

Alle gegebenen Informationen sind vertraulich
Dieser Fragebogen kann nur mit einer Code-Nummer zurückverfolgt werden

- Wenn Ihr Kind zwischen 0 und 3 Jahren ist, beantworten Sie bitte Teil A & Teil D
- Wenn Ihr Kind zwischen 4 und 6 Jahren ist, beantworten Sie bitte Teil A, Teil B & Teil D
- Wenn Ihr Kind 7 Jahre oder älter ist, beantworten Sie bitte Teil A, Teil B, Teil C & Teil D

To cite this questionnaire:
DunnGalvin A, Flokstra-de Blok BMJ, Burks AW, Dubois AEJ, Hourihane JO. Food allergy QoL questionnaire for children aged 0-12 years: content, construct, and cross-cultural validity. Clin Exp Allergy 2008 Jun;38(6):977-986.

Teil A: Für alle Altersgruppen

1. Wegen der Nahrungsmittelallergie…	**überhaupt nicht**				→		**extrem**
	0	1	2	3	4	5	6
hat mein Kind Angst vor Lebensmitteln.	☐	☐	☐	☐	☐	☐	☐
fühlt sich mein Kind anders als andere Kinder.	☐	☐	☐	☐	☐	☐	☐
ist mein Kind frustriert durch die Einschränkungen in seiner Ernährung.	☐	☐	☐	☐	☐	☐	☐
hat mein Kind Angst, neue Lebensmittel auszuprobieren.	☐	☐	☐	☐	☐	☐	☐
beunruhigt meine Sorge über mögliche allergische Reaktionen mein Kind.	☐	☐	☐	☐	☐	☐	☐
fühlt sich mein Kind körperlich belastet.	☐	☐	☐	☐	☐	☐	☐
fühlt sich mein Kind emotional belastet.	☐	☐	☐	☐	☐	☐	☐
hat mein Kind eine weniger vielfältige Nahrungsmittelauswahl.	☐	☐	☐	☐	☐	☐	☐

2. Wegen der Nahrungsmittelallergie wird mein Kind negativ beeinflusst, da…	**überhaupt nicht**				→		**extrem**
	0	1	2	3	4	5	6
es mehr Aufmerksamkeit als andere Kinder seines Alters bekommt.	☐	☐	☐	☐	☐	☐	☐
es schneller selbstständig werden muss als andere Kinder seines Alters.	☐	☐	☐	☐	☐	☐	☐
sein Umfeld eingeschränkter ist als das anderer Kinder seines Alters.	☐	☐	☐	☐	☐	☐	☐

3. Wegen der Nahrungsmittelallergie ist das soziale Umfeld meines Kindes eingeschränkt durch die begrenzte Auswahl an…	**überhaupt nicht**				→		**extrem**
	0	1	2	3	4	5	6
Restaurants, in die wir als Familie sicher gehen können.	☐	☐	☐	☐	☐	☐	☐
Ferienzielen, in die wir als Familie sicher reisen können	☐	☐	☐	☐	☐	☐	☐

4. Wegen der Nahrungsmittelallergie sind die Möglichkeiten meines Kindes eingeschränkt…	**überhaupt nicht**				→		**extrem**
	0	1	2	3	4	5	6
an sozialen Aktivitäten bei anderen Personen zuhause teilzunehmen. (Übernachtungen bei Freunden, Feiern, Spielen)	☐	☐	☐	☐	☐	☐	☐

Teil B: Für Kinder zwischen 4 und 12 Jahren.

5. Wegen der Nahrungsmittelallergie sind die Möglichkeiten meines Kindes eingeschränkt…	**überhaupt nicht** 0	1	2	3	→ 4	5	**extrem** 6
an Kindergarten-/Schulveranstaltungen teilzunehmen, an denen Lebensmittel angeboten werden. (Klassenfeiern, Naschereien, Mittagessen)	☐	☐	☐	☐	☐	☐	☐

6. Wegen der Nahrungsmittelallergie …	**überhaupt nicht** 0	1	2	3	→ 4	5	**extrem** 6
ist mein Kind besorgt, dass es immer beim Essen aufpassen muss.	☐	☐	☐	☐	☐	☐	☐
fühlt sich mein Kind bei Aktivitäten ausgegrenzt, an denen Lebensmittel angeboten werden.	☐	☐	☐	☐	☐	☐	☐
hat mein Kind Angst, unbeabsichtigt eine Zutat zu essen, auf die es allergisch reagiert.	☐	☐	☐	☐	☐	☐	☐
hat mein Kind Angst, mit nicht vertrauten Erwachsenen/Kindern zu essen.	☐	☐	☐	☐	☐	☐	☐
hat mein Kind Angst davor, an neue Orte zu gehen.	☐	☐	☐	☐	☐	☐	☐
ist mein Kind traurig/wütend, weil gemeinsame Familienaktivitäten (Auswärtsessen, Feiern, Ausflüge) eingeschränkt sind.	☐	☐	☐	☐	☐	☐	☐
ist mein Kind wegen den Einschränkungen im sozialen Umfeld frustriert.	☐	☐	☐	☐	☐	☐	☐
ist mein Kind generell ängstlicher als andere Kinder seines Alters.	☐	☐	☐	☐	☐	☐	☐
ist mein Kind generell vorsichtiger als andere Kinder seines Alters	☐	☐	☐	☐	☐	☐	☐
ist mein Kind nicht so selbstsicher in sozialen Situationen wie andere Kinder seines Alters.	☐	☐	☐	☐	☐	☐	☐
wünscht sich mein Kind, dass die Nahrungsmittelallergie verschwinden würde.	☐	☐	☐	☐	☐	☐	☐

Teil C: Für Kinder zwischen 7 und 12

7. Wegen der Nahrungsmittelallergie …	**überhaupt nicht**				→		**extrem**
	0	1	2	3	4	5	6
ist mein Kind besorgt über seine Zukunft. (Möglichkeiten, Beziehungen)	☐	☐	☐	☐	☐	☐	☐
meint mein Kind, dass viele Menschen nicht verstehen, wie schwerwiegend eine Nahrungsmittelallergie sein kann.	☐	☐	☐	☐	☐	☐	☐
ist mein Kind beunruhigt über die schlechte Kennzeichnung von Lebensmitteln.	☐	☐	☐	☐	☐	☐	☐
fühlt sich mein Kind generell in seinem Leben eingeschränkt.	☐	☐	☐	☐	☐	☐	☐

Teil D: Für alle Altersgruppen

Bitte beantworten Sie die folgenden Fragen in Bezug auf die 6-Punkte Skala

0 = extrem unwahrscheinlich
1 = sehr unwahrscheinlich
2 = eher unwahrscheinlich
3 = wahrscheinlich
4 = recht wahrscheinlich
5 = sehr wahrscheinlich
6 = extrem wahrscheinlich

8. Für wie wahrscheinlich **halten Sie es**, dass Ihr Kind…?

	6-Punkte Skala						
	0	1	2	3	4	5	6
…unabsichtlich das Lebensmittel verzehrt, gegen das es allergisch ist?	☐	☐	☐	☐	☐	☐	☐
…eine schwere Reaktion hat, wenn das Lebensmittel unabsichtlich verzehrt wird?	☐	☐	☐	☐	☐	☐	☐
…durch seine Nahrungsmittelallergie in eine lebensbedrohliche Lage kommen wird?	☐	☐	☐	☐	☐	☐	☐
…sich selbst wirksam behandelt, beziehungsweise von anderen im Falle eines versehentlichen Verzehrs des allergieauslösenden Lebensmittels wirksam (inkl. der Nutzung des Epipens) behandelt wird?	☐	☐	☐	☐	☐	☐	☐

9. Für wie wahrscheinlich **hält es Ihr Kind**, dass es…?

	6-Punkte Skala						
	0	1	2	3	4	5	6
… unabsichtlich das Lebensmittel verzehrt, gegen das es allergisch ist?	☐	☐	☐	☐	☐	☐	☐
… eine schwere Reaktion hat, wenn das Lebensmittel unabsichtlich verzehrt wird?	☐	☐	☐	☐	☐	☐	☐
… durch seine Nahrungsmittelallergie in eine lebensbedrohliche Lage kommen wird?	☐	☐	☐	☐	☐	☐	☐
…sich selbst wirksam behandelt, beziehungsweise von anderen im Falle eines versehentlichen Verzehrs des allergieauslösenden Lebensmittels wirksam (inkl. der Nutzung des Epipens) behandelt wird?	☐	☐	☐	☐	☐	☐	☐

Appendix E Questionnaire on allergic reactions

1. Sind seit der letzten Befragung allergische Reaktionen bei Ihrem Kind aufgetreten?
   [Have any allergic reactions occurred in your child since the last interview?]
   - ☐ Ja *[yes]*
   - ☐ nein ⇨ Frage 57 *[no ⇨ question 57]*
   - ☐ Weiss ich nicht mehr ⇨ Frage 57 *[do not know ⇨ question 57]*

2. Wie oft sind seit der letzten Befragung allergische Reaktionen bei Ihrem Kind aufgetreten?
   [How often have allergic reactions occurred in your child since the last questionnaire?]
   _ _

Bitte füllen Sie die folgenden Fragen für so viele allergische Reaktionen aus, wie Sie bei Ihrem Kind seit der letzten Befragung beobachtet haben.
[Please fill in the following questions for as many allergic reactions as you have observed in your child since the last questionnaire]

3. Wann ist die allergische Reaktion/ sind die allergischen Reaktionen aufgetreten?
   [When did the allergic reaction(s) occur?]
   1. Reaktion: __ __ ____ *[1. Reaction]*

   Falls Ihnen die genauen Daten nicht bekannt sind, geben Sie bitte einen ungefähren Zeitraum in Wochen an (z.B. vor 3 Wochen).
   [If you do not know the exact dates, please give an approximate period in weeks (e.g., 3 weeks ago).]
   1. Reaktion: _____
   [1. reaction]

4. Welche Speisen/ Lebensmittel wurden jeweils zuletzt gegessen?
   [Which dishes/foods were eaten last in each case?]
   1. Reaktion: _____
   [1. reaction]

5. Welches Lebensmittel wird als Auslöser der allergischen Reaktion verdächtigt?
[Which food is suspected to be the trigger of the allergic reaction?]

1. Reaktion: _____
[1. reaction]

6. Wie lange nach dem Verzehr traten die Symptome auf?
[How long after consumption did the symptoms appear?]

	Sofort *[Immediately]*	Nach 5-10 Minuten *[After 5-10 minutes]*	Nach 10-30 Minuten *[After 10-30 minutes]*	Nach 30-60 Minuten *[After 30-60 minutes]*	Nach 1-2 Stunden *[After 1-2 hours]*	Nach einem halben Tag *[After half a day]*	Am nächsten Tag *[On the next day]*	Später [Later]	Weiss ich nicht mehr *[do not know]*
1. Reaktion *[1. reaction]*	☐	☐	☐	☐	☐	☐	☐	☐	☐

* ✍ Bitte spezifizieren *[Please specify]:*

_____

7. An welchem/n Ort/en sind die allergischen Reaktionen aufgetreten?
[Where did the allergic reaction(s) occur?]

- ☐ Zu Hause *[At home]*
- ☐ Im Restaurant/ in der Kantine *[In the restaurant/canteen]*
- ☐ Bei Freunden/ Verwandten *[At friends/ relatives]*
- ☐ Im Kindergarten/ in der Schule *[In the kindergarten/ at school]*
- ☐ Weiss ich nicht mehr *[I do not know any more]*
- ☐ An einem anderen Ort: *[In another place]*

_____

1. Reaktion *[1. Reaction]*

8. Welche Symptome einer allergischen Reaktion haben Sie bei Ihrem Kind auf der Haut beobachtet?
[What symptoms of an allergic reaction have you observed on your child's skin?]

	Keine *[none]*	Lokal (örtlich, auf bestimmte Körperstelle(n) bezogen *[Local (referring to a specific part(s) of the body)]*	Generalisiert (den ganzen Körper betreffend) *[Generalised (affecting the entire body)]*
Juckreiz *[Itching]*	☐	☐	☐

Rötung der Haut *[Reddening of the skin]*	☐	☐	☐
Quaddeln auf der Haut *[Hives on the skin]*	☐	☐	☐
Geschwollene Gesichtspartien *[Swollen areas of the face]*	☐	☐	☐

9. Welche Symptome einer allergischen Reaktion haben Sie bei Ihrem Kind im Bereich des Mundes, Magen- oder Darmtrakts beobachtet?
[What symptoms of an allergic reaction have you observed in your child's mouth, stomach or intestinal tract?]

	Keine *[None]*	Leicht *[light]*	Mittel *[medium]*	Stark *[strong]*
Rötungen im Mundbereich *[Redness around the mouth]*	☐	☐	☐	☐
Schluckstörungen *[Dysphagia]*	☐	☐	☐	☐
Übelkeit *[Nausea]*	☐	☐	☐	☐
Erbrechen *[Vomiting]*	☐	☐	☐	☐
Bauchschmerzen *[Abdominal pain]*	☐	☐	☐	☐
Durchfall [*Diarrhoea]*	☐	☐	☐	☐

10. Welche Symptome einer allergischen Reaktion haben Sie bei Ihrem Kind im Bereich der Augen, Lunge und Atmung beobachtet?
[What symptoms of an allergic reaction have you observed in your child in the area of the eyes, lungs and breathing?]

	Keine *[None]*	Leicht *[light]*	Mittel *[medium]*	Stark *[strong]*
Fliessschnupfen *[Runny nose]*	☐	☐	☐	☐
Entzündung der Bindehaut *[conjunctivitis]*	☐	☐	☐	☐
Veränderung der Stimme *[Change of voice]*	☐	☐	☐	☐
Engegefühl im Hals *[Tightness in the throat]*	☐	☐	☐	☐
Bellender Husten *[Barking cough]*	☐	☐	☐	☐
Hustenattacke	☐	☐	☐	☐
Pfeifen / Giemen bei der Ausatmung *[Whistling / wheezing on exhalation]*	☐	☐	☐	☐
Pfeifen bei der Einatmung *[Whistling during inhalation]*	☐	☐	☐	☐
Atemnot *[Shortness of breath]*	☐	☐	☐	☐

11. Welche Symptome einer allergischen Reaktion haben Sie bei Ihrem Kind in Bezug auf den Kreislauf und das Bewusstsein beobachtet?
[What symptoms of an allergic reaction have you observed in your child in terms of circulation and consciousness?]

	Keine *[None]*	Leicht *[light]*	Mittel *[medium]*	Stark *[strong]*
Kalte Hände, Füsse / Zittern *[Cold hands, feet / shivering]*	☐	☐	☐	☐
Schwindel *[Dizziness]*	☐	☐	☐	☐
Benommenheit *[Lightheadedness]*	☐	☐	☐	☐

12. Hat Ihr Kind das Bewusstsein verloren?
[Has your child lost consciousness?]

Ja *[yes]* ☐
Nein *[no]* ☐

Appendix F Methods to measure diet diversity

Table F1 Methods to measure diet diversity in literature

Author and year	Maslin, Dean, et al., 2016	Steyn et al., 2014				WHO, 2010	FAO, 2010	Roduit et al., 2014	Nwaru et al., 2014
Aim	Diet diversity in allergic children	Sensitivity and specificity of different food group indicators to identify micronutrient deficiencies				Diet diversity on individual level	Diet diversity on (household and) individual level WDDS	Diet diversity for allergy prevention	Diet diversity for allergy prevention
Instrument	Adapted version of a validated FFQ (76 foods and drinks)	24 h recall				24 h recall	24 h recall	FFQ	age-specific dietary questionnaires???
Age group	8- to 27-month-old children (CMA and control)	1 to 9 y				6-23 months	15-49 women (individual level)	0-12 months	3-12 months
Food groups	**8 food groups?** 1. non- water drinks 2. readymade baby food 3. cereals 4. diary, egg, substitutes, soya 5. meat and fish, vegetarian substitutes? 6. fruits 7. vegetables 8. sweets, miscellaneous foods	**6 food groups** 1. all starch staples 2. all dairy 3. all animal foods excluding diary 4. all legumes and nuts 5. Vitamin A rich fruit and vegetables 6. other fruits and vegetables	**9 food groups** 1. all starch staples 2. all dairy 3. organ meat 4. Eggs 5. flesh foods 6. all legumes & nuts 7. Vitamin A-rich dark green leafy vegetables 8. other vitamin A-	**13 food groups** 1. all starch staples 2. all dairy 3. organ meat 4. Eggs 5. flesh foods 6. Small fish eaten whole 7. all legumes & nuts 8. Vitamin A-rich dark green leafy vegetables 9. Vitamin A-rich deep yellow/orange/red vegetables	**21 food groups (?)** 1. all starch staples 2. milk/yogurt 3. cheese 4. organ meat 5. Eggs 6. red meat 7. chicken/birds 8. insects, grubs small animals 9. large whole fish/seafood 10. small fish 11. cooked dry beans & peas 12. Nuts and seeds	**7 food groups** 1. grains, roots, and tubers 2. legumes & nuts 3. dairy products (milk, yogurt, cheese) 4. flesh foods (meat, fish, poultry, and liver/organ meats) 5. eggs 6. vitamin A-rich fruits and vegetables 7. other fruits and vegetables	**9 food groups** 1. Starchy staples (combination of cereals, white roots, and tubers) 2. Dark green leafy vegetables 3. Other Vitamin A rich fruits and Vegetables 4. Other fruits and vegetables 5. Organ meat 6. Meat and fish 7. Eggs 8. Legumes, nuts, and seeds	**6 food groups** 1. vegetables or fruits 2. cereals 3. bread 4. meat 5. cake 6. yogurt	**12 groups?** 1. cow's milk and formula 2.potatoes 3. carrots 4. turnip 5. fruits and berries 6. cereals (rye, wheat, oats, and barley) 7. other cereals (maize, rice, millet, and buckwheat) 8. meat 9. fish 10. egg 11. cabbage

Author and year	Maslin, Dean, et al., 2016	Steyn et al., 2014				WHO, 2010	FAO, 2010	Roduit et al., 2014	Nwaru et al., 2014
			rich - vegetables & fruit 9. other fruits and vegetables	10. Vitamin A-rich fruits 11. Vitamin C-rich vegetables 12. Vitamin C-rich fruits 13. All other fruits & vegetables	13. soybeans & products 14. Vitamin A-rich dark green leafy vegetables 15. Vitamin A-rich deep yellow/orange/red vegetables 16. vitamin A- rich fruits 17. Vitamin C-rich vegetables 18. Vitamin C-rich fruits 19. All other fruits 20. All other vegetables (Publication lists just 20!)		9. milk and milk products		12. spinach and lettuce.
Reference period	28 days	24 hours				24 hours	24 hours	4 weeks	???
Score calculation	Diet variety score (DVS) was calculated as the number of times 'never' is selected on the frequency option for each food. The DVS% for each category was calculated as a percentage of the items in each food category that had never been eaten. Therefore, a higher DVS and DVS%	The Dietary Diversity Score (DDS) is defined as the number of food groups consumed at least once in a period of 24h.				Minimum dietary diversity: Proportion of children 6-23 months of age who receive foods from 4 or more food groups. Calculation: For each of the 7 food groups, as a point if any	Dietary diversity scores are calculated by summing the number of food groups consumed in at the household or by the individual respondent over the 24 h recall period.	The food diversity score is a total count of the number of different food items included in the child's diet.	We defined food diversity as the number of complementary foods introduced at 3, 4, 6, and 12 months of age.

Author and year	Maslin, Dean, et al., 2016	Steyn et al., 2014	WHO, 2010	FAO, 2010	Roduit et al., 2014	Nwaru et al., 2014
	indicate a less varied diet.		food in the group was consumed			

Note. FFQ = Food Frequency questionnaire

Appendix G Diet diversity questionnaire

1. Wird Ihr Kind noch gestillt? *[Is your child still being breastfed]*
   - ☐ Ja *[yes]*
   - ☐ Nein [no]

2. Erhält ihr Kind eine Säuglingsnahrung/-milch oder Ersatzmilch? *[Does your child receive formula or substitute milk]*
   - ☐ Nein *[no]*
   - ☐ ja, welche? *[yes, which one]*

   ✎ _____

3. Vermeiden Sie es aufgrund der Nahrungsmittelallergie neue Lebensmittel in die Ernährung Ihres Kindes einzuführen? *[Do you avoid introducing new foods into your child's diet because of the food allergy?]*
   - ☐ Ja *[yes]*
   - ☐ Nein *[no]*

4. Welche Nahrungsmittel lassen Sie aufgrund der Nahrungsmittelallergie ihres Kindes weg? [*Which foods do you omit because of your child's food allergy?]*

   ✎ _____

Welche der folgenden Lebensmittel und Getränke hat Ihr Kind im letzten Monat gegessen oder getrunken? Die Auswahl enthält alle Lebensmittel(gruppen) unabhängig von der Allergenkarenz Ihres Kindes. Bitte kreuzen Sie die Lebensmittel auch an, wenn sie nur in kleinen Mengen gegessen wurden.
[Which of the following foods and drinks has your child eaten or drunk in the last month? The selection includes all foods (groups) regardless of your child's allergen clearance. Please tick the foods even if they were only eaten in small quantities.]

5. **Gemüse [*Vegetables]***	**Ja *[yes]***	**Nein *[no]***
Dunkelgrünes Blattgemüse (z.B. Blattsalate, Spinat, Brokkoli) und Speisen und Getränke daraus (z.B. Smoothie, Gratin) [*Dark green leafy vegetables (e.g. lettuce, spinach, broccoli) and dishes and drinks made from them (e.g. smoothie, gratin)]*	☐	☐
Anderes grünes Gemüse (z.B. Zucchetti, Erbsen, Kohlrabi) und Speisen und Getränke daraus (z.B. Gurkensalat) *[Other green vegetables (e.g. courgettes, peas, kohlrabi) and dishes and drinks made from them (e.g. cucumber salad)]*	☐	☐
Gelbes oder oranges Gemüse (z.B. Karotten, Kürbis, Süsskartoffeln) und Speisen und Getränke daraus (z.B. Saft, Suppe, Wähe)	☐	☐

[Yellow or orange vegetables (e.g. carrots, pumpkin, sweet potatoes) and dishes and drinks made from them (e.g. juice, soup, wähe)]

Anderes Gemüse (z.B. Tomaten, Sellerie, Aubergine, frischer Mais) oder Speisen und Getränke daraus (z.B. Saft, Püree, Smoothie) ☐ ☐
[Other vegetables (e.g., tomatoes, celery, aubergine, fresh maize) or dishes and drinks made from them (e.g., juice, puree, smoothie)]

Falls Sie gegessene Lebensmittel aus der Gruppe «Gemüse» nicht eindeutig zuordnen können, schreiben Sie sie bitte in das folgende Textfeld:
[*If you cannot clearly assign eaten foods from the group "Vegetables", please write them in the following text field:]*

✍_____

6. **Früchte *[Fruits]*** **Ja *[yes]*** **Nein *[no]***

Früchte mit orangem oder gelbem Fruchtfleisch (z.B. Aprikose, Pfirsich, Mango) oder Speisen und Getränke daraus (z.B. Saft, Wähe, Desserts) ☐ ☐
[Fruits with orange or yellow flesh (e.g., apricot, peach, mango) or foods and drinks made from them (e.g., juice, honey, desserts)]

Andere Früchte (z.B. Apfel, Banane, Birne, Beeren) oder Speisen und Getränke daraus (z.B. Saft, Wähen, Fruchtjoghurt) ☐ ☐
[Other fruits (e.g., apple, banana, pear, berries) or dishes and drinks made from them (e.g., juice, wähen, fruit yoghurt)]

Falls Sie gegessene Lebensmittel aus der Gruppe «Früchte» nicht eindeutig zuordnen können, schreiben Sie sie bitte in das folgende Textfeld:
[If you cannot clearly assign eaten foods from the group "Fruits", please write them in the following text field:]

✍_____

7. **Getreideprodukte, Kartoffeln & Hülsenfrüchte** **Ja *[yes]*** **Nein *[no]***
[Cereal products, potatoes & legumes]

Glutenhaltige Getreide (z.B. Weizen, Roggen, Gerste) oder Getreideprodukte (z.B. Weizenbrei, Brot) ☐ ☐
[Cereals containing gluten (e.g. wheat, rye, barley) or cereal products (e.g. wheat porridge, bread)]

Glutenfreie Getreide (z.B. Reis, Hirse, Buchweizen) oder Speisen und Getränke daraus (z.B. glutenfreies Brot, Hirseflocken, Reisdrink) ☐ ☐
[Gluten-free cereals (e.g. rice, millet, buckwheat) or foods and drinks made from them (e.g. gluten-free bread, millet flakes, rice drink)]

Kartoffeln oder Speisen und Getränke daraus (z.B. Kartoffelstock, Kartoffelgratin, Pommes) ☐ ☐

[Potatoes or food and drinks made from them (e.g. mashed potatoes, potato gratin, French fries)]

Soja oder Speisen und Getränke daraus (z.B. Sojadrink, Edamame, Tofu) *[Soy or foods and drinks made from it (e.g. soy drink, edamame, tofu)]*	☐	☐
Andere Hülsenfrüchte (z.B. Bohnen, Erbsen, Kichererbsen in frischer und getrockneter Form) oder Speisen und Getränke daraus (z.B. Falafel, Hummus) *[Other legumes (e.g. beans, peas, chickpeas in fresh and dried form) or dishes and drinks made from them (e.g. falafel, hummus)]*	☐	☐

Falls Sie gegessene Lebensmittel aus der Gruppe «Getreideprodukte, Kartoffeln und Hülsenfrüchte» nicht eindeutig zuordnen können, schreiben Sie sie bitte in das folgende Textfeld:
[If you cannot clearly assign eaten foods from the group "Cereal products, potatoes and pulses", please write them in the following text field:]

✍_____

8. **Fleisch, Fisch & Eier *[Meat, Fish & Eggs]***	**Ja *[yes]***	**Nein *[no]***
Fleisch (z.B. Poulet, Rind, Schwein) und Speisen daraus (z.B. Schinken, Wurst) *[Meat (e.g., chicken, beef, pork) and dishes made from it (e.g. ham, sausage)]*	☐	☐
Innereien (z.B. Leber, Bries, Niere) oder Speisen daraus (z.B. Leberwurst) *[Innards (e.g., liver, sweetbreads, kidney) or dishes made from them (e.g., liver sausage)]*	☐	☐
Fisch (z.B. Kabeljau, Lachs) oder Meeresfrüchte (z.B. Scampi, Muscheln) oder Speisen daraus (z.B. Fischknusperli, Fischsauce) [*Fish (e.g. cod, salmon) or seafood (e.g. scampi, mussels) or dishes made from them (e.g. fish crispies, fish sauce)]*	☐	☐
Hühnerei und Speisen und Getränke daraus (z.B. Cake, Omelette) *[Hen's egg and food and drinks made from it (e.g., cake, pancakes)]*	☐	☐
Eier anderer Geflügelarten (z.B. Wachtel, Ente) oder Speisen und Getränke daraus *[Eggs of other poultry species (e.g., quail, duck) or dishes and beverages made from them]*	☐	☐

Falls Sie gegessene Lebensmittel aus der Gruppe «Fleisch, Fisch und Eier» nicht eindeutig zuordnen können, schreiben Sie sie bitte in das folgende Textfeld:
[If you cannot clearly assign eaten foods from the group "Meat, fish and eggs", please write them in the following text field:]

✍_____

9. **Milch & Milchprodukte *[milk & dairy products]***	**Ja *[yes]***	**Nein *[no]***
Kuhmilch pur (z.B. Vollmilch, Milchdrink) *[Pure cow's milk (e.g., whole milk, milk drink)]*	☐	☐
Kuhmilch in Backwaren (z.B. Zopf, Guetzli) *[Cow's milk in baked goods (e.g., Zopf, biscuits)]*	☐	☐
Joghurt oder Produkte mit Joghurt (z.B. Birchermüsli, Fruchtjoghurt) [*Yoghurt or products with yoghurt (e.g., Birchermüsli, fruit yoghurt)]*	☐	☐
Käse oder Produkte mit Käse (z.B. Pizza, Gratins) *[Cheese or products with cheese (e.g., pizza, gratins)]*	☐	☐
Andere Produkte mit Kuhmilch (z.B. Desserts, Quark) bitte unten spezifizieren *[Other products with cow's milk (e.g., desserts, curd cheese) please specify below]*	☐	☐
Milch oder Milchprodukte anderer Säugetiere (z.B. Ziege, Schaf oder Stute) *[Milk or milk products from other mammals (e.g., goat, sheep or mare)]*	☐	☐

Falls Sie gegessene Lebensmittel aus der Gruppe «Milch & Milchprodukte» nicht eindeutig zuordnen können, schreiben Sie sie bitte in das folgende Textfeld:
[If you cannot clearly allocate eaten foods from the group "Milk & dairy products", please write them in the following text field:]

✍_____

10. **Öle, Fette & Nüsse [*Oil, fats & nuts]***	**Ja *[yes]***	**Nein *[no]***
Pflanzenöl (z.B. Rapsöl, Olivenöl, Erdnussöl) oder Pflanzenöl in Speisen und Getränken (z.B. Pommes, Gebratenes) [*Vegetable oil (e.g., rapeseed oil, olive oil, peanut oil) or vegetable oil in food and drinks (e.g., chips, fried food)]*	☐	☐
Butter oder Butter in Speisen (z.B. Guetzli, Buttergemüse) *[Butter or butter in dishes (e.g., biscuits, buttered vegetables)]*	☐	☐
Margarine oder Margarine in Produkten (z.B. Guetzli, Cake) *[Margarine or margarine in products (e.g., biscuits, Cake)]*	☐	☐
Nüsse (z.B. Mandeln, Haselnüsse, Cashew) oder Produkte daraus (z.B. Nuss-Nougat Creme, Nussschokolade) *[Nuts (e.g., almonds, hazelnuts, cashew) or products made from them (e.g., nut nougat cream, nut chocolate)]*	☐	☐
Erdnüsse oder Produkte daraus (z.B. Erdnussbutter, Erdnussflips) *[Peanuts or products made from them (e.g., peanut butter, peanut flips)]*	☐	☐
Samen (z.B. Sesam, Kürbiskerne, Sonnenblumenkerne) oder Speisen aus Samen (z.B. Sesammus, Kürbiskernbrot)	☐	☐

[Seeds (e.g,,. sesame seeds, pumpkin seeds, sunflower seeds) or foods made from seeds (e.g., sesame puree, pumpkin seed bread)]

Falls Sie gegessene Lebensmittel aus der Gruppe «Öle, Fette und Nüsse» nicht eindeutig zuordnen können, schreiben Sie sie bitte in das folgende Textfeld:
[If you cannot clearly assign eaten foods from the group "Oils, fats and nuts", please write them in the following text field:]

✍_____

11. **Kräuter & Gewürze *[Herbs & Spices]***	**Ja *[yes]***	**Nein *[no]***
Kräuter (z.B. Petersilie, Basilikum, Rosmarin) oder Speisen oder Getränke mit Kräutern (z.B. Pfefferminztee, Zürcher Geschnetzeltes) *[Herbs (e.g., parsley, basil, rosemary) or food or drinks with herbs (e.g., peppermint tea, Zürcher Geschnetzeltes)]*	☐	☐
Gewürze (z.B. Paprikapulver, Zimt, Pfeffer) oder Speisen oder Getränke mit Gewürzen (z.B. Curry, Zimtschnecken) *[Spices (e.g., paprika powder, cinnamon, pepper) or food or drinks with spices (e.g., curry, cinnamon buns)]*	☐	☐

Falls Sie gegessene Lebensmittel aus der Gruppe «Kräuter und Gewürze» nicht eindeutig zuordnen können, schreiben Sie sie bitte in das folgende Textfeld:
[If you cannot clearly assign eaten foods from the group "Herbs and spices", please write them in the following text field:]

✍_____

Appendix H Baseline questionnaire

1. Datum *[Date]* _ _ _ _ _ _ _ _ _

2. Bitte geben Sie Ihre Patienten ID an
   [Please enter your patient ID] _ _ _ _

3. Welches Geschlecht hat Ihr Kind?
   [What is the gender of your child?]
   - ☐ weiblich
   - ☐ männlich

4. Wer beantwortet die Fragen?
   [Who answers the questions?]
   - ☐ Mutter *[Mother]*
   - ☐ Vater *[Father]*
   - ☐ eine andere Person, wer?
     [another person, who?]

5. Wie gross ist Ihr Kind in cm?
   [How tall is your child in cm?] _ _ _

6. Wann wurde Ihr Kind geboren?
   [*When was your child born?]* Tag _ _ Monat _ _ Jahr _ _ _ _ *[day/month/year]*

7. Wie viel wiegt Ihr Kind?
   [What is the weight of your child?] Kilogramm _ _ _ Gramm _ _ _[*Kilogram/gram]*

8. Welche Nationalität/en hat ihr Kind?
   [What nationality/ies does your child have?] ✍_____

9. Wie viele Personen wohnen normalerweise in Ihrem Haushalt, Sie selbst mitgerechnet?
   [How many people normally live in your household, including yourself?] Anzahl Personen: _ _ *[number of persons]*

10. Wie würden Sie Ihren Haushalt beschreiben? Ist dies ein…
    [How would you describe your household? Is this a...]
    - ☐ Paar *mit* Kind/Kindern?
      [Couple with child/children?]
    - ☐ Ein-Eltern-Haushalt mit Kind/Kindern (Alleinerziehende/r)?
      [Single-parent household with child/children (single parent)?]
    - ☐ Anderer Haushalt, wie zum Beispiel eine Wohngemeinschaft mit Freund(inn)en oder Bekannten, anderen Familienangehörigen, etc.?
      [Other household, such as a shared flat with friends or acquaintances, other family members, etc.?]
    - ☐ Keine Angaben *[Not specified]*

11. ☐ Keine Ausbildung abgeschlossen

Was ist Ihr höchster Bildungsabschluss?
[*What is your highest educational qualification?]*

[*No training completed]*

- ☐ Obligatorische Schule (9 Jahre)
  [*Compulsory school (9 years)]*
- ☐ 2-jährige berufliche Grundbildung mit eidg. Berufsattest
  [2-year basic vocational training with federal vocational certificate]
- ☐ 3- oder 4-jährige berufliche Grundbildung mit eidg. Fähigkeitszeugnis
  [3 or 4-year basic vocational training with federal certificate of proficiency]
- ☐ Fachmittelschule, Diplommittelschule
  [*Vocational School]*
- ☐ Berufsmaturität
  [*Voccational Matura]*
- ☐ Gymnasiale Maturität (Gymnasium)
  [High school Matura (Gymnasium)]
- ☐ Höhere Berufsbildung (Eidg. Fähigkeitsausweis, Eidg. Diplom bzw. Meisterdiplom)
  [Specialised vocational training (Federal Specialist Certificate, federal diploma or. Master-Diploma)]
- ☐ Höhere Fachschule (HF Diplom)
  [Professional college (Diploma)]
- ☐ Fachhochschule, Pädagogische Hochschule
  [University of Applied Sciences, University of Teacher Education]
- ☐ Universitäre Hochschule
  [University]
- ☐ Keine Angaben
  [Not specified]
- ☐ Andere-bitte spezifizieren:
  [Other, please specify:]

✍ _____

12. Wie hoch ist in etwa das Einkommen Ihres Haushaltes pro Jahr?
    [What is the approximate income of your household per year?]

- ☐ weniger als CHF 50.000
  [less than CHF 50'000]
- ☐ CHF 50.000- CHF 100.000
- ☐ CHF 100.000- CHF 200.000
- ☐ mehr als CHF 200.000
  [more than CHF 200.000]
- ☐ keine Angaben *[Not specified]*

13. Gehen Sie wegen der Nahrungsmittelallergie Ihres Kindes in die Ernährungsberatung?

- ☐ Ja ⇨ Frage 14 *[yes ⇨ question 14]*
- ☐ Nein ⇨ Frage 15 *[No ⇨ question 15]*

14. Aus welchen Gründen gehen Sie zur Ernährungsberatung?

- ☐ Weil meine Ärztin, mein Arzt das empfohlen hat. *[Because my doctor recommended it]*
- ☐ Um zu erfahren, was mein Kind essen kann und was nicht. *[To know what my child can and cannot eat.]*
- ☐ Um sicherzustellen, dass die Ernährung meines Kindes ausgewogen ist. *[To ensure that my child's diet is balanced.]*
- ☐ Um Tipps zur Umsetzung der Allergenkarenz im Alltag zu erhalten (z.B. Kindergeburtstage, Kindergarten/Schule etc.). *[To get tips on how to implement allergen avoidance in everyday life (e.g., children's birthday parties, kindergarten/school etc.)]*
- ☐ Keine Angaben *[Not specified]*
- ☐ Sonstige Gründe - bitte spezifizieren: *[Other reasons - please specify:]*

✍ _____

15. Aus welchen Gründen gehen Sie nicht zur Ernährungsberatung?

- ☐ Weil mir meine Ärztin, mein Arzt das nicht vorgeschlagen hat. *[Because my doctor did not suggest this to me.]*
- ☐ Weil der Aufwand, zur Ernährungsberatung zu gehen, zu gross ist. [*Because the effort to go to dietary counselling is too big.]*
- ☐ Weil ich mir die Informationen auch auf andere Weise beschaffen kann (z.B. im Internet) *[Because I can also get the information in other ways (e.g., on the internet).]*
- ☐ Weil die Allergenkarenz einfach durchzuführen ist. *[Because allergen avoidance is easy to carry out.]*
- ☐ Weil mir die Kosten zu hoch sind. *[Because the costs are too high.]*
- ☐ keine Angaben *[Not specified]*
- ☐ Sonstige Gründe- bitte spezifizieren: *[Other reasons - please specify:]*

✍ _____

16. Hatte Ihr Kind schon einmal eine anaphylaktische Reaktion?
[Has your child ever had an anaphylactic reaction?]
- ☐ Ja *[yes]*
- ☐ Nein *[no]*
- ☐ weiss ich nicht *[do not know]*

17. Hat Ihr Kind ein Notfallset verschrieben bekommen**?**
- ☐ Ja *[yes]*
- ☐ Nein *[no]*
- ☐ weiss ich nicht *[do not know]*

18. Welche Nahrungsmittelallergie(n) wurde(n) bei Ihrem Kind im Spital diagnostiziert? Allergie auf…

(Bitte kreuzen Sie alle zutreffenden an)

What food allergy(ies) was your child diagnosed with in hospital? Allergy to...

(Please tick all that apply)

- ☐ Kuhmilch *[cow's milk]*
- ☐ Hühnerei *[hen's egg]*
- ☐ Weizen *[Wheat]*
- ☐ Früchte *[Fruits]*
- ☐ Gemüse *[Vegetables]*
- ☐ Soja *[Soy]*
- ☐ Erdnuss *[Peanut]*
- ☐ Haselnuss *[Haselnut]*
- ☐ Andere Nüsse *[other nuts]*
- ☐ Sesam *[Sesame]*
- ☐ Fisch *[Fish]*
- ☐ Krebstiere *[Crustaceans]*
- ☐ Weichtiere *[Molluscs]*
- ☐ Andere – bitte spezifizieren
  [Others - please specify:]

✎ _____

19. Bitte geben Sie für alle Lebensmittel an, ob Ihr Kind darauf allergisch reagiert und die Art der Reaktion, die Sie für dieses Lebensmittel beobachtet haben.
[For all foods, please indicate whether your child is allergic to them and the type of reaction you have observed for that food.]

Augen, Gesicht, Haut:	z.B. Hautrötung, Jucken der Haut/des Mundes/im Hals, Verschlimmerung der Neurodermitis, Augenbrennen, laufende Nase, Schwellungen im Gesicht/Hals
[***Eyes, Face, Skin***	*e.g., reddening of the skin, itching of the skin/mouth/throat, aggravation of neurodermatitis, burning eyes, runny nose, swelling of the face/neck]*
Lunge, Atmung:	z.B. Atemnot, Pfeifen, Keuchen, blaue Lippen
*[**Lungs, breathing***	*e.g., shortness of breath, whistling, wheezing, blue lips]*
Bauch:	z.B. Erbrechen, Durchfall, Bauchschmerzen
[***Stomach***	*e.g., vomiting, diarrhoea, abdominal pain]*
Kreislauf/Bewusstsein:	z.B. niedriger Blutdruck, Schock, Kollaps, Bewusstlosigkeit

[Circulation/Consciousness*: e.g., low blood pressure, shock, collapse, unconsciousness]*

Lebensmittel *[Food]*	Keine Reaktion *[No reaction]*	Augen, Haut, Gesicht *[Eyes, Face, Skin]*	Lunge/ Atmung *[Lungs, breathing]*	Bauch *[Stomach]*	Kreislauf/ Bewusstsein *[Circulation/ Consciousness]*	andere Reaktionen *[other reactions]*	Weiss ich Nicht *[do not know]*
Kuhmilch [*Cow's milk]*	☐	☐	☐	☐	☐	☐	☐
Andere Milch (z.B. Schafsmilch) [Other milk e.g., sheeps milk]	☐	☐	☐	☐	☐	☐	☐
Hühnerei *[Hen's egg]*	☐	☐	☐	☐	☐	☐	☐
Andere Eier *[Other eggs]*	☐	☐	☐	☐	☐	☐	☐
Weizen *[Wheat]*	☐	☐	☐	☐	☐	☐	☐
Früchte *[Fruits]*	☐	☐	☐	☐	☐	☐	☐
Gemüse *[Vegetables]*	☐	☐	☐	☐	☐	☐	☐
Soja [*Soy]*	☐	☐	☐	☐	☐	☐	☐
Erdnuss *[Peanut]*	☐	☐	☐	☐	☐	☐	☐
Haselnuss *[Haselnut]*	☐	☐	☐	☐	☐	☐	☐
Andere Nüsse *[other nuts]*	☐	☐	☐	☐	☐	☐	☐
Sesam *[Sesame]*	☐	☐	☐	☐	☐	☐	☐
Fisch *[Fish]*	☐	☐	☐	☐	☐	☐	☐
Krebstiere *[Crustaceans]*	☐	☐	☐	☐	☐	☐	☐
Weichtiere *[Molluscs]*	☐	☐	☐	☐	☐	☐	☐

Andere Reaktionen bitte spezifizieren (Beispiel: Sesam führt zu Blasen im Mund)
[Please specify other reactions (example: sesame seeds cause blisters in the mouth).]

✍_____

20. Bitte spezifizieren Sie die Früchtesorten, auf die Ihr Kind allergisch reagiert:
[*Please specify the types of fruit to which your child is allergic:]*

✎_____

21. Bitte spezifizieren Sie die Gemüsesorten, auf die Ihr Kind allergisch reagiert:
[Please specify the vegetables your child is allergic to:]

✎_____

Appendix I Sample size calculation for allergic reaction as outcome parameter

Table I1 Sample size calculation for allergic reaction as outcome based on literature

Author, year	**Design, participants, and setting**	**Frequency of accidental allergic reactions (AAR)/reactions per person year**	**Risk of bias/comments**	**Sample size calculation** (http://clincalc.com/Stats/SampleSize.aspx)
	Observational Studies			
Vetander et al., 2016	**Design:** Retrospective cross-sectional study based on a parent answered questionnaire; review of food allergic reactions over a one-year period, symptoms were counted just once; Anaphylaxis and other Symptoms were investigated. **Time period:** 12 months **Age:** 16 years **Type of food allergy:** Any food allergy **Diagnosis:** Diagnosed with Food Allergy by a physician **Setting:** Population based cohort, Sweden	N=3153 n=269 (8.5%) Food related symptoms (AAR) n=24 (0.8%) Anaphylaxis =0.08 reactions/person year	Recall bias, Selection bias (Diagnosis based on parent's declaration) →not the right age group	**Study Parameters** Incidence, group 1 8.5% Incidence, group 2 5.95% *30% dec* Alpha 0.05 Beta 0.2 Power 0.8 **Sample Size** Group 1 1617 Group 2 1617 Total 3234
Boyano-Martinez et al., 2009	**Design:** Retrospective cross-sectional study based on a systematized questionnaire administered by a physician, Reactions classified as mild,	N=88 (44 boys) n=35 (40%) AAR n=21 one AAR n=12 two AAR	Recall bias	**Study Parameters** Incidence, group 1 39%

Author, year	Design, participants, and setting	Frequency of accidental allergic reactions (AAR)/reactions per person year	Risk of bias/comments	Sample size calculation (http://clincalc.com/Stats/SampleSize.aspx)
	moderate, and severe according to investigator-defined criteria. **Period of time:** 12 months **Age:** 18 to 147 months (mean **Type of food allergy:** cow's milk **Diagnosis:** According to previous established standards **Setting:** Hospital, Spain	n=1 three AAR n=1 five AAR in total 53 AAR n=28 (53%) mild n=17 (49%) moderate n=8 (15%) severe =0.39 reactions/person year		Incidence, group 2 27.3% *30% dec* Alpha 0.05 Beta 0.2 Power 0.8 **Sample Size** Group 1 253 Group 2 253 Total 506
Boyano-Martinez et al., 2012	**Design:** Retrospective cross-sectional study based on a systematized questionnaire administered by a physician, Reactions classified as mild, moderate, and severe according to investigator-defined criteria. **Period of time:** 12 months **Age:** 27-176 month (median age 52.2 month) **Type of food allergy:** hen's egg **Diagnosis:** According to previous established standards **Setting:** Hospital, Spain	N=92 (55 boys) n=19 (21%) AAR n=16 one AAR n=2 two AAR n=1 four AAR in total 24 AAR n=10 (53%) mild n=12 (50%) moderate n=2 (10%) severe =0.2 reactions/person year	Recall bias	**Study Parameters** Incidence, group 1 20% Incidence, group 2 14% *30% dec* Alpha 0.05 Beta 0.2 Power 0.8 **Sample Size** Group 1 614 Group 2 614 Total 1228
Fleischer et al., 2012	**Design:** Prospective cohort study. Participants were asked to contact the study site at time of reaction. Additionally, participants were queried at every clinical visit and telephone	N=512 n=367 (71%) subjects with all reactions n=1171 reactions total	Recall bias Selection bias (unclear diagnosis)	**Study Parameters** Incidence, group 1 77%

Author, year	Design, participants, and setting	Frequency of accidental allergic reactions (AAR)/reactions per person year	Risk of bias/comments	Sample size calculation (http://clincalc.com/Stats/SampleSize.aspx)
	follow upped. A 36-item questionnaire was used to obtain details about the reaction. Participants received written information material about managing the child's food allergy. **Period of time:** 0-48.4 month (median 35.5 month) (0-4 years) **Age:** 3-15 month at enrollment **Type of food allergy:** Any type of food allergy; children with existing peanut allergy were excluded. **Diagnosis:** convincing allergic reaction to milk and/or egg with a positive prick test to the trigger food (n=308) and/or moderate to severe atopic dermatitis and a positive skin test to milk and/or egg **Setting:** 5 US sites (New York, NY; Baltimore, MD; Little Rock, AR, Denver, CO; and Durham, NC)	n=269 (52.5%) reported more than one reaction n= 495 (42.4%) mil k n=246 (21.0%) egg n=93 (7.9%) peanut → at enrollment children with existing peanut were excluded n=821 (70.1%) mild n=216 (18.4%) moderate n=134 (11.4) severe →Not all reactions accidental! Some were on purpose! 35.5/12=2.95 years→ 512*2.95=1515 0.77 reaction/person year		Incidence, group 2: 53.9% *30% dec* Alpha: 0.05 Beta: 0.2 Power: 0.8 **Sample Size** Group 1: 65 Group 2: 65 Total: 130
J. W. Yu et al., 2006	**Design:** The parents of children with peanut allergy completed questionnaires about accidental exposure to peanut occurring over the period of the preceding year. **Period of time:** 225patient years **Age:** >=4 years (mean 8.1) **Type of food allergy:** peanut	N=252 (63% boys) n=35 AAR 9.7% (23 Children among the 237 observed for one year having at least 1 AAR) 35 AAR/225 patient years = 0.14 AAR/person year	Nonresponse bias Recall bias Before introduction of allergen	**Study Parameters** Incidence, group 1: 14% Incidence, group 2: 9.8% *30% dec* Alpha: 0.05 Beta: 0.2 Power: 0.8

<table>
<tr><th>Author, year</th><th>Design, participants, and setting</th><th>Frequency of accidental allergic reactions (AAR)/reactions per person year</th><th>Risk of bias/comments</th><th>Sample size calculation (http://clincalc.com/Stats/SampleSize.aspx)</th></tr>
<tr><td></td><td>Diagnosis: Diagnosis at the Montreal Children’s hospital
Setting: hospital</td><td></td><td>declaration in prepacked food</td><td><table><tr><th colspan="2">Sample Size</th></tr><tr><td>Group 1</td><td>932</td></tr><tr><td>Group 2</td><td>932</td></tr><tr><td>Total</td><td>1864</td></tr></table></td></tr>
<tr><td></td><td>Pre-Post study</td><td></td><td></td><td></td></tr>
<tr><td>Ewan & Clark, 2005</td><td>Design: Different designs are reported. Here the pre-post design is most relevant. Information on how allergic reactions were assessed pre-enrollment is missing. Post-enrollment reactions were assessed prospectively. After enrollment parents and children received intensive allergy training and
Period of time: mean 3.3 years post enrollment
Age: mean age at presentation was 6.3 years, range 10 months–15 years
Type of food allergy: Nuts and peanut</td><td>Pre-enrollment: 0.55 reactions/person year (95% CI 0.52–0.58)
Post-enrollment: 0.07 reactions/person year (95% CI 0.06–0.08)</td><td>Recall bias especially for pre-enrollment

Before introduction of allergen declaration in prepacked food</td><td><table><tr><th colspan="2">Study Parameters</th></tr><tr><td>Incidence, group 1</td><td>55%</td></tr><tr><td>Incidence, group 2</td><td>7%</td></tr><tr><td>Alpha</td><td>0.05</td></tr><tr><td>Beta</td><td>0.2</td></tr><tr><td>Power</td><td>0.8</td></tr><tr><th colspan="2">Sample Size</th></tr><tr><td>Group 1</td><td>13</td></tr><tr><td>Group 2</td><td>13</td></tr><tr><td>Total</td><td>26</td></tr></table></td></tr>
</table>

Appendix J Permission to reprint the guideline development article

E-mail confirming the permission to reprint the article 'Development of a practice guideline for dietary counselling of children with IgE-mediated food allergy' in this thesis.

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Viele Grüße
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Sebastian Lux
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aus meiner Sicht spricht nichts dagegen, wenn Sie die Orginalquelle im Allergo Journal International angeben. Dies würde dann einem Nachdruck der Arbeit in Ihrer Promotionsarbeit entsprechen. Ich würde dies auf jeden Fall befürworten. Die Genehmigung hierfür muss allerdings der Verlag erteilen.

Lieber Herr Lux,
können Sie das bitte entsprechend genehmigen.

Mit besten Grüßen,
T. Jakob

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From my point of view, there is nothing to be said against when giving the original source in the Allergo Journal International. This would then correspond to a reprint of the paper in your doctoral thesis. I would definitely be in favour of this. However, the publisher must give the permission.
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could you please authorise this accordingly?

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An: Jakob, Thilo <Thilo.Jakob@derma.med.uni-giessen.de>
Betreff: Nachträglicher Open Access oder Genehmigung zur Verwendung eines Artikels in PhD-These

Sehr geehrter Herr Prof. Jakob,

nach einigen Umwegen unter anderem über die Open Access Stelle von Springer gelange ich jetzt mit meinem Anliegen direkt an Sie als Editor. Im August 2020 haben wir im Allergo Journal International einen Artikel mit dem Titel 'Development of a practice guideline for dietary counselling of children with IgE-mediated food allergy' veröffentlicht, den ich gerne in mein PhD inkludieren würde. Zum Zeitpunkt der Veröffentlichung war leider noch nicht bekannt, dass dies möglich ist, da die University of Plymouth, UK, an der ich mein PhD schreibe, noch eine Monographie verlangt. Die Vorschriften wurden aber mittlerweile etwas gelockert, so dass ich diesen Artikel einfügen dürfte.

Deshalb habe ich mit der Open Access Stelle von Springer Kontakt aufgenommen und um nachträglichen Open Access gebeten. Leider war das Peer-Review bereits beendet, bevor der Vertrag zwischen Springer und den Schweizer Hochschulen abgeschlossen wurde, weshalb er nicht mehr unter diesen Vertrag fällt. Die Open Access Stelle hat mir dann auf Nachfrage mitgeteilt, dass es auch gegen Gebühr nicht mehr möglich sei, diesen Artikel nachträglich über sie öffentlich zugänglich zu machen und mir geraten, mich an den Editor zu wenden (s. Mail im Anhang) . Mit Herrn Lux hatte ich auch schon Kontakt, aber er konnte mir auch nicht weiterhelfen. Mir geht es vor allem um die Genehmigung, den Artikel in mein PhD aufnehmen zu dürfen, entweder mit oder ohne Open Access.

Bei Rückfragen können Sie sich gerne bei mir melden. Ich danke Ihnen schon jetzt für die Bearbeitung meines Anliegens.

Freundliche Grüsse

Julia Eisenblätter

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Appendix K Key questions for guideline development rated by dietitians

P (Patient, Population, or Problem): If not otherwise sated, the population is children with IgE-mediated food allergy and their families

I (Intervention, Exposure, or Prognostic Factor): Varies between questions

C (Comparison): Not always applicable

O (Outcomes): If not otherwise stated, Quality of life, allergic symptoms, nutritional status, and food diversity

Table K1 Key PICO-questions for guideline development rated by dietitians regarding their importance for practice of dietary counselling

Key Questions	**Rating**	**Number of ratings**	**Number of comments**
A: Assessment			
1. Which questions should be asked in nutrition assessment to get an insight into nutritional status, eating habits and potentially undetected sources of allergens?	4.4	8	1
2. Which methods should be used to assess dietary intake of children with diagnosed food allergy?	4.0	9	5
3. Which nutrients should be considered in the assessment depending on the child's allergy?	4.8	9	2
4. Which anthropometric measures should be used to detect a potential malnutrition and how are they interpreted?	3.5	8	2
5. Which biochemical data, medical tests and procedures are relevant for counselling?	4.8	9	6
6. Which nutrition related physical findings are collected and considered in the counselling process?	4.0	9	3
7. Which information on the personal, medical, and social situation of the child is requested?	4.1	9	4
8. Which disease related information is requested?			

B: Diagnosis			
9. Which nutrition diagnoses (IDNT) should be considered?	4.1	9	1
C: Intervention			
10. How should lactating mothers of children with a diagnosed food allergy be counselled?	4.6	9	2
11. Which infant formula should be used for children with diagnosed cow's milk allergy to avoid symptoms, secure normal growth, and a balanced diet?	4.9	8	8
12. Which interventions to avoid nutrient deficiencies are discussed in dietary counselling of children with food allergy?	4.6	9	2
13. Which information do the children and their parents need to avoid the culprit food without being unnecessarily restricted?	4.8	9	4
14. How can Quality of life of these children and their parents be promoted despite the restriction of the elimination diet?	4.6	9	2
15. Which topics regarding food law should be discussed in dietary counselling?	4.9	9	3
16. How can children with food allergy and their parents be prepared for risk situations?	4.0	9	1
17. How can children with food allergy and their parents be prepared for new situations due to the development of the child?	3.9	9	1
18. Which counselling tools are used in dietary counselling of children with food allergies?	4.5	8	2
19. Which tasks should dietitians undertake in the management of symptoms and anaphylactic reactions?	3.3	8	2
20. What needs to be considered regarding consulting style, language as well as wording in dietary counselling?	4.1	8	5
21. Which persons in the child's environment should become involved in the dietary counselling process?	3.8	9	1
22. How should the interprofessional cooperation be determined to optimise the care of the children and their parents?	4.3	8	2
D: Monitoring and Evaluation			

23. How often and at what intervals should the children and their parents be counselled?	4.4	8	3
24. How can monitoring and evaluation of the outcomes be implemented?	4.3	8	1
25. Which anthropometric data should be monitored to ensure adequate growth of the child with food allergy?	3.9	8	1
26. Which biochemical data, medical tests and procedures should be monitored to ensure a good nutritional status, quality of life and reduction of symptoms?	4.3	7	0
27. Which nutrition related physical findings are collected and considered in the counselling process?	3.8	8	0

Note. Dietitians participating in this online survey could rate on a scale of 0 to 5 stars, how important it would be to include the question into the practice guideline.

Appendix L Overview of the results of the systematic reviews

Figure L1 Flow of information through the different phases of the systematic review on the PICO-question "Which nutrients should be considered in the assessment of children with diagnosed IgE-mediated food allergy depending on the child's allergy". Based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram (Moher et al., 2009).

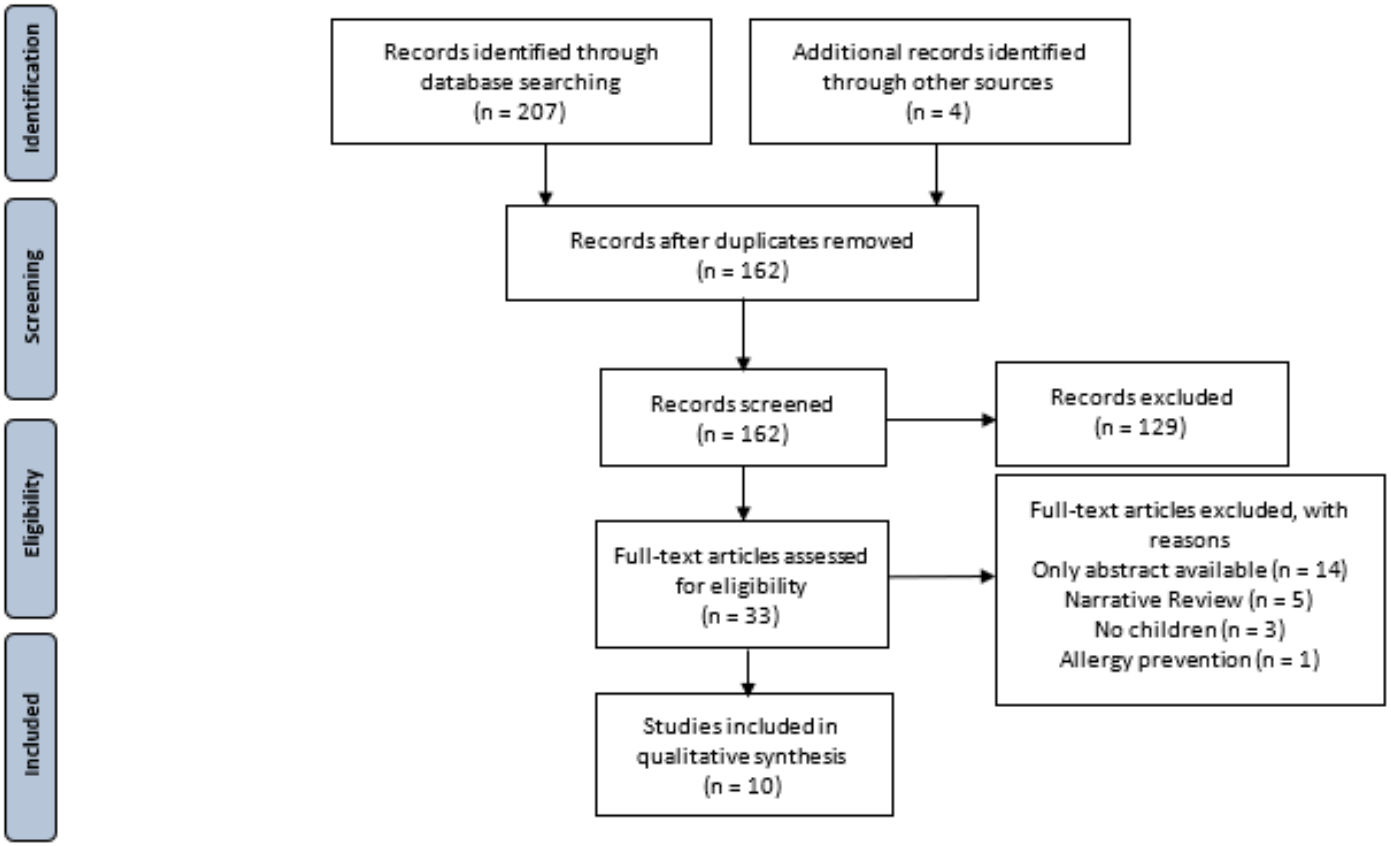

Table L1 Overview of included studies regarding the PICO question: "Which nutrients should be considered in the assessment of children with diagnosed IgE-mediated food allergy depending on the child's allergy?"

Autor, year, country	Study design	Subjects	Comparison	Relationship to Growth (Assessment/ Standard used)	Relationship to Nutrient Intake (Nutrition Assessment Method/Standard used)	Comments, limitations, bias	Judgement*
Food allergy							
Costa et al., 2014, Brazil	Retrospective cohort study	Children with IgE and non-IgE mediated food allergies (n = 228) Age: Median 10 months	Children without food allergy (n = 126) Age: Median 36.5 months	Weight for age Z-score Median (range): -0.95 (-5.30 to 2.25) (food allergy) vs -0.30 (-4.77 to 4.80) healthy controls (P = .0005) Z-score ≤ -2: 18.4% Height for age Z-score Median (range): -0.41 (-5.04 to 2.81) (food allergy) vs -0.01 (-4.78 to 2.55) healthy controls (P = .0030) Z-score ≤ -2: 15.9% BMI for age Z-score Median (range): -0.85 (-6.20 to 3.59) (food allergy) vs -0.33 (-3.06 to 6.55) healthy controls (P = .0053) Z-score ≤ -2: 15.4% (WHO growth charts)	Not reported	Retrospective data collection, missing data in medical records, no differentiation between food allergies, possible selection bias: control group with suspected food allergy but negative diagnosis, median age differs	Class D, rating -
J. Kim et al., 2013, Korea	Cohort study	Atopic dermatitis and allergy to egg (n = 41)	Atopic dermatitis and other food allergy (n = 79)	Not reported	Statistically significant lower intake of vitamin A, B1, B2, niacin, and cholesterol	No healthy control group, for some subgroups the sample size is very small, adults	Class B, rating 0

Autor, year, country	Study design	Subjects	Comparison	Relationship to Growth (Assessment/ Standard used)	Relationship to Nutrient Intake (Nutrition Assessment Method/Standard used)	Comments, limitations, bias	Judgement*
		Age: 1- 65 years	Age: 1- 65 years		(3-day food diary at each visit post challenge)	and children, Potential recall bias, uncertain how many food diaries of each patient were used, no differentiation between age groups per food allergy	
		Atopic dermatitis and allergy to wheat and soybean (n = 59) (s. above)	Atopic dermatitis and other food allergy (n = 61) (s. above)		Statistically significant lower intake of energy, protein, calcium, P, Fe, K, Zn, vitamin B2, vitamin B6, and niacin (s. above)		
		Atopic dermatitis and allergy to beef, pork, and chicken (n = 72) (s. above)	Atopic dermatitis and other food allergy (n = 48) (s. above)		Statistically significant lower intake of Fe and higher intake of potassium, vitamin A, B2. (s. above)		
Meyer et al., 2014, United Kingdom	Cross sectional study	Children with IgE and non-IgE mediated food allergy (n = 97)	World Health Organisation standards for malnutrition	Weight for age Z-score median (range): 0.22 (-3.57 to 3.41) Z-score ≤ -2: 8.5% Height for age Z-score Median (range): -0.06 (-5.03 to 3.12) Z-score ≤ -2: 11.5% Weight for height Z-score Median (range):	Not reported.	Data collection in the hospitals was not standardised, selection bias possible, no information on treatment, no healthy control group	Class D, rating -

Autor, year, country	Study design	Subjects	Comparison	Relationship to Growth (Assessment/ Standard used)	Relationship to Nutrient Intake (Nutrition Assessment Method/Standard used)	Comments, limitations, bias	Judgement*
		Age: Median (range) age of 27 (0.5-149) months		0.51 (-2.58 to 2.58) Z-score ≤ -2: 3.7% (Dietitians in 13 centres in the UK collected height and weight of patients seen in one defined week/WHO standards for malnutrition)			
Vassilopoulou E. et al., 2017,Cyprus	Cross sectional study	School children with self-reported food allergy (n = 28) Age: 6-11 years	School children without food allergy (n = 30)	Not reported	Statistically significant lower intake of energy, calcium, niacin, vitamin E and fibre, but higher intake of sugar and fructose in children with food allergy. (24-hours recall, one weekday and one weekend day)	Food allergy is self-reported, data based on two 24-hours recalls	Class D, rating -
Multiple food allergies							
Costa et al., 2014, Brazil	Retrospective cohort study	Children with ≥ 3 foods excluded (n = 53) Age: Median age at Diagnosis 10 months	Children with ≤ 2 foods excluded (n = 153)	BMI for age Z-score ≤ -2: 16.9% (≥ 3 foods) vs 16.3% (≤ 2 foods)	Not reported	s. above	s. above
J. Kim et al., 2013, Korea	Cohort study	Subjects with 1 food allergy (n = 45)	Subjects with 2 or 3 food allergies	Not reported	Intake of energy, protein, lipid, phosphorus, zinc, vitamin B1, B2 niacin and cholesterol decreased as	s. above	s. above

Autor, year, country	Study design	Subjects	Comparison	Relationship to Growth (Assessment/ Standard used)	Relationship to Nutrient Intake (Nutrition Assessment Method/Standard used)	Comments, limitations, bias	Judgement*
		Age: 1-65 years, both groups Duration: Not reported	(n = 75)		the number of food allergens increased.		
Meyer et al., 2014, United Kingdom	Cross sectional study	Children with ≥ 3 foods excluded (n = 31) Age: Median (range) age of 27 (0.5-149) months for both groups	Children with ≤ 2 foods excluded (n= 66)	Weight for age Z-score ≤ -2: 10% vs 7.8% (p = .044) Height for age Z-score ≤ -2: 14.2% vs 10% (not significant) Weight for height Z-score ≤ -2: 3.5% vs 4% (not significant) (Assessment s. above)	Not reported	s. above	s. above
Milk allergy							
Dong et al., 2018, China	Cohort study	Children with milk allergy (n=60) Age: Mean age 3 ± 0.9 months at enrolment	Age matched healthy children (n=60) Age: Mean age 2.8 ± 1.2 months at enrolment	Weight for age Z-scores were significant lower in the milk allergy group at 6, 9, 12 and 18 months, but not at 24 months. Length for age No significant difference in length for age Z-score.	Energy intake was significant lower in the milk allergy group after 6 months but not at 12, 18 and 24 months.	Relatively high dropout rate (18% in the milk allergy group and 21% in the control group)	Class B, rating +

Autor, year, country	Study design	Subjects	Comparison	Relationship to Growth (Assessment/ Standard used)	Relationship to Nutrient Intake (Nutrition Assessment Method/Standard used)	Comments, limitations, bias	Judgement*
		Duration: 24 months	Duration: 24 months	Weight for length Z-score was significant lower at 9 and 12 months in the milk allergy group. (height/length and weight were measured at routine physical examination / WHO standard)	(3-day food diary at age 6, 12, 18 and 24 months)		
J. Kim et al., 2013, Korea	Cohort study	Atopic dermatitis and allergy to cow's milk (n = 43) Age: 1 to 65 Duration:	Atopic dermatitis and other food allergies (n = 77)	Not reported	Statistically significant lower intake of energy, lipids, calcium, sodium, zinc, and vitamin B2. (s. above)	s. above	s. above
Maslin, Oliver E.M., et al., 2016, United Kingdom	Case control study	Children on milk elimination diet (n=13) Age: Mean age at diet commenced 14 weeks (range 5-36 weeks)	Healthy children (n=26)	Not reported	Across the study period selenium intake was higher for infants consuming a milk free diet whereas vitamin C intake was higher for infants consuming an unrestricted diet. Differences were found between the two groups for protein, calcium, iron, and vitamin E intake at differing time points. (Food diaries at least covering a period of 12 weeks/UK Recommended Nutrient Intakes)	Small sample size, children with milk allergy received dietary counselling	Class C, rating +

Autor, year, country	Study design	Subjects	Comparison	Relationship to Growth (Assessment/ Standard used)	Relationship to Nutrient Intake (Nutrition Assessment Method/Standard used)	Comments, limitations, bias	Judgement*
		Duration: 20 weeks					
Kvammen et al., 2018; Thomassen et al., 2017, Finland	Cross sectional study	Children on a milk elimination diet (n = 57) Age: 0 to 2 years	Reference standards	Weight for age Z-score ≤ -2 = 10.5% Length for age Z-score ≤ -2 = 5.3 % BMI for age Z-score ≤ -2 = 10.5 % (Length, weight, and head circumference)	Data not meaningful, because breast milk was not included in the calculation. Those not receiving breast milk met all recommended daily intakes for the investigated nutrients. (3-day food diary / Nordic Nutrition Recommendations 2012)	Breast milk was not included in the calculation of nutrient intake; parents received dietary counselling, no control group	Class D, rating +
Tuokkola et al., 2017, Finland	Case control study	Children with milk allergy (n = 90) Birth cohort Duration: 28 months	Children with no elimination diet (n = 265) Birth cohort Duration: 28 months	Children with milk elimination grew slower than healthy controls (p=0.009). (Weight and height/length were measured at visits at three, six and twelve months and then annually up to the age of five years / Finish National growth charts)	Intakes of protein and calcium were significant lower in children in the milk elimination group than the controls. (3-day food diary including supplements at the age of one, two and three years.)	Retrospectively analysed data of the Finnish Type 1 Diabetes Prediction and Prevention study. Only infants carrying human leucocyte antigen (HLA) genotypes were included (possible selection bias)	Class C, rating 0
Milk vs milk and wheat (cereal) allergy							
Berry et al., 2015, Finland	Prospective cohort study	Children with milk allergy (n = 18)	Children with milk and wheat allergy (n = 28)	No statistically significant differences between groups; means for anthropometric	No statistically significant differences between groups.	No healthy control group; parents received	Class B, rating +

Autor, year, country	Study design	Subjects	Comparison	Relationship to Growth (Assessment/ Standard used)	Relationship to Nutrient Intake (Nutrition Assessment Method/Standard used)	Comments, limitations, bias	Judgement*
		Mean age 16.3 ± 8.7 months at enrolment Duration: 28 months	Mean age 16.8 ± 7.6 months at enrolment Duration 28 months	measures were below the average for age in both groups (height/length and weight measured at each visit on average at 12, 21, and 28 months of age/ Finish Board of Health growth charts)	(3-day food diary was kept at each visit on average at 12, 21, and 28 months of age/ Nordic Nutrition Recommendations)	dietary counselling	
Tuokkola et al., 2017, Finland	Case control study	Children with milk allergy (n = 90) Birth cohort Duration: 5 years	Children with milk and wheat, barley or rye allergy (n = 130) Birth cohort Duration: 5 years	The growth of children with both milk and wheat, barley or rye elimination diets followed similar pattern to those with only a milk allergy. (Weight and height/length were measured at visits at 3, 6 and 12 months and then annually up to the age of five years / Finish National growth charts)	Not reported	s. above	s. above

Note. * The judgement of the literature is based on the recommendations by the Academy of Nutrition and Dietetics (Handu et al., 2016). A: Randomised controlled trials, cluster randomized controlled trials or randomized crossover trails; B: Prospective cohort study or retrospective cohort study C: Nonrandomised controlled trial, case control study or diagnostic study; D: Noncontrolled trial, before – after studies; M: Meta-analysis or systematic reviews; Minus/Negative (-) means that most validity questions were answered with "No"; Neutral (0) means that the answer of some specific validity questions was "No"; Plus/Positive (+) means that most validity questions were answered "Yes".

Table L2 Overview of differences in nutrient intake of participants with a specific elimination diet compared to a control group.

Autor and year	Energy	Protein	Carbohydrate	Dietary fibre	Fat	Vitamin A	Vitamin D	Vitamin E	Vitamin C	Thiamine (Vit B1)	Riboflavin (Vit B2)	Niacin	Pantothenic acid	Pyridoxin (Vit B6)	Folic acid	Cobalamin (Vit B12)	Calcium	Iodine	Iron	Magnesium	Phosphorus	Selenium	Zinc
Milk elimination diet																							
Dong et al., 2018	↓[1]	↔	↓[1]		↔																		
Kim et al, 2013	↓	↔	↔	↔	↓	↔		↔	↔	↔	↓	↔			↔		↓		↔		↔		↓
Maslin et al., 2016									↓													↑	
Tuokkola et al, 2017[2]	↔	↓	↔	↑	↔	↔	↔	↑	↑	↔	↓	↔	↓	↔	↔	↓	↓	↓	↑	↔	↓	↓	↔
Tuokkola et al, 2017[3]	↔	↓	↔	↑	↔	↔	↔	↑	↑	↔	↓	↔		↔	↔	↓	↓	↓	↑	↔	↓	↓	↔
Tuokkola et al, 2017[4]	↔	↓	↔	↑	↔	↔	↔	↑	↔	↔	↓	↔		↔	↔	↓	↓	↓	↑	↔	↓	↔	↔


Egg elimination diet
Kim et al, 2013
Wheat, barley or rye elimination diet
Tuokkola et al, 2017 2
Tuokkola et al, 2017 3
Tuokkola et al, 2017 4
Cow's milk and wheat, barley or rye elimination diet
Tuokkola et al, 2017 2
Tuokkola et al, 2017 3
Tuokkola et al, 2017 4
Wheat and soybean elimination diet
Kim et al, 2013

Beef, pork or chicken elimination diet																						
Kim et al, 2013	↔	↔	↔	↔	↔	↑		↔	↔	↔	↑	↔		↔	↔		↑		↓		↔		↔

↓ represents a significant lower intake of this nutrient in the corresponding food allergy group, ↔ represents no difference between the groups and ↑ represents a significant higher intake of this nutrient in the corresponding food allergy group. A grey cell means that no appropriate data is reported for this nutrient in the corresponding study.[1] A significant difference was only observed at the age of six months; [2] At the age of one year; [3] At the age of two years; [4] At the age of three years.

Figure L2 Flow of information through the different phases of the systematic review on the PICO-question “Which infant formula should be used for children with diagnosed cow’s milk allergy to avoid symptoms, secure normal growth and a balanced diet?”. Based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram (Moher et al., 2009).

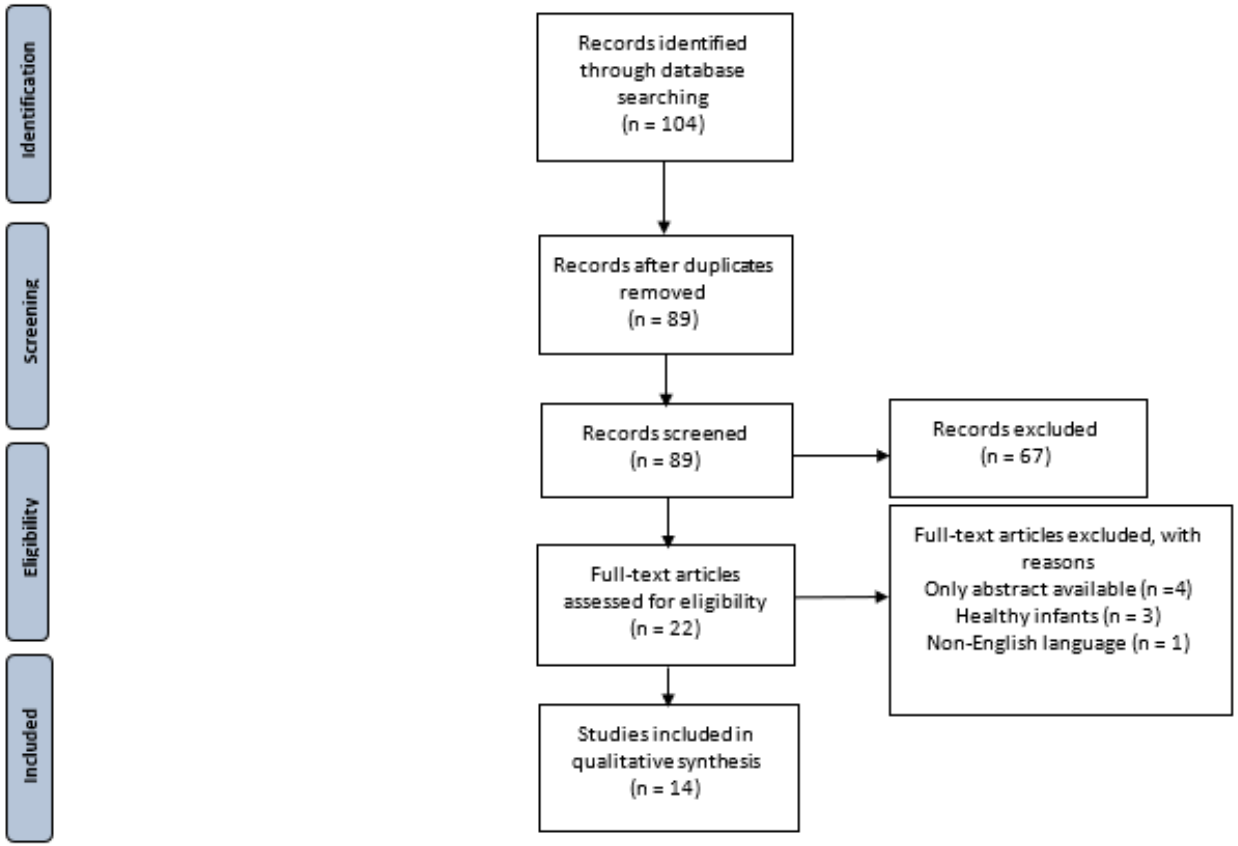

Table L3 Overview of included studies (primary reports and systematic reviews) on the PICO question: "Which infant formula should be used for children with diagnosed cow's milk allergy to avoid symptoms, secure normal growth and a balanced diet?"

Author, year, country	Study design	Intervention (Brand)	Comparison (Brand)	Subjects / duration of the intervention	Relationship to Growth (Assessment/ Standard used)	Relationship to symptoms and tolerance development (Assessment method)	Comments, limitations, bias	Judgement*
Amino Acid Formula								
Berni Canani et al., 2017, Italy	Multicentre randomized controlled trial	Amino acid formula (n = 21) (Neocate® or Neocate Advance® > 12 months)	Extensively hydrolysed whey formula (n=19) (Hypolac DMF srl®)	Infants with IgE or non IgE-mediated cow's milk allergy (age 5-12 months) Duration: 12 months.	At 12 months weight z score value was similar between the two groups and aged-matched healthy controls with no significant difference.	Not reported	Sponsored by Nutricia® (Potential industry bias)	Class A, rating +
Vanderhoof et al., 2016, France	Noncontrolled trial	Amino Acid Formula (n = 30) (Nutramigen® AA)	n/a	Infants (aged 1-12 months) with suspected cow's milk allergy, a history of weight loss and persistent allergy symptoms while on an extensively hydrolysed formula. Duration: 3 months	Mean weight gain (z score) improved (+0.43 +/-0.28). (Standard not reported)	Symptoms: Improvement was observed for all allergic manifestations, both in terms of the number of infants presenting symptoms and symptom intensity. (Scoring Atopic Dermatitis (SCORAD) / Gastrointestinal symptom score (I-GERQ-R parental))	Sponsored by Mead Johnson Nutrition® (Potential industry bias)	Class D, rating +

Author, year, country	Study design	Intervention (Brand)	Comparison (Brand)	Subjects / duration of the intervention	Relationship to Growth (Assessment/ Standard used)	Relationship to symptoms and tolerance development (Assessment method)	Comments, limitations, bias	Judgement*
Probiotics								
Berni Canani, Nocerino, Terrin, et al., 2013, Italy	Prospective cohort study	Amino acid formula (n = 33), Extensively hydrolyzed casein formula (n=55), Extensively hydrolyzed casein formula + Lactobacillus rhamnosus GG (n=71), soy formula (n=55), rice formula (n=46)	n/a	Infants with IgE- and non IgE-mediated food allergy (aged 1-12 months) were divided into groups according to the formula used. Duration: 12 months	Not reported	Tolerance development: The rate of acquiring tolerance was significantly higher ($p < 0.5$) in children receiving extensively hydrolysed casein formula (43.6%) and extensively hydrolysed casein formula + Lactobacillus rhamnosus GG (78.9%) compared with the other groups: rice formula (32.6%), soy formula (23.6%) and amino acid formula (18.2%) (Double blind placebo-controlled food challenge)	Financing of the study not reported, no comparison with extensively hydrolysed whey formula	Class B, rating 0

Author, year, country	Study design	Intervention (Brand)	Comparison (Brand)	Subjects / duration of the intervention	Relationship to Growth (Assessment/ Standard used)	Relationship to symptoms and tolerance development (Assessment method)	Comments, limitations, bias	Judgement*
Berni Canani, Di Costanzo, et al., 2017, Italy	Randomized controlled trial	Extensively hydrolysed casein formula containing Lactobacillus rhamnosus GG (Nutramigen LGG®) (n=110)	Extensively hydrolysed casein formula (Nutramigen®) (n=110)	Children (aged 3 to 8 months) with IgE-mediated cow's milk allergy Duration: 36 months	The time-related changes in weight, lengths and height were comparable between the two formulas (data was not shown).	Allergic Manifestations: Occurrence of at least one allergic episode 39% (44/95) extensively hydrolysed casein formula and 24% (23/98) extensively hydrolysed casein formula + Lactobacillus rhamnosus GG) (Allergic manifestations were diagnosed by using standardised criteria) Tolerance development: Absolute risk difference was 0.20 (95% CI, 0.05-0.35, P < .01) at 12 months, 0.24 (95% CI, 0.08-0.41; P < .01) at 24 months and 0.27	The study was supported by a grant from Mead Johnson Nutrition® (potential industry bias), loss to follow up 12%	Class A, rating +

Author, year, country	Study design	Intervention (Brand)	Comparison (Brand)	Subjects / duration of the intervention	Relationship to Growth (Assessment/ Standard used)	Relationship to symptoms and tolerance development (Assessment method)	Comments, limitations, bias	Judgement*
						(95% CI, 0.11-0.43; P <.001) at 36 months. (Double blind placebo-controlled food challenge)		
Dupont, Hol, & Nieuwenhuis, 2015, Netherlands	Randomized, double-blind control trial	Extensively hydrolysed casein-based formula (Allernova®) plus probiotics (Lactobacillus Casei CLR431 and B Lactis BB-12) (n=59)	Extensively hydrolysed casein-based formula (n=59) (Allernova®)	Infants with diagnosed cow's milk allergy (unclear, if IgE- and non IgE- or just non-IgE-mediated) (aged less than 6 months). Duration: 1 month.	No significant difference in growth related data.	All infants that were fed the study formula tolerated it well, Scores improved with both formulas. (Allergic symptoms were registered after food challenges/ Scoring Atopic Dermatitis Index (SCORAD))	Study financed by the Dutch Ministry of Economic Affairs, Post hoc analysis	Class A, rating +
Synbiotics								
Harvey et al., 2014, United States	Noncontrolled trial (study 2)	Amino acid formula (Neocate® DHA/ARA) with synbiotics (fructo-oligosaccharides	n/a	Infants (age range, birth to 3 years) with IgE- mediated cow's milk allergy	Not reported (only 7 days)	No allergic symptoms were detected.	Study financially supported by Nutricia ® advanced Medical Nutrition (Potential industry bias)	Class D, rating -

Author, year, country	Study design	Intervention (Brand)	Comparison (Brand)	Subjects / duration of the intervention	Relationship to Growth (Assessment/ Standard used)	Relationship to symptoms and tolerance development (Assessment method)	Comments, limitations, bias	Judgement*
		and pectin-derived oligosaccharides as well as Bifidobacterium breve M-16V) (n=30)		Duration: 7 days		(Double blind placebo-controlled Food Challenge / clinical symptoms during feeding period were reported by parents)	Only 7 days of observation, only 24 completed the 7-day feeding period	
Burks et al., 2015, United States	Prospective, randomized, double-blind controlled trial	Amino acid formula (Neocate® Infant DHA/ARA) plus synbiotics (oligofructose, long chain inulin, acidic oligosaccharides, Bifidobacterium breve M-16V) (n=54)	Amino acid formula (Neocate® Infant DHA/ARA) (n=56)	Infants with IgE- or non IgE mediated cow's milk allergy (aged 0-8 months) Duration: 4 months.	No difference was found between formulas regarding weight, height. (WHO growth standards)	Both formulas were well tolerated and reduced allergic symptoms. (Scoring Atopic Dermatitis (SCORAD), allergic symptoms (dermatological, respiratory, gastrointestinal))	Nutricia® supported the study (potential industry bias), Dropout rate 18%	Class A, rating +
Thickened Formula								

Author, year, country	Study design	Intervention (Brand)	Comparison (Brand)	Subjects / duration of the intervention	Relationship to Growth (Assessment/ Standard used)	Relationship to symptoms and tolerance development (Assessment method)	Comments, limitations, bias	Judgement*
Dupont et al., 2014; Dupont, Kalach, et al., 2015, France	Prospective double-blind Randomised Controlled Trial	Thickened (pectin-based) amino acid formula (Novalac®) (n=42)	Reference amino acid formula (Neocate®) (n=33)	Infants (< 18 months) with confirmed IgE- and non IgE- mediated cow's milk allergy failing to respond to extensively hydrolyzed formula. Duration 6 months	There were no significant differences between the two groups in any of the anthropometric z scores. (Standards not stated)	At 3 months, the dominant allergic symptom had disappeared in 76.2% of the infants with the intervention formula and in 51.5% of the infants with reference formula (P=0.026). (Allergic symptoms itemized by pediatricians according to previous position papers) SCORAD scores significantly improved more with intervention than with reference formula (-27.3 +/-2.3 vs -20.8+/-2.2, P=0.048). 92.9% had normal stools with intervention vs 75.8% with reference formula (P=0.051).	The study was funded by United Pharmaceuticals® (Potential industry bias)	Class A, rating +

Author, year, country	Study design	Intervention (Brand)	Comparison (Brand)	Subjects / duration of the intervention	Relationship to Growth (Assessment/ Standard used)	Relationship to symptoms and tolerance development (Assessment method)	Comments, limitations, bias	Judgement*
						(Scoring Atopic Dermatitis Index (SCORAD))		
Dupont et al., 2016, France	Prospective, noncontrolled multicenter trial	Thickened extensively hydrolysed casein formula (Allernova AR®) (n = 30)	n/a	Infants (< 12 months) with confirmed IgE or non IgE-mediated cow's milk allergy.	The growth z-scores, negative at study inclusion, significantly improved.	Crying and regurgitation scores, significantly decreased by 4.2 ± 4.0, 0.9 ±1.2 and 0.7 ± 1. 1 respectively, after 14 days of feeding (p< 0.001). (Cow's milk related Symptom Score (CoMiSS)) Scoring Atopic Dermatitis index, of 33.2 ± 14.8 at inclusion in 9 patients, significantly decreased by 15.5 ± 6.7 and 21.1 ± 11.2, after 14 and 45 days of feeding, respectively (p< 0.001).	The study was funded by United Pharmaceuticals® (Potential industry bias) No control group	Class B, rating +

Author, year, country	Study design	Intervention (Brand)	Comparison (Brand)	Subjects / duration of the intervention	Relationship to Growth (Assessment/ Standard used)	Relationship to symptoms and tolerance development (Assessment method)	Comments, limitations, bias	Judgement*
				Duration: 4 months	(Standards not stated)	(Scoring Atopic Dermatitis Index (SCORAD)) Percentage of infants having normal stool consistency significantly improved from 66.7 % (20/30) at inclusion to 90.0 % (27/30) after 14 days of feeding (p= 0.020). (Bristol stool scale)		
Vandenplas et al., 2016, Belgium	Prospective double-blind Randomised Controlled Trial	Thickened extensively hydrolysed casein formula (n=36) (Name of the formula not given)	Extensively hydrolysed casein formula (non-thickened) (n=41) (Name of the formula not given)	Infants (younger than 6 months) with IgE or non IgE-mediated cow's milk allergy. Duration: 6 months	No difference in growth parameters. (WHO- Child Growths Standards)	The decrease of the daily number of regurgitations was significantly higher with the thickened formula after one month. The CoMISS decrease did not differ between both groups. (Cow's milk related Symptom Score	Funding of the study was not reported (potential industry bias) very high dropout rate (48%); cow's milk allergy could not be confirmed in all cases as parents refused food challenge.	Class A, rating -

Author, year, country	Study design	Intervention (Brand)	Comparison (Brand)	Subjects / duration of the intervention	Relationship to Growth (Assessment/ Standard used)	Relationship to symptoms and tolerance development (Assessment method)	Comments, limitations, bias	Judgement*
						(CoMiSS)/Vandenplas regurgitation score)		
Amino acid with nucleotides								
Berni Canani, Nocerino, Leone, et al., 2013, Italy	Noncontrolled trial	Amino acid formula containing nucleotides (Sineall, Humana, Milan, Italy) (n=60)	Amino acid formula (Neocate, Nutricia, Milan, Italy) as Placebo in the food challenge	Infants with IgE - (n=29) or non-IgE- (n =31) mediated cow's milk allergy Age $\leq$ 4 years Duration: 7-day home feeding	Not reported	No patient presented early or delayed clinical reactions. (Double blind placebo-controlled food challenge/ delayed symptoms were reported by parents and confirmed by physician)	Partly sponsored by Humana® (Potential industry bias), short study period, no control group	Class D, rating +
Rice formula								
Vandenplas et al., 2014a, 2014b, Belgium	Noncontrolled trial	Rice protein-based formula (n=40)	n/a	Infants (1-6 months) with IgE- and non IgE-mediated cow's milk allergy.	Normal growth was observed. (WHO- Child Growths Standards)	The symptom-based score was significantly lower after 1 month of study formula feeding than during food challenge at the beginning ($p < .0001$)	United Pharmaceuticals provided free formula and financial support for the study (Potential industry bias) No control group	Class D, rating -

Author, year, country	Study design	Intervention (Brand)	Comparison (Brand)	Subjects / duration of the intervention	Relationship to Growth (Assessment/ Standard used)	Relationship to symptoms and tolerance development (Assessment method)	Comments, limitations, bias	Judgement*
				Duration: 6 months.		(Self-developed symptom-based score)		
Casein versus whey formula								
Vandenplas et al., 2013, Belgium	Prospective double-blind Randomised Controlled Trial	Extensive casein hydrolysate plus probiotics (Nutramigen lactobacillus GG® (10^7 CFU/g powder)) (n=61)	Extensive whey hydrolysate (Althera®) plus Bifidobacterium lactis (10^7 CFU/g powder) (n=55)	Infants (median age 80 vs 64 days) with mild to moderate IgE- and non-IgE-mediated cow's milk allergy Duration: 10 months.	No statistical difference in weight, length, head circumference and z-scores were detected. (Standards not stated)	Extensively hydrolysed whey and extensively hydrolysed casein formula are equally effective. (Self-developed symptom-based score / Bristol stool scale)	The study was financially supported by Nestlé Nutrition (Potential industry bias); the trial was stopped prematurely, as it had already shown its objective.	Class A, rating+

Note. *****Abbreviations as in Table L1.

Figure L3 Flow of information through the different phases of the systematic review on the PICO-question “Which information do the children with IgE-mediated food allergy and their parents need to avoid the culprit food without being unnecessarily restricted?” Based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram (Moher et al., 2009)

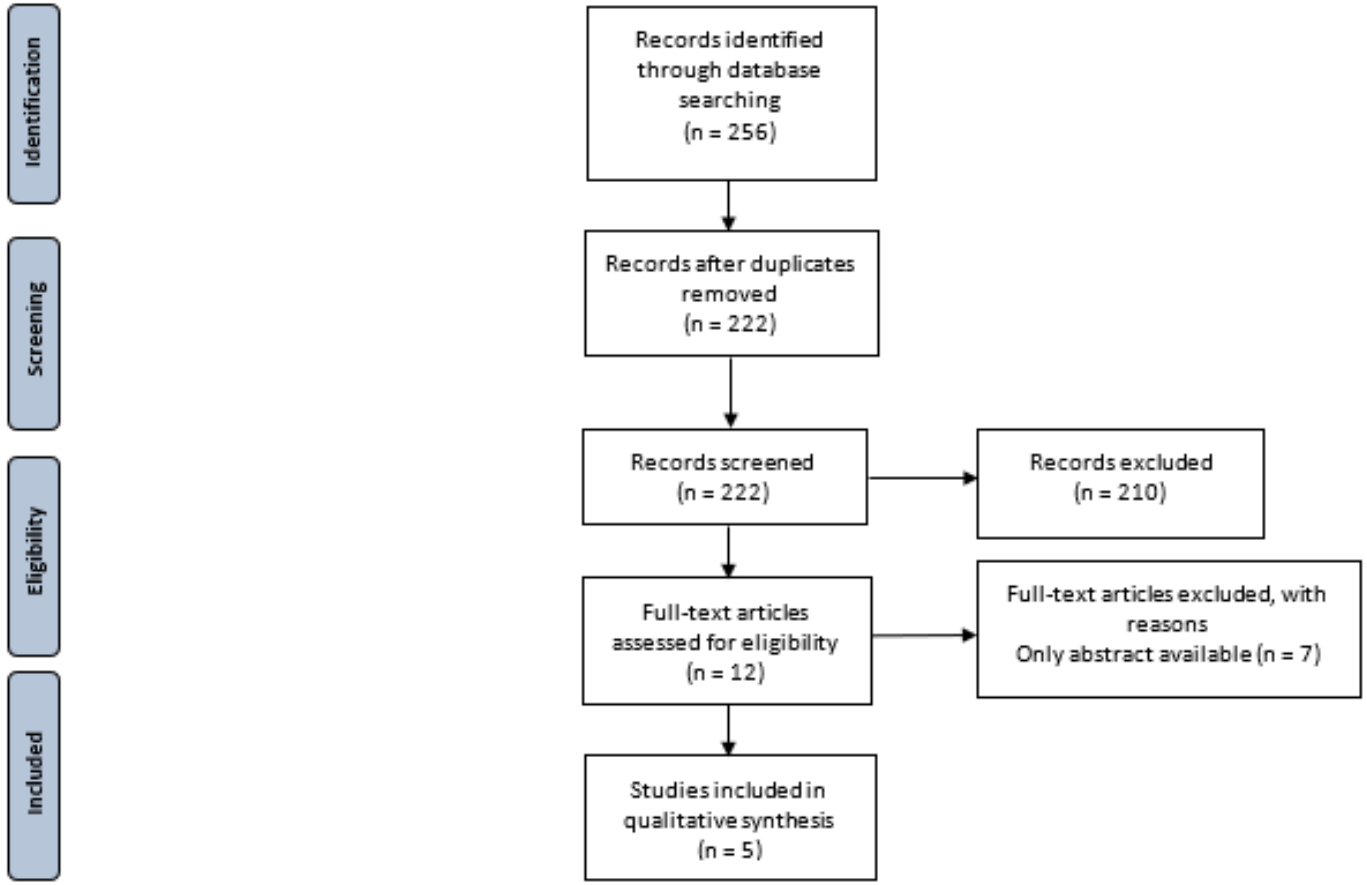

Table L4 Summary of primary reports and systematic reviews on the PICO question: “Which information do the children with IgE-mediated food allergy and their parents need to avoid the culprit food without being unnecessarily restricted?”

Authors, year, country	Study design	Intervention	Comparison	Subjects / Duration and description of the intervention	Relationship to growth / nutrition ((Assessment/ Standard used)	Relationship to symptoms and tolerance development (Assessment method)	Comments, limitations, bias	Judgment*
Dietary counselling								
Berni Canani et al., 2014, Italy	Noncontrolled trial	Children with food allergy before dietary counselling (n=91) Children with food allergy after dietary counselling	Healthy controls at T0 (n=66)	Children (aged 6 to 36 months) with food allergy. At enrolment visit children underwent a personalized dietary counselling session. Duration: 6 months	At enrolment, energy and protein intakes were lower in children with food allergy. A weight to length ratio < -2 standard derivations was more frequent in children with food allergy than in healthy controls. 6 months after dietary counselling the energy intake of children with food allergy was like healthy control at baseline. (3-day food diary)	Not reported	No follow-up data on children without food allergy. No control group with food allergy.	Class D, rating 0
S. H. Kim et al., 2016, Korea	Noncontrolled trial	Individualized nutrition intervention. (N=77)	No control group	Children with atopic dermatitis and food allergy (aged 4 months to 16 years) received an individualized nutrition intervention	Weight for height score significantly improved after the intervention. However, height for age significantly decreased.	Scoring Atopic Dermatitis Index (SCORAD) significantly decreased.	No control group; high dropout rate Short study period, only 35 children	Class D, Rating -

Authors, year, country	Study design	Intervention	Comparison	Subjects / Duration and description of the intervention	Relationship to growth / nutrition ((Assessment/ Standard used)	Relationship to symptoms and tolerance development (Assessment method)	Comments, limitations, bias	Judgment*
				(5 hours dietary counselling).	No significant changes in macronutrient intake was observes. (24 h recall / 3-day food diaries)	(Scoring Atopic Dermatitis Index (SCORAD))	completed the intervention.	
Baked egg/baked milk								
Esmaeilzadeh et al., 2018, Iran	Randomised controlled trial	Baked milk for 6 months, baked cheese after 6 months after challenge (n=42)	Milk free (n = 42)	Children (aged 6 month to 3 years) with cow's milk allergy who tolerated baked milk were randomly divided into intervention and control group. Intervention group was asked to consume baked milk as muffins for the first 6 months and then baked cheese for another 6 months.	Not reported	Tolerance development: Significant (P=.018) difference in milk tolerance. (88% (37/42) intervention group and 67% (28/42) control group) (Food challenge) Adverse events: 2 patients developed anaphylaxis after eating the baked milk muffin	Unclear, if baked egg or baked cheese is responsible for tolerance induction	Class A, rating -
Netting et al., 2017, Australia	Randomised controlled trial	Baked egg (n = 21)	Egg free (n = 22)	Children (6 months to 5 years) with IgE-mediated egg allergy. Intervention group received 10 g baked egg (1.3 g protein) 2 to 3 times per week for 6 months. Raw egg oral	Not reported	Tolerance development: No significant difference in raw egg tolerance between groups, (23.5% (4/17) intervention group and 33.3% (6/18) control group)	Did not reach estimated sample size!	Class A, Rating +

Authors, year, country	Study design	Intervention	Comparison	Subjects / Duration and description of the intervention	Relationship to growth / nutrition ((Assessment/ Standard used)	Relationship to symptoms and tolerance development (Assessment method)	Comments, limitations, bias	Judgment*
				food challenge one month after ceasing the intervention product.		(Open food challenge)		
Written versus oral advice								
Norman M. et al., 2016, Australia	Randomised controlled trial	Written dietary advice and monthly text messages (n = 36)	Standard verbal dietary advice (n = 39)	Children (2-16 years) with nut allergy were supplied with intervention (recipe booklet, monthly reminder text messages) or provided standard verbal dietary advice. After 6 months they were assessed regarding non-allergic nut ingestion, quality of life and nut reactions.	Introduction of non-allergic nuts: 6/32 in the intervention group and 3/33 introduced non-allergic nuts as recommended. 25/32 (intervention group) and 24/33 (control group) introduced any amount of non-allergic food in the diet. There was no significant difference between groups. (online survey with recall over the last month)	Not reported		Class A, rating +

Note. *Abbreviations as in Table 1.

Appendix M Evidence supporting the recommendations

Table M1 Evidence supporing the recommendations of the practice guideline

No	Evidence supporting the recommendation	Strength /Quality
1	**Diet history**	**Consensus**
	1 Consensus Paper: Giovannini et al., 2014 2 Narrative Reviews: Collins, 2016; Venter et al., 2012	R R
2	**Content of diet history**	
2a	**Intake of foods and beverages**	**Consensus**
	1 Guideline:ASCIA, 2017 1 Consensus Statement: Giovannini et al., 2014 3 Narrative Reviews: Collins, 2016; Szépfalusi et al., 2015; Venter et al., 2012	R R R
2b	**Tolerated foods**	**Consensus**
	1 Guideline:ASCIA, 2017 1 Consensus Statement: Giovannini et al., 2014 4 Narrative Reviews: Cummings et al., 2010; Shaker & Venter, 2016; Szépfalusi et al., 2015; Venter, Mazzocchi, et al., 2017	R R R
2c	**Avoided food(group)s and reasons therefore**	**Consensus**
	1 Guideline: ASCIA, 2017 1 Consensus Statement: Giovannini et al., 2014 1 Narrative Review: Collins, 2016	R R R
2d	**Use of substitute products and/or supplements**	**Consensus**
	1 Guideline: ASCIA, 2017 1 Consensus Statement: Giovannini et al., 2014 1 Narrative Review: Collins, 2016	R R R
3	**Suitable assessment methods**	**Consensus**
	1 Guideline: ASCIA, 2017 1 Consensus Paper: Giovannini et al., 2014 1 Qualitative Study: Ruch, 2017 1 Narrative Review: Venter et al., 2012	R R R R
4	**Evaluation of assessment**	**Consensus**
	1 Guideline: ASCIA, 2017 1 Narrative Review: Groetch & Nowak-Wegrzyn, 2013	R R
5	**Weight and height**	**Consensus**
	2 Guidelines: ASCIA, 2017; NICE, 2011 1 Consensus Paper: Giovannini et al., 2014 2 Narrative Review: Collins, 2016, Skypala et al., 2015 1 Qualitative study: Ruch, 2017	R R R R
6	**Diagnostic tests and diet specific laboratory parameters**	**Consensus**
	1 Guideline: ASCIA, 2017 1 Consensus Paper: Giovannini et al., 2014 2 Narrative Reviews: Collins, 2016; Venter et al., 2012	R R R
7	**Overall impression of the child**	**Consensus**
	1 Guideline: NICE, 2011 3 Narrative Review: Collins, 2016; Green Corkins, 2015; Skypala et al., 2015	R R
8	**Content of client history**	**Consensus**
8a	**Medical situation**	
	3 Guidelines: ASCIA, 2017; NICE, 2011; Worm et al., 2015 1 Narrative review: Venter et al., 2012	R R
8b	**Language requirements**	**Consensus**
	Expert group opinion only	R
9	**Allergy specific medical history**	
9a	**Known allergies and other atopic diseases and other medical diagnoses**	**Consensus**

No	Evidence supporting the recommendation	Strength /Quality
	3 Guidelines: ASCIA, 2017; Muraro, Werfel, et al., 2014; Worm et al., 2015 2 Narrative Reviews: Collins, 2016; Venter et al., 2012 1 Qualitative Study: Ruch, 2017	R R R
9b	**Symptoms of food allergy**	**Consensus**
	2 Guidelines: Muraro, Werfel, et al., 2014; Worm et al., 2015 2 Narrative Reviews: Collins, 2016; Venter et al., 2012	R R
9c	**Atopic diseases in the family**	**Consensus**
	2 Guideline: Muraro, Werfel, et al., 2014; Worm et al., 2015 2 Narrative reviews: Skypala et al., 2015; Szépfalusi et al., 2015; Venter et al., 2012 1 Qualitative study:Ruch, 2017	R
10	**Substitutes for children with CMA**	**Fair**
	<u>Introduction</u> 3 Guidelines: (ASCIA, 2017; Fiocchi et al., 2010; Worm et al., 2015) 1 Consensus statement: Giovannini et al., 2014 3 Narrative Reviews: Agostoni et al., 2016; Collins, 2016; Mazzocchi et al., 2017 <u>EHF</u> 1 Consensus Statement: Kansu et al., 2016 4 Narrative Review: Agostoni et al., 2016; Collins, 2016; Host & Halken, 2014; Mazzocchi et al., 2017; Silva et al., 2014; Vandenplas, 2017 1 Cost effectiveness study: Taylor et al., 2012 1 Randomized Controlled Trial: Dupont, Hol, & Nieuwenhuis, 2015 <u>AAF</u> 2 Guidelines: ASCIA, 2017; Muraro, Werfel, et al., 2014 1 Consensus Statement: Giovannini et al., 2014 2 Narrative Reviews: Collins, 2016; Mazzocchi et al., 2017; Venter et al., 2012 <u>EHF vs AAF:</u> 1 Randomized Controlled Trial: Berni Canani, Nocerino, et al., 2017 1 Cohort study: Vanderhoof et al., 2016 <u>Formula choice</u> 1 Cohort study: Berni Canani, Nocerino, Terrin, et al., 2013 1 Systematic Review: Hill et al., 2007 <u>Probiotics (Lactobacillus GG)</u> 1 Randomized Controlled Trials: Berni Canani, Di Costanzo, et al., 2017; Berni Canani, Nocerino, Terrin, et al., 2013 1 Cohort Study: Berni Canani, Nocerino, Terrin, et al., 2013	 R R R R R M A+ R R R A+ B0 B0 M A+ B0
11	**Unsuitable substitutes for CMA**	**Consensus**

No	Evidence supporting the recommendation	Strength /Quality
	Soy und Rice formula:	
	2 Guidelines. ASCIA, 2017; Worm et al., 2015	R
	1 Narrative Review: Vandenplas, 2017	R
	Partially hydrolyzed Formula and lactose free formula	
	3 Guidelines: ASCIA, 2017; Muraro, Werfel, et al., 2014; Worm et al., 2015	R
	1 Narrative Review: Collins, 2016	R
	Cereal Drinks:	
	1 Guideline:	R
	1 Consensus Statement: Giovannini et al., 2014	R
	Milk of other mammalians	
	4 Guidelines: ASCIA, 2017; Fiocchi et al., 2010; Muraro, Werfel, et al., 2014; Worm et al., 2015	R
	1 Consensus Statement: Giovannini et al., 2014	R
	1 Narrative Review: Mazzocchi et al., 2017	R
	Self-made formula	R
	1 Guideline: ASCIA, 2017	
12	**Prevention and treatment of nutrient deficiency**	**Consensus**
	1 Consensus Statement: Giovannini et al., 2014	R
	3 Narrative Reviews: Groetch & Nowak-Wegrzyn, 2013 Venter et al., 2012 Shaker & Venter, 2016	R
12a I	**Alternative products to replace avoided food(s)**	**Consensus**
	2 Guidelines: Fiocchi et al., 2010; Muraro, Werfel, et al., 2014	R
	3 Narrative Reviews: Collins, 2016; Groetch & Nowak-Wegrzyn, 2013; Venter et al., 2012	
12a II	**Use of substituted products**	**Consensus**
	1 Guideline: ASCIA, 2017	R
	2 narrative Review: Groetch & Nowak-Wegrzyn, 2013Meyer et al., 2012	R
	1 Qualitative Study: Ruch, 2017	R
12b	**Alternative products for meal preparation**	**Consensus**
	2 Guidelines: (ASCIA, 2017; Worm et al., 2015)	R
	1 Qualitative Study: Ruch, 2017	R
	1 Narrative Review: Meyer et al., 2012	R
12c	**Where appropriate discuss supplementation**	**Weak**
	1 Consensus Statement: Giovannini et al., 2014	R
	2 Guidelines: (ASCIA, 2017; Fiocchi et al., 2010)	R
	3 Narrative Review: Groetch & Nowak-Wegrzyn, 2013; Mazzocchi et al., 2017; Venter et al., 2012	R
	1 Qualitative Study: Ruch, 2017	R
	1 Cross Sectional Study: Henriksen et al., 2000	D0
12c I	**Where appropriate discuss supplementation - Calcium**	**Consensus**
	1 Guideline :ASCIA, 2017	R
	1 Consensus Statement : Giovannini et al., 2014	R
13	**Training in allergen avoidance**	**Consensus**
	3 Guidelines: Boyce et al., 2010; Fiocchi et al., 2010; Muraro, Werfel, et al., 2014	R
	4 Narrative Reviews: Groetch & Nowak-Wegrzyn, 2013; Mazzocchi et al., 2017; Szépfalusi et al., 2015; Venter et al., 2012	R
13a	**How to avoid the allergen uptake: Which products may contain the allergy-eliciting food and respectively, which foods should be avoided.**	**Consensus**

No	Evidence supporting the recommendation	Strength /Quality
	5 Guidelines ASCIA, 2017; Boyce et al., 2010; Fiocchi et al., 2010; Muraro, Werfel, et al., 2014; Worm et al., 2015 1 Qualitative Study: Ruch, 2017 2 Narrative Reviews: Collins, 2016; Venter et al., 2012	R R R
b	**Meal preparation safety and techniques**	**Consensus**
	2 Guidelines:(ASCIA, 2017; Worm et al., 2015) 1 Qualitative Study: Ruch, 2017 3 Narrative Reviews: Collins, 2016; Sicherer & Sampson, 2018; Venter & Meyer, 2010	R R R
c	**Discussion of unnecessary restrictions**	**Consensus**
	4 Guidelines: ASCIA, 2017; Boyce et al., 2010; Muraro, Werfel, et al., 2014; Worm et al., 2015 2 Narrative Reviews: Groetch & Nowak-Wegrzyn, 2013; Venter et al., 2012	R R
d	**Effects of the disease on nutrition**	**Consensus**
	2 Guidelines: Fiocchi et al., 2010; NICE, 2011 1 Qualitative Study: Ruch, 2017 2 Narrative Reviews: Brough et al., 2015; Mazzocchi et al., 2017	R R R
14	**Quality of life promotion**	
14a	**Recommendation to assure a clear diagnosis**	**Consensus**
	1 Guideline: 3 Narrative Reviews:	R R
14b	**Consider individual tolerance**	**Consensus**
	1 Guidelines: ASCIA, 2017; Muraro, Werfel, et al., 2014; Worm et al., 2015 3 Narrative Reviews: Brough et al., 2015; Mazzocchi et al., 2017; Sicherer & Sampson, 2018	R R
14c	**Consider personal preferences**	**Consensus**
	2 Guidelines: Boyce et al., 2010; Worm et al., 2015 1 Narrative Review: Collins, 2016 1 Qualitative study:Ruch, 2017	R R R
14d	**Handling of out of home consumption**	**Consensus**
	1 Guideline:ASCIA, 2017 2 Narrative Review: Collins, 2016; Venter & Meyer, 2010	R R
14e	**When indicated discuss oral food challenges with allergist**	**Consensus**
	1 Case Control Study: Soller et al., 2014 1 Cross Sectional Study: van der Velde, J. L. et al., 2012	C0 C0
15	**Food law**	
15a	**General information on food laws**	**Consensus**
	3 Guidelines: ASCIA, 2017; Boyce et al., 2010; Muraro, Werfel, et al., 2014 3 Narrative Reviews: Collins, 2016; Groetch & Nowak-Wegrzyn, 2013; Shaker & Venter, 2016 1 Qualitative Study:Ruch, 2017	R R R
15b	**Reading and interpreting ingredient lists**	**Consensus**
	5 Guidelines: ASCIA, 2017; Fiocchi et al., 2010; Muraro, Werfel, et al., 2014; NICE, 2011; Worm et al., 2015 1 Narrative Review: Collins, 2016 1 Qualitative Review:Ruch, 2017	R R R
15c	**Handling precautionary labelling**	**Consensus**
	2 Guidelines: Boyce et al., 2010; Worm et al., 2015 4 Narrative Reviews Brough et al., 2015; Collins, 2016; Groetch & Nowak-Wegrzyn, 2013; Sicherer & Sampson, 2018 1 Qualitative Study: Ruch, 2017	R R R
16	**Risk situations**	**Consensus**
	1 Guideline: Worm et al., 2015 1 Narrative Review: Venter et al., 2012 1 Qualitative Study: Ruch, 2017	R R R
16al	**Restaurants**	**Consensus**

No	Evidence supporting the recommendation	Strength /Quality
	2 Guidelines: ASCIA, 2017; Worm et al., 2015 2 Narrative Reviews: Collins, 2016; Meyer et al., 2012; Venter et al., 2012 1 Cross Sectional Study: Eigenmann & Zamora, 2002 1 Qualitative Study:Ruch, 2017	R R D0 R
16aII	**Traveling with food allergy**	**Consensus**
	1 Guideline: ASCIA, 2017 2 Narrative Reviews: Meyer et al., 2012; Sicherer & Sampson, 2018 1 Qualitative Study: Ruch, 2017	R R R
16aIII	**Third party care (e.g. school, nursery, grandparents)**	**Consensus**
	1 Guideline: ASCIA, 2017 2 Narrative Reviews: Collins, 2016; Meyer et al., 2012 1 Qualitative Study:Ruch, 2017	R R R
16 b	**Contaminations**	**Consensus**
	s. Recommandation 13 b	
17	**New situations**	**Consensus**
	1 Guideline: Boyce et al., 2010 4 Narrative Reviews: Collins, 2016; Palmer, 2017; Venter et al., 2012; West, 2017	R R
18	**Counselling aids**	**Consensus**
	1 Guideline: NICE, 2011 1 Qualitative Study: Ruch, 2017	R R
19	**Accidental reactions**	**Consensus**
	1 Guidelines: ASCIA, 2017; Boyce et al., 2010; Muraro, Werfel, et al., 2014; Worm et al., 2015 3 Narrative Review: Collins, 2016; Sicherer & Sampson, 2018; Szépfalusi et al., 2015 2 Qualitative Studies: Mackenzie et al., 2015; Ruch, 2017	R R R
20	**Counselling style and language**	**Consensus**
	1 Guideline: NICE, 2011 1 Narrative Review: Collins, 2016	R R
21	**Target group**	**Consensus**
	2 Guidelines: Fiocchi et al., 2010; Muraro, Werfel, et al., 2014 1 Narrative Review: Collins, 2016 1 Cross sectional Study: Eigenmann & Zamora, 2002	R R D0
22	**Interprofessional cooperation**	**Consensus**
	1 Guideline: Muraro, Werfel, et al., 2014 1 Consensus Statement: Giovannini et al., 2014 2 Narrative Reviews: Shaker & Venter, 2016; Sicherer & Sampson, 2018	R R R
23	**Monitoring of weight and height**	**Consensus**
	3 Guidelines: ASCIA, 2017; Boyce et al., 2010; Muraro, Werfel, et al., 2014 1 Consensus Statement: Giovannini et al., 2014 2 Narrative Reviews: Venter et al., 2012 Sicherer & Sampson, 2018	R R R
24	**Monitoring of natural course and laboratory parameters**	**Consensus**
	3 Guidelines: Boyce et al., 2010; Fiocchi et al., 2010; Muraro, Werfel, et al., 2014; Worm et al., 2015 2 Narrative Reviews: Groetch & Nowak-Wegrzyn, 2013; Szépfalusi et al., 2015	R R
25	**Monitoring of symptoms**	**Consensus**
	1 Narrative Review: Collins, 2016	R

Note. AAF = Amino Acid Formula, CMA = Cow's Milk Allergy, EHF = Extensive Hydrolysed Formula

Appendix N Documentation of expert panel discussion

The following sections show the documentation of the expert panel discussion in step 2 of the translation and cultural adaption of FAQLQ-PF. Proposed variants by the author are highlighted in blue.

General translations:

Because of food allergy, my child feels…

Durch die/seine …/Wegen/Aufgrund der /seiner…
Nahrungsmittelallergie/Lebensmittelallergie fühlt sich/ist mein Kind

Comments:

Wegen der Nahrungsmittelallergie, … Eine Teilnehmerin ist für Aufgrund der… Nahrungsmittelallergie ist geläufiger als Lebensmittelallergie. „Fühlt sich“ weglassen, da es im Deutschen nicht passt. Fraglich ist allerdings, ob die Aussage noch die gleiche ist.

Ratingskala

English	Proposals German	Comments
0 = not at all	0 = überhaupt nicht/gar nicht/nicht	The best is „überhaupt nicht“. It is not too close to „kaum“.
1= a little bit	1= kaum	
2 = slightly	2 = etwas	
3 = moderately	3 = mittelmässig/moderat/mässig/teils-teils	„Mittelmässig“ is the best version
4 = quite a bit	4 = recht stark	„Ziemlich“ is better than „recht“, omit „stark“
5 = very much	5 = sehr stark	Omit „stark“
6 = extremely	6 = extrem (stark)	Omit „Stark“

1. Because of food allergy, my child feels… anxious about food

A: Wegen der Nahrungsmittelallergie fühlt sich mein Kind… ängstlich/beunruhigt wegen Lebensmitteln.
B: Wegen der/seiner Nahrungsmittelallergie…. ist (zeigt/verhält sich) ängstlich gegenüber Lebensmitteln.

Comments/final version:

None of the proposed variants. Omit «Fühlt sich».

New version
→Wegen der Nahrungsmittelallergie…hat mein Kind Angst vor Lebensmitteln.

2. Because of food allergy, my child feels …different from other children

A: Wegen der Nahrungsmittelallergie fühlt sich mein Kind… anders als andere Kinder.

Comments/final version:

Wegen der Nahrungsmittelallergie…fühlt sich mein Kind anders als andere Kinder.

3. Because of food allergy, my child feels ...frustrated by dietary restrictions

A: Wegen/Aufgrund der Nahrungsmittelallergie fühlt sich mein Kind…eingeschränkt durch die Ernährungsbeschränkungen.
B: Durch die Nahrungsmittelallergie fühlt sich mein Kind…frustriert durch die Ernährungseinschränkungen/diätetischen Restriktionen.

Comments/final version:

Wegen der Nahrungsmittelallergie ist…ist mein Kind frustriert durch die Einschränkungen in seiner Ernährung.

4. Because of food allergy, my child feels …afraid to try unfamiliar foods

A: Wegen der Nahrungsmittelallergie fühlt sich mein Kind…verängstigt, neue Lebensmittel auszuprobieren.
B: Aufgrund der Nahrungsmittelallergie fühlt sich mein Kind…ängstlich, unbekannte Lebensmittel auszuprobieren.

Comments/final version:

Wegen der Nahrungsmittelallergie…hat mein Kind Angst neue Lebensmittel auszuprobieren.

5. Because of food allergy, my child feels ….concerned that I am worried that he/she will have a reaction to food.

A: Wegen/Aufgrund der Nahrungsmittelallergie fühlt sich mein Kind… beunruhigt, dass mir Sorgen mache, dass es eine allergische Reaktion auf ein Lebensmittel haben wird.
B: Durch die Nahrungsmittelallergie fühlt sich mein Kind…besorgt, dass ich beunruhigt/ängstlich bin, dass es eine allergische Reaktion haben könnte.

Comments/final version:

Wegen der Nahrungsmittelallergie…ist mein Kind beunruhigt, dass ich mir Sorgen mache, dass es eine allergische Reaktion auf ein Lebensmittel haben könnte.

6. Because of food allergy, my child…experiences physical distress.

A: Aufgrund der Nahrungsmittelallergie…erfährt/verspürt mein Kind physischen Stress.
B: Wegen der Nahrungsmittelallergie…empfindet mein Kind körperlichen Stress.

Comments/final version:

Wegen der Nahrungsmittelallergie…verspürt mein Kind körperlichen Stress. →körperlicher Stress für Eltern besser verständlich →verspürt besser als empfindet oder erfährt

7. Because of food allergy, my child …experiences emotional distress

A: Aufgrund der Nahrungsmittelallergie…erfährt/verspürt mein Kind emotionalen Stress.
B: Wegen der Nahrungsmittelallergie…fühlt sich mein Kind seelisch belastet.

Comments/final version:

Wegen der Nahrungsmittelallergie…fühlt sich mein Kind seelisch belastet. → Emotionally stressed better understandable, even if emotional stress would fit better with the preceding question.

8. Because of food allergy, my child …has a lack of variety in his her diet

A: Aufgrund der Nahrungsmittelallergie…mangelt es meinem Kind an einer vielfältigen Lebensmittelauswahl/Ernährung.
B: Wegen der Nahrungsmittelallergie…hat mein Kind eine weniger vielfältige Ernährung

Comments/final version:

Wegen der Nahrungsmittelallergie…mangelt es meinem Kind an einer vielfältigen Nahrungsmittelauswahl. «Nahrungsmittelauswahl» better than «Lebensmittelauswahl» „Mangelt“ rather the correct translation for „lack of“.

9. Because of food allergy, my child has been negatively affected by…Receiving more attention than other children of his/her age

A: Aufgrund der Nahrungsmittelallergie wird mein Kind negativ beeinflusst, da… es mehr Aufmerksamkeit als andere Kinder seines Alters bekommt/erfährt
C: Durch die Nahrungsmittelallergie wird mein Kind negativ beeinflusst, da…es mehr Beachtung/Zuwendung als andere Kinder seines Alters bekommt/erfährt.

Comments/final version:

Wegen der Nahrungsmittelallergie wird mein Kind negative beeinflusst, da…es mehr Aufmerksamkeit als andere Kinder seines Alters bekommt. «Aufmerksamkeit» or «Beachtung» better than Zuwendung. «Bekommt» better understandable for parents.

10. Because of food allergy, my child has been negatively affected by …Having to grow up more quickly than other children of his/her age

A: Aufgrund der/Durch die Nahrungsmittelallergie wird mein Kind negativ beeinflusst, da… es schneller /früher erwachsen werden muss als andere Kinder seines Alters
B: Mein Kind wird durch die Nahrungsmittelallergie negativ beeinflusst, da…es schneller gross werden muss, als andere Kinder seines Alters.

Comments/final version:

Wegen der Nahrungsmittelallergie wird mein Kind negativ beeinflusst, da…es schneller selbstständig werden muss als andere Kinder seines Alters. „Erwachsen werden“ or „gross werden“ not suitable for young children as very far away.

11. Because of food allergy, my child has been negatively affected by …His/her environment being more restricted than other children of his/her age

A: Aufgrund der/Durch die Nahrungsmittelallergie wird mein Kind negativ beeinflusst, da …sein Umfeld/seine Umgebung eingeschränkter ist als das anderer Kinder seines Alters.
B: Mein Kind wird durch die Nahrungsmittelallergie negativ beeinflusst, da…seine Umgebung eingeschränkter ist als die anderer Kinder seines Alters.

Comments/final version:

Wegen der Nahrungsmittelallergie wird mein Kind negativ beeinflusst, da…sein Umfeld eingeschränkter ist als das anderer Kinder seines Alters.

12. Because of food allergy, my child's social environment is restricted because of limitations on…Restaurants we can safely go to as a family

A: Durch die Nahrungsmittelallergie ist das soziale Umfeld meines Kindes eingeschränkt durch die begrenzte Auswahl an…Restaurants in die wir als Familie sicher gehen können.
B: Aufgrund/Wegen der Nahrungsmittelallergie ist das soziale Umfeld meines Kindes beeinflusst, aufgrund von Limitationen an… Restaurants in die wir als Familie sicher gehen können.

Comments/final version:

Wegen der Nahrungsmittelallergie ist das soziale Umfeld meines Kinders eingeschränkt, durch die begrenzte Auswahl an…Restaurants in die wir als Familie sicher gehen können.

13. Because of food allergy, my child's social environment is restricted because of limitations on …Holiday destinations we can safely go to as a family

A: Durch die Nahrungsmittelallergie ist das soziale Umfeld meines Kindes eingeschränkt durch die begrenzte Auswahl an…Feriendestinationen/Ferienregionen/Feriendestinationen in die wir als Familie sicher reisen können.

Comments/final version:

Wegen der Nahrungsmittelallergie ist das soziale Umfeld meines Kinders eingeschränkt, durch die begrenzte Auswahl an…Ferienzielen in die wir als Familie reisen können.

14. Because of food allergy, my child's ability to take part has been limited… In social activities in other people's houses (sleepovers, parties, playtime)

A: Durch die Nahrungsmittelallergie sind die Möglichkeiten meines Kindes eingeschränkt…an sozialen Aktivitäten in den Häusern anderer Personen teilzunehmen (Übernachtungen bei Freunden, Feiern, Spielen).
B: Aufgrund der Nahrungsmittelallergie hat mein Kind weniger Möglichkeiten…an sozialen Aktivitäten bei anderen teilzunehmen (Übernachtungen bei Freunden, Feiern, Spielen).
C: Aufgrund der Nahrungsmittelallergie sind die Möglichkeiten meines Kindes limitiert … an sozialen Aktivitäten im Haus anderer Personen teilzunehmen (Übernachtungen bei Freunden, Feiern, Spielen).

Comments/final version:

Wegen der Nahrungsmittelallergie sind die Möglichkeiten meines Kindes eingeschränkt…an sozialen Aktivitäten bei anderen Personen zuhause teilzunehmen (Übernachtungen bei Freunden, Feiern, Spielen)

15. Because of food allergy, my child's ability to take part has been limited… In preschool/school events involving food (class parties/treats/lunchtime)

A: Aufgrund der Nahrungsmittelallergie sind die Möglichkeiten meines Kindes limitiert … an Kindergarten-/Schulveranstaltungen teilzunehmen, bei denen Nahrungsmittel angeboten werden (Klassenfeiern, Treats? Naschereien?/Mittagessen).
B: Durch die Nahrungsmittelallergie sind die Möglichkeiten meines Kindes beschränkt…an Kindergarten-/Schulveranstaltungen mit Lebensmitteln teilzunehmen (Klassenfeiern, Treats? Naschereien?/Mittagessen).

Comments/final version:

Wegen der Nahrungsmittelallergie sind die Möglichkeiten meines Kindes eingeschränkt…an Kindergarten-/Schulveranstaltungen teilzunehmen, an denen Lebensmittel angeboten werden.

16. Because of food allergy, my child feels…Anxious when going to new places

A: Durch die Nahrungsmittelallergie fühlt sich mein Kind …ängstlich, wenn es an unbekannte Orte geht.
B: Wegen der Nahrungsmittelallergie fühlt sich mein Kind…ängstlich/besorgt, an neue Orte zu gehen.

Comments/final version:

Wegen der Nahrungsmittelallergie…hat mein Kind Angst davor, an neue Orte zu gehen.

17. Because of food allergy, my child feels…Concerned that he/she must always be cautious about food

A: Durch die Nahrungsmittelallergie fühlt sich mein Kind … besorgt, dass es immer vorsichtig mit Essen sein muss.
B: Aufgrund der Nahrungsmittelallergie fühlt sich mein Kind…bekümmert immer beim Essen aufpassen zu müssen.

Comments/final version:

Wegen der Nahrungsmittelallergie…ist mein Kind besorgt immer beim Essen aufpassen zu müssen.

18. Because of food allergy, my child feels… 'Left out' in activities involving food

A: Durch die Nahrungsmittelallergie fühlt sich mein Kind …ausgegrenzt bei Aktivitäten mit Lebensmitteln.
B: Aufgrund der Nahrungsmittelallergie fühlt sich mein Kind…ausgeschlossen bei Aktivitäten, an denen Lebensmittel angeboten werden.

Comments/final version:

Wegen der Nahrungsmittelallergie…fühlt sich mein Kind ausgegrenzt/ausgeschlossen bei Aktivitäten, an denen Lebensmittel angeboten werden.

19. Because of food allergy, my child feels…Upset that family social outings (eating out, celebrations, days out) have been limited by food allergy

A: Durch die Nahrungsmittelallergie fühlt sich mein Kind… verärgert, dass gemeinsame Familienaktivitäten (Auswärtsessen, Feiern, Ausflüge) *(aufgrund der Nahrungsmittelallergie)* limitiert/beschränkt/eingeschränkt sind.
B: Aufgrund der Nahrungsmittelallergie fühlt sich mein Kind…verärgert über die Beschränkung von gemeinsamen Familienaktivitäten (Auswärtsessen, Feiern, Ausflüge) *(durch die Nahrungsmittelallergie).*

Comments/final version:

Wegen der Nahrungsmittelallergie… ist mein Kind traurig/wütend, dass gemeinsame Familienaktivitäten eingeschränkt sind (Auswärtsessen, Feiern, Ausflüge) Unclear whether “upset” can also be “traurig”→ clarify with native speaker

20. Because of food allergy, my child feels…Anxious about accidentally eating an ingredient to which he/she is allergic

A: Durch die Nahrungsmittelallergie fühlt sich mein Kind…ängstlich versehentlich eine Zutat zu essen auf die es allergisch ist/reagiert.
B: Aufgrund der Nahrungsmittelallergie fühlt sich mein Kind…besorgt, dass es versehentlich ein Lebensmittel essen könnte, auf das es allergisch ist/reagiert.

Comments/final version:

Wegen der Nahrungsmittelallergie…hat mein Kind Angst versehentlich eine Zutat zu essen, auf die es allergisch reagiert.

21. Because of food allergy, my child feels…Anxious when eating with unfamiliar adults/children

A: Durch die Nahrungsmittelallergie fühlt sich mein Kind…ängstlich/besorgt, wenn es mit unbekannten Erwachsenen/Kindern isst.
B: Aufgrund der Nahrungsmittelallergie fühlt sich mein Kind…ängstlich/besorgt mit nicht vertrauten Erwachsenen/ Kindern zu essen.

Comments/final version:

Wegen der Nahrungsmittelallergie… hat mein Kind Angst mit nicht vertrauten Erwachsenen/Kindern zu essen.

22. Because of food allergy, my child feels…Frustrated by social restrictions

A: Durch die Nahrungsmittelallergie fühlt sich mein Kind…frustriert aufgrund der sozialen Einschränkungen.
B: Aufgrund der Nahrungsmittelallergie fühlt sich mein Kind…enttäuscht durch die sozialen Restriktionen.

Comments/final version:

Wegen der Nahrungsmittelallergie…ist mein Kind wegen der sozialen Einschränkungen frustriert.

23. Because of food allergy, my child… Is more anxious in general than other children of his/her age

A: Durch die Nahrungsmittelallergie … ist mein Kind generell ängstlicher als andere Kinder seines Alters.
B: Aufgrund/Wegen der Nahrungsmittelallergie…ist mein Kind im Allgemeinen ängstlicher als andere Kinder in seinem Alter.

Comments/final version:

Wegen der Nahrungsmittelallergie… ist mein Kind generell ängstlicher als andere Kinder seines Alters.

24. Because of food allergy, my child… Is more cautious in general than other children of his/her age

A: Durch die Nahrungsmittelallergie …ist mein Kind generell vorsichtiger als andere Kinder seines Alters.
B: Aufgrund der Nahrungsmittelallergie…ist mein Kind im Allgemeinen achtsamer als andere Kinder in seinem Alter.

Comments/final version:

Wegen der Nahrungsmittelallergie…ist mein Kind generell vorsichtiger als andere Kinder seines Alters

25. Because of food allergy, my child… Is not as confident as other children of his/her age in social situations

A: Durch die Nahrungsmittelallergie …ist mein Kind nicht so selbstsicher in sozialen Situationen wie andere Kinder seines Alters.
B: Aufgrund der Nahrungsmittelallergie…ist mein Kind unsicherer als andere Kinder in gessellschaftlichen Situationen.

Comments/final version:

Wegen der Nahrungsmittelallergie… Ist mein Kind nicht so selbstsicher in sozialen Situationen wie andere Kinder seines Alters.

26. Because of food allergy, my child… Wishes his/her food allergy would go away

A: Durch die Nahrungsmittelallergie …wünscht sich mein Kind die Nahrungsmittelallergie würde verschwinden.
B: Aufgrund der Nahrungsmittelallergie…wünscht sich mein Kind, dass die Nahrungsmittelallergie weggehen würde.

Comments/final version:

Wegen der Nahrungsmittelallergie… wünscht sich mein Kind, dass die Nahrungsmittelallergie verschwinden würde.

27. Because of food allergy, my child feel…Worried about his/her future (opportunities, relationships)

A: Durch die Nahrungsmittelallergie…ist mein Kind besorgt über seine Zukunft (Möglichkeiten, Beziehungen).
B: Aufgrund der Nahrungsmittelallergie fühlt mein Kind…sich besorgt über seine Zukunft (Chancen, Beziehungen)

Comments/final version:

Wegen der Nahrungsmittelallergie… ist mein Kind besorgt über seine Zukunft. (Möglichkeiten, Beziehungen)

28. Because of food allergy, my child feels…That many people do not understand the serious nature of food allergy

A: Durch die Nahrungsmittelallerg fühlt mein Kind…dass viele Menschen/Personen die schwerwiegenden Folgen, die eine Nahrungsmittelallergie haben kann, nicht verstehen.
B: Aufgrund der Nahrungsmittelallergie fühlt mein Kind…, dass viele Personen/Menschen die Ernsthaftigkeit/ Gefahr von Nahrungsmittelallergien nicht verstehen

Comments/final version:

Wegen der Nahrungsmittelallergie… meint mein Kind, dass viele Menschen nicht verstehen, wie schwerwiegend eine Nahrungsmittelallergie sein kann.

29. Because of food allergy, my child feels…Concerned by poor labelling on food products

A: Durch die Nahrungsmittelallergie…ist mein Kind besorgt über die schlechte Kennzeichnung/Deklaration von Lebensmitteln.
B: Aufgrund der Nahrungsmittelallergie…fühlt sich mein Kind besorgt hinsichtlich der schlechten Kennzeichnung/Deklaration von Lebensmittelprodukten.

Comments/final version:

Wegen der Nahrungsmittelallergie… ist mein Kind beunruhigt über die schlechte Kennzeichnung von Lebensmitteln.

30. Because of food allergy, my child feels…That food allergy limits his/her life in general

A: Durch die Nahrungsmittelallergie…fühlt sich mein Kind generell in seinem Leben eingeschränkt.
B: Aufgrund der Nahrungsmittelallergie… fühlt mein Kind, dass die Nahrungsmittelallergie sein Leben grundsätzlich limitiert

Comments/final version:

Wegen der Nahrungsmittelallergie… fühlt sich mein Kind generell in seinem Leben eingeschränkt.

Appendix O Summary of the results of the pre-test of FAQLQ-PF

Table O1 Characteristics of study participants

ID	Father/Mother	Sex of the child	Age (years)	Food allergy
P1	Mother	male	10	Wheat, rye, barley, egg
P2	Mother	male	7	Hazelnut, pollen cross-reactions likely
P3	Mother	male	2	Wheat, spelt, barley, tomato, aubergine, hazelnut, kiwi
P4	Mother	male	NI. (0-3)	Nuts
P5	Mother (Spanish native speaker, but speaks sufficient German)	male	NI. (0-3)	Hazelnuts, peanuts, wheat gluten, legumes
P6	Mother	male	9	Nuts
P7	Father	male	2	Milk, wheat, soy, eggs
P8	Mother	female	5	Shrimps
P9	Mother	male	1	Wheat, egg, nuts, certain fruit
P10	Mother (not German native speaker)	male	12	Hazelnut, Walnut, Peanut, Pistachios, pecan nuts

Note. NI = No indication

Table O2 Quotes from the parents on each question of FAQLQ-PF and FAIM.

Wegen der Nahrungsmittelallergie,…
1 Hat mein Kind Angst vor Lebensmitteln.
- *Possibly make two categories in the question => allergy-causing and non-allergy-causing foods* (P1) - *This question is only possible with parents of older children. Cannot be assessed in this age group. Tick option: I cannot judge* (P9)
2 Fühlt sich mein Kind anders als andere Kinder.
- *"Possibly categorise in which situations: School, birthday party, hobby / club"* (P1) - *"It is difficult to judge when the child is too young. Answer is interpretation of the mother"* (P9)
3 Ist mein Kind frustriert durch die Einschränkungen in seiner Ernährung.
- *"Statement is judgmental «frustriert»" (*P4)
4 Hat mein Kind Angst, neue Lebensmittel auszuprobieren.
- *Possibly make two categories in the question => allergy-causing and non-allergy-causing foods* (P1) - *It is not possible to discuss this with the child because it is still too young. Also in question 1, she cannot assess whether the child is afraid of food.* (P3) - *No worries at his age* (P7) -
5 Ist mein Kind beunruhigt, dass ich mir Sorgen mache, dass es eine allergische Reaktion haben könnte.
- *Not sure if all parents are so open and want to answer this question* (P5) - *Complicated because putting myself in the child's shoes and thinking about whether the child is worried that I am worried. The sentence difficult to understand.* (P6) - *Possibly too complicated for non-native speaking parents (P9)* (Comment student: Mother speaks in dialect)

Wegen der Nahrungsmittelallergie,…
6 Leidet mein Kind körperlich.
- *«Körperlich»: recreate (concretise) a few examples in brackets* (P1) - What does physical «körperlich» mean? «Körperliche Reaktionen» is the mother's proposal (P4) - Possibly choose another word for "körperlich", not clearly understandable (P5) - *The question is whether physical suffering is meant at the moment of the reaction, because otherwise there is no physical suffering. Specify!* (P9) - *If he eats nuts, then yes. Then he suffers physically. Otherwise not! Specify whether suffering occurs when allergy-causing food is eaten or not.* (P10)
7 Fühlt sich mein Kind seelisch belastet.
- What does “seelisch belastet” mean? Eventuelley better "Macht sich Kind Gedanken" (P4) - *As parents you can't say exactly* (P7) - *It is not appropriate to ask this question. Everything that concerns the psyche should be left at home and not asked.* (P8) - *Possibly choose a different word for “seelisch”, e.g, «belastet» and leave out “seelisch”.* (P9)
8 Mangelt es meinem Kind an einer vielfältigen Nahrungsmittelauswahl.
- *The word "mangelt" could be difficult to understand by other people (people whose mother tongue is not German* (P4) - Complicated writing. Suggestion: «Hat mein Kind Einschränkung» (P9)
Wegen der Nahrungsmittelallergie wird mein Kind negativ beeinflusst, da…
- *Does it have to be judged? (negatively influenced…in question), possibly «… wird mein Kind beeinflusst, da…”(*P1) - *Omit the word "negativ”* (P9)
9 Es mehr Aufmerksamkeit als andere Kinder seines Alters bekommt.
- *Put more simply: «Mein Kind bekommt mehr Aufmerksamkeit.»* (P4)
10 Es schneller selbstständig werden muss als andere Kinder seines Alters.
- *Put more simply* «muss schneller selbständig werden»(P4) - *Child is too young for her to answer it* (P9)
11 Sein Umfeld eingeschränkter ist als das anderer Kinder seines Alters.
- *Specify the environment, the question is too abstract. (Be more specific about what is meant by environment, home? Family? Daycare?)* -
Wegen der Nahrungsmittelallergie ist das soziale Umfeld meines Kindes eingeschränkt durch die begrenzte Auswahl an…
- *long introduction* (P4)
12 Restaurants in die wir als Familie sicher gehen können.
No comment
13 Ferienzielen in die wir als Familie sicher reisen können.
- *Necessary question. Very good!*
14 An sozialen Aktivitäten bei anderen Personen zuhause teilzunehmen. (Übernachtungen bei Freunden, Feiern, Spielen)
- «Hat mein Kind weniger Möglichkeiten» omit «sozialen Aktivitäten» (P4)

Wegen der Nahrungsmittelallergie sind die Möglichkeiten meines Kindes eingeschränkt…
15 An Kindergarten-/Schulveranstaltungen teilzunehmen, an denen Lebensmittel angeboten werden. (Klassenfeiern, Naschereien, Mittagessen)
- *Notes that a distinction could be made between situations where food is an issue and those where it is not e.g., food is less of a problem on a bike tour. (P1)*
Wegen der Nahrungsmittelallergie …
16 Hat mein Kind Angst davor, an neue Orte zu gehen.
No comment
17 Ist mein Kind besorgt, dass es immer beim Essen aufpassen muss.
-Very important
18 Fühlt sich mein Kind bei Aktivitäten ausgegrenzt, an denen Lebensmittel angeboten werden.
- «ausgegrenzt» eventually replace with «anders» (P6)
19 Ist mein Kind traurig/wütend, weil gemeinsame Familienaktivitäten (Auswärtsessen, Feiern, Ausflüge) eingeschränkt sind.
No comment
20 Hat mein Kind Angst, versehentlich eine Zutat zu essen, auf die es allergisch reagiert.
No comment
21 Hat mein Kind Angst, mit nicht vertrauten Erwachsenen/Kindern zu essen.
No comment
22 Ist mein Kind wegen der sozialen Einschränkungen frustriert.
- formulate more neutrally, because otherwise social restrictions are already assumed (P1) - *social stuff = "touchy subject"* Student comment: I don't think the mother understood that it was about restrictions in activities that limit and frustrate. Probably meant social/psychological problems (P8)
Wegen der Nahrungsmittelallergie …
23 Ist mein Kind generell ängstlicher als andere Kinder seines Alters.
- *specify in question what is included: E.g., learning to ride a bike not more anxious* (P1)
24 Ist mein Kind generell vorsichtiger als andere Kinder seines Alters
- *only until the child knows something, is the word "generell" necessary* (P1)
25 Ist mein Kind nicht so selbstsicher in sozialen Situationen wie andere Kinder seines Alters.
No comments
26 Wünscht sich mein Kind, dass die Nahrungsmittelallergie verschwinden würde.
No comments
Wegen der Nahrungsmittelallergie…
27 Ist mein Kind besorgt über seine Zukunft. (Möglichkeiten, Beziehungen)
- *Possibly add professional in the parenthesis, so that it is more concrete.* (P1) - *Possibly not necessary, difficult for child. Mother finds it difficult to put herself in the son's shoes.* (P6)

28 Meint mein Kind, dass viele Menschen nicht verstehen, wie schwerwiegend eine Nahrungsmittelallergie sein kann.
- *Child does not think about it* (P6)
29 Ist mein Kind beunruhigt über die schlechte Kennzeichnung von Lebensmitteln.
- *Possibly highlight whether foods are prepackaged or sold open.* (P1)
30 Fühlt sich mein Kind generell in seinem Leben eingeschränkt.
- *Possibly omit "general"? Subdivide according to different environments* (P1)
FAIM
F1. Für wie wahrscheinlich halten Sie es, dass Ihr Kind…?
1 …versehentlich das Lebensmittel verzehrt, gegen das es allergisch ist?
- *Better to ask if it has happened many times that the child has accidentally eaten something to which he/she is allergic. Separation between emotional or rational, I am not a fortune teller, is a guessing question as it is now* (P3) - *Word "verzehrt" was not understood* (P10)
2 …eine schwere Reaktion hat, wenn das Lebensmittel versehentlich verzehrt wird?
- *Not logical, not a fortune teller, Ev. write, "fear that your child will have a severe reaction..."* (P3) - *Is the word «versehentlich» necessary. Possibly better choose «unabsichtlich»?* (P4)
3 …an seiner Nahrungsmittelallergie sterben wird?
- *"will die from his food allergy". Possibly add a column with "I do not want to answer".* (P1) - *Question is not appropriate, difficult for certain parents, confrontation with it* (P2) - *Formulate more precisely, ev. fear....Anxiety is too strong* (P3) - *might be difficult for some parents to answer* (P4) - *«Sterben könnte [could die]» insead of «sterben wird [will die]»* (P5) - *Borderline: OK for parents to answer. Not for child* (P6) - *Fierce: Do not ask this question* (P8) - *This question is brutal* (P9)
4 …sich selbst wirksam behandelt, beziehungsweise von anderen im Falle eines versehentlichen Verzehrs des allergieauslösenden Lebensmittels wirksam (inkl. der Nutzung des Epipens) behandelt wird?
- *Sentence too long, replace «beziehungsweise» with «oder»* (P4) - *Too young becomes 2 years old* (Comment student: I have the impression that one part of the sentence is being overread. (P7) - *Question is very long and somewhat complicated* (P9) - *Long sentence, but it was understood* (P10)
F2. Für wie wahrscheinlich hält es Ihr Kind, dass es…?
- *Part D, Questions F2: Not answered. Not possible with a 2-year-old. He is not allowed to choose LM himself.* (P3) - *Part D, Questions F2 Children in the 0-3 years category are too young. Do not yet have their own opinion. Do not yet know how dangerous allergies can be. (P4)* - *Part D, Quesstion 4: Child is too young* (P5) - *Child is too young for the questions about the child.* - *Child is too young to answer these questions* (P9) - *Perspective "your child" was difficult. «Verzehrt»: Difficult word.* (P10)

1 … versehentlich das Lebensmittel verzehrt, gegen das es allergisch ist?
No comment
2 … eine schwere Reaktion hat, wenn das Lebensmittel versehentlich verzehrt wird?
«Verzehrt» difficult word (P10)
3 … an seiner Nahrungsmittelallergie sterben wird?
- No. Do not ask this question - Dealing with this is not necessary (P8)
4…sich selbst wirksam behandelt, beziehungsweise von anderen im Falle eines versehentlichen Verzehrs des allergieauslösenden Lebensmittels wirksam (inkl. der Nutzung des Epipens) behandelt wird?
No comment
General feedback
Was the order reasonable? - perhaps not starting with the topic of fear Part D of the questionnaire (said that she noticed the tendency towards the middle there) (P1) - It is good that the question concerning the fear of dying is not a question from the beginning. A few simple questions at the beginning of the questionnaire = very good. Wish: Boxes for each question where it says "cannot answer" and a few pre-printed lines where you can write a reason. - Are all relevant aspects covered? - Basically, school and family are the easier environment. Clubs, hobbies, leisure time, peer groups => more difficult environment; the participant describes this environment as very important for her son at the moment and as a major factor influencing his quality of life (possibly distinguish more in the questionnaire between the different environments). - Part A, question 14: social activities, with 2-year-old in day care centre, later day school? (P3) - Find this question 14 an important category. Ask more questions about different social activities (do not group everything together but ask about the different social activities individually). (P3) - Was it easy to answer the questionnaire? - In general, questions are too long (P4) - On page 2 of the questionnaire there is a box with "answer options", this legend would be more practical to have on each page. Because otherwise you always have to turn the page and look up which number means what. Miscellaneous - Title: What I don't need to understand G-FAQLQ-PF is written m largest. Better subtitle large (P6) - Page 1 Introductory text questionnaire: Write in direct form "Parents tell us" instead of "Parents told us". - Some color would be nice. Nice title page. Possibly choose a children's design. (P9) - Mother thinks that the topic of external care could be addressed more in the questionnaire. For the mother, this is a big factor influencing the quality of life (P9). - Questionnaire is very nice (P10)

Note. The quotes were originally in German. This is a translation of the quotes for this thesis only.

Appendix P Comparison of mean scores, Cronbach α, floor and ceiling effects and correlations between validation studies.

Table P1 Comparison of mean FAQLQ scores and subscale sores between validation studies

FAQLQ-PF-G	Age group (y)	German N=148	Original(Dunn Galvin et al., 2008) N=124	French(Wassenberg et al., 2012) N=62	Spanish(Manso et al., 2017) N=54	Thai(Limpitikul et al., 2020) N=90	Japanese(Mizuno et al., 2016) N=120	Portuguese(Mendonça et al., 2020) N=201
Total score	0-3	3.1	3.6	1.67	2.1	3.5	2.8	2.44
	4-6	3.4	3.9	3.13	2.8	3.8	3.4	NR
	7-12	4.2	4.0	2.94	3.0	4.4	3.8	NR
EI score	0-3	2.8	RR	1.21	1.6	3.4	2.6	NR
	4-6	3.2	3.8	3.03	2.6	3.9	3.3	NR
	7-12	4.0	3.9	2.78	2.9	4.5	3.6	NR
FA score	0-3	2.4	NR	1.76	2.1	4.3	2.0	NR
	4-6	3.3	4.1	3.31	3.2	4.2	3.3	NR
	7-12	4.0	4.0	3.27	3.4	**4.7**	4.3	NR
SDL Score	0-3	4.0	NR	2.02	2.6	3.4	3.4	NR
	4-6	3.8	3.8	3.05	2.7	3.5	4.3	NR
	7-12	4.4	4.1	2.81	2.6	3.8	4.0	NR

Note. NR = Not reported

Table P2 Comparison of Cronbach's α between validation studies

FAQLQ-PF-G	Age group (y)	German N=148	Original N=124	French [a] N=62	Spanish N=54	Thai N=90	Japanese N=120	Portuguese N=201
Total score	0-3	0.898	0.89	NR	0.897	0.951	0.87	0.85
	4-6	0.954	0.93	NR	0.960	0.927	0.92	NR
	7-12	0.946	0.91	NR	0.952	0.967	0.97	NR
EI score	0-3	0.872	NR	NR	0.882	0.875	0.80	NR
	4-6	0.896	0.93	NR	0.856	0.799	0.81	NR
	7-12	0.876	0.94	NR	0.896	0.919	0.93	NR
FA score	0-3	0.727	NR	NR	0.823	0.867	0.79	NR
	4-6	0.883	0.89	NR	0.946	0.854	0.87	NR
	7-12	0.869	0.94	NR	0.895	0.900	0.94	NR
SDL Score	0-3	0.787	NR	NR	0.809	0.891	0.77	NR
	4-6	0.891	0.92	NR	0.916	0.870	0.86	NR
	7-12	0.891	0.90	NR	0.830	0.898	0.94	NR

Note. [a] Cronbach's α overall 0.748
Abbreviation: NR=Not reported

Table P3 Comparison of floor/ceiling effect between validation studies

FAQLQ-PF-G	Age group (y)	German N=148	Original N=124 (1)	French N=62 (2)	Spanish N=54 (3)	Thai N=90 (4)	Japanese N=120 (5)	Portuguese (Brazil) N=201 (6)
Total score	0-3	4.9/0.0	4.2/5.0	NR	13.6/0.0	NR	NR	NR
	4-6	0.0/0.0	3.4/7.3	NR	0.0/0.0	NR	NR	NR
	7-12	0.0/0.0	5.6/2.1	NR	0.0/0.0	NR	NR	NR
EI score	0-3	7.3/0.0	NR	NR	**40.9**/0.0	NR	NR	NR
	4-6	0.0/0.0	1.2/6.0	NR	5.9/0.0	NR	NR	NR
	7-12	0.0/0.0	3.3/3.2	NR	0.0/0.0	NR	NR	NR
FA score	0-3	**19.5**/0.0	NR	NR	**45.4**/0.0	NR	NR	NR
	4-6	0.0/0.0	0.1/1.2	NR	11.7/0.0	NR	NR	NR
	7-12	0.0/0.0	0.5/3.7	NR	0.0/0.0	NR	NR	NR
SDL Score	0-3	4.9/0.0	NR	NR	13.6/0.0	NR	NR	NR
	4-6	0.0/0.0	2.2/0.1	NR	5.9/0.0	NR	NR	NR
	7-12	0.0/1.6	1.8/3.1	NR	14.3/0.0	NR	NR	NR

Note. Abbreviations: NR=Not reported. Numbers in bolt indicate floor or ceiling effect

Table P4 Spearman correlations between FAQLQ-PF and FAIM between validation studies

FAQLQ-PF-G	German N=148	Original (1)	French [a] N=62 (2)	Spanish N=54 (3)	Thai N=90 (4)	Japanese N=120 (5)	Portuguese N=201 (6)
Total score	0.336*	NR	0.85[b]	0.365-0.510*	NR	0.560*	NR
EI score	0.294*	0.577*	NR	0.440-0.666*	NR	0.393*	NR
FA score	0.307*	0.614*	NR	0.126-0.547*	NR	0.639*	NR
SDL Score	0.283*	0.549*	NR	0.510-0.571*	NR	0.627*	NR

Note. Abbreviations: NR=Not reported

* $p < 0.05$

[a] only parent's perspective included,

[b] level of significance not reported

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Appendix Q Implementation of recommendations

Table Q1 Implementation of recommendations for nutrition assessment documented by dietitians (N = 29)

Recommendations: Nutrition Assessment	Implemented	Not implemented	Not relevant	Missing
Food/Nutrition Related History				
26. Diet history The dietitian should obtain a diet history	26	3	0	0
27. Content of diet history The diet history should include the following:				
e) Intake of foods and beverages	25	4	0	0
f) Tolerated foods	26	3	0	0
g) Avoided food(group)s and reasons therefore	22	4	4	0
h) Use of substitute products and/or supplements	20	3	6	0
28. Suitable assessment methods The dietary intake of the child with diagnosed food allergy can be obtained via diet history, 24 h recall or a dietary record. In case of risk of nutrient deficiency, a three-day food diary should be taken.	20	8	0	1
29. Evaluation of assessment Depending on the allergy the intake of specific nutrients will be evaluated.	17	10	2	0
Anthropometric Measurements				
30. Weight and height The dietitian should consider height and weight in the assessment and compare it to growth charts with children of the same age and gender.	24	3	2	0
Biochemical Data, Medical Tests and Procedures				
31. Diagnostic tests and diet specific laboratory parameters The dietitian considers results of allergy specific diagnostic tests (specific IgE, skin prick tests and food challenges) in the assessment. If they are not available, they should be requested. If available, the dietitian includes diet specific laboratory parameters in the assessment.	18	3	8	0
Nutrition-Focused Physical Findings				
32. Overall impression of the child The dietitian should consider the overall impression of the child in the assessment. Moreover, allergy-specific co-morbidities should be documented. This requires close collaboration with the allergist.	14	7	8	0
Client History				
33. Content of client history The client-assessment for children with food allergy should include:				
c) Medical situation	20	4	4	1
d) Language requirements	14	0	14	1
34. Allergy specific medical history The dietitian should assess the following aspects, if not present in the medical records:				
d) Known allergies and other atopic diseases and other medical diagnoses	25	2	2	0
e) Symptoms of food allergy	23	2	2	0
f) Atopic diseases in the family	12	10	7	0

Table Q2 Implementation of recommendations for nutrition interventions documented by dietitians (N = 29)

Recommendations: Nutrition Intervention	Implemented	Not implemented	Not relevant	Missing
Food and/or Nutrient Delivery				
35. Substitutes for children with CMA The selection of an adequate infant formula for children with CMA should be in consultation with the responsible allergist. The allergist will prescribe the formula. For the selection, various individual factors should be considered such as nutrient content, cost and flavour. The nutrient intake of the child should be regularly monitored. A stepwise approach is recommended: 1. First choice: breast milk, eventually avoidance of the culprit food 2. Formula with extensively hydrolysed cow's milk protein (EHF) 3. Amino Acid Formula (AAF) *(comment: In Switzerland costs are covered by medical insurance, if EHF is not effective)*	7	0	22	0
36. Unsuitable substitutes for CMA For CMA, the following products are *not* suitable as breast milk substitute and therefore *cannot* be recommended:	7	0	22	0
37. Prevention and treatment of nutrient deficiency Careful support and monitoring of the diet by an experienced dietitian are important to avoid or treat nutrient deficiencies. Therefore, the following interventions are recommended:				
a) Education on alternative products with adequate nutrient coverage I. Alternative products to replace avoided food(s) II. Use of substituted products	21	1	7	0
b) Alternative products for meal preparation	18	3	8	0
c) Where appropriate discuss supplementation	8	2	19	0
Nutrition Education				
38. Training in allergen avoidance The dietitian should empower the child with food allergy and the parents to avoid the allergy-eliciting food in daily life without being too restricted. Therefore, the following topics should be discussed in dietary counselling:				
a) How to avoid the allergen uptake: Which products may contain the allergy-eliciting food and respectively, which foods should be avoided	24	3	2	0
b) Meal preparation safety and techniques	18	7	4	0
c) Discussion of unnecessary restrictions	15	5	9	0
d) Effects of the disease on nutrition	11	9	9	0
39. quality of life promotion To improve the quality of life of the child and their parents, the dietitian should discuss the following topics:				
a) Recommendation to assure a clear diagnosis	10	4	15	0
b) Consider individual tolerance	14	6	9	0
c) Consider personal preferences	10	7	12	0
d) Handling of out of home consumption	11	3	15	0
e) When indicated discuss oral food challenges with allergist	13	4	12	0

Recommendations: Nutrition Intervention	Implemented	Not implemented	Not relevant	Missing
40. Food law The legal basis of allergen information on prepacked and non-prepacked food should be communicated in an understandable way. This should contain:				
a) General information on food laws	19	9	1	0
b) Reading and interpreting ingredient lists	23	5	1	0
c) Handling precautionary labelling	24	4	1	0
41. Risk situations The dietitian should sensitise children and their parents to situations with risk without unnecessarily alarming them. Therefore, the following topics should be discussed:				
c) Out of home consumption I. Restaurants II. Traveling with food allergy III. Third-party care (e.g., school, nursery, grandparents)	9	5	15	0
d) Contaminations	16	5	8	0
42. New situations Children develop and grow constantly, therefore, new situations arise, which should be discussed in dietary counselling. Ideally, dietary counselling should happen before foreseeable changes. For example, the implementation of solid foods to prevent additional allergies according to current guidelines.	13	5	11	0
Nutrition Counselling				
43. Counselling aids It can be helpful to use counselling aids for counselling of children with food allergies and their parents.	25	4	0	0
44. Accidental reactions Instructions on how to act in case of an accidental reaction (including anaphylaxis) is generally the duty of the physician. The dietitian can play a supporting role by double checking, if the emergency plan and drugs are available and that the patient knows how to use them. The dietitian can recommend anaphylaxis-training and consult the physician if no emergency plan exists but is necessary.	8	10	11	0
45. Counselling style and language The counselling style and the language used should be adequate for the age of the child, be clear and understandable to both the parents and child, and their socioeconomic status should be considered. In case of language difficulties an interpreter should be utilised.	4	1	24	0
46. Target group Dietary counselling should address the child depending on his/her age as well as the parents. As required, relatives, friends, teachers and further persons that look after the child can be included. Alternatively, parents may be empowered to inform others.	7	4	18	0
Coordination of Care				
47. Interprofessional cooperation The optimal management of children with food allergy should use a multidisciplinary approach. The dietitian will work closely with the allergist and other health professionals and refers to further contacts when required.	26	3	0	0

Table Q3 Implementation of recommendations for nutrition monitoring documented by dietitians (N = 29)

Recommendations: Nutrition Monitoring and Evaluation	Implemented	Not implemented	Not relevant	Missing
Anthropometric Measurements				
48. Monitoring of weight and height Weight and height as well as the development along the centile curve should be assessed on a regular basis.	19	7	3	0
Biochemical Data, Medical Tests and Procedures				
49. Monitoring of natural course and laboratory parameters To be controlled on a regular basis if the allergy persists. This is generally the duty of the allergist. However, the dietitian can consult the allergist and request to undertake a food challenge. If malnutrition is suspected, it is reasonable to evaluate relevant laboratory parameters.	9	9	11	0
Nutrition-Focused Physical Findings				
50. Monitoring of symptoms The dietitian should ask, if an accidental allergic reaction occurred (symptoms, anaphylaxis). The development of physical findings (e.g., change of eczema) should be considered in monitoring.	6	10	13	0

Appendix R Means of FAQLQ-PF-G scores

For better comparison with other studies, mean FAQLQ-PF scores were calculated, even though data was not normally distributed.

Table R1 Means scores and standard derivation of FAQLQ-PF-G scores per age group and timepoint

Age group (y)	FAQLQ-PF-G	N	Mean score (SD) baseline	N	Mean score (SD) 3-months	N	Mean score (SD) 6-months
0 - 3	Total Score	42	1.52 (0.53)	42	1.57 (0.53)	40	1.73 (0.70)
	Subscale Scores						
	Emotional Impact		1.33 (0.47)		1.42 (0.50)		1.56 (0.65)
	Food Anxiety		1.35 (0.58)		1.32 (0.46)		1.38 (0.64)
	Social Dietary Limitation		1.87 (0.95)		1.96 (0.91)		2.24 (1.21)
4 - 6	Total Score	3	3.14 (1.31)	3	3.51 (1.61)	3	3.50 (1.43)
	Subscale Scores						
	Emotional Impact		2.73 (1.21)		3.00 (1.38)		3.03 (1.25)
	Food Anxiety		4.24 (1.44)		4.38 (1.70)		4.33 (1.65)
	Social Dietary Limitation		2.44 (1.35)		3.15 (1.83)		3.15 (1.43)
7 - 10	Total Score	3	1.74 (0.69)	3	2.01 (0.82)	3	2.03 (0.60)
	Subscale Scores						
	Emotional Impact		1.73 (0.68)		1.79 (0.62)		2.05 (0.64)
	Food Anxiety		1.83 (0.63)		2.38 (0.87)		2.29 (0.71)
	Social Dietary Limitation		1.67 (0.78)		1.85 (1.01)		1.74 (0.53)

Note. FAQLQ-PF scores and subscale scores range from 1 ‘no impairment’ to 7 ‘maximal impairment’.