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QUALITY OF LIFE IN CAREGIVERS OF CHILDREN WITH FOOD ALLERGIES

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Summary of MRP

SECTION A

The prevalence of food allergies in the general population is increasing. Scholarly consensus is that caring for a child with food allergies is burdensome, and can impair parental quality of life. Yet it is unclear what interventions are most effective in supporting caregivers of affected individuals. This paper aimed to conduct a narrative review of interventions that target parents of children with food allergies and compare the acceptability and efficacy of these interventions. A systematic search of four databases yielded 15 papers that met the inclusion criteria. Eight studies used a pre-test post-test design, four used a post-test design, two were randomised controlled trials and one a case-control design. Six studies were educational interventions, five were psychological interventions, and four were supportive interventions. The review found that all interventions had high acceptability with participants, and educational interventions reported an improvement in food-allergy knowledge. Of the psychological interventions, there was some evidence for the use of cognitive behavioural interventions in supporting mothers. However, many of the studies suffered from significant methodological problems, including lack of control groups, biased samples and use of unvalidated outcome measures. Controlled research studies are needed so that these interventions can be more robustly evaluated.

SECTION B

Caring for a child with a food allergy can be burdensome and negatively affect parental quality of life. The mechanisms for improving quality of life in parents of food-allergic children are not yet understood, but recent studies have suggested that information provision can enhance self-efficacy, and in turn quality of life. The present study developed an online self-help website that aimed to improve quality of life and psychological wellbeing in parents of children with food allergy. The website was developed in consultation with parents and allergy specialists. Parents of children with food allergy (N=205) participated in a randomised controlled trial, comparing the website intervention with a waitlist control. No significant differences were found between the website intervention group and the control group between baseline and post-intervention (4 weeks) on any outcome (quality of life, depression, anxiety or stress) or in any potential mediator (self-efficacy and intolerance of uncertainty). Analysis of adherence data identified low engagement with the website, suggesting that the intervention may not have been best suited to the participating parents. Feedback recommended that the intervention would be better targeted at parents of newly diagnosed children. Study limitations are discussed.

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MAJOR RESEARCH PROJECT (MRP) SECTION A: LITERATURE REVIEW PAPER

Supportive interventions for parents of children with food allergies: A narrative review

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Abstract

The prevalence of food allergies in the general population is increasing. Scholarly consensus is that caring for a child with food allergies is burdensome, and can impair parental quality of life. Yet it is unclear what interventions are most effective in supporting caregivers of affected individuals. This paper aimed to conduct a narrative review of interventions that target parents of children with food allergies and compare the acceptability and efficacy of these interventions. A systematic search of four databases yielded 15 papers that met the inclusion criteria. Eight studies used a pre-test post-test design, four used a post-test design, two were randomised controlled trials and one a case-control design. Six studies were educational interventions, five were psychological interventions, and four were supportive interventions. The review found that all interventions had high acceptability with participants, and educational interventions reported an improvement in food-allergy knowledge. Of the psychological interventions, there was some evidence for the use of cognitive behavioural interventions in supporting mothers. However, many of the studies suffered from significant methodological problems, including lack of control groups, biased samples and use of unvalidated outcome measures. Controlled research studies are needed so that these interventions can be more robustly evaluated.

Keywords:

Food allergy, Parents**,** Caregivers, Intervention, Quality of Life, Wellbeing

1. INTRODUCTION

1.1. The impact of allergies

Food allergy affects 3-6% of the population and scholarly consensus is that prevalence rates are increasing (Du Toit et al., 2018; Sicherer, 2011; Sicherer & Sampson, 2010, Valenta, Hochwallner, Linhart & Pahr, 2015). Such allergies can have a significant negative impact on individuals and their caregivers (Sicherer, 2011).[1]

Receiving a food allergy diagnosis can itself cause significant stress. This process can be lengthy and challenging, frequently requiring multiple tests (Akeson, Worth & Sheikh, 2007). Methods of diagnosis include elimination diets, skin prick tests (where a small sample of the allergen is placed on the skin and the reaction is observed), in-vitro diagnostic tests and oral food challenges (Baral & Hourihane, 2005). Diagnosis is further complicated by the inaccessibility of specialist allergy services (Akeson et al. 2007).

Living with food allergies is often just as stressful as receiving the diagnosis. Although usually diagnosed in childhood (Valenta et al., 2015), food allergy is often a lifelong condition, with 20% of individuals maintaining their allergy into adulthood (Knibb, Barnes & Stalker, 2016). Additionally, the most common food allergies are caused by a group of "major allergens" -- including milk, eggs, and nuts -- but individuals may develop an allergy to any food (Baral & Hourihane, 2005).

Managing food allergies requires vigilance, and can be burdensome (Flokstra de Bok & Dubois, 2009). Because recommendations for preventative strategies remain inconclusive and a cure for food allergies does not currently exist, the primary management advice is to avoid the allergen (McQuaid, Farrow, Esteban, Jandasek & Rudders, 2015). In practice, this guidance requires individuals and their caregivers to always be aware of the ingredients in

[1] For concision, "parents" and "caregivers" will be used interchangeably throughout, while "individuals" and "people" refer to children with allergies.

their food (e.g., by diligently checking recipes and food labels), to prevent reactions caused by exposure to even trace amounts of the allergen (Sicherer et al., 2012; Williams, Parra & Elkin, 2009). Additionally, reactions may be triggered by touching or inhaling the allergy protein if it can aerosolise (e.g., by boiling milk; Leornardi et al., 2014). Therefore, people with allergies must also account for cross contamination in their environment, ensuring that surfaces the allergen has contacted are cleaned thoroughly before the individual touches it (Williams, Parra & Elkin, 2009).

When these precautions fail, allergic reactions can present a significant risk to the allergic individual. These reactions are unpredictable and can be fatal (Vargas et al., 2011). They are caused by a specific immune response where the body recognises the harmless allergen as a threat, and responds with a host of symptoms that vary in severity (Sicherer, 2011). Mild reactions are often localised to a single area and may include an itchy rash, hives (urticaria), swelling, watering of the eyes, and nasal congestion. Moderate reactions may spread to other parts of the body (e.g., the digestive system) and cause symptoms such as vomiting or diarrhoea (Baral & Hourihane, 2005). Severe reactions (known as "anaphylaxis") are often sudden in onset and are characterised by several features which occur simultaneously across multiple bodily systems (Akeson et al., 2007). These features may include any of the symptoms observed in mild and moderate reactions, as well as cardiorespiratory compromise. In general, reaction severity is unpredictable: a mild reaction on one occasion does not rule out an anaphylactic reaction to the same allergen in the future (Kemp & Hu, 2008).

Individuals experiencing anaphylaxis must go to the hospital. Although anaphylactic reactions can be treated effectively with a timely dose of intramuscular epinephrine via an adrenaline auto-injector (e.g., an Epipen), symptoms may re-emerge. Individuals may require

multiple doses and breathing support (Baral & Hourihane, 2005). Emergency care is therefore recommended for anyone experiencing an anaphylactic reaction.

1.2. Challenges for parents of children with allergies

Like any chronic illness (Knibb & Horton, 2008; Meltzer & Booster, 2016; Williams & Hankey, 2015), an allergy diagnosis has emotional, psychological and financial implications. Research has highlighted three particular challenges individuals with food allergies and their caregivers face (Klinnert & Robinson, 2008). First, children are generally asymptomatic in the absence of the allergen. Some caregivers have stated that the "invisibility" of the allergy can result in others not recognising the importance of management plans or responding to requested accommodations for the child with hostility (e.g., accusing parents of being neurotic; Stjerna, Worth, Harden & Lauritzen, 2017; Williams & Hankey, 2015). Parents have reported increased anxiety due to these negative social interactions (Williams & Hankey, 2015).

Second, parents who are instructed to maintain a high level of vigilance as a part of allergy management may experience anxiety, and impose excessive restrictions on their child. Vigilance behaviours are enhanced in states of anxiety and can often result in unhelpful coping strategies (Mathews, 1990); reducing these behaviours is sometimes a component of psychological interventions for anxiety (e.g., dropping safety behaviours in cognitive behavioural therapy for Panic; Clark, 1986). Moreover, reactions from accidental exposure to allergens are not uncommon, even when numerous preventative steps have been taken, which may exacerbate parental anxiety and reinforce the need for further vigilance (Rosen, Albin & Sicherer, 2014; Sicherer et al., 2012).

Finally, the unpredictability of allergic reactions can provoke negative beliefs around ambiguity among parents. In an analysis of parental understanding of allergy risk and management, Stjerna et al. (2017) find that parents feel the need to manage a "death risk"

which depends both on context and on those who are interacting with their child. Because this risk is easier to manage when both are familiar, caregivers may actively avoid uncertain environments, even when the overall risk of fatal anaphylaxis is low (Kemp & Hu, 2008).

1.3. Parental mental health and quality of life

Given these challenges, it is perhaps unsurprising that caregivers regularly report poorer mental health, lower self-confidence and impaired quality of life (QoL; Birdi, Cooke & Knibb, 2016; Klinnert & Robinson, 2008; Knibb, Barnes & Stalker, 2016; Warren, Otto, Walkner & Gupta, 2016). QoL can be defined as an individual's perception of their position in life (Flokstra-de Bok & Dubois, 2009). It is a "multi-dimensional construct including emotional, social, environmental and physical domains" (Knibb et al., 2016), which should be considered in the context of a person's culture, values and goals.

Wellbeing in caregivers is inhibited by three factors. First, diagnosis factors impair QoL. For example, parents are more likely to experience higher levels of stress when their child has multiple allergies, narrowing the foods s/he can eat, or a heightened sensitivity that has previously resulted in regular or severe reactions (Ravid et al., 2012; Springston, Smith, Shulruff, Pongracic, Holl & Gupta, 2010; Warren et al., 2016). Parents also reported increased stress related to allergies to specific foods that are ubiquitous (e.g., wheat; Howe, Flanxmanm Teich & Greenhawt, 2014).

Second, the nature of allergy management tasks also influence parental anxiety and QoL. As caregivers' abilities to competently care for a child with food allergies is necessary for safe management of the symptoms, families can face high levels of responsibility, stress and burden (Aika, Ito & Yamamoto, 2017). A growing body of evidence concludes that these parents experience distress related to guilt and worry (Birdi et al., 2016; Klinnert & Robinson, 2008; Williams et al., 2009). Further, a review by Shaker, Schwartz and Ferguson (2017) stated that those who have been prescribed an auto-injector also report higher levels of

anxiety. These authors suggested that the presence of this life-saving medication can leave parents worrying about the need to correctly identify symptoms of anaphylaxis and appropriately administer the injection. Some parents have confirmed that they exercise caution in the use of auto-injectors due to fears around causing their child unnecessary pain or discomfort (Klinnert & Robinson, 2008).

Third, fears of "handing over" care to others also inhibits QoL in caregivers (Williams & Hankey, 2008), which can result in increased parental responsibility. Numerous studies have reported that given the ever-present threat of anaphylaxis, parents often feel safer managing the burden alone (Knibb et al., 2016; Gupta et al., 2008). This sense of responsibility may have consequences not only for the child, who may miss out on social interactions, but also for the whole family. Gupta et al. (2008) identified mothers who stopped working to stay at home with their child, due to fears that caregivers in other settings (e.g., day-care or school) would not provide adequate care.

These three links between allergy management and inhibited QoL appear to be mediated by individual factors. The first of these is self-efficacy (SE; Knibb et al., 2016). Derived from Bandura's (1977) Social Learning Theory, SE is a construct that can be defined as "the confidence and belief in your ability to carry out certain actions and manage situations" (Knibb et al., 2015). SE is a construct that can be enhanced (Wichit, Mnatzaganian, Courtney, Schulz, & Johnson, 2017). For example, LeBovidge et al. (2008) found that an intervention aiming to increase self-confidence in parents of children with food allergies reduced perceived burden. Knibb and Horton (2008) identified a second mediator: people with strong "illness identities" were more likely to report higher levels of distress and employ less helpful coping behaviours, while those with a strong sense of personal control reported lower levels of distress.

1.4. Implications of psychosocial difficulties

Beyond negatively impacting QoL, increased parental stress can also have significant implications for the child's development. Increased anxiety is common following a diagnosis, and although most caregivers' anxiety will reduce as they gain confidence in their allergy management skills, some caregivers will remain highly anxious (Klinnert & Robinson, 2008). While anxiety may motivate the creation of appropriate allergy-management plans, parents experiencing high levels of anxiety are also more like to adopt "maladaptive" ways of coping and place unnecessary restrictions on their child (Klinnert & Robinson, 2008). For example, in order to avoid dangerous allergic reactions, caregivers might risk malnutrition through stringent elimination diets, or impose unreasonable social restrictions that risk the child not reaching developmental milestones (Klinnert & Robinson, 2008; Warren et al., 2016). Further, Dahlquist et al. (2014) identified that the "highly involved" parenting necessary for adequate food allergy management can generalise to situations where such involvement is not necessary, which may put these children at risk of difficulties in autonomy development.

There is also increasing evidence on the impact of caring for children with food allergies on caregivers' relationships more broadly. Parents report experiencing difficulties in their relationships with extended family and social networks, placing them at risk of isolation (Gupta et al., 2010). In one study, parents commented that the nature of allergy management meant that accommodations for their child needed to be considered in every relationship they had, and that general decision-making was regularly impacted in order to account for allergies (e.g., deciding on a restaurant; Gupta et al. 2008). Moreover, caregivers have reported strain in marital relationships, often due to differences in parenting philosophy (Gupta et al., 2008).

Conversely, a strong sense of personal control, hope for improvement, and social support have been identified as protective for parental wellbeing (Alanne, Laitinen,

Söderlund, & Paavilainen, 2012; Knibb & Horton, 2008; Williams & Hankey, 2015). Parents have reported that access to support and guidance from other parents of food-allergic children is useful (Coulson & Knibb, 2007). However, negative experiences are a stronger predictor of lower QoL than social support is of enhanced QoL (Williams & Hankey, 2015).

1.5. Rationale

In summary, allergy diagnoses are a serious and potentially chronic health difficulty that can negatively impact the lives of those affected as well as their caregivers. The current lack of curative treatments requires caregivers to engage in vigilance behaviours to avoid the allergen, which may be burdensome. Further, these behaviours can impair QoL and provoke anxiety among parents, in turn potentially hindering the child's development and impacting caregivers' relationships.

Given the increasing prevalence of allergy diagnosis, and the related consequences for individuals with allergies and their families, there is a need to better understand what support is helpful for caregivers. However, to the author's knowledge, there are no published reviews examining interventions aimed at supporting caregivers of children with allergies. Improved support for this population has the potential to improve not only parental wellbeing, but also allergy management outcomes for children with food allergies.

1.6. Aims

This paper aimed to conduct a narrative review based on a systematic search of the literature examining interventions aimed at parents of children with food allergies. Specifically, the review sought to summarise the reported efficacy and acceptability of these interventions. The review also aimed to identify gaps in the literature, and discuss implications for research and clinical practice.

2. METHODS

2.1. Literature search

All searches were conducted on December 18th, 2018. Databases were searched from inception and included Web of Science, Psychinfo, Pubmed and CINAHL. Search terms or "key concepts" included (allerg* OR anaphyla*) AND (parent* OR mother* OR father* OR care* OR mom* OR mum* OR dad* OR famil*) AND (intervention* OR psycholog* OR therap* OR experiment* OR education* OR psycho-education* OR psych* OR support "psychological education" OR treatment OR "psycho-social" OR psychosocial OR therapy OR group OR course OR "self-help" OR management OR plan). Searches were broadened to include relevant terms in "title", "abstract" and "keyword". Papers were initially screened by title, and then abstract (Figure 1). Additional articles were searched for in reference sections of included studies and using Google Scholar.

2.2. Eligibility criteria

The following inclusion criteria were employed in order to meet the aims of the review:

1. Studies were included if authors evaluated any intervention that targeted parents (biological or adoptive) or primary caregivers (e.g., foster carers) of children with food allergies.
2. Interventions targeting non-primary caregivers (e.g., school staff) or children were included so long as they contained a component addressing parental needs.
3. Because this literature is small, all intervention types were included (psychological, social, behavioural) if they were aimed at parents of children with food allergies.
4. Papers were not excluded on the basis of research design, and so both quantitative and qualitative papers were included as long as they adhered to all other criteria.

5. The study needed to be published in an English-language, peer-reviewed journal.

Additionally, the following exclusion criteria were applied:

1. Studies focused only on other chronic health difficulties, or only on non-food allergies, were excluded.
2. The review was limited to parents of children currently between the ages of 0 and 18 years, as adult children are less likely to be under the primary care of their parents.
3. Studies were excluded if their intervention did not directly target parental outcomes (e.g., studies evaluating adherence to medical treatment plans to benefit children or medical professionals).

2.3. Quality assessment tools

Because studies included for this review used both qualitative and quantitative designs, quality assessment was guided by the Mixed Methods Appraisal Tool (MMAT; Pluye et al., 2015). This is an effective and practical tool for systematic reviews that include varied study designs and mixed methods, and has been used in recent reviews in the allergy literature (El Turki, Smith, Llewellyn & Jones, 2017). The tool consists of two screening questions, followed by four criteria for appraising study design (Appendix A). The MMAT scores range from 0-100% (where all four criteria are met). Among randomised controlled trials (RCTs), quality was also assessed using the Cochrane Risk of Bias tool (Higgins et al., 2011). This tool addresses six domains of potential bias, and assessments are made for multiple items under each domain. These assessments inform an overall judgement about whether the potential risk of bias is low, unclear or high (Appendix B).

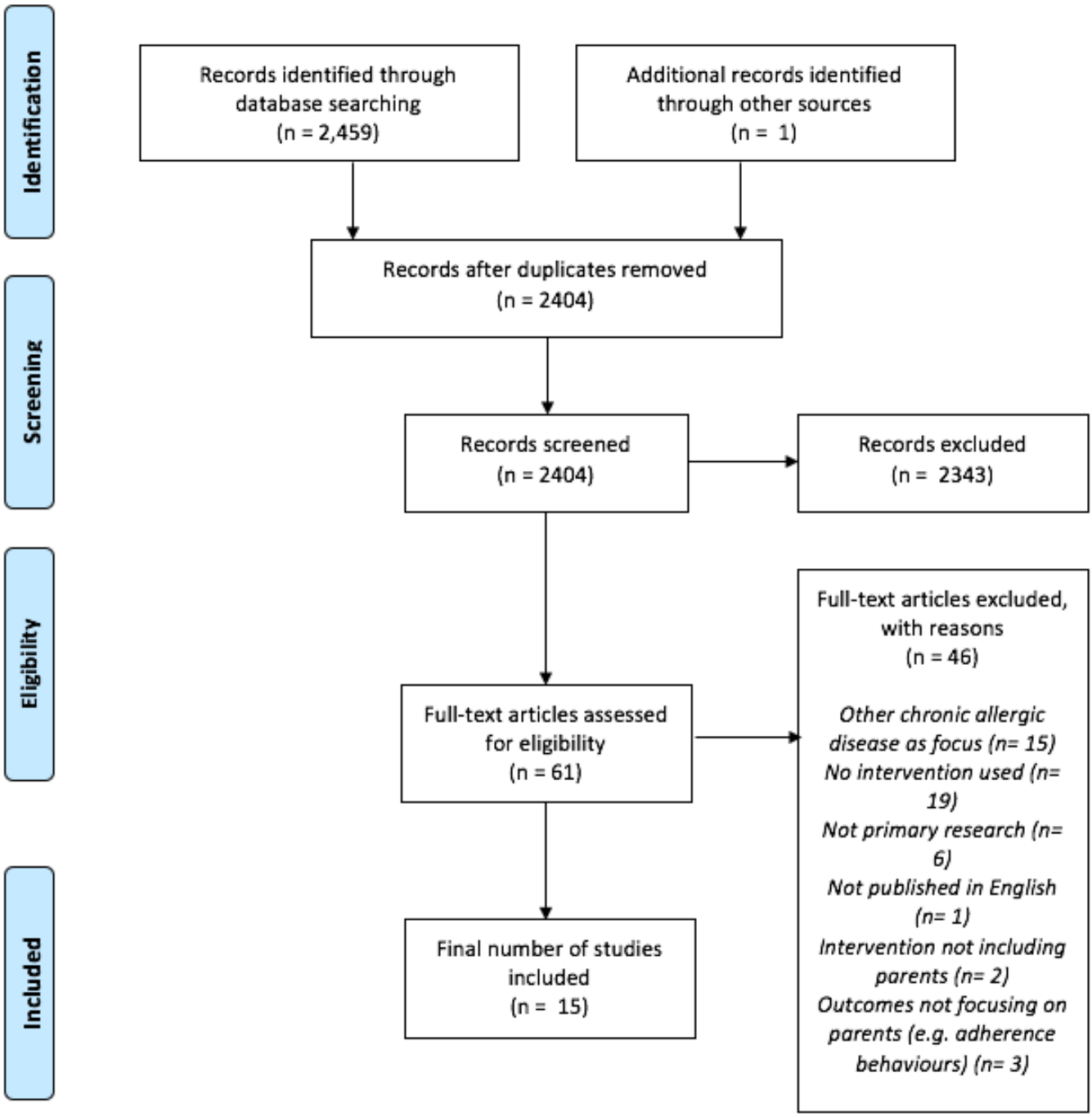

Figure 1: PRISMA diagram of literature search (Moher, Liberati, Tetzlaff & Altman, 2009).

2.4. Structure of this review

Due to the small number of studies and their varied methodologies, the papers' findings and quality will be discussed concurrently, rather than consecutively. This approach enables the relative robustness of particular findings to be taken into account. Implications for future research and considerations for clinical practice are subsequently discussed.

3. NARRATIVE REVIEW

3.1. Overview of studies

Of the 15 studies, seven were conducted in the United States (Baptist et al., 2012; Lebovidge et al., 2008; Maurer, Byrd-Bredbenner & Grasso, 2007; Rosen et al., 2014; Sharma, Prematta & Fausnight, 2012; Sicherer et al., 2012; Wahl, Stephens, Ruffo & Jones, 2015), three were conducted in the United Kingdom (Boyle et al., 2017; Knibb & Semper, 2013; Knibb, 2015), three in mainland Europe (Contreras-Porta et al., 2016; Polloni et al., 2015; Ruiz-Baques et al., 2018), one in Canada (Stewart, Letourneua, Masuda, Anderson & McGhan, 2011), and one in Australia (Danchin, De Bono, Allen, Tang & Hiscock, 2016).

Eight used a single-group pre-test post-test design (Contreras-Porta et al., 2016; Danchin et al., 2016; Knibb & Semper, 2013; Lebovidge et al., 2008; Maurer et al., 2007; Rosen et al., 2014; Ruiz-Baques et al., 2018; Sicherer et al., 2012) and four used a single-group post-test design (Polloni et al., 2015; Sharma et al., 2012; Stewart et al., 2011; Wahl et al., 2015). Two studies were RCTs (Baptist et al., 2012; Boyle et al., 2017), and one used a non-random case control design (Knibb, 2015). Broadly, the studies' interventions focused on providing education or information, psychological support to mothers or families, or supportive interventions that aimed to improve wellbeing (which did not involve a psychological intervention; see Table 1).

3.2. Overview of quality assessment

3.2.1. MMAT.

Of the 15 studies, one scored 100% (Boyle et al., 2017), one scored 75% (Knibb, 2015), six scored 50% (Baptist et al., 2012; Contreras-Porta et al., 2016; Maurer et al., 2007; Rosen et al., 2014; Ruiz-Baques et al., 2018; Stewart et al., 2011), four scored 25% (Danchin et al., 2016; Knibb & Semper, 2013; LeBovidge et al., 2008; Sicherer et al., 2012) and three did not meet any of the appraisal criteria and scored 0% (see Appendix A for details; Sharma et al., 2012; Polloni et al., 2015; Wahl et al., 2015).

3.2.2. Cochrane risk of bias tool for the RCTs

Boyle et al. (2017) was rated as having an overall low risk of bias. The primary methodological concern was the lack of blinding of participants, experimenters and outcome assessors. Additionally, outcome measures were primarily self-reported, with a corroborating measure (salivary response) provided for one outcome. The authors attempted to reduce bias where possible and reported processes appropriately. Baptist et al. (2012) was rated as "unclear" due to failing to report processes such as randomisation, reducing confidence in the reported results (see Appendix B).

Table 1: Summary of reviewed studies

Study; quality score	Population	Design	Study summary	Intervention type	Outcome measures	Results
Maurer, Byrd-Bredbenner, & Grasso (2007)[1] MMAT: 50%	667 participants completed pre-test measures and 474 completed post-test measures. Participants were 58% female, 59% over-50, 83% white. The campaign ran in all counties across the state of New Jersey, USA.	Pre-test post-test	Authors created an educational campaign to better inform caregivers of children with food allergies and the general public of best practice food allergy management. The campaign was released and publicised in numerous media outlets including via newspapers, radio and in a PSA video that was shown across supermarkets and cinemas in the State.	Educational intervention for caregivers and the general public	An unvalidated 8-item criterion referenced knowledge test based on campaign materials. Reliability calculated as 0.77 (Livingston's coefficient) Acceptability was not assessed.	Authors contacted State residents randomly before and after the campaign broadcast. Post-test scores showed a statistically significant increase in knowledge scores, and authors concluded that the campaign was an effective way of providing information to caregivers in the general public.
LeBovidge, Timmons, Rich, Rosenstock, Fowler, Strauch, ... & Schneider (2008) MMAT: 25%	62/385 food allergic-children and their parent(s) attended a ½ day workshop. Participants were primarily white, female and university educated. The study was set in a hospital in Boston, USA.	Pre-test post-test	Authors developed and implemented a group intervention to improve perceived parental competence to manage food allergies.	Psychological group intervention for parents	- Medical information (*ad hoc* questionnaire) - Family Coping with Food Allergy Questionnaire; 18 item measure developed by authors to assess perceived competence. Reported internal consistency ($\alpha = 0.91$). - FAQoL-PB; 17 item validated measure of QoL.	Authors reported that higher levels of burden were associated with lower levels of information in pre-workshop measures. Authors concluded that parental confidence improved significantly from pre-workshop to post-workshop, and again at follow up. They also found a significant decrease in parental burden from pre-workshop to follow up. Authors reported the intervention was acceptable for participants.

[1] Study reported development of educational materials, but these are not discussed in this review

Table 1: Summary of reviewed studies, continued

Stewart, Letourneau, Masuda, Anderson, & McGhan (2011) MMAT: 50%	Participants were 19 parents of food allergic children (7-11 y/o) based in Canada. The majority of participants came from high income households, attended university (>90%) and lived in urban settings.	Qualitative study using a post-test evaluation	Researchers developed and evaluated the perceived usefulness and acceptability of an online allergy support group for parents of children with food allergies.	Supportive intervention, no psychological component	Outcomes gathered via individual semi-structured interviews, no formal outcome measures were used.	Participants reported that they benefitted from the support group, highlighting reduced feelings of social isolation, and the ability to ask sympathetic peers questions and gain advice as helpful.
Baptist, Dever, Greenhawt, Polmear-Swendris, McMorris & Clark (2012) MMAT: 50% Cochrane risk of bias: Some concerns/unclear risk of bias	58 participants (47 at 3 month follow up) were recruited from an allergy clinic in Michigan, USA. The majority of participants were white, and from middle class households.	Pilot single-blind Randomised Controlled Trial (RCT)	Authors implemented a self-regulation intervention to improve food allergy related quality of life in parents of children with food allergies. The intervention group received phone calls from a trained clinician at 2 week intervals to discuss allergy management strategies. The study used a placebo control.	Individual psychological intervention for parents	- FAQoL-PB; validated questionnaire to assess QoL - Unvalidated 8-item self-efficacy questionnaire developed by the authors. No reporting on reliability.	At 3 months, the intervention group had a statistically significant improvement in 4 domains (helplessness, anxiety, frustration and confidence in the FAQoL-PB questionnaire and on 1 item in the self-efficacy questionnaire. The authors did not report acceptability.
Sharma, Prematta, & Fausnight (2012) MMAT: 0%	29/98 individuals affiliated with the institution in Pennsylvania, USA, and in attendance of the support groups completed an online survey. 97% participants were female, 79%	Post-test questionnaire	Authors evaluated whether having a food allergy specialist present in support groups reduces parental anxiety and improves the relationship between parents and their allergy specialist.	Supportive intervention, no psychological component	Acceptability of intervention and anxiety related to caring for a children with food allergies was assessed in a 30-item unvalidated questionnaire designed by the authors.	77% respondents reported a decrease in food allergy anxiety and most reported an improvement in their child's QoL. More than 90% reported that it was beneficial to have an allergy specialist present in support group meetings, and that this made it easier for them to discuss concerns with their own specialists.

Table 1: Summary of reviewed studies, continued

	were university educated.					
Sicherer, Vargas, Groetch, Christie, Carlisle, Noone & Jones (2012) MMAT: 25%	A convenience sample of 32 parents attending an allergy clinic were recruited to trial educational materials. Sample was selected from New York, USA.	Pre-test post-test	Authors aimed to explore the effectiveness of educational materials for parents of children with food allergies.	Educational intervention for parents	- Authors assessed participant knowledge and correct administration of auto-injector to assess effectiveness of educational materials. - Acceptability was assessed using a 4-point Likert scale satisfaction questionnaire developed by the authors.	Results demonstrated an improvement in technique for administering epinephrine pens, increased comfort with treatment, improvement in food allergy knowledge and overall satisfaction with educational materials. These benefits were maintained at follow-up 1 year later. Authors reported high acceptability and efficacy of the intervention.
Knibb & Semper (2013) MMAT: 25%	Participants were 124 parents attending an allergy clinic for diagnostic tests. 50 participants completed post-test measures 6 weeks later. The sample was drawn from an allergy clinic in the UK. Participants were primarily female (80%), and white British (77.6%)	Pre-test post-test questionnaire	Study authors aimed to assess whether visiting an allergy clinic (for support and a diagnosis) influences parental anxiety and depression. Measures were completed before and after the visit, and visit outcomes were also measured (i.e., if a food allergy diagnosis was given)	Supportive intervention, no psychological component	- Study specific demographic questionnaire to assess allergies and acceptability of support offered at their allergy clinic. - The Hospital Anxiety and Depression scale (HADS) is a 14-item validated measure to assess anxiety and depression.	Authors reported that 86.4% of parents reported suspected food allergy had an impact on their family prior to attendance, 76% had made changes to their child's diet, 32.5% had mild to severe anxiety and 13.1% had mild to severe depression. However, researchers observed no changes in outcomes at follow up.
Rosen, Albin & Sicherer (2014) MMAT: 50%	Participants were 50 caregivers of children with food allergies. Individuals	Pre-test post-test questionnaire	Authors aimed to develop and validate audio-visual based food allergy educational materials for	Audi-visual educational intervention for parents	- Outcomes were assessed in a food-allergy knowledge	Results identified an improvement in food allergy knowledge between pre and post knowledge scores, and high

Table 1: Summary of reviewed studies, continued

	were recruited from an allergy clinic in NY, USA. Sample consisted of a white (66%), upper-income (82% >80,000 per annum), female (76%) individuals. Additionally, sample was well educated, with 90% of the sample completing undergraduate or post graduate university degrees.		parents of children with food allergies.		questionnaire designed by authors. - Acceptability of the materials and interventions were assessed in a 7-point Likert scale satisfaction questionnaire designed by study authors.	levels of satisfaction for the materials amongst participants (a mean score above 6).
Knibb (2015) MMAT: 75%	Participants were 11 mothers (5 CBT intervention; 6 control treatment as usual), attending a local allergy clinic. All participants were white British and female.	Non-randomised case control study	Evaluating the benefits of CBT to improve psychological outcomes for mothers of children with food allergies.	Psychological intervention for mothers	- 14-item HADS questionnaire to assess depression and anxiety. - Perceived Stress Scale (PSS), validated 14 item measure for stress. - FAQoL-PB to assess QoL. - WHO QoL scale- 26-item validated questionnaire. -Penn State Worry questionnaire: 16-item validated measure. - General Health Questionnaire; a validated questionnaire assessing general mental health	Participants were 11 mothers (5 CBT intervention; 6 control treatment as usual), attending a local allergy clinic. At baseline the CBT group had significantly higher anxiety and depression, and poorer general mental health than the control group but these differences no longer existed following the intervention. The control group maintained significantly lower general mental health, and that the intervention group demonstrated a decrease in depression, anxiety and worry (with large effect sizes $r > 0.6$). Authors concluded that CBT seems to be an appropriate and effective intervention for mothers.

Table 1: Summary of reviewed studies, continued

Polloni Lazzarotto, Bonaguro, Toniolo, Celegato & Muraro (2015) MMAT: 0%	100 consecutive psychological treatments held at a food allergy referral centre were selected. 26% of these were family intervention, 9% individually for mothers and 2% individually for fathers. All treatments were conducted by a psychologist. The study was conducted in Italy. No demographic details were reported.	Post-test questionnaire design	Authors analysed the data for psychological treatments offered to individuals and their families. They were interested in the reasons that individuals would access support from the service, and to identify the usefulness of psychological interventions to support this population. All interventions were grouped together (individual, parental, group session, etc.)	Psychological intervention for parents and families	Authors assessed effectiveness of psychological interventions using a measure with two questions, adapted from the Strengths and Difficulties questionnaire.	Authors reported that that requests for support were due to emotional/social problems (40%), difficulties managing food allergy (40%), eating problems (18%) and behavioural problems (2%). Authors indicated that participants reported that psychological interventions made them feel "a bit better" (67%) or "much better" (33%).
Wahl, Stephens, Ruffo & Jones (2015) MMAT: 0%	4818 individuals at 247 schools and community sites based in Seattle, Washington (USA) participated. 15% of the sample was reported to consist of parents, volunteers, coaches and food service workers. No demographic details were reported.	Post-test design	Aimed to increase food allergy knowledge and self-efficacy for all caregivers of children with food allergies through in-person training.	Educational intervention for caregivers	Outcomes were assessed with a feedback questionnaire asking participants about changes to knowledge levels following the intervention. No formal, objective knowledge questionnaire was administered.	Results identified that respondents felt more confident to manage food allergies after their training, and suggested that attendees retained information about food allergy management. However no baseline measures were recorded to demonstrate actual change.

Table 1: Summary of reviewed studies, continued

Contreras-Porta, Ruiz-Baqués, Hortal, Torres, Pla, Santisteban, & de la Maza (2016) MMAT: 50%	174/184 participants completed both workshops and were recruited through social media websites. Sample were 56% mothers, 39% fathers and 4.9% caregivers. All were recruited in Spain. No other demographic details were reported.	Pre-test post-test study	Authors aimed to evaluate the provision of in-person educational workshops in improving QoL in children with food allergies and their parents	Educational intervention for parents	- Outcomes were measured using a 40-item knowledge questionnaire developed by the authors. - Acceptability of the intervention was assessed with a 5-point Likert scale satisfaction questionnaire designed by the authors.	Authors reported that 74/184 participants completed both workshops and were recruited through social media websites. Participants demonstrated improvements in food allergy management knowledge in 72.5% items on the knowledge questionnaire. Authors concluded that workshops were both acceptable and effective at improving food allergy management knowledge but they were unable to assess QoL due to lack of validated measures.
Danchin, De Bono, Allen, Tang & Hiscock (2016) MMAT: 25%	Participants were 10-12 paediatricians in Victoria, Australia. They opted in to the study and had no previous training in allergy management. Participants also included allergy patients (N = 32) belonging to allocated clinicians who were taken from the clinic waiting lists.	Pre-test post-test study	Study aimed to provide GPs with training to better diagnose and manage food allergies, and that this would improve child QoL and parental mental health in parents of children with mild-moderate allergy presentations who might wait longer to access specialist appointments.	Supportive intervention, no psychological component	- Outcomes for paediatricians were assessed using the Chicago Food Allergy Research Survey. - Parents completed validated measures including the Depression Anxiety Stress Scales 21 (DASS), FAQoL-PB, PeDQL Family impact scale. - Satisfaction measured in a follow-up questionnaire designed by study authors.	Clinicians reported improved competency in managing food allergy their food allergy knowledge increased by 69-75%. 82% families returned baseline surveys and 92% were satisfied with the care they received. Authors reported that parental mental health improved, (particularly anxiety) but that gains were small and this result was not significant. Mean scores for parental stress were below clinical cut-off in both timepoints.
Boyle, Umasunthar, Smith, Hanna, Procktor,	Participants were 200 mothers, recruited from	Randomised Controlled Trial (RCT)	Authors aimed to examine whether a brief single session of CBT would help reduce maternal state anxiety	Psychological intervention for mothers	- The following outcome measures were used: Stait Trait Anxiety Inventory	Authors reported that there was no difference in state anxiety between intervention and control group 6 weeks, except

Table 1: Summary of reviewed studies, continued

Phillips,... & Vickers (2017) MMAT: 100% Cochrane risk of bias: Low risk of bias	allergy clinics in London, UK. All participants were female, 53% participants had a university degree and 59% were non-white.				Scale (STAI-S), PSS, Strengths and Difficulties Questionnaire (SDQ), Screen for Child Anxiety Related Emotional Disorders (SCARED), Food Allergy Impact Scale (FAIS), Food Allergy Quality of Life Questionnaire. - Objective measure of stress; salivary cortisol levels	for a subgroup that started with moderate/high levels of anxiety at Time 1 (with a moderate effect size r = 0.5). Authors also found that the intervention reduced risk perception and salivary cortisol response (however with a low effect size). In conclusion, authors identified that a brief intervention that incorporates risk perception may have an effect on parental anxiety for those reporting higher levels of distress.
Ruiz-Baqu es, Contreras-Porta, Marques-Mejias, Cárdenas, Capel, Ariño, ... & Chivato (2018) MMAT: 50%	Participants were 135 carers and parents (75.4% mothers, 14.6% fathers, 10% caregivers) of children with food allergies. Individuals were recruited online via social media websites, and the study was conducted in Spain.	Pre-test post-test questionnaire	Authors aimed to identify whether a 2-week online educational programme could improve QoL in parents of children with food allergies.	Educational intervention for parents	- Outcomes were measured using an ad-hoc 40-item knowledge questionnaire designed by the authors. - Acceptability of the intervention was assessed with a 5-point Likert satisfaction questionnaire.	Authors reported improvements on15/30 items on their knowledge test, and there was a significant improvement in 8 items. Engagement in the programme was good, with 76.2% participants visiting the website up to 25 times and 23. 8% more than 26 times in 2 weeks. Slightly lower attendance for live streams (27.5%, 18.3% and 15.9%). Authors reported a high level of satisfaction with the programme.

3.3. Educational interventions

Six of the 15 reviewed studies reported on the implementation of an educational intervention aimed at caregivers (Contreras-Porta et al., 2016; Maurer et al., 2007; Rosen et al., 2014; Ruiz-Baques et al., 2018; Sicherer et al., 2012; Wahl et al., 2015). Among these, four studies measured an increase in knowledge as their primary outcome (Contreras-Porta et al., 2016; Maurer et al., 2007; Rosen et al., 2015; Ruiz-Baques et al., 2018). The first, Maurer et al. (2007), used a pre-test post-test design to assess the efficacy of a widespread educational campaign, aiming to improve knowledge of allergy management both in the general public and among parents. After developing materials with input from expert caregivers and allergy specialists, the campaign was advertised across numerous print and electronic broadcast outlets (including newspapers, webpages and video advertising). The authors reported a significant increase in knowledge scores post-test, concluding that provision of information via media outlets was effective. However, as participants were alerted to the campaign through pre-testing, they may have been primed to notice the advertising or motivated to research allergy management themselves. Also, the authors did not have data to identify whether the general population saw the materials, potentially limiting generalisability of the findings. Further, the study lacked a control group, so it is unclear whether the observed changes occurred as a result of the intervention.

Three other pre-test post-test studies (Contreras-Porta et al., 2016; Rosen et al., 2014; Ruiz-Baques et al., 2018) aimed to increase parents' knowledge. The studies presented information through varying formats, using: two face-to-face workshops (Contreras-Porta et al., 2016), educational videos (Rosen et al., 2014), and a 2-week online programme consisting of interactive question-and-answer sessions, discussion threads and written and recorded content (Ruiz-Baques et al., 2018). Despite the variation in presentation format and length of intervention, all four studies reported increases in food allergy knowledge in

participants between pre-test and post-test measures, as well as reporting high levels of satisfaction from participants. However, none of these studies used a control group, and all suffer from sampling problems. Two studies indicated that their sample was drawn from "patient associations", where group members had an existing knowledge of food allergy management (Contreras-Porta et al., 2016; Ruiz-Baques et al., 2018), while Rosen et al. (2014) recruited from an allergy clinic waiting list in the United States, which may have limited their sample to individuals who had health insurance. Although the latter study reported that the sample was more "economically and racially diverse" than prior studies in the literature, it was still not representative of the local population. These authors noted that individuals from minority groups are less likely to have health insurance, and more likely to experience poorer health outcomes. Such disparities raise concerns about whether these studies' samples are representative of the general or clinical population, limiting the generalisability of their findings, particularly in settings without universal healthcare.

In contrast, Wahl et al. (2015) conducted face-to-face training sessions in 247 schools to improve not only food allergy knowledge, but also perceived competence in caring for food-allergic individuals. The primary demographic in this study was teachers, but workshops were also attended by parents, caregivers, nurses and administrators. They concluded that respondents reported an increase in knowledge and confidence to manage food allergies as a result of the training. At follow-up, these authors also gathered information about workshop participants that had responded to an allergic reaction since their attendance. They stated that individuals described increased confidence in managing the reactions as a result of the training, and that in nine cases, participants had identified symptoms and responded effectively to an individual who was reacting to an unknown allergen. However, there are significant problems with measurement in this study, which lacked a baseline score due to using a post-test design. Further, recorded improvements in knowledge and effectiveness

were based on feedback (e.g., "how are your problems after the intervention?"), with no complementary objective measures. These outcomes are highly susceptible to bias as they rely entirely on participant recall and measure perception.

The sixth and final educational intervention was the only one to target the role of information in improving practical provision of care to children with food allergies. Sicherer et al. (2012) assessed correct administration of an adrenaline auto-injector as the primary outcome, but also measured reported comfort with treatment, intervention satisfaction, and food allergy knowledge. The authors reported improvements in administering auto-injector devices, with fewer errors made by participants, as well as improvements in food allergy knowledge and high participant satisfaction that was maintained at one year follow-up.

These six studies all used a pre-test post-test or post-test design. Due to the nature of these designs, no causal inferences can be made. Researchers cannot be confident that outcomes were not influenced by factors external to the intervention. Further, although some researchers collected demographic and allergy-related medical information from participants, they did not have large or diverse enough datasets to examine differences based on these variables. This combination of problems likely resulted in sampling bias across all six studies.

Moreover, these studies had significant problems with the way that knowledge was assessed: all six created measures of their own, and only three reported on their validity or reliability (Maurer et al., 2007; LeBovidge et al., 2008; Rosen et al., 2014). Although three studies identified the process for creating knowledge outcomes that were based on literature reviews, expert input, or drawing from validated measures (Contreras-Porta et al., 2016; Rosen et al., 2014; Ruiz-Baques et al., 2018), no study used the same measure. Although many studies were interested in food allergy knowledge, it was unclear whether researchers used similar definitions of this outcome, given that studies occurred in different settings

where standards or expectations of knowledge may differ. The inconsistency in measurement and lack of validated questionnaires means that conclusions of "knowledge" levels in tested populations may not be generalisable to other populations or settings.

In summary, these educational interventions report effectiveness via improvements to practical management and allergy knowledge, as well as high levels of participant satisfaction. However, these studies also suffer from a number of methodological constraints such as lack of control groups, biased sampling strategies and lack of validated outcome measures.

3.4. Psychological interventions

Five studies evaluated psychological interventions for parents and caregivers of children with food allergies (Baptist et al., 2012; Boyle et al., 2017; LeBovidge et al., 2008; Knibb, 2015; Polloni et al., 2015). Two of these attempted to improve parental outcomes by targeting SE (Baptist et al., 2012; LeBovidge et al., 2008). Scholars have suggested that SE could improve caregivers' wellbeing by increasing their confidence that they can adequately manage food allergies (Knibb et al., 2016). The first study ran four half-day, psychologist-led workshops aiming to present relevant information about allergy management and facilitate discussion (LeBovidge et al., 2008). Although the authors did not outline the psychological model that informed specific workshop content, they motivated their intervention by noting that the broader chronic illness literature suggests that perceived self-competence in managing a child's illness was related to improved adaptive functioning in families. They reported that their workshop increased perceived parental competence (self-efficacy) and reduced parental burden between pre- and post-workshop measures. Their findings also indicate that group interventions may be a cost-effective way of providing support to this population. However, as the intervention was not randomly assigned to participants, the observed outcomes cannot be causally linked to the intervention. As the authors note, the

study design also prevented them from identifying which components of the half-day long workshop had been the most beneficial, and from determining whether other factors such as peer support may have contributed to reported outcomes. Further, because workshop facilitators administered outcome measures, there was an increased chance of social desirability bias amongst respondents.

The second study ran a pilot RCT aiming to improve self-regulation and improve QoL (Baptist et al., 2012). The authors designed their intervention based on a self-regulation model (Clark, Gong & Kaciroti, 2001) to support health-related behaviour change by increasing engagement with services and boosting self-confidence. Parents in the intervention group received three 25-minute telephone sessions with a trained clinician to help them set goals, problem-solve and implement coping behaviours. A placebo control group received a single phone call with no counselling element. The authors used multiple linear regression to analyse their data, and stated that the study was sufficiently powered to find an effect. They reported that QoL improved across only four out of 17 domains (helplessness, anxiety, frustration and confidence) on the outcome questionnaire at a three month follow-up. The authors concluded that interventions targeting self-efficacy had the potential to improve food allergy-related QoL in caregivers. However, this trial suffered some methodological difficulties. Most notably, the authors did not report the randomisation schedule, nor provide a description of the blinding process. Although 47 individuals completed measures at both time points, it is unclear how many individuals were allocated to each group, and whether randomisation was effective. Further, the authors did not use validated questionnaires to assess self-efficacy, so it is unclear whether their reported outcomes are generalisable or reliable.

Two studies evaluated the role of Cognitive Behavioural Therapy (CBT) in improving psychological outcomes for mothers of children with food allergies (Boyle et al., 2017;

Knibb, 2015). Knibb (2015) provided mothers with a 12-week course of individualised CBT, and found that participants reported a decrease in depression and anxiety symptoms compared to treatment-as-usual control participants. This study used a case control design, scored favourably on the MMAT (75%; Appendix A), and was the only study that evaluated the impact of a full course of therapy (CBT) for improving psychological outcomes. However, while this study provides some support for the use of CBT as an effective treatment for this population, there are numerous design problems that reduce the generalisability of its findings. For one, participants were not randomised, and instead they self-selected into treatment and control groups. The author therefore could not determine whether pre-existing differences contributed to improvements; for example, as those in the CBT group reported worse QoL at baseline, perhaps they were more motivated to engage with therapy. Further, although the author highlighted some descriptive differences between groups, the sample was too small to identify whether these were statistically significant. This issue raises questions about the reported outcomes, and whether changes could be attributed to group differences rather than to the intervention.

In contrast, Boyle et al. (2017) ran an RCT to evaluate whether a brief, single session of CBT could reduce maternal state anxiety compared to a control group of "standard care". The authors reported a decrease in anxiety only in a subgroup of mothers who received the intervention whose baseline scores were "moderate to severe", though this difference did not remain significant at a 1 year follow-up. Additionally, the authors found that addressing "risk perception" in caregivers reduced anxiety for those reporting higher levels of distress. This study outlined their randomisation process in detail, and scored 100% on the MMAT. It was not possible to blind the study because participants, clinicians and outcome assessors would have been aware of the difference between treatment (CBT) and control, but the authors attempted to increase the validity of their outcomes by collecting a more objective measure of

stress (salivary response) alongside their self-report measures. Results from this study can be considered as possible evidence for the short-term benefit of a brief Cognitive Behaviour Therapy-based intervention in reducing state anxiety in mothers with moderate to high reported distress. However, as the study was not blinded, this may have introduced bias into the results. Further, as the applied treatment was individualised it is difficult to ascertain if it was the whole treatment episode, or a component of the intervention that was useful, or else whether another factor (e.g., the therapeutic relationship) was most beneficial.

The final study to assess the usefulness of psychological therapy for caregivers reviewed chart data post-test for therapy offered to 100 attendees at an allergy referral centre (Polloni et al. 2015). The authors reported the most common reasons for referral as emotional or social problems, difficulties managing food allergies, eating problems, and behavioural problems. Although they did not evaluate individual outcomes for each type of therapy, they found that 67% of selected cases reported psychological therapy made them feel "a bit better", and 33% "much better". This study's use of previously recorded data enabled the authors to access large numbers of records and reduce the influence of experimenter effects since the therapists offering treatment would not have been aware that the treatments were going to be analysed. However, this study suffered from significant methodological problems. Experimenters could only report recorded information, and had no control if databases were missing pertinent historical or clinical data. As a result, the authors did not report participants' demographic characteristics and could not control for any such confounders. Additionally, as data were collected post-test and there was no comparison group in this study, reported outcomes may not be a result of the interventions.

Broadly, the studies evaluating psychological interventions used more robust designs that included intervention and control groups, and provided suggestions for the potential benefits of these interventions to support parents of children with food allergies. However, the extent

to which the these interventions are likely to improve psychological wellbeing elsewhere remains unclear, as does whether they might only benefit particular sub-groups of the population (e.g., mothers with clinically significant anxiety scores; Boyle et al., 2014). Like studies evaluating educational interventions, methodological problems such as inconsistent or invalidated outcome measures and unrepresentative samples limit the validity of the findings.

3.5. Supportive interventions

The final four studies in this review used supportive interventions that did not include formal psychological therapy (Danchin et al., 2016; Knibb & Semper, 2013; Sharma et al., 2012; Stewart et al., 2011). Stewart et al. (2011) evaluated an online support group for parents of children with food allergies and assessed outcomes post-test using semi-structured interviews. Attendees reported that the group helped them to feel less isolated and allowed them to ask for advice from peers with similar difficulties. The authors concluded that parents may benefit from being signposted to similar groups, which may be more easily accessible for busy or overwhelmed parents. This study provided the literature with "rich" data around parental experiences and the acceptability of the online support group. Further, the authors reported detailed notes regarding rationale and coding decisions. However, they neither discussed the influence of context on their findings nor reflected on their own potential biases when noting emergent themes in their analysis. There is little consideration to the role of diversity, socio-economic status or geographical location of participants. All of these issues limit the generalisability of their findings.

Rather than targeting parental wellbeing directly, the next two studies examined the role of specialist input in improving psychological wellbeing in parents (Knibb & Semper, 2013; Sharma et al, 2012). Sharma et al. (2012) found that the presence of an allergy specialist in a face-to-face support group reduced reported anxiety and helped participants feel more comfortable asking their allergy specialist questions about their child's care. However, this

study used a post-test design and relied on participant recall to identify improvements in anxiety, and so has significantly limited reliability and validity. The second study used a pre-test post-test design (Knibb & Semper, 2013). The authors recruited individuals waiting for diagnostic tests at a specialist allergy clinic, and sought to identify whether receiving this diagnostic input improved their psychological wellbeing. However, they found no difference between baseline and follow-up. Both of these studies reported low response rates, and it is unclear whether non-response biased their results. Neither study had a control or comparison group.

The final study aimed to improve the mental health of parents of children with a "mild-moderate" food allergy by providing training to community paediatricians (Danchin et al., 2016). The intervention was developed to address reports in the literature that inadequate clinician training results in contradictory medical advice, contributing to parental anxiety (Birdi et al., 2016). Following the training intervention, the clinicians' consultation plans were assessed for accurate medical guidance. The authors measured knowledge change in clinicians, as well as reported QoL, psychological wellbeing and satisfaction levels among parents who were registered with the clinicians. They found that training improved clinicians' competence in supporting parents with food-allergy management and stated that it appeared a feasible intervention. Additionally, although the authors reported that parent participants' mental health improved marginally, these changes were not significant. This study was the only intervention to measure knowledge improvements using a validated questionnaire. Again, however, there are methodological concerns with this study: there was no control group and the authors were unable to control for confounding variables. It is therefore unclear whether any improvements to parental QoL were related to the intervention. Further, the study excluded children with what they defined as "severe" food allergies (i.e., children with more than three allergies, and those who had a history of anaphylactic reactions). Besides

constraining the generalisability of the results, this exclusion criteria is also problematic because parents of those with more "severe" allergies may be more likely to need support.

Overall, these studies provide mixed evidence for the benefits of these supportive interventions. Participants agreed that such interventions are appropriate for parents. However, significant methodological problems – including poor generalisability, lack of control groups and sampling bias – limit inferences about these interventions' efficacy. Any conclusions about the utility of supportive interventions should therefore be considered cautiously.

4. DISCUSSION

4.1. Summary of findings

Taken together, the 15 studies evaluated in this review point to the relative lack of robust research evaluating psycho-social interventions for this population. When assessed for quality, seven scored between 0 and 25% on the MMAT, six scored 50% and only two scored 75-100%. Only two RCTs met the inclusion criteria; of these, only one had low risk of bias. The generally poor methodological quality of reviewed studies, reflected in problematic designs, sampling bias and unvalidated outcome measures, prevent any definitive conclusions about these interventions' efficacy.

Nonetheless, these studies suggest a number of implications for researchers and clinicians seeking to improve the psychological wellbeing of caregivers of children with food allergies. First, these studies suggest that there is a need for educational input for caregivers. These results are in line with the broader literature evaluating the needs of parents of children with chronic health difficulties, which suggests that illness-specific education interventions improve parental mental health outcomes (Melnyk, Feinstein, Moldenhouer & Small, 2001). The majority of the educational interventions aimed to address discrepancies in parental

food-allergy knowledge; these studies all reported knowledge increases among their participants, as well as improvements to allergy-management skills. Moreover, these educational interventions appeared to be acceptable and valued by parents. However, all of the studies evaluating educational interventions lacked a control group, greatly reducing their internal validity. It is unclear whether the observed outcomes would have occurred in the absence of the intervention. Given that participants were not randomly allocated to the treatment, observed changes might have been the result of particular group characteristics. Additionally, none of the studies considered the implications of increased knowledge on parental wellbeing. Existing research reports that parents of children with food allergies have unmet informational needs (Hu, Grbich & Kemp, 2007), and have suggested that improving access to clear and concise information from a credible source would positively influence parental QoL and reduce perceived stress (Flokstra-de Bok & Dubois, 2009; Vargas et al., 2011).

Second, the studies mobilising psychological interventions provide tentative support for the use of a cognitive behavioural model to inform acceptable and effective interventions for mothers of children with food allergies (Boyle et al., 2017; Knibb, 2015). CBT has been shown to facilitate improvements in the wellbeing of parents of children with other health difficulties (e.g., chronic pain), as the model is flexible and can be adapted to suit the needs of the individual (Palermo, Wilson, Peters, Lewandowski & Somhegyi, 2009), and is currently the recommended treatment for people struggling with low mood or anxiety (NICE, 2009; NICE; 2011). However, Knibb's (2015) case control study did not randomise participants, so it is not possible to state that reported improvements did not occur as a result of confounding factors rather than the therapy.

Third, the reviewed studies also suggest that targeting parental SE may be beneficial. Both LeBovidge et al. (2008) and Baptist et al. (2012) reported improved QoL following

interventions aimed at improving SE, as well as high participant satisfaction. These results provide additional support for psychological interventions targeting wellbeing of parents of children with other chronic illnesses (Law, Fisher, Fales, Noel & Eccleston, 2014; Law, Fisher, Eccleston & Palermo, 2019). However, the reviewed studies also suffer from significant methodological issues. Lack of randomisation and a comparison group in LeBovidge et al. (2008), and unclear randomisation schedule in Baptist et al. (2012), limit the validity of these studies' reported outcomes.

Fourth, there was little evidence to support the efficacy of interventions which were neither educational nor psychological. Among studies using these "supportive interventions", two found no significant effect on parental wellbeing (Danchin et al., 2016; Knibb & Semper, 2013). On the other hand, respondents viewed these interventions as acceptable. Results from Stewart's (2011) qualitative evaluation indicated that participants found online support accessible, and that the group intervention may have helped participants feel less isolated. This finding is in line with the broader literature, which highlights the acceptability and feasibility of online (Palermo et al., 2009; Reger & Gahm, 2009) and group (Coulson & Knibb, 2007; Rosselló & Jiménez-Chafey, 2006) interventions.

Finally, all of these studies suffer from a common problem of recruiting an appropriate sample. Each of the reviewed studies used an opportunistic sampling strategy to recruit participants, which may have resulted in a participant pool of caregivers with a particular interest in the study area, or with higher than average needs. Participation through self-selection reduced the validity of these studies' outcomes. That this problem was constant across all studies points to a broader challenge in defining the population of interest and accessing a representative sample.

4.2. Critique of this review

To the author's knowledge this is the first review seeking to evaluate the efficacy of supportive interventions for caregivers of children with food allergies. The review has been able to highlight gaps in the literature and makes recommendations for further research below.

Although there may be value in considering the separate influence of interventions by "type" (for example, psychological versus educational), this review included all intervention types, which introduced difficulties when comparing studies. However, this approach was deemed necessary due to the paucity of studies evaluating a single intervention type or therapeutic model. Further, the review included studies that were aimed at a variety of caregivers (including teachers and the general public), which meant that it was not possible to know the extent to which the intervention results applied specifically to parents. However, it was felt that the dearth of research in this area meant that a broader scope was ultimately useful in understanding the wider literature aimed at this population.

4.3. Clinical implications

The results of this review cannot provide sufficient evidence to make strong recommendations for interventions that might be implemented in clinical settings. However, despite the limited evidence base for parental interventions, the literature is clear about the increasing prevalence of allergies (Du Toit et al., 2018; Sicherer, 2011; Sicherer & Sampson, 2010, Valenta et al., 2015) and the negative implications for affected individuals and their caregivers (Ravid et al., 2012).

Although recommendations cannot currently be made for the most suitable intervention, clinicians must be aware of the growing needs of this population. There is increasing emphasis on the integration of physical health and mental health provision (National Health Service England, NHS; 2014). With increasing understanding of the interrelatedness of these

sectors, policy-makers have reported that failing to address individual needs in a holistic way results in worse outcomes that are socially and economically costly (Department of Health and Social Care, 2011). This is reflected in the allergy literature: numerous studies have noted the negative consequences for poorly supported parents that could be addressed by adequate provision of social, practical and psychological support (Alanne et al., 2012; Coulson & Knibb, 2007; Klinnert & Robinson, 2008; Sanagavarapu, 2017).

In line with the evidence presented in the broader chronic health literature, parents of children with food allergies may benefit from tailored interventions to better manage stress and anxiety associated with caregiving responsibilities. Furthermore, clinicians should consider ways of increasing accessibility of supportive services (e.g., using online platforms), which may be more acceptable for parents under a lot of strain or who are part of difficult to reach populations.

4.4. Research implications

The results of this review provide tentative suggestions for interventions to benefit parents of children with food allergies. However, it remains unclear whether the encouraging results demonstrated in these early studies are replicable elsewhere. In particular, four gaps in the current literature provide promising avenues for future research.

First, there is particular demand for research which uses more methodologically robust designs to test the efficacy of educational and psychological interventions in supporting parents of children with allergies. Specifically, future studies should seek to conduct RCTs, which are valued by the NHS (Milne et al., 2008) and would better enable researchers to consider the efficacy of such interventions and make causal claims. Although there are ethical considerations around randomisation and limiting access to a treatment that has been hypothesised to be beneficial, a control group may still be obtained by comparing multiple "treatments", or else by using a waitlist control.

Second, future research should attempt to recruit more representative samples. The samples studied in the literature are disproportionately comprised of white, female, educated and middle-to-high income individuals. Food allergy prevalence rates amongst diverse groups are still unknown (McQuaid, Farrow, Esteban, Jandasek & Rudders, 2015). However, some preliminary research has suggested that those from minority groups are more likely to experience food allergy related anxiety (Goodwin et al., 2017), and that non-Caucasian children are less likely to be prescribed epinephrine injectors (McQuaid et al., 2015). Considering the growing consensus of the increased burden on parents of children with food allergies (Klinnert & Robinson, 2008), it may be important to study populations who might have access to fewer supportive resources. Until these groups are better represented in this literature, alternative research designs may help overcome this problem: for example, online interventions can increase under-represented groups' access to services (Reger & Gahm, 2009; Richards & Richardson, 2012), as noted by Stewart et al. (2011). Adequately powered RCTs would be beneficial to evaluate whether these interventions are efficacious among such sub-groups.

Third, future studies should utilise validated questionnaires. The studies reviewed here relied on self-reported and *ad hoc* outcome measures, making it difficult for scholars and clinicians to aggregate their findings because it is unclear whether these outcomes are measuring the same thing. Using validated questionnaires would support better internal validity and more reliable comparison of results across studies.

Finally, researchers should develop interventions aimed at increasing knowledge not only among caregivers but also among their immediate social networks. The literature suggests that parents may experience additional distress due to lack of understanding from friends and family, and the reviewed studies that used these interventions were acceptable to participants. Recent events present a unique opportunity for researchers to study this question: a series of

high-profile anaphylaxis fatalities that likely occurred due to insufficient allergen labelling has brought greater media focus on allergies and their impact (British Broadcasting Corporation, 2019). It is unclear whether this coverage has induced greater understanding of the challenges of allergy management among the wider public, but future research might explore whether media attention has reduced the perceived "invisibility" of allergies that has been reported by parents in the literature.

5. CONCLUSION

The paucity of high-quality research evaluating interventions to support parents of children with food allergies is apparent. However, the studies summarised in this review suggest that future research should develop interventions that provide educational input to caregivers, which may influence their psychological wellbeing. Although limited, the evidence provides an indication that further support in the form of CBT could also offer mothers some benefits, but has not been tested on other groups. However, the reviewed research suffers from methodological constraints which limit the validity of reported outcomes. Therefore, future research should use more methodologically sound designs and use validated outcome measures.

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Major Research Project (MRP) Section B: Empirical Research Paper

The PASCAL Study: A randomised controlled trial of an online self-help intervention for parents of children with food allergies

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For submission to the *Journal of Allergy and Clinical Immunology: In Practice*

Abstract

Caring for a child with a food allergy can be burdensome and negatively affect parental quality of life. The mechanisms for improving quality of life in parents of food-allergic children are not yet understood, but recent studies have suggested that information provision can enhance self-efficacy, and in turn quality of life. The present study developed an online self-help website that aimed to improve quality of life and psychological wellbeing in parents of children with food allergy. The website was developed in consultation with parents and allergy specialists. Parents of children with food allergy (N=205) participated in a randomised controlled trial, comparing the website intervention with a waitlist control. No significant differences were found between the website intervention group and the control group between baseline and post-intervention (4 weeks) on any outcome (quality of life, depression, anxiety or stress) or in any potential mediator (self-efficacy and intolerance of uncertainty). Analysis of adherence data identified low engagement with the website, suggesting that the intervention may not have been best suited to the participating parents. Feedback recommended that the intervention would be better targeted at parents of newly diagnosed children. Study limitations are discussed.

1. Introduction

Food allergy affects 3-6% of the general population and can significantly impact allergic individuals and their carers (Sicherer, 2011). Furthermore, numerous scholars suggest that food allergies are increasing in prevalence (Du Toit et al., 2018; Sicherer, 2011; Sicherer & Sampson, 2010, Valenta, Hochwallner, Linhart & Pahr, 2015).

Although allergies affect individuals in different ways, there are a number of common difficulties experienced by those with a diagnosis. Allergies are most commonly identified in early childhood (Valenta et al., 2015), and receiving a conclusive diagnosis can be time-consuming, further compounded by specialist allergy clinics that are difficult to access (Akeson, Worth &, Sheikh, 2007; Hu, Grbich & Kemp, 2007). Furthermore, a selection of "major allergens" are responsible for the majority of reactions (e.g., milk, eggs and nuts), but individuals may develop an allergy to any food (Allen & Koplin, 2012; Nwaru et al., 2014). The causes of food allergy are not yet established, but studies suggest that a combination of environmental factors and a genetic disposition can restrict oral tolerance to allergens (Sicherer & Sampson, 2010). Moreover, although food allergies can "resolve" (i.e., affected individuals can develop tolerance to the allergen), an allergy diagnosis can also be chronic and lifelong (Baral & Hourihane, 2005).

Individuals with allergies are typically symptom free in the absence of the allergen, but when reactions occur, they can be severe and must be taken seriously. Allergic reactions are triggered by a specific immune response where harmless allergens are perceived by the body as a threat (Sicherer & Sampson, 2010). Reactions can simultaneously impact numerous bodily systems as they increase in severity (Akeson et al., 2007). Mild reactions are typically localised to a single area (e.g., watering eyes, hives, itchy rash and/or swelling), and moderate reactions may include earlier mild indications in addition to symptoms in other bodily systems (e.g., the digestive tract), resulting in vomiting and diarrhoea. Severe

reactions (i.e., anaphylaxis) can be life threatening (Vargas et al., 2011) and are usually categorised by a sudden onset of symptoms that can compromise respiratory functioning and may trigger hypotension and cardiovascular collapse (Baral & Hourihane, 2005).

Appropriate allergy management can be burdensome for those affected. As curative treatments for food allergies do not yet exist (Du Toit et al., 2018), the primary advice provided to affected individuals is to avoid any exposure to the allergen, and maintain emergency preparedness in the case of accidental contact (Baral & Hourihane, 2005). In practice, this requires that food-allergic individuals (and their caregivers) maintain high levels of vigilance, and diligent label-checking is encouraged. Furthermore, as reactions can also be triggered by touch, individuals must be cautious to avoid exposure to an allergen through cross-contamination in their environment (Williams, Parra & Elkin, 2009).

Following an allergy diagnosis in childhood, caregivers become responsible for adhering to safe management plans, but medical support for parents is often inadequate (Akeson et al., 2007). Caring for a child with a food allergy has been shown to have emotional, psychological and financial implications for families (Klinnert & Robinson, 2008; Knibb & Horton, 2008; Meltzer & Booster, 2016; Williams & Hankey, 2015). Studies have reported that food allergy in children is related to poorer parental quality of life (QoL) and mental health (Birdi, Cooke & Knibb, 2016). Additionally, evidence suggests that parental anxiety related to anaphylaxis can be transferred to the child (Akeson et al., 2007), impacting on the child's longer-term outcomes.

QoL can be defined as an individual's perception of their position in life (Warren, Otto, Walkner & Gupta, 2016), which encompasses social, emotional, environmental and physical domains (Knibb, Barnes & Stalker, 2016). The literature also refers to health-related ("condition specific") quality of life, which measures the experience of illness rather than objective severity (Warren et al., 2016). This paper refers to food-allergy QoL, which can

therefore be defined as the influence of food allergy diagnoses on individuals and their caregivers. There is a dearth of evidence exploring the correlates of increased parental stress in relation to child allergy symptoms. However, two potential theoretical explanations of stress and anxiety in this population are intolerance of uncertainty or low self-efficacy.

Intolerance of uncertainty (IU) is a construct originally identified as a key maintenance factor in generalised anxiety disorder (GAD; Buhr & Dugas, 2002). However, recent research has highlighted that it may be an important construct underlying a number of psychological disorders (Einstein, 2014). IU can be defined as a cognitive bias that predisposes individuals to interpret uncertain situations as inherently negative. As such, individuals will perceive future uncertain events as threatening, regardless of the probability of negative outcomes actually occurring (Mahoney & McEvoy, 2012).

Studies have found that parents of children with food allergies are likely to experience high levels of uncertainty (Kemp & Hu, 2008). For example, the possibility of fatal anaphylaxis is thought to be hugely burdensome for parents of food-allergic children (Knibb et al., 2016), as diagnostic tests cannot predict the likelihood of a life-threatening reaction. Williams et al., (2009) report that parents who engage in behaviours to maintain a safe environment for their children cannot maintain full control of any environment, and accidental exposure to allergens can easily occur (Flokstra-de Bok & Dubois, 2009). Furthermore, adolescents and young people are at an increased risk of severe reactions that may cause death (Bock, Munoz-Furlong & Sampson, 2001), potentially as a result of reduced adherence to appropriate allergy-management plans (e.g., carrying adrenaline auto-injectors; Akeson, et al., 2007). Resultantly, caregivers report understandable heightened stress and anxiety at developmental milestones (e.g., when children are due to start day-care, school or university; Klinnert & Robinson, 2008), as well as in situations where they must “hand over” care to others who do not prioritise allergy management; these events may represent

increased exposure to uncertain amounts of risk (Stjerna, Worth, Harden & Olin Lauritzen, 2017).

Nonetheless, studies have highlighted that food-allergy related fatalities are relatively uncommon when anaphylaxis is managed appropriately: Baral and Hourihane (2005) indicate risk of death to be 1 in 800,000. However, there is little research examining whether supporting parents to tolerate the uncertainty around this low-chance but high-consequence outcome might lead to improvements in parental QoL.

Another potential maintaining factor for parental stress may be reduced parental self-efficacy (SE) related to having a food-allergic child (Streisand, Swift, Wickmark, Chen & Holmes, 2005). Recent studies have provided support for the benefits of enhancing SE to improve QoL in parents of children with allergies (Knibb et al., 2016; Knibb, Barnes & Stalker, 2015). Derived from Bandura's (1977) Social Learning Theory, SE is a construct that can be defined as "the confidence and belief in your ability to carry out certain actions and manage situations" (Knibb et al., 2015). Bandura (1977) stated that SE was a construct that could be enhanced (Wichit, Mnatzaganian, Courtney, Schulz, & Johnson, 2017), and there is evidence that traditional psychological interventions (e.g., Cognitive Behavioural Therapy) can increase SE (Petrozzi et al., 2015). Scholars have suggested that receiving credible information may also be a mechanism to enhance self-efficacy (Strecher, McEvoy DeVellis, Becker & Rosenstock, 1986) but research evaluating the effectiveness of information provision in enhancing food allergy related SE is needed.

Broadly, there is also limited research evaluating interventions targeting QoL in parents of children with food allergies. Existing studies have primarily implemented educational interventions, reporting improvements in allergy knowledge and management in caregivers (Maurer, Byrd-Bredbenner & Grasso, 2007; Sicherer et al., 2012; Wahl, Stephens, Ruffo & Jones, 2015). Although some studies suggest that knowledge-based interventions

could improve QoL in parents (Contreras-Porta et al., 2016; Ruiz-Baques et al., 2018), this has not been formally evaluated. Recent studies exploring the role of psychological interventions in supporting parents have demonstrated improvements using cognitive behavioural therapy to address food-allergy related anxiety and depression (Boyle et al., 2017; Knibb, 2015). However, there is a lack of randomised controlled trials targeting QoL in this population.

A growing evidence base suggests that online self-help can be an effective way to treat difficulties such as depression and anxiety in the general population, and there is increasing interest in incorporating this modality into standard practice in multiple healthcare domains (Christensen, Griffiths & Jorm, 2004; Spek et al., 2007; Venmark et al., 2010; Williams & Martinez, 2008). Web-based interventions are thought to increase accessibility of services to underrepresented groups, and are less resource-intensive than equivalent face-to-face interventions (Reger & Gahm, 2009; Richards & Richardson, 2012). Although few studies have explored the role of online interventions for parents of children with allergies, one study provided caregivers with access to a programme of interactive educational workshops online (Rosen, Albin & Sicherer, 2014). Their participants reported high levels of satisfaction and improvements in quality of life. However, outcomes used by authors measured knowledge improvement and satisfaction, and did not use validated questionnaires to assess QoL.

In summary, the burden and reduced QoL experienced by caregivers is well-documented, but there is a paucity of research targeting QoL in this population. Additionally, due to increasing demands of services, there has been an increase in the provision of web-based care, which has the potential to support hard-to-reach groups. Developing accessible and effective online interventions for this population may benefit the wellbeing of parents of children with food allergies, but also improve outcomes for their children. Therefore, the

present study aimed to develop a brief, online, self-help intervention intended to increase QoL in parents of children with food allergies. Drawing on the above mentioned theory, which outlined that information provision leads to better participant satisfaction and allergy management, this intervention aimed to provide accessible educational information. This intervention would potentially target IU and SE, which scholars have suggested can influence QoL outcomes. The efficacy of the described website was evaluated in a randomised controlled trial (RCT), comparing it to a waitlist control condition.

Based on the above-outlined literature, it was hypothesised that:

1. Caregivers of children with food allergies allocated to receive the online intervention would show greater improvements in food-allergy QoL, from baseline (week 0) to post-intervention (week 4), than waitlist controls.
2. The improvements in food-allergy QoL in the intervention group, relative to control, would be maintained at follow-up (week 8).
3. Participants allocated to the intervention arm would show greater improvements in secondary outcomes of depression, anxiety and stress, from baseline (week 0) to post-intervention (week 4), than controls.
4. Improvements in secondary outcomes for those in the intervention arm would be maintained at follow-up (week 8), compared to controls.
5. The relative improvements in QoL and secondary outcomes in the intervention arm, from baseline to post-intervention, would be mediated by increased self-efficacy and reduced intolerance of uncertainty, compared to controls.

2. Methods

2.1. Design

The study used a single-blind randomised control trial (RCT) to explore the effectiveness of an online self-help intervention for parents of children with food allergies, compared to a waitlist control. The intervention was co-developed in consultation with a parental allergy support group and a paediatric allergy specialist. Self-report outcome measures were collected at three time points: baseline (week 0), post-intervention (week 4) and follow-up (week 8). A final feedback questionnaire was sent to participants at 12 weeks. Participants across both groups were able to access any additional support outside of the study, as per usual care. The control group were given access to the website after completing follow-up outcome measures at 8 weeks, at the end of the study, prior to the feedback questionnaire (week 12).

The RCT was registered on an international register of trials maintained by the United States Library of Medicine prior to the start of the study (clinicaltrials.gov; registration number: NCT03529747; Appendix C). Randomisation was carried out using a pre-set schedule on the Qualtrics platform, assigning participants to groups on a 1:1 ratio, however due to technical limitations allocation was not blocked. Participants were required to enter a unique identifier to ensure that questionnaires could be linked at future time points.

2.2. Participants

Participants for the RCT were recruited online via social media websites (Appendix D). Recruitment was supported by three large voluntary sector organisations (Allergy UK, Anaphylaxis Campaign, and Food Allergy Research and Education, or FARE), each of which allowed study advertisements to be posted on their Facebook pages or via Twitter.

Parents or caregivers who identified as having a child under the age of 18 with a food allergy were eligible to take part. Participants were required to have access to the internet and be comfortable reading English. Participants were excluded if they had consulted on the design and content of the website (See section 2.4).

An *a priori* power calculation was conducted using a power analysis programme (G*Power; Faul, Erdfelder, Lang & Buchner, 2007). Using Cohen's (1992) guidelines, calculations based on a large effect size of 0.8 and an alpha of $p = .05$ suggested that a minimum of 37 participants per trial arm was required to sufficiently power the study (Appendix E).

2.3. Measures

Participation in the study occurred entirely online. Outcome measures (Appendix F) were collected using Qualtrics, a secure data collection platform.

2.3.1. Quality of life.

Reported change in the primary outcome, food allergy-related quality of life (QoL) was measured using the Food Allergy Quality of Life-Parental Burden scale (FAQoL-PB; Cohen, Noone, Muñoz-Furlong & Sicherer, 2004).

The FAQoL-PB is a condition-specific, 17-item questionnaire that uses a seven-point Likert scale ranging from 1 (not troubled) to 7 (extremely troubled) for each question. Scores can range between 17 and 119, with higher scores indicating higher parental burden and lower QoL. The questions explore the impact of food allergy on parents' emotions and coping abilities, time, activities, and their general health (e.g., "How troubled are you by your concerns for your child's health because of their food allergy?" (Knibb & Stalker, 2013).

The FAQoL-PB has good internal consistency and good test-retest reliability (α = 0.93-0.95; Cohen et al., 2004; Flokstra-de Bok & Dubois, 2009). It has been

validated with populations in the United States and the United Kingdom (Cohen et al., 2004; Knibb & Stalker, 2013), and is able to discriminate differences reported in QoL between parents of children with a single versus multiple allergies. The FAQoL-PB was found to have high internal validity ($\alpha > 0.85$) in a moderate UK sample (754 parents), and a significant correlation with health and parental impact measures (Knibb & Stalker, 2013).

2.3.2. Anxiety, stress and depression.

Anxiety was assessed using the Generalized Anxiety Disorder screener (GAD-7) (Spitzer, Kroenke, Williams & Löwe, 2006), which is a seven-item self-report measure that aims to identify whether individuals are experiencing symptoms associated with generalised anxiety. This measure has been validated in both clinical samples and in the general population (Löwe et al., 2008; Spitzer et al., 2006), with good internal consistency ($\alpha > 0.89$) in a large general sample (N = 5036).

The Patient Health Questionnaire (PHQ-8) was used to measure change in depression symptoms. The PHQ-8 is an eight-item self-report scale that has been validated in both clinical and population-based studies ($\alpha = 0.86$-0.89; Kroenke et al., 2009).

The GAD-7 and PHQ-8 both use a four-point Likert scale where respondents report the frequency of symptoms over the past two weeks; ranging from zero (“Not at all”) to three (“Nearly every day”). The GAD-7 scores range from 0-21, and the PHQ-8 from 0-24, where higher scores indicate higher levels of generalised worry or depression.

Finally, the Perceived Stress Scale (PSS; Cohen, Kamarck & Mermelstein, 1983) was used to assess the degree to which life events are perceived as stressful by respondents, evaluating the perceived controllability and predictability of these

events. A review of the psychometric evidence for this measure identified good internal validity and test-retest reliability ($\alpha > 0.7$; Lee, 2012). Lee (2012) reported that the shortened 10-item questionnaire used in the present study, as a better measure than the 14-item or four item version. The PSS assesses perceived stress over the past month, using a five-point Likert scale where answers range from 0 ("Never") to 4 ("Very Often"). The scale has a maximum score of 40, with higher scores indicating higher levels of stress.

2.3.3. Mediators.

Intolerance of uncertainty (IU) was assessed using the Intolerance of Uncertainty Scale (IUS; Buhr & Dugas, 2002), which has excellent internal consistency and good test-retest reliability over a five-week period ($\alpha > 0.94$; Sexton & Dugas, 2009). The IUS is a 27-item self-report questionnaire that assesses negative beliefs about uncertainty and its perceived consequences (e.g., "Uncertainty stops me from having a firm opinion"). The IUS consists of a five-point Likert scale where answers range from 1 ("Not at all characteristic of me") to 5 ("Entirely characteristic of me"). Scores may range between 27 and 135, with higher scores indicating higher levels of IU.

The second mediator, namely food allergy self-efficacy, was assessed using the Food Allergy Self-Efficacy Scale for Parents (FASE-P; Knibb et al., 2015), which is a self-report measure that aims to identify parental confidence in managing their child's food allergy. The scale consists of 21 items and is scored on a scale from 0 ("Cannot do at all") to 100 ("Highly certain can do"). Total scores are divided by 21 to create a final mean score where lower scores are indicative of lower self-efficacy. The questionnaire was validated in a population sample of 250 (Knibb et al., 2015). The FASE-P demonstrated good internal consistency ($\alpha > 0.88$) and was strongly correlated with the FAQL-PB questionnaire (Knibb et al., 2015).

2.3.4. Demographic questionnaire

A demographic questionnaire was developed for the study through consultation of the literature and discussions with experts in the area. At baseline, participants answered 31 questions about their characteristics, and the characteristics of their child or children (see Appendix G).

2.3.5. Feedback questionnaire

A 13-item questionnaire was developed to collect participant feedback on the study and website and was completed by all participants at week 12. The questionnaire consisted of a mix of Likert scale (e.g., "How much do you agree or disagree with the statement *'web-based support for carers/parents us useful'*"?) and open-ended questions (e.g., "what aspect(s) of the website did you find the most useful?") where participants could report on their website access and tell researchers their thoughts about the website content (Appendix H).

2.4. Public patient involvement (PPI) and intervention development

The website was developed in consultation with existing literature and discussion through a series of focus groups with service user consultants in accordance with the National Institute for Health Research (NIHR) guidelines (NIHR, 2014). An allergy specialist was also consulted for content recommendations and medical guidance.

Service user consultants attended a focus group through a regional Allergy Support Group, who were affiliated with the Anaphylaxis Campaign. This group consisted of six mothers, one father, and one grandmother, with varying experience in food allergy management. One parent had a baby, two had children who were adolescents and the rest were carers of primary school-aged children. Most parents were carers of children with multiple food-allergies. All members were provided with

a Terms of Reference sheet explaining the purpose of the focus group, and how the information we gathered might be used (Appendix I). These individuals were aware that consulting would exclude them from participating in the RCT. They were provided with downloadable content from the website and a summary of study outcomes following the completion of the study.

The group provided feedback on recruitment advertisements and options for the proposed intervention. Summaries of areas currently lacking in the literature for parental support that might inform the website content were presented as discussion points in the group. These included information provision and QoL, and psychological interventions for psychological wellbeing.

After the website content had been drafted, the consultants were asked to provide feedback on content, and to contribute to the "Frequently Asked Questions" section. Furthermore, individuals also consented for their "Top Tips" for other parents to be featured on the website. A discussion summary from the focus group can be found in Appendix J. The content for the final website is summarised in *Table 1* (See complete website content in downloadable form and example webpages in Appendix K).

Table 1: Website content summary by page.

Website page	Title	Information summary
1	What is an allergy?	This page provides a simple definition of an allergy, and guidance on how to recognise symptoms of an allergic reaction.
2	Food allergy vs food intolerance	Clearly indicates the difference between allergies and intolerances, and supports individuals to learn how to identify allergens in foods (via label checking).
3	Anaphylaxis	Definition of anaphylaxis, information about how to recognise symptoms, and steps to take in the case of an anaphylactic reaction.
4	Auto-injectors	Guidelines on correct administration of automatic adrenaline injectors (AAI), providing distinction between instructions from the three main AAI providers (Emerade, Epipen and Jext). Viewers are linked to training videos on the provider websites. This page also had a video recorded by an allergy specialist outlining correct administration.
5	Managing anxiety	Simple cognitive-behavioural formulation for stress and worry is presented ("hot cross bun" cycle).
6	The worry diagram	A "worry tree" is outlined, using allergy-specific worries suggested by parents in the PPI focus group.
7	Psychological resources	Signposting to local support services (including IAPT) and online self-help information sites (e.g., getselfhelp.co.uk). Information for further allergy information is also included.
8-11	Frequently asked questions (FAQs)	Based on questions raised by group members from the PPI focus group and commonly reported uncertainties identified in the literature.
12	Myth busting	Challenging common myths and misconceptions around food allergy and management plans.
13	Top tips for parents of food allergic children	Tips provided by the PPI focus group, aiming to normalise anxiety and stress related to caring for a food-allergic child.
Additional	Allergy Profile	An individualised allergy profile that can be downloaded so that caregivers can be aware of symptoms specific to the child they are caring for.

2.5. Assignment and access to intervention

The intervention was delivered via a password protected website (pascalstudy.co.uk) that was established for the study using a website development platform called Wix. The study was provided with the name "PASCAL" to facilitate advertising, which stands for "(PA)rental (S)upport for (C)hildren with (AL)lergies".

Those interested in participating in the study followed a link to Qualtrics, where they were presented with the study information sheet (Appendix L). Consent was then requested online, and those who were eligible were invited to complete baseline measures and demographic questionnaires; participants were then randomly allocated to either waitlist or treatment groups. Qualtrics then notified individuals of the group to which they had been allocated (see Appendix M containing messages sent to participants). Those in the intervention group were provided the study URL and password so that they had immediate access to the website.

Links to complete outcomes at post-intervention (week 4) and follow up (week 8) as well as for study feedback (week 12) were sent to participants via email. Additional reminder emails were sent to participants to encourage completeness of data. Outcome data collection was blinded to group allocation as measures were collected online with no involvement from researchers. Participants in the control group were invited to view the website following their completion of follow-up questionnaires at week 8.

2.6. Ethical considerations

Ethical approval for the study was granted by the Salomons, Canterbury Christ Church University ethics panel (Appendix N). The implementation of a web-based intervention meant that our sample would not be receiving face-to-face support, nor telephone contacts with researchers. However, following numerous discussions with experts and service user consultants it was felt that the content of the website would be

unlikely to cause distress or harm to participants. Nevertheless, all participants were provided with supportive resources (Appendix K) regardless of group allocation. Additionally, as participants were not excluded from the study if they lived outside of the United Kingdom (UK), individuals were reminded that some of the resources were specific to the UK. These individuals were encouraged to seek any additional support from their primary care physician or to access care as usual if needed. Moreover, all participants were signposted to large allergy support organisations, who are better resourced to provide further guidance. For example, the "FARE" website allows visitors to search for local support groups across four countries.

Additional consideration was given to email reminders, and a reminder limit was agreed to prevent participants from receiving too many emails and feeling coerced to engage.

Participants were aware that they could contact researchers should they have any concerns about the study or the website. Participants were reminded that they could seek support or treatment as usual if it felt necessary in addition to study involvement.

2.7. Analysis plan

The primary outcome measure was change in self-reported food allergy QoL between baseline and post-intervention (week 4), as measured by total score on the FAQoL-PB scale. Change in FAQoL-PB scores between baseline and follow-up (week 8) was a secondary outcome. Other secondary outcomes included corresponding changes in scores of the other dependent variables (PHQ-8, GAD-7 and PSS) and potential mediating variables (FASE-P and IUS).

Change scores were calculated by subtracting each participant's post-intervention and follow-up scores from their baseline scores. An intention to treat analysis was employed, so that available data were included regardless of the extent to which participants

completed the intervention. This led to a complete case analysis, whereby only participants who had completed outcome questionnaires were included.

Exploratory data analysis revealed deviations from normality for multiple measures at all time points (Appendix O). Due to this, non-parametric Mann-Whitney U tests were used to analyse differences in change scores to ensure a sufficient assessment of effectiveness. Effect sizes were calculated using Rosenthal's (1991) r statistic (Field & Hole, 2003). The analysis was conducted using SPSS version 24 (IBM Corp, 2016).

A per protocol analysis was not conducted. The treatment was provided in a "single dose" through access to the website at the start of the study, and it was not possible to check adherence to the treatment (i.e., individual website use).

3. Results

3.1. Participants

Figure 1 shows the flow of participants through the RCT. Of the 257 participants who enrolled in the study by following the advertising link, 52 opted out after the study information sheet or did not complete 100% of baseline measures (and were therefore not allocated to a group). Of the 205 individuals that were randomised, the CONSORT diagram follows the completion rates for outcome measures at each time point. One individual was excluded from the analysis because s/he completed baseline (0 week) measures, but no measures at any other time point.

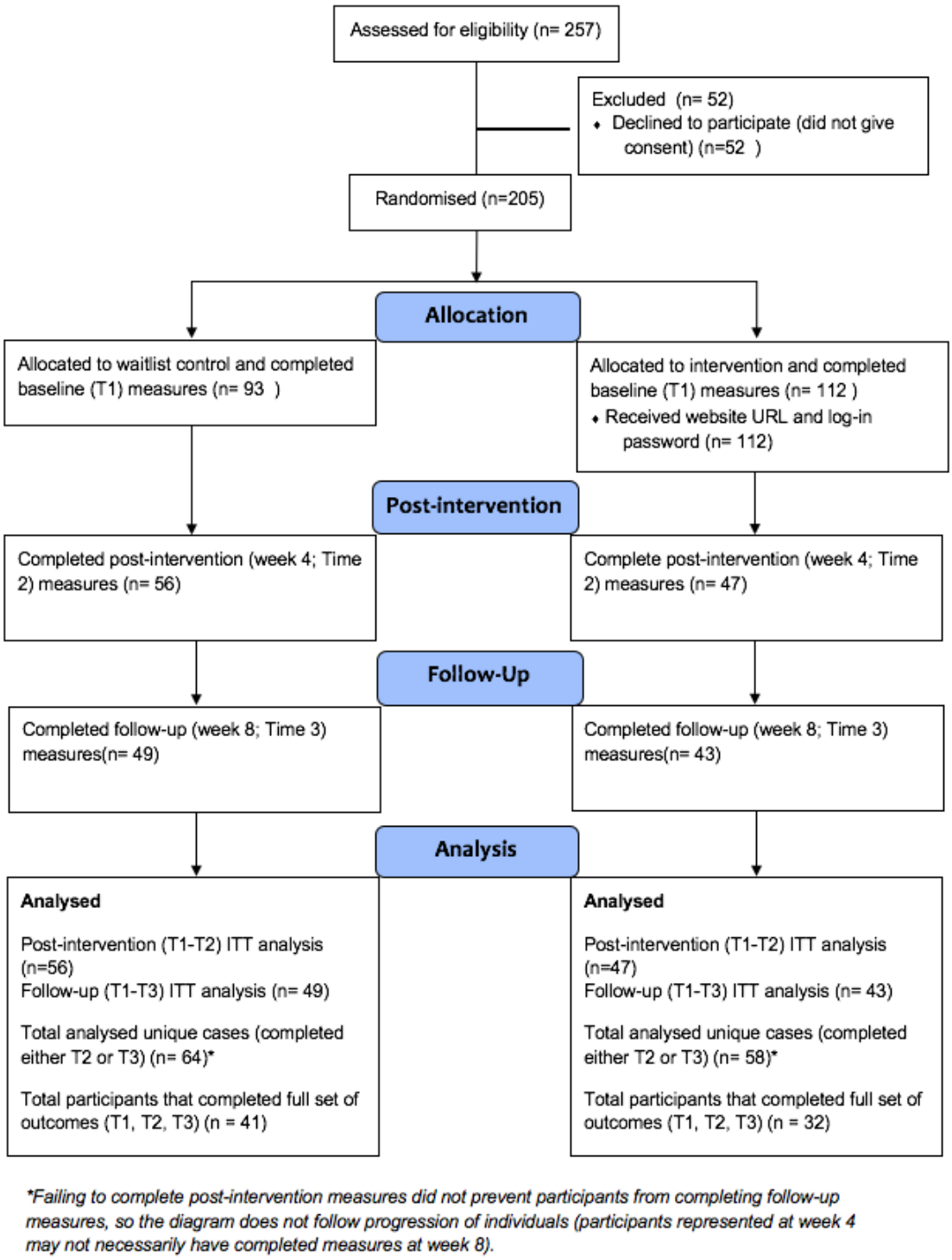

Figure 1: CONSORT diagram identifying flow of participants through the RCT

3.2. Baseline data

Demographic details of the 205 RCT participants are outlined in Table 2. The sample was largely female (97%) and from the United Kingdom (81%). Additionally, the sample was primarily comprised of individuals who identified as being white (91.2%), and who were university-educated (78%). The majority of participants did not report any ongoing physical or mental health difficulties. However, 11.2% reported a diagnosis of an anxiety disorder. There were no significant differences between participants allocated to the intervention and control conditions on any demographic variable ($p > 0.05$ for all variables).

Demographic data for children, as reported by caregivers across both groups can be viewed in Table 3. If parents had more than one food-allergic child, data were recorded for their oldest child. The mean child age was 8 years old, and children were diagnosed with an allergy on average at 1.7 years. 41.5% of the children were female and 76% of caregivers reported their child had multiple allergies. The frequency of reported allergies mirrors existing findings in the literature.

Some differences were identified between the control and intervention group, with the intervention group significantly more likely to contain parents of children with multiple allergies ($p = .011$). Given this difference, it is unsurprising that a significant difference by allergen was also found: the two most common allergens were more likely to be present in the intervention group than the control group ($p = .022$ peanut; $p = .017$ tree nut). However, these did not remain significant when a Bonferroni correction for multiple comparisons was applied. These differences may have been the result of a Type 1 error. There were no significant differences between the children of parents in the intervention compared to the control group on any other demographic variable.

Table 2: Demographic characteristics of RCT participants

	Both conditions	**Intervention group**	**Control group**	**Between group comparisons**	***p*-value**
	N= 205	**N= 112**	**N= 93**		
	Mean (SD)	**Mean (SD)**	**Mean (SD)**		
Age (years)	38.95 (6.89)	38.96 (6.7)	38.94 (7.14)	U = 5118.500, Z = -0.212	*p* = .832
	N (%)	**N (%)**	**N (%)**		
Gender					
Female	(97%)	109 (97.3%)	90 (96.8%)	χ^2 = 0.54	*p* = .817
Country				χ^2 = 2.958	*p* = .398
United Kingdom	166 (81%)	88 (78.6%)	78 (83.87%)		
United States	21 (10.2%)	15 (13.39%)	6 (6.45%)		
Europe- other	11 (5.4%)	5 (4.46%)	6 (6.45%)		
Other	7 (3.4%)	4 (3.57%)	3 (3.23%)		
Ethnicity				χ^2 = 2.898	*p* = .408
White	187 (91.2%)	102 (91.07%)	85 (92.39%)		
Asian	7 (3.4%)	7 (6.25%)	4 (4.34%)		
Mixed race	7 (3.4%)	7 (6.25%)	3 (3.26%)		
Black	3 (1.5%)	3 (2.68%)	0 (0%)		
Missing	1 (0.5%)	0	1		
Employment status				χ^2 = 5.867	*p* = .209
Part-time	73 (35.6%)	35 (31.25%)	38 (40.86%)		
Full-time	70 (34.1%)	36 (32.14%)	34 (36.56%)		
Homemaker /carer	46 (22.4%)	29 (25.89%)	17 (18.28%)		
Self-employed	15 (7.3%)	11 (9.82%)	4 (4.3%)		
Unemployed	1 (0.5%)	1 (0.89%)	0 (0%)		
Education				χ^2 = 2.049	*p* = .359
Undergraduate degree	86 (42%)	42 (37.5%)	44 (47.31%)		
Postgraduate degree	74 (36%)	43 (38.39%)	31 (33.33%)		
No degree	45 (22%)	27 (24.11%)	18 (19.35%)		
Current health				χ^2 = 4.628	*p* = .328
No difficulties	151 (73.7%)	79 (75.24%)	72 (80.9%)		
Anxiety	23 (11.2%)	13 (12.38%)	10 (11.24%)		
Physical health diagnosis	10 (4.9%)	5 (4.76%)	5 (5.62%)		
Missing	11 (5.4%)	7 (6.67%)	4 (4.49%)		
Complex mental health	5 (2.4%)	5 (4.76%)	0 (0%)		
Depression	5 (2.4%)	3 (2.86%)	2 (2.25%)		
Previous psychological support				χ^2 = 0.429	*p* = .512
No	119 (58%)	63 (58.33%)	56 (62.92%)		
Missing	8 (3.9%)	4 (3.7%)	4 (4.49%)		

Table 3: Demographic characteristics of food-allergic children

	Both conditions	**Intervention group**	**Control group**	**Between group comparisons**	***p*-value**
	N= 205 **Mean (SD)**	**N= 112** **Mean (SD)**	**N= 93** **Mean (SD)**		
Child age (years)	8.08 (4.74), **N= 108***	7.36 (4.87), **N= 52**	8.75 (4.55), **N= 56**	U = 1189.500 Z = -1.639	*p* = .101
Age at diagnosis (years)	1.7 (2.15)	1.6 (2.08)	1.8 (2.23)	U = 4729.500 Z = -1.172	*p* = .241
	N (%)	**N (%)**	**N (%)**		
Gender				χ_2 = 0.532	*p* = .466
Female	85 (41.5%)	49 (43.75%)	36 (38.71%)		
Multiple allergies	156 (76.1%)	93 (83.06%)	63 (67.74%)	χ_2 = 6.534	*p* = .011*
Allergen					
Peanut	134 (65.4%)	81 (72.32%)	53 (57%)	χ_2 = 5.276	*p* = .022*
Tree nut	122 (59.5%)	75 (67%)	47 (50.54%)	χ_2 = 5.690	*p* = .017*
Milk	86 (42%)	50 (44.64%)	36 (38.71%)	χ_2 = 0.734	*p* = .391
Egg	94 (45.9%)	55 (49.11%)	39 (41.94%)	χ_2 = 1.053	*p* = .305
Sesame	40 (19.5%)	25 (22.32%)	15 (16.13%)	χ_2 = 1.241	*p* = .265
Soya	30 (14.6%)	20 (17.86%)	10 (10.75%)	χ_2 = 2.053	*p* = .152
Wheat	20 (9.8%)	13 (11.61%)	7 (7.53%)	χ_2 = 0.961	*p* = .327
Fish	19 (9.3%)	12 (10.71%)	7 (7.53%)	χ_2 = 0.614	*p* = .433
Shellfish	8 (3.9%)	6 (5.36%)	2 (2.15%)	χ_2 = 1.393	*p* = .238
Comorbid diagnoses					
Asthma	110 (53.7%)	61 (54.46%)	49 (52.69%)	χ_2 = 0.064	*p* = .800
Eczema	138 (67.3%)	78 (69.64%)	60 (64.52%)	χ_2 = 0.607	*p* = .436
Hay fever	86 (42%)	49 (43.75%)	37 (39.78%)	χ_2 = 0.328	*p* = .567
Medication					
Antihistamines	193 (94.1%)	108 (96.43%)	85 (91.4%)	χ_2 = 2.333	*p* = .127
Auto-injector (AAI)	181 (88.3%)	99 (88.39%)	82 (88.17%)	χ_2 = 0.002	*p* = .961
Anaphylaxis					
AAI Training	153 (74.6%)	85 (75.89%)	68 (73.12%)	χ_2 = 0.207	*p* = .649
Administered AAI	49 (23.9%)	30 (26.79%)	19 (20.43%)	χ_2 = 1.128	*p* = .288
Administered AAI from carer	23 (11.2%)	13 (11.61%)	10 (11.61%)	χ_2 = 0.037	*p* = .847
Child attended hospital for reaction	126 (61.5%)	70 (62.5%)	56 (60.22%)	χ_2 = 0.112	*p* = .738
Anaphylactic reaction[3]	105 (51.2%) N = 183	59 (59%) N=100	46 (51.69%) N=83	χ_2 = 0.237	*p* = .626
Management plan	172 (83.9%)	92 (82.14%)	80 (86.02%)	χ_2 = 0.566	*p* = .452

[3] Missing values (N = 22) were excluded.

Baseline data for all outcome measures at each time point are presented in Table 4; there were no significant differences between the intervention and control groups on any outcome at baseline ($p > .05$ for all measures, see Appendix P for comparisons), suggesting that randomisation was effective.

3.3. Retention

Of the 205 participants, 103 (50.2%) completed measures at post-intervention (week 4). This figure decreased to 92 participants at follow-up (week 8), meaning that 44.9% of the original sample had been retained (see Figure 1). Retention observed at each time point is also not linear, as participants were able to miss post-intervention measures, but still complete follow-up measures. The total number of unique cases of participants (completing at least post-intervention or follow-up) was 64 in the intervention group and 58 in the control group. A total of 73 participants completed all three rounds of outcome measures.

There was no evidence of bias introduced by attrition. Exploratory analyses found that there were no significant differences in outcome scores on baseline measures between those participants who completed post-intervention measures and those who dropped out (all *p*-values > .05; APPENDIX P). Additionally, no significant differences were found between those participants who completed measures at both post-intervention and follow-up time points and those who did not (all *p*-values > .05; APPENDIX P). There were also no differences in baseline characteristics between participants who remained in the study, and those that failed to complete follow up measures.

Table 4: Descriptive statistics for intention-to-treat analysis at each time point

	Baseline (Week 0)				**Post-intervention (Week 4)**				**Follow-up (Week 8)**			
	Treatment (n=112)		**Control (n=93)**		**Treatment (n=47)**		**Control (n= 56)**		**Treatment (n=43)**		**Control (n=49)**	
	Mean (SD)	**Median (IQR)**	**Mean (SD)**	**Median (IQR)**	**Mean (SD)**	**Median (IQR)**	**Mean (SD)**	**Median (IQR)**	**Mean (SD)**	**Median (IQR)**	**Mean (SD)**	**Median (IQR)**
QoL-PB *(/119)*	84.16 (19.06)	86.00 (19.06)	85.44 (19.34)	90.00 (27.50)	78.32 (19.11)	79.00 (30.00)	80.55 (20.30)	82.00 (29.75)	72.76 (21.21)	72.00 (37.00)	79.39 (18.89)	83.00 (27.50)
PHQ-8 *(/24)*	4.96 (4.93)	4.00 (6.00)	4.44 (4.15)	4.00 (16.00)	5.45 (5.20)	3.00 (7.00)	5.34 (4.86)	4.00 (7.50)	4.74 (4.76)	4.00 (7.00)	6.29 (5.12)	5.00 (6.00)
GAD-7 *(/27)*	5.70 (4.93)	5.00 (6.00)	6.02 (5.43)	5.00 (8.50)	5.55 (5.52)	4.00 (7.00)	6.43 (5.84)	5.00 (7.00)	5.40 (4.69)	4.00 (7.00)	7.35 (6.16)	6.00 (9.50)
PSS *(/40)*	17.50 (7.25)	17.50 (8.50)	17.17 (6.62)	18.00 (8.50)	16.87 (8.02)	16.00 (10.00)	17.48 (7.24)	18.50 (9.50)	15.77 (7.68)	16.00 (9.00)	18.22 (7.70)	20.00 (11.50)

3.4. Intervention effects

Descriptive statistics for outcome measures for all time points in both groups are summarised in Table 4. For the primary trial outcome of parental quality of life, contrary to hypothesis, change scores between baseline and post-intervention did not differ between the intervention group and the control group (FAQoL-PB: U = 1223.500, Z = -.613, p = .54, r = -.06). Also contrary to the primary hypothesis, quality of life change scores between baseline and follow-up did not differ between the intervention group and the control (FAQoL-PB: U = 1040.500, Z = -.102, p = .919, r = -.01).

Furthermore, change scores between baseline and post-intervention did not differ significantly between the intervention group and control group on any of the secondary measures (PHQ: U = 1285.500, Z = -.204, p = .838, r = -.02; GAD: U = 1303.000, Z = -.87, p = .931, r = -.085; PSS: U = 1310.500, Z = -.037, p = .971, r = -.036). Similarly, change scores between baseline and follow-up did not differ between the intervention and control group on any of the secondary measures (PHQ: U = 807.500, Z = -1.940, p = .052, r = -.20; GAD: U = 929.000, Z = -.983, p = .326, r = -.10; PSS: U = 933.500, Z = -.942, p = .346, r = -.098). Visual representation of change scores across each measure are presented in Figures 2-5.

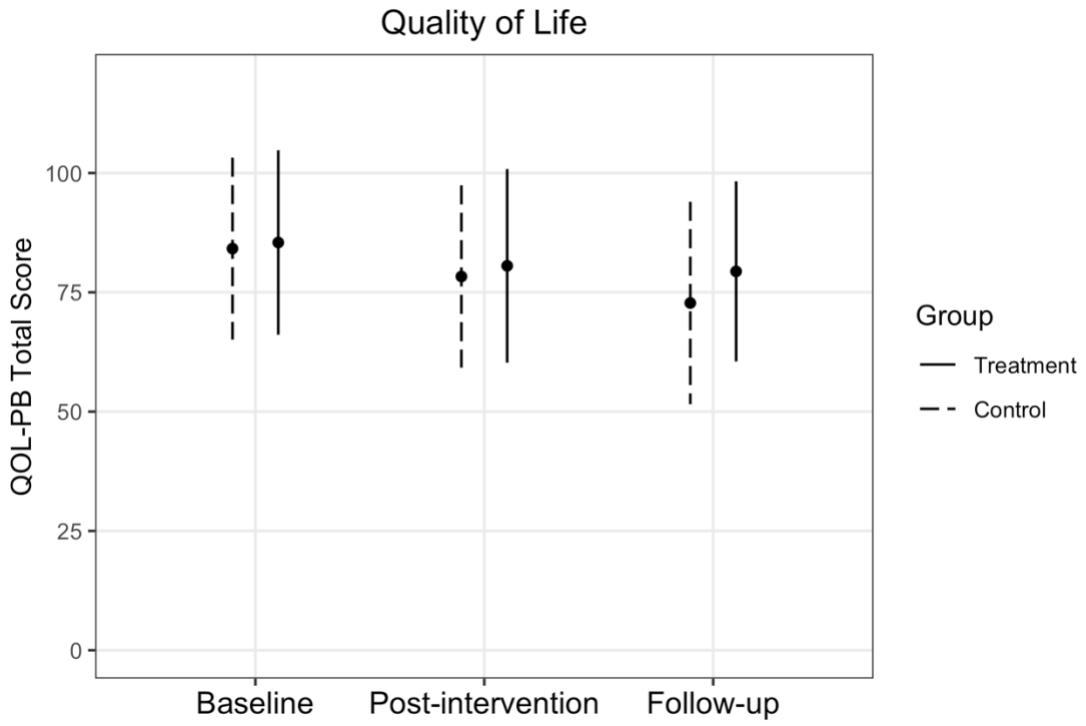

Figure 2: FAQoL-PB scores (range 17-119) by intervention group and time period. Dots indicate mean scores, with lines for standard deviations.

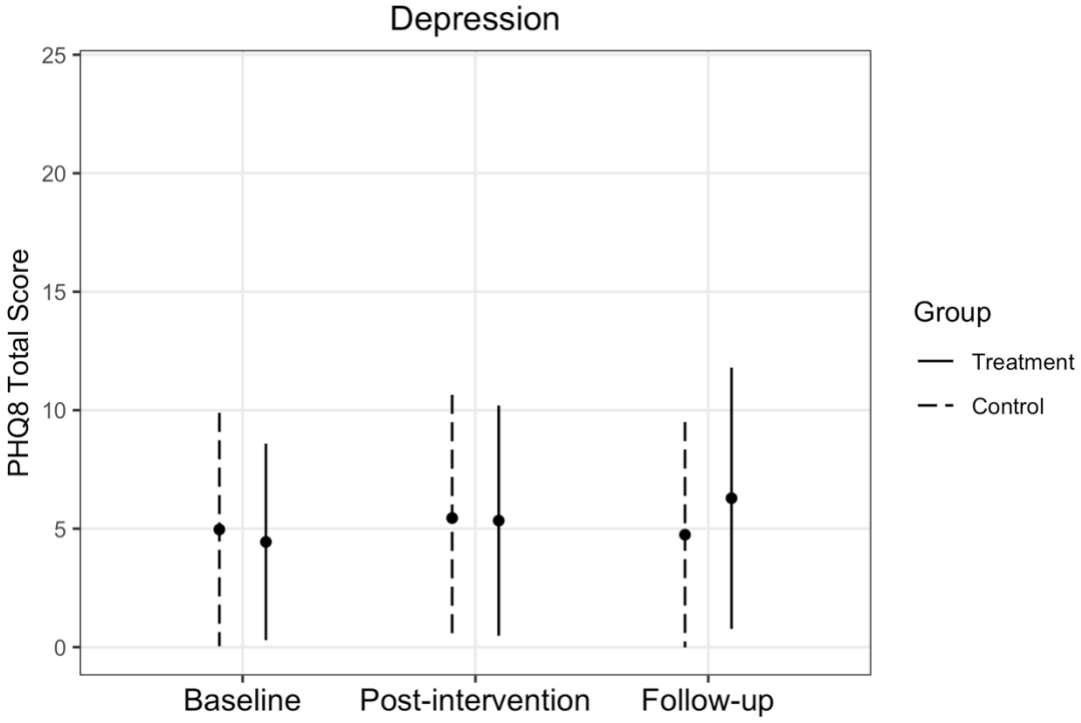

Figure 3: PHQ-8 scores (range 0-24) by intervention group and time period. Dots indicate mean scores, with lines for standard deviations.

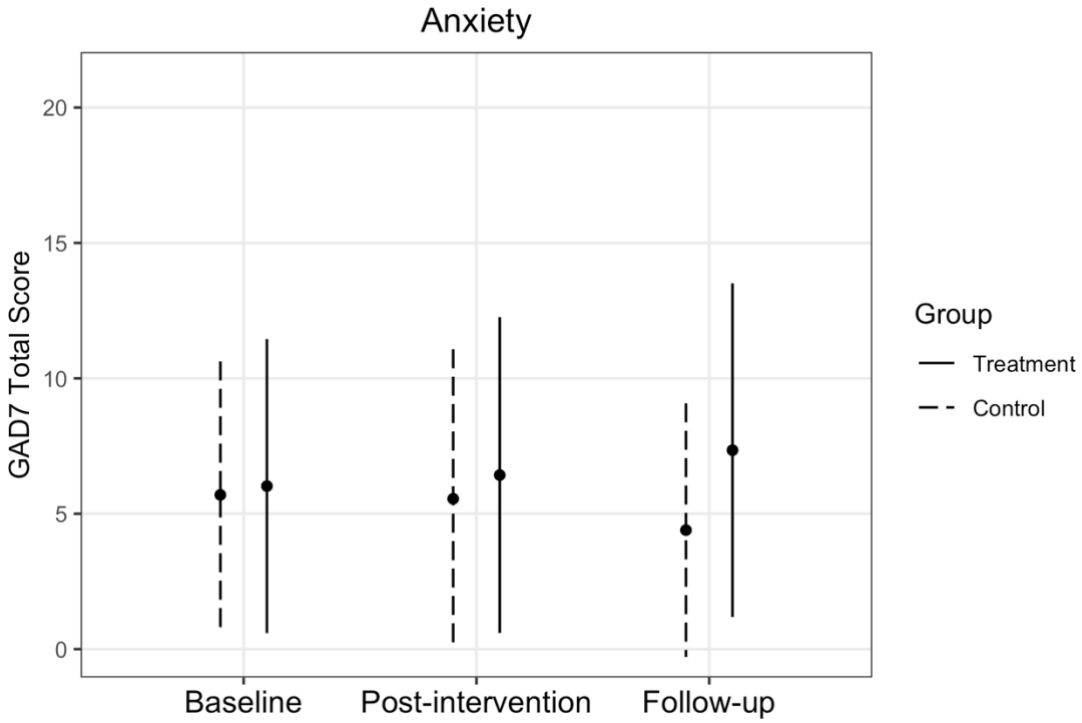

Figure 4: GAD-7 scores (range 0-21) by intervention group and time period. Dots indicate mean scores, with lines for standard deviations.

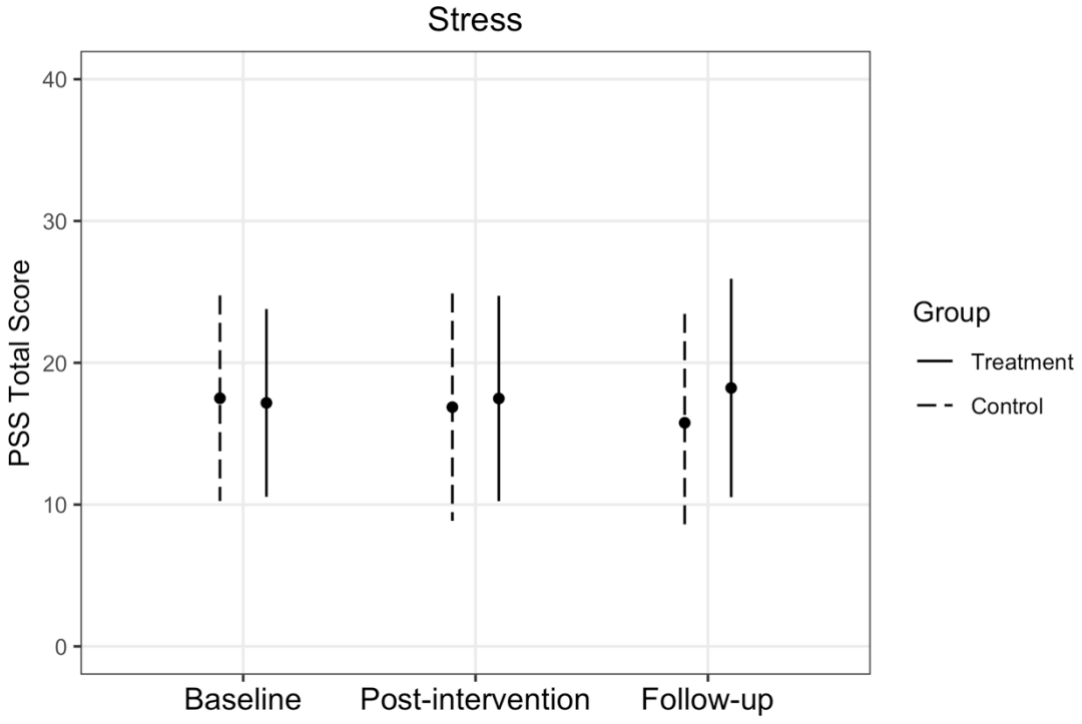

Figure 5: PSS scores (range 0-40) by intervention group and time period. Dots indicate mean scores, with lines for standard deviations.

3.4.1. Mediators.

As analysis of change scores did not find significant differences between the intervention and control groups between baseline (week 0) and either time point (week 4 and week 8), mediation analysis was not justified.

Furthermore, baseline to post-intervention change scores did not differ significantly between intervention and control groups for either of the purported mediators (IUS: U = 1282.000, Z = -0.040, p = .968, r = -0.004; FASE-P: U 1121.000, Z = -1.454, p = .146, r = -0.14). Change scores between baseline and follow-up also did not significantly differ between groups (IUS: U = 811.500, Z = -1.733, p = .083, r = -0.18; FASE-P: U = 969.500, Z = -0.657, p = .511, r = -0.07).

3.4.2. Sub-group analysis.

Given that no intervention effects were found, *post hoc* exploratory analyses were conducted using six variables (Table 5). The goal of this analysis was to determine whether intervention effects were found among respondents for whom the intervention might have been most effective, using baseline outcome measures as well as demographic characteristics associated with experiencing increased burden (e.g., time since diagnosis), as reported in the literature.

For the depression and anxiety variables, clinically significant (≥ 10) sub-groups were constructed using the validated cut-off for the PHQ-8 and the GAD-7, respectively (Kroenke et al., 2009; Löwe et al., 2008). As the FAQoL-PB and PSS did not have validated cut-off points, median values were used to create sub-groups for those with more impaired QoL and high stress. Two final sub-groups were constructed from children with multiple allergies, and from those who had received a diagnosis within the last three years. Although it would have been pertinent to analyse a "newly

diagnosed" subgroup (<1 year), this was not possible due to an insufficient sample size (N=6).

Within each sub-group, change scores in every dependent variable were compared between baseline (week 0) and post-intervention (week 4), between the treatment and control groups.

In those with clinically significant depression, there was a significant difference in change scores on the FAQoL-PB outcome between the intervention and treatment group between baseline and post-intervention (U = 939.000, Z = -2.068, p = .039, r = -.53). Amongst this sub-group of participants with clinically significant depression (N = 15), the intervention group saw a reduction in average FAQoL-PB score from 96.7 (SD = 12.6) to 83.2 (SD = 23.3), in comparison to the control group where the average FAQoL-PB score barely altered (pre mean= 96.5; SD = 11.9; post mean = 96.3; SD = 7.2; Appendix Q). However, this result did not remain significant when a Bonferroni correction for multiple comparisons was applied. This indicates that this result could have occurred as a result of a Type 1 error.

No significant differences in change scores were found between the intervention and control group in any other sub-group (all $p > 0.05$; Table 5).

Table 5: Sub-group analyses, intervention versus control group, between baseline (week 0) and post-intervention (week 4) time points, by dependent variable.

		Quality of Life (FAQoL-PB)		Depression (PHQ-8)		Anxiety (GAD-7)		Stress (PSS)	
Sub-group		**Between group comparisons**	***p*-value**	**Between group comparisons**	***p*-value**	**Between group comparisons**	***p*-value**	**Between group comparisons**	***p*-value**
Quality of Life									
High FAQoL-PB[4] (Score ≥ 68)	N = 45	U = 196.5, Z = -1.079	*p* = .281	U = 240, Z = -0.070	*p* = .944	U = 231.5, Z = - 0.267	*p* = .789	U = 188.5, Z = - 1.266	*p* = .205
Depression									
PHQ ≥ 10	N = 15	U = 9.5, Z = - 0.205	*p* = .036*	U = 26.5, Z = - 0.059	*p* = .953	U = 26, Z = - 0.119	*p* = .905	U = 24, Z = - 0.355	*p* = .722
Anxiety									
GAD ≥ 10	N = 21	U = 34.5, Z = - 0.819	*p* = .413	U = 33, Z = - 0.937	*p* = .349	U = 34.5, Z = -.822	*p* = .411	U = 43, Z = - 0.156	*p* = .876
Perceived Stress									
High PSS (Score ≥ 21)	N = 39	U = 162, Z = - 0.520	*p* = .603	U = 158, Z = - 0.638	*p* = .523	U = 163.5, Z = - 0.477	*p* = .633	U = 177.5, Z = - 0.072	*p* = .942
Multiple Allergies									
Allergy ≥ 2	N = 78	U = 711.5, Z = - 0.485	*p* = .627	U = 710.5, Z = - 0.502	*p* = .616	U = 684.5, Z = - 0.766	*p* = .444	U = 653 Z = -1.073	*p* = .283
Time Since Diagnosis									
≤ 3 years	N = 31	U = 33, Z = - 1.255	*p* = .209	U = 48, Z = - 0.118	*p* = .906	U = 43.5, Z = - 0.467	*p* = .640	U = 46.5 Z = - 0.229	*p* = .819

[4] Higher FAQoL-PB scores indicate more impaired QoL

* Indicates significance p < 0.05

3.5. Engagement and adherence

Website access data were recorded by Google Analytics, however as participants did not create individual accounts it was not possible to track individual participant adherence to the intervention. All participants regardless of group allocation had been given access to the website by January, 2019. Information pertaining to average duration (minutes) spent on the website was collected for the duration of the study (October, 2018- February, 2019) and analysed (Appendix R).

A total of 108 hits on the website were recorded, with an average duration of 2.65 minutes (SD = 5.85). There was a minimum of 0.00 minutes and a maximum of 28.10 minutes duration.

A total of 60 hits recorded an access time of 0.00 minutes, which would not have been sufficient time to view a single page of the website past the log in page. After sub-setting the data to only the hits with a duration longer than zero (00:00+), a total of 48 hits were recorded, and a new average duration of 5.97 (SD = 7.59) minutes spent on the website. The minimum time among this subsample was recorded as 0.28 minutes spent on the website. The distribution of all website access data can be seen in Figure 6.

3.6. Website feedback

Of the initial 205 participants, 35 (17.1%) completed the feedback questionnaire (week 12). Broadly, respondents commented that the web-based support was useful, but reported adherence to the website was low, and corroborated the data taken from Google Analytics reported above. Feedback responses are summarised in Figures 7-10.

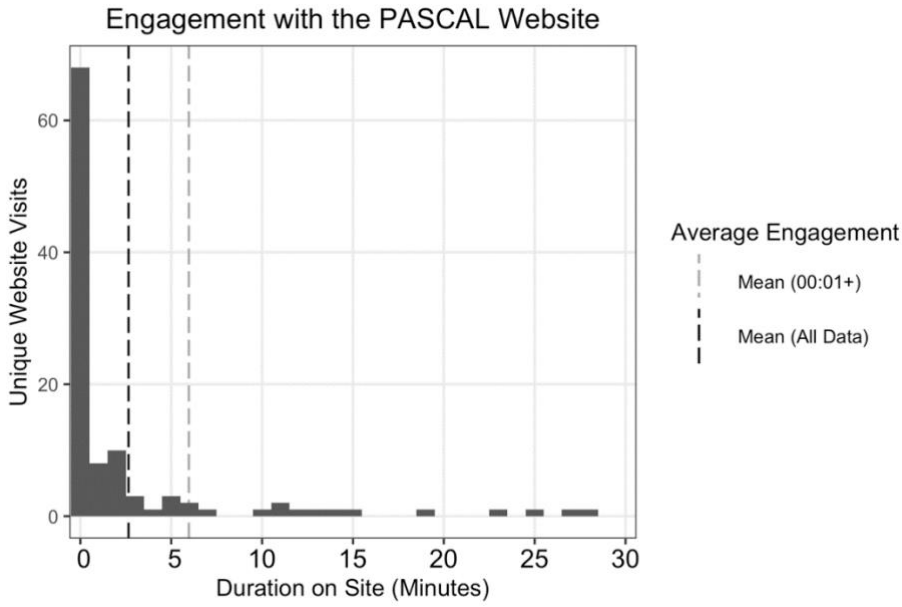

Figure 6: Histogram of website access data between October 2018 and February 2019.

Of the 35 respondents, 21 (60%) stated that they visited the website less than once a month, and six (17%) reported that they had never visited the website (Figure 7). Moreover, 17 (49%) respondents reported that they only spent a few minutes looking at the materials, and 14 (40%) spent less than 30 minutes on the website (Figure 8).

Of the 35 respondents, 77% of participants stated that they either "strongly agreed" or "agreed" that web-based support for parents was useful. No participants stated that they disagreed web-based support was helpful (Figure 9). Additionally, 18 (51%) participants stated that they were "very likely" or "likely" to use the information from the website in the future. A further six (17%) of individuals stated that they were "very unlikely" or "not likely" to use information from the website in the future (Figure 10).

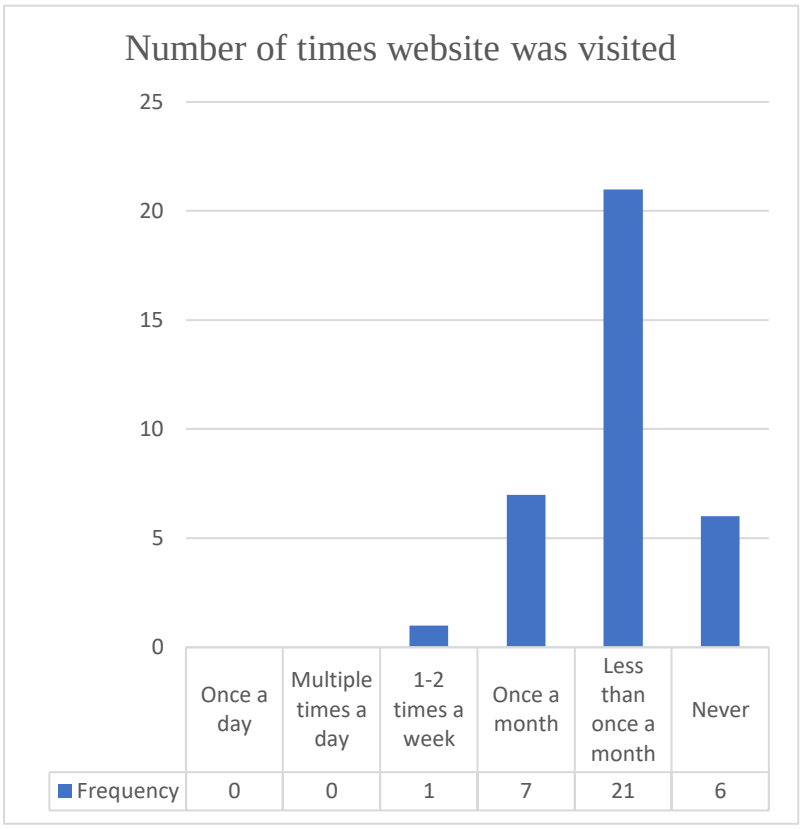

Figure 7: Participant reported website access

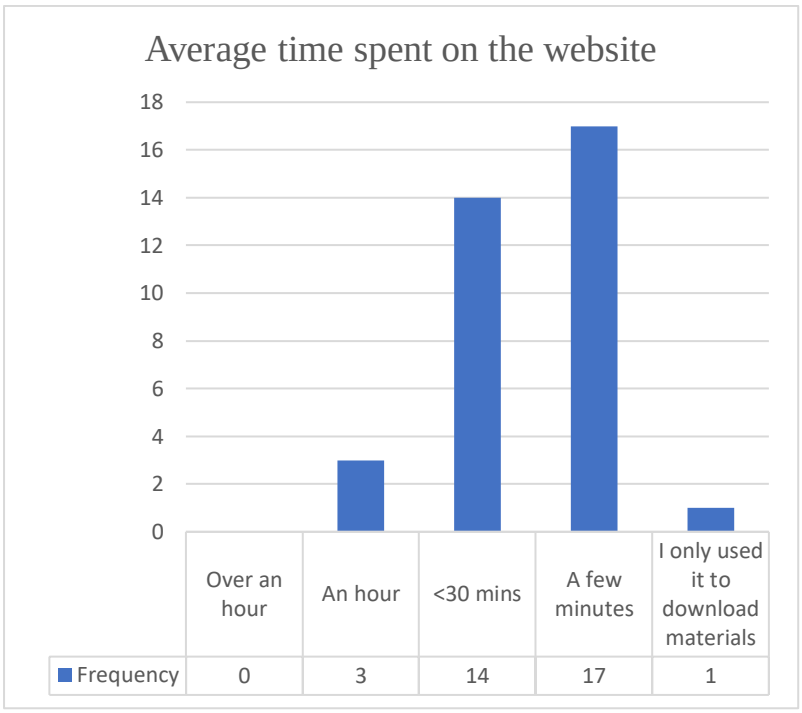

Figure 8: Participant reported time spent on the website

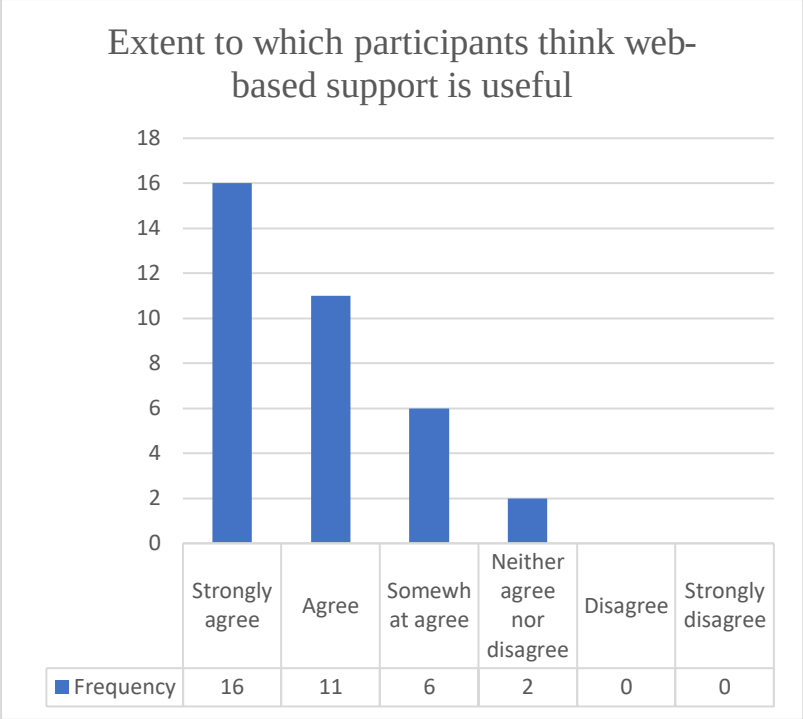

Figure 9: Participant reported acceptability of online support

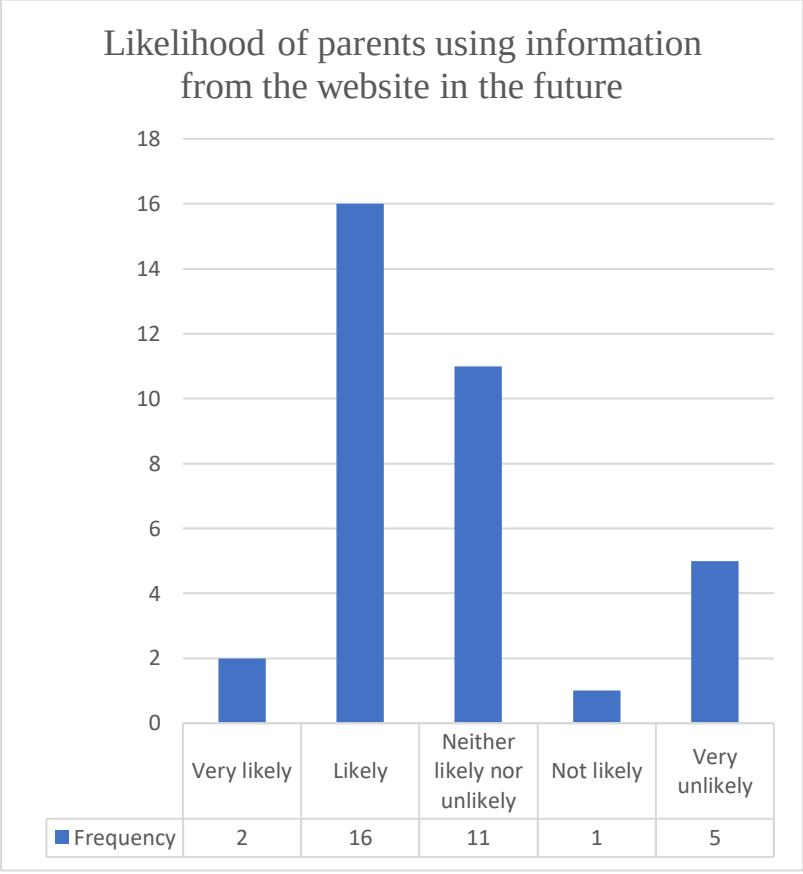

Figure 10: Participant reported continued use of website materials

Table 6: Summary of categories generated for content analysis from open-ended questions

Question	Respondents N (%)	Category	Subcategory	Frequency in comment(s)
What aspect(s) of the website did you find the most useful?	**33 (16%)**	Information provision	Materials/content	8
			Simple/accessible information	13
			Giving materials to others	2
		Psycho-social	Psychological support	1
			Signposting	2
			Normalising	3
		Did not use the website		4
Are there any aspect(s) of the website did you not find useful?	**28 (13.7%)**	Information provision	Too brief or simplistic	4
			Not tailored to local area/not relevant	3
		Functionality		1
		Did not access website		3
		No/not sure		18
Is there anything you think it would be helpful to change about either the website's content or presentation?	**30 (14.6%)**	More detailed information		6
		Support for children		3
		Functionality		2
		No		15
		No access to website		3
Do you have any additional comments about the study or the website?	**31 (15.6%)**	Useful	New to allergies	2
			Attention to the area of allergies	2
		Thanks for the study		2
		No time to review the website		2
		More psychological support		1
		Local support		1
		No additional comment		16
		Didn’t see the website		4

Table 7: Inter-rater reliability for open-ended questions

Question	κ Statistic (SE)	Proportion of maximum possible κ
What aspect(s) of the website did you find the most useful?	$\kappa = 0.76$ (0.09)	1
Are there any aspect(s) of the website did you not find useful?	$\kappa = 0.79$ (0.19)	0.89
Is there anything you think it would be helpful to change about either the website's content or presentation?	$\kappa = 0.86$ (0.14)	1
Do you have any additional comments about the study or the website?	$\kappa = 1$	1

Answers provided to the four open text questions were analysed using content analysis (Appendix S). A descriptive summary of generated categories can be viewed in Table 5. In assessing the reported usefulness of the website, two main categories were identified: usefulness of materials and the accessibility of website content. Of the website materials, the "allergy action plan" was highlighted as being helpful by three participants. Six individuals commented on the easy format of the website, and the convenience of all of the information being centrally located. Other comments highlighted the perceived normalising effect of the study (e.g., *"it confirmed that my anxieties were legitimate")*, or that they had passed the information on to other external carers. Only one individual identified the "stress-management" element as useful.

When asked whether there were aspects of the website they did not find useful, 18 respondents answered "no". Four respondents reported that the content was too brief or lacking in depth. Four respondents commented that the resource may be helpful to those who had a newly diagnosed child, and three stated that they were already well-informed

about allergy management (e.g., "*As we are not new to allergy, we were already very well informed but I think for anyone recently diagnosed it was a very good informative site."*). One individual identified a functional problem with the site (unable to download a document from a signposted website), and another stated that region-specific information would have been valued.

When asked whether there would be anything helpful to change about the website's content or presentation, 15 participants stated that they wanted more detailed and in-depth allergy information. One participant suggested more signposting links, and another wanted more specialised knowledge (e.g., *"Food-dependent, exercise-induced anaphylaxis triggered by co-incidence of culprit food and physical effort."*) Five participants requested additional resources for their food-allergic children.

When asked to provide any additional comments, no single category was most common. Two participants highlighted again that content would be useful for parents with a new diagnosis, and two others stated that any further research relating to allergies was useful. Two individuals stated that they had not had time to review the website adequately.

Inter-rater reliability was calculated using Cohen's kappa (Cohen, 1960). All four questions retained a substantial to almost perfect kappa statistic ($\kappa > 0.76$; Landis & Koch, 1977); these are outlined in Table 6.

4. Discussion

4.1. Overview

The PASCAL website was developed as an informational resource for parents of food-allergic children, with the aim of improving parental food-allergy QoL and reducing psychological distress. Its efficacy was evaluated in a waitlist controlled RCT.

Contrary to the study hypotheses, no significant differences were found between the control and intervention group on change scores for any of the dependent variables (QoL, depression, anxiety or stress), at post-intervention or follow-up. Additionally, no differences were found between the intervention and control group in change scores for either self-efficacy or intolerance of uncertainty.

4.2. Impact on quality of life and wellbeing

To the author's knowledge, this is the first controlled trial of a web-based supportive educational intervention for parents of children with food allergies. Previous research has highlighted that that QoL is impaired in caregivers of children with food allergies (Flokstra-de Bok & Dubois, 2009; Knibb et al., 2016; Valenta et al., 2015; Warren et al., 2016), however there is limited research evaluating interventions that target parental wellbeing or QoL (Ravid et al., 2012; Warren et al., 2016).

Furthermore, to the author's knowledge, there have been no controlled studies targeting QoL through provision of information in this population. Sicherer and colleagues (2012) report that reduced access to educational resources increases parental distress, and some researchers have suggested benefits of educational programmes in improving QoL or mental wellbeing in this population (Ruiz-Baques et al., 2018, Sicherer et al., 2012). However, most existing studies have used educational interventions to improve allergy knowledge, or to improve practical management skills (e.g., AAI administration; Sicherer et al., 2012).

The results of the present study do not provide evidence for the benefits of information provision in improving the wellbeing of caregivers of food-allergic children. It is possible that educational resources do not have a significant effect on parental QoL. However, due to the significant problems with intervention fidelity, other explanations should also be considered.

Hu et al. (2007) states that parental food allergy needs change over time, and that these needs are highly dependent on context (e.g., the basic information desired by parents immediately after a diagnosis likely differs from the specific information needs of parents who are navigating their first holiday abroad). The authors suggest that in provision of information, the extent to which it matches the current needs of parents is as important as the quality and quantity of information. Klinnert and Robinson (2008) report that parental anxiety also fluctuates, and that levels are heightened immediately post-diagnosis. It is possible that the current intervention was not best suited to the needs of the parents enrolled as participants: when considering parent demographic variables, the elapsed time since diagnosis indicated that most enrolled parents were experienced caregivers. Furthermore, a frequent request that emerged from participant feedback was for more in-depth content and the suggestion that the website might be better suited to those new to allergy management.

Additionally, the literature highlights that following diagnosis, most caregivers will see a reduction in their anxiety as they gain knowledge and confidence in their ability to manage their child's allergy (Klinnert & Robinson, 2008). However, there is a suggestion that a small but significant subgroup may experience significant psychological distress. These individuals may resort to "maladaptive" coping strategies to manage, and so might be more likely benefit from a supportive intervention (Klinnert & Robinson, 2008). Despite this, the present study was unable to identify any intervention effects even when analysing participants with the highest baseline scores across all dependent variables. However these sub-groups contained small numbers of participants and were likely not sufficiently powered to identify an effect. Nor could the author ascertain whether intervention effects existed for those with new diagnoses (in the past year) in the present study, as this subgroup was too small (N=6).

Furthermore, as all participants were recruited from existing support groups and social networks, individuals may already have had access to relevant support and resources. This raises some questions about how representative the selected participants were of the broader allergy population, as individuals who are part of online support groups may have different needs to those who are not. Future research should seek to recruit participants using random or stratified sampling strategies in order to reduce the chance of sampling bias.

4.3. Attrition and adherence

Additionally, non-significant results may be related to attrition and adherence. Specifically, data collected via Google Analytics, which was corroborated by participant feedback, indicated that overall adherence to the intervention was poor. It is possible that the intervention was not truly tested as individual participant usage could not be tracked on the website and so a per protocol analysis could not be conducted.

Although web-based support has been identified as an unmet need (Rosen et al., 2014) and has the potential to increase access to support for underrepresented groups (Reger & Gahm, 2009; Richards & Richardson, 2012), other scholars suggest that individuals may regard online information as unreliable and are less likely to seek information on the internet (Alvarez-Perea et al., 2018). However, the fact that participants completed outcome measures at a higher rate than accessing the website suggests a high-level of acceptability for online allergy-focused research. Additionally, participant feedback primarily agreed that web-based support for parents was useful.

Participant feedback also indicated that some individuals did not have time to access the website, so longer follow-up periods in future studies may be beneficial. Others reported that technical difficulties reduced the likelihood of accessing the website (e.g., participants losing the website link and not knowing how to return).

Web-based studies are prone to high attrition rates (Richards & Richardson, 2012). The overall rate in the present study (63.9%) by follow-up is above average for web-based studies as a whole (57%), however remains below rates reported for unsupported self-help interventions (74%; Waller & Gilbody, 2009). Lack of support for participants may be a factor that may have contributed to attrition in this study. Some authors have identified that any contact (e.g., telephone) aids retention in web-based studies, and that benefits are seen even if support is administrative rather than therapeutic (Richards & Richardson, 2012; Spek et al., 2007). Although attempts were made to remind participants to complete outcome measures, limited resources and technical issues meant that it was not possible to remind individuals to access the website or to offer additional therapeutic support. It is possible that attrition occurred because the website was not acceptable or useful, but the majority (77%) of participant feedback responses identified that web-based support is useful.

4.4. Clinical implications

On the basis of the present study and lack of an existing evidence base, there currently is not a basis for recommending online self-help interventions to improve QoL in this population. However, numerous authors have reported that a small but significant sub-group of caregivers of children with food allergies will not see a reduction in anxiety following diagnosis (Klinnert & Robinson, 2008). Given the potentially negative implications of this for the child's outcomes, medical professionals should be aware that these individuals may benefit from additional support or a referral for psychological interventions.

4.5. Limitations

Several limitations of the study should be noted. Although attempts were made to recruit participants from a variety of backgrounds (e.g., via culturally diverse support

groups on social media), the final sample was composed of primarily well-educated, Caucasian, women. The current literature fails to adequately evaluate whether ethnic or racial differences exist within the allergy population. However, growing research has identified disparities between white and non-white families in their access to specialist support (McQuaid, Farrow, Esteban, Jandasek & Rudders, 2015). The generalisability of the current findings is therefore limited, and efforts in future studies should be made to seek the perspectives of underrepresented groups in this literature (e.g., minority groups, fathers).

Additionally, it is unclear whether the selected sample of participants was representative of the wider population of caregivers for individuals with food allergies. Future research should seek to recruit a more representative sample to improve the generalisability of study findings. Furthermore, the post-hoc subgroup analyses were conducted on very small samples, and it is unclear whether these were sufficiently powered to interpret meaningfully. There may be benefits to evaluating the needs of caregivers identified in these subgroups, as those with lower baseline QoL and higher levels of depression and anxiety may be more likely to require psycho-social support.

Whilst attrition levels were not greater than rates reported in other unsupported web-based studies, adherence to the intervention was very low. It would be beneficial to better understand reasons for drop-out or lack of engagement. This might be achieved through increasing support to participants to encourage qualitative feedback. Furthermore, functionality of the website might be addressed to enable individual log-in access and to better monitor adherence.

5. Conclusion

This is the first RCT of a web-based self-help intervention for parents of food-allergic children. Contrary to hypotheses, no significant intervention effects were observed on any

measure at any time point. Furthermore, adherence data indicated that the website was accessed infrequently. These outcomes suggest that the intervention may not be suited to the needs of the broader population of caregivers of food-allergic children. Participant feedback praised the accessibility of website information and suggested that the website content might be more appropriate for parents of newly diagnosed food-allergic children. The results from this study do not provide support for the role of information provision in improving QoL in this population. However, they provide some suggestions for how future interventions could be improved. In particular, in order to more robustly assess the benefits of online information provision for QoL, additional support might be provided to encourage better engagement with such interventions.

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MAJOR RESEARCH PROJECT (MRP) SECTION C: APPENDICES OF SUPPORTING MATERIAL

Appendix A: Mixed Methods Appraisal Tool (MMAT) for reviewed studies

DESIGN	METHODOLOGICAL QUALITY CRITERIA
All types	A) Are there clear qualitative and quantitative research questions (or objectives*), or a clear mixed methods question (or objective*)? B) Do the collected data allow address the research question (objective)? E.g., consider whether the follow-up period is long enough for the outcome to occur (for longitudinal studies or study components).
Qualitative	1.1. Are the sources of qualitative data (archives, documents, informants, observations) relevant to address the research question (objective)? 1.2. Is the process for analyzing qualitative data relevant to address the research question (objective)? 1.3. Is appropriate consideration given to how findings relate to the context, e.g., the setting, in which the data were collected? 1.4. Is appropriate consideration given to how findings relate to researchers' influence, e.g., through their interactions with participants?
Quantitative- Randomised controlled (trials)	2.1. Is there a clear description of the randomization (or an appropriate sequence generation)? 2.2. Is there a clear description of the allocation concealment (or blinding when applicable)? 2.3. Are there complete outcome data (80% or above)? 2.4. Is there low withdrawal/drop-out (below 20%)?
Quantitative non-randomised	3.1. Are participants (organizations) recruited in a way that minimizes selection bias? 3.2. Are measurements appropriate (clear origin, or validity known, or standard instrument; and absence of contamination between groups when appropriate) regarding the exposure/intervention and outcomes? 3.3. In the groups being compared (exposed vs. non-exposed; with intervention vs. without; cases vs. controls), are the participants comparable, or do researchers take into account (control for) the difference between these groups? 3.4. Are there complete outcome data (80% or above), and, when applicable, an acceptable response rate (60% or above), or an acceptable follow-up rate for cohort studies (depending on the duration of follow-up)?
Quantitative descriptive	4.1. Is the sampling strategy relevant to address the quantitative research question (quantitative aspect of the mixed methods question)? 4.2. Is the sample representative of the population understudy? 4.3. Are measurements appropriate (clear origin, or validity known, or standard instrument)? 4.4. Is there an acceptable response rate (60% or above)?
Mixed methods	5.1. Is the mixed methods research design relevant to address the qualitative and quantitative research questions (or objectives), or the qualitative and quantitative aspects of the mixed methods question (or objective)? 5.2. Is the integration of qualitative and quantitative data (or results*) relevant to address the research question (objective)?

		5.3. Is appropriate consideration given to the limitations associated with this integration, e.g., the divergence of qualitative and quantitative data (or results*) in a triangulation design? *Criteria for the qualitative component (1.1 to 1.4), and appropriate criteria for the quantitative component (2.1 to 2.4, or 3.1 to 3.4, or 4.1 to 4.4), must be also applied.*	
Study	Design (type)		Score
1) Maurer, Byrd-Bredbenner, & Grasso (2007)	Single-group pre-test post-test design (Quantitative non-randomised)	A) YES. Authors identified a clear objective for the study: to develop and evaluate an educational campaign aimed at individuals who provide care for food-allergic children. B) YES. The authors recruited a sample of the population in a single US State to evaluate their intervention (n=474). Post-test measures were administered only a week after the campaign, which may have been sufficient to identify any changes to knowledge, however it would not be able to assess the retainment of information without a larger follow-up time period. 3.1) Selection bias was limited in recruitment for the evaluation—individuals were contacted by telephone. Numbers were generated using a "random-digit-dial" procedure that ensured that all state residents were equally likely to be contacted. However the study does not outline what time during the day calls were made, and what efforts were made to access individuals who were difficult to reach. The final sample however was biased towards white (83%), older (59% 50 years or older) women (58%). It is unclear how representative the sample is of the local population, and whether results can be generalised outside of these settings. (*) 3.2) Researchers collected demographic information, and administered an unvalidated 8-item knowledge test based on the campaign materials. Reliability of the knowledge test was ascertained by researchers at pre-test stage (0.77). 3.3) A single group design was used with no comparison or control group. This greatly limits the conclusions that might be drawn from the study, as confounding and external variables could not be controlled for (for example, individuals may have been inspired to complete additional research due to the allergy marketing materials, and a change in score cannot be causally linked to the intervention). 3.4) 474/667 (71%) participants completed the measures at both time points. (*)	**
2) LeBovidge, Timmons, Rich, Rosenstock,		A) YES. Authors identified a clear objective for the study: to develop and evaluate a group intervention for parents and children to	*

Fowler, Strauch, ... & Schneider (2008)	Single-group pre-test post-test design (Quantitative non-randomised)	improve competence in coping with food allergy management. B) YES. Collected data was appropriate to address the objectives of the study. Follow up questionnaires were also sent to participants to better assess with any changes could be maintained. 3.1) Individuals were recruited using opportunistic sampling strategies. All eligible attendees of an allergy programme were invited to attend the workshops. The sample was biased towards parents who could speak English, and had access to healthcare (United States) via insurance. This is reflected in their non-diverse sample, which was primarily white, well-educated, mothers. 3.2) Authors used a mix of unvalidated measures and data was all self-report. Their primary variable (competence) was measured by an unvalidated questionnaire that they had created, but demonstrated good internal reliability (0.91). Parental burden was measured using the FAQL-PB, which is a measured validated for use with UK populations (Knibb & Stalker, 2013). It is also unclear which components of the workshop might have been useful/not useful for attendees. 3.3) A single group design was used with no comparison or control group. This greatly limits the conclusions that might be drawn from the study, as confounding and external variables could not be controlled for and any changes in outcomes cannot be causally linked to the group intervention. 3.4) All individuals who attended the workshop completed measures at Time 1 and 2, and 83% completed measures at follow-up. Authors did not identify any differences between completers and non-completers (based on demographic characteristics, medical information or scores on outcome measures). (*)	
3) Stewart, Letourneau, Masuda, Anderson, & McGhan (2011)	Single-group post-test design (Qualitative)	A) YES. Objectives are not directly stated, however it appears as though authors want to understand the effects of an online peer support group for parents of food-allergic children, and explore whether this support is in line with their support preferences. B) YES. A small sample of 19 parents attended the support group intervention, however the study has been able to adequately answer their question regarding the preferences and experience of this online support group. Results from this group cannot be generalised to other populations and settings. 1.1) Detailed telephone interviews with participants were the only source of data used in this study. Authors indicated that interviews were recorded, transcribed and coded using suitable software. This	**

		was appropriate and relevant to explore the aforementioned research objective. (*) 1.2) Qualitative description and thematic content analysis was used to analyse interview data. Authors briefly describe the development of themes in conjunction with the coding framework derived from the research questions. Authors outline how coding disagreements were addressed, and detailed notes around memos and rationale for codes were kept (although these were not accessible). (*) 1.3) Authors do not discuss the influence of context on their findings. There is little discussion about the role of income, ethnic/racial diversity or geographical location of participants. Authors reflect on the role of complexity in diagnosis and management that influences how useful any single intervention might be. 1.4) Although some consideration is giving to coding practice in analysis, authors do not discuss the role of facilitators or researchers and their influence on findings.	
4) Baptist, Dever, Greenhawt, Polmear-Swendris, McMorris & Clark (2012)	Pilot single blind randomised control trial	A) YES. Researchers identified a clear research question whether FA related QoL in parents of food-allergic children could be improved through a self-regulation intervention. B) MAYBE. Data collected may identify whether an intervention (delivered by a trained clinician) improves self-regulation. Authors also collected data at a 3 month follow up to identify whether changes had been maintained. However all data is reliant on participant self-report, and measure self-efficacy using an unvalidated questionnaire. Additionally the sample consisted of predominantly white, middle class subjects. 2.1) Authors state that individuals were randomly allocated to intervention and control arms, however they fail to detail the randomisation schedule. 2.2.) Authors did not provide a description of the blinding process- it is unclear how this was achieved. 2.3) 47/58 participants were retained (81%) and completed measures at the 3 month follow up. (*) 2.4) 19% participants did not complete the full set of measures. (*)	**
5) Sharma, Prematta, & Fausnight (2012)	Single-group post-test design (Quantitative non-randomised)	A) YES. Authors aimed to evaluate whether having a food allergy specialist present in an allergy support group improves the relationship between parents and their child's allergist and their quality of life. B) NO. Although the questionnaire may provide researchers with some information about the preferences of group members, response rate was very low. Additionally, the questionnaire used was unvalidated so it is unclear whether	

		the research questions posed by authors have been adequately answered. 3.1) All participants identified as Caucasian women and 79% of them had a university education, and it is unclear how representative this sample is of the population. The lack of diversity in the sample means that more diverse narratives are lacking. Participants were recruited via an email mailing list, and self-selected into the study. 3.2) Participants were provided with an unvalidated 30-item questionnaire devised by study authors. A sample of this questionnaire was not provided, and it is unclear whether questions collected quantitative data or whether they asked for some qualitative feedback. 3.3) The study did not include a control or comparison group, greatly limiting authors' ability to make any claims of causality. 3.4) Only 29.6% of contacted attendees completed the questionnaire, leaving the study with a small sample size.	
6) Sicherer, Vargas, Groetch, Christie, Carlisle, Noone & Jones (2012)	Single-group pre-test post-test design (Quantitative non-randomised)	A) YES. The authors aimed to develop and evaluate a food allergy education programme. Their primary measure was correct administration of an auto-injector. Secondary outcomes were comfort with auto-injector administration and a reduction in allergic reactions. B) YES. The authors considered the necessary numbers of participants for the study, and accounted for predicted attrition. They completed follow-up 1 year later, and found that improvements had been maintained. 3.1) The study used a convenience sample of parents presenting at an allergy clinic. Although the sample was primarily Caucasian (81%), minority groups were better represented than other studies in the area with 17% African American's, 2% Asian, 3% Hispanic. The sample also consisted of mostly well-educated individuals from middle class backgrounds. 3.2) Recorded outcomes for food-allergy knowledge, demographic information, auto-injector competency and comfort were appropriate to answer the question posed by researchers. However, outcomes were gathered using (unvalidated) measures devised by the authors, and thus difficult to replicate. It is unclear how valid or reliable these measures were. As there was no control group, it is not possible to make causal claims about the efficacy of the study's intervention. 3.3) The study did not include a control or comparison group, greatly limiting authors' ability to make any claims of causality. 3.4) All 60 participants completed measures at Time 1 and Time 2. 33 (55%) of these participants were retained at the 1 year follow up. (*)	*

7) Knibb & Semper (2013)	Single-group pre-test post-test observational design (Quantitative non-randomised)	A) YES. Authors aimed to evaluate parental anxiety and depression in parents before and after a visit to an allergy clinic in order to ascertain whether the provision of a diagnosis influenced parental wellbeing. B) YES/MAYBE. Data were appropriate to answer the question posed, however there was a short follow up period, and problems with the study design mean that it authors cannot determine whether any changes or lack of changes are associated with the visit to the clinic. 3.1) The study used a convenience sample- parents attending an allergy clinic were approached in the waiting room and given information about the study. The sample consisted of mainly white British (77.6%) mothers (80%). Authors did not attempt to minimise selection bias. 3.2) Authors gathered information about allergy knowledge and management behaviours using a self-devised questionnaire, but an established and validated measure (Hospital Anxiety and Depression Scale [HADS]) was used to measure levels of anxiety and depression. The authors compared their responses to norm data from a clinical sample of parents of children with a chronic illness. (*) 3.3) The study did not include a control or comparison group, greatly limiting authors' ability to make any claims of causality. 3.4) Sample consisted of 124 individuals at pre-test and post-test, and 50 individuals (40%) responded at follow up, 6 weeks later. This follow up period may have been too short for any effect to be noticed.	*
8) Rosen, Albin & Sicherer (2014)	Single-group pre-test post-test design (Quantitative descriptive study)	A) YES. The study aimed to create, validate and evaluate web-based audio-visual educational materials for parents of food-allergic children. B) YES. Data were suitable to answer the question posed by researchers, but problems with the study design limit the conclusions that can be drawn from the study. 4.1) A convenience sample (n=50) was recruited from a hospital-based allergy clinic in NY, USA. The authors did not take action to reduce sampling bias, however they ensured that the sample validating their educational materials had not been involved in the development of the content. 4.2) Although the sample was predominantly White (66%), some ethnic and racial diversity was represented with 12% of the sample identifying as Black, 12% as Asian and 8% as other. 94% of the sample had college/university degrees, and 82% reported a household income above $80,000 per year. 4.3) The authors sought to validate their educational materials using pre and post knowledge tests, and	**

		ascertain satisfaction with the materials using a likert-scale based questionnaires devised by the authors. These measures were based on needs assessments and consultation with allergy experts. These measures were appropriate. (*) 4.4) The 50 participants were recruited in order to adequately power the study. All participants completed the measures before and after viewing educational materials. The study would have benefitted from a follow up to ascertain whether knowledge improvements were maintained. (*)	
9) Knibb (2015)	Non-randomised case control study (Quantitative non-randomised)	A) YES. The study had a clear aim to examine the appropriateness and effectiveness of CBT to improve psychological outcomes in parents of food-allergic children. B) YES. The collected data are appropriate to address the question posed by researchers. 3.1) All participants were recruited from a local allergy clinic (Midlands, UK). All participants were included under the constraints of the same exclusion and inclusion criteria. However, the sample was small, and not representative of the local population; all participants were white women. 3.2) All outcomes were measured using established and validated measures of depression, anxiety, stress, parental burden and quality of life. These measures were appropriate to answer the question posed by the researchers. However, for ethical reasons participants self-selected into the experimental or control group. Although the control group participants opted in to the control group because they were not interested in CBT (and those currently accessing psychological support were excluded), it is possible that these could have sought support during the course of the study. However, there was no indication that individuals could have been exposed to the treatment(*) 3.3) Authors considered differences across groups, and reported descriptives. No obvious differences existed between groups, except for in numbers of egg and tree nut allergy. They were unable to check for statistical differences between groups due to small sample size. (*) 3.4) No participants withdrew from the study, but 2 (18%) participants were lost to follow-up. (*)	***
10) Polloni Lazzarotto, Bonaguro, Toniolo, Celegato & Muraro (2015)	Single-group post-test design (Quantitative descriptive studies)	A) YES. Authors aimed to investigate psychological treatments offered to food-allergic children and their families. B) YES. The collected data addresses the question raised by researchers. 4.1) Participants were selected by convenience- the first 100 consecutive treatments held at an allergy research centre in Italy were chosen. This service is dedicated to providing support for families and	

		patients to alleviate the psycho-social burden of food allergy. Data were collected from hospital records. (*) 4.2) Demographic details of the sample were not reported, so it is not possible to determine whether the sample was representative. The study did not describe inclusion or exclusion criteria as sample was drawn from the group of interest. 4.3) Effectiveness of treatments were measured using a 2-question adaptation of the follow up questions to the strengths and difficulties questionnaire. It is unclear whether any other outcome measures were used, and authors did not identify or make comparisons between treatment types. 4.4) Not applicable as the study drew from pre-reported data.	
11) Wahl, Stephens, Ruffo & Jones (2015)	Single-group post-test design (Quantitative descriptive study)	A) YES. Study aims were clear: to develop and evaluate the effectiveness of educational workshops in improving QoL and self-efficacy in food-allergic children and their caregivers. B) YES/MAYBE. Participants completed appropriate measures at three time points following their attendance at a workshop. These were appropriate in answering the questions posed by the researchers. 3.1) Authors did not select participants based on explicit criteria. Details of the workshops were mailed to school nurses, administrators and child-care centres in the Greater Seattle area. Researchers conducted 247 presentations, with a total of 4818 attendees. No inclusion or exclusion criteria was noted, and all interested caregivers were invited to attend. Demographic data was not reported, so ethic/racial diversity and average income is unknown. Primary attendees were teachers. 3.2) All outcomes were measured using self-report questionnaires about reported confidence in use of workshop content (e.g. administering auto-injectors, recognising symptoms), and no validated or objective measure of increased knowledge (e.g. knowledge test) was administered, although some questions aiming to measure knowledge retention and a request for participants to identify "three key messages" was asked at the secondary online survey. It is unclear what questions were asked. Furthermore, authors adjusted a question "whether they were likely to change the way they managed children with food allergies" so that earlier forms of the questionnaire had additional options that were later removed for participants in order to simplify the survey. 3.3) The authors did not use a control or comparison group. Additionally, the lack of pre-intervention measures further impacts the ability to draw conclusions about the effectiveness of the study and make any causal claims.	

		3.4) The study started with a sample size of 4818 attendees. Although 1586 (33%) individuals consented to being contacted for the second questionnaire, only 332 (21%) of individuals completed this measure. 94 (29%) of respondents at time 2 indicated that they had been involved in a food allergy incident and 53 of these individuals completed a phone interview (time 3).	
12) Contreras-Porta, Ruiz-Baqués, Hortal, Torres, Pla, Santisteban, & de la Maza (2016)	Single-group pre-test post-test design (Quantitative descriptive study)	A) YES. The authors aimed to develop and evaluate an educational programme for families of food-allergic children. B) YES. The data collected are appropriate to answer the question posed by the researchers. 3.1) Authors recruited participants from 7 different urban locations in Spain, via social media networks (opportunistic sampling). Individuals were recruited through "patient association" networks, where members would have already had information about appropriate allergy management. The majority of the sample were mothers (56%, with 36% fathers and 4.9% caregivers. Details around income or ethnic/racial diversity was reported. It is unclear how representative the sample is. 3.2) Authors identified a lack of validated measures pre-existing in the literature. They created an ad-hoc questionnaire based on bibliographic review and expert opinion. The questionnaire consisted of 40 items, and all items were explicitly addressed in the intervention/educational programme. (*) 3.3) The study did not include a control or comparison group, greatly limiting authors' ability to make any claims of causality. 3.4) The study retained 174/184 (94%) across both workshops. (*)	**
13) Danchin, De Bono, Allen, Tang & Hiscock (2016)	Single-group pre-test post-test design (Quantitative descriptive study)	A) YES. Authors aimed to develop a training programme for community-based general paediatricians to increase acceptable support for families waiting for specialist input. B) YES. Collected data are appropriate to address the question posed by researchers. 3.1) Paediatricians were recruited from a paediatric research network, and had expressed an interest in allergy research (with no prior experience in management). They were all experienced clinicians with an 18.2 years of experience since qualification. Family participants were recruited from the hospital's pre-existing waiting list. Individuals were excluded children over the age of 7, those with multiple (>3 allergies) and diagnosed anaphylaxis and previous specialist input. As the study used an opportunistic sampling method, they were unable to minimise sampling bias. Some demographic characteristics were recorded, but no information on ethnic or racial diversity was reported.	*

		3.2) Paediatrician participants completed a pretraining survey at baseline and 3 months post training, and allergy knowledge was assessed with an established research survey. Families also completed measures at baseline and follow up, and outcomes were measured using validated anxiety and depression questionnaires. Authors also calculated socio-economic status using an index calculator. (*) 3.3) The study did not include a control or comparison group, greatly limiting authors' ability to make any claims of causality. 3.4) All families completed baseline measures, and 82% returned the follow up survey. All clinicians returned both measures.	
14) Boyle, Umasunthar, Smith, Hanna, Procktor, Phillips,... & Vickers (2017)	Randomised Control Trial (Quantitative randomised control trial)	A) YES. Authors reported the results from a prospective RCT for a brief CBT intervention in mothers of food-allergic children aiming to reduce state anxiety. B) YES. Collected data is appropriate to answer the questions posed by researchers. 2.1) Yes, authors identify that randomisation occurred in computer generated blocks of 4, stratified by maternal state. Randomisation was completed by an independent statistician. (*) 2.2) Researchers were unable to blind clinicians, participants or outcome assessors. They attempted to increase validity of the self-reported outcome data by also collected an objective measure of stress (salivary samples). (*) 2.3) 83% of participants contributed to all of the measures at one year (165/200) (*) 2.4) Drop-out was low, reported at 17% at one year. (*)	****
15) Ruiz-Baques, Contreras-Porta, Marques-Mejias, Cárdenas, Capel, Ariño, ... & Chivato (2018)	Single-group pre-test post-test design (Quantitative descriptive study)	A) Authors aimed to develop an educational programme aimed at parents of food-allergic children and evaluate the effectiveness of said programme. B) Data were appropriate to address the question posed by the researchers. 3.1) Authors did not report the applied inclusion and exclusion criteria for the study, and recruited participants by encouraging them to pre-register to take part in the educational programme and complete pre-test questionnaires. The sample was 75% mothers, 15% fathers and 10% caregivers and all were recruited from Spain. Authors did not report any other demographic characteristics of participants, so it is unclear how representative the sample is. 3.2) Educational materials were developed with the support of researchers and allergy specialists. The authors on the lack of specific validated measures, so assessed outcomes using an ad-hoc questionnaire based on a literature review and of the opinions of allergy specialists. The 40 item questionnaire was	**

		designed to evaluate food allergy knowledge and assess the impact of the online programme. (*) 3.3) The study did not include a control or comparison group, greatly limiting authors' ability to make any claims of causality. 3.4) 130/207 individuals completed the educational intervention and completed measures pre- and post-test (63%). (*)	

Appendix B: Completed Cochrane Risk of Bias Tool for Randomised Control Trials

Study details

Reference	Boyle, R. J., Umasunthar, T., Smith, J. G., Hanna, H., Procktor, A., Phillips, K., ... & Vickers, B. (2017). A brief psychological intervention for mothers of children with food allergy can change risk perception and reduce anxiety: Outcomes of a randomized controlled trial. *Clinical & Experimental Allergy*, *47*(10), 1309-1317. **https://doi.org/10.1111/cea.12981**

Study design

- ☒ Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias	Maternal Trait Anxiety, Perceived risk of fata; anaphylaxis, perceived risk of any fatality
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Table 3

Is the review team's aim for this result…?

- ☐ to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☒ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☒ Journal article(s) with results of the trial

☐	Trial protocol
☐	Statistical analysis plan (SAP)
☐	Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐	Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐	“Grey literature” (e.g. unpublished thesis)
☐	Conference abstract(s) about the trial
☐	Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐	Research ethics application
☐	Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐	Personal communication with trialist
☐	Personal communication with the sponsor

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Description	Response options
1.1 Was the allocation sequence random?	Yes, allocation sequence was random. Authors identify that randomisation occurred in computer generated blocks of 4, stratified by maternal state. Randomisation was completed by an independent statistician.	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Groups were similar at baseline.	N
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias arising from the randomization process?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?	It was not possible to blind participants, clinicians or outcome assessors to treatment allocation.	Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?		N
2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?		NA
2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Appropriate statistical analyses were used.	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA

Risk-of-bias judgement	Some risk of bias exists, as authors were not able to blind participants or clinicians to treatment groups. However, the study attempted to increase validity of the results by collecting complementary objective measures of anxiety (salivary samples).	Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?	It was not possible to blind participants, clinicians or outcome assessors to treatment allocation.	Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were important co-interventions balanced across intervention groups?		NA
2.4. Could failures in implementing the intervention have affected the outcome?	Implementation of the intervention was successful for most of the participants.	N
2.5. Did study participants adhere to the assigned intervention regimen?		PY
2.6. If N/PN/NI to 2.3 or 2.5 or Y/PY/NI to 2.4: Was an appropriate analysis used to estimate the effect of adhering to the intervention?		NA
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Description	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		Y
3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?		NA
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	Authors identify reasons for missing data	PN
3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?	N=80 in experimental group, 9 lost to follow up, 3 withdrew (bereavement, time pressure) N=85 in control group, 4 lost to follow up, 1 withdrew	PN
3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Description	Response options
4.1 Was the method of measuring the outcome inappropriate?		N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?		PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?		Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	Although additional objective measures were also collected (salivary responses) for the primary outcome (anxiety).	PY
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Description	Response options
5.1 Was the trial analysed in accordance with a pre-specified plan that was finalized before unblinded outcome data were available for analysis ?		NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		N
5.3 ... multiple analyses of the data?		N
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to selection of the reported result?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement	The study suffers from some methodological concerns which may have resulted in biased results- namely the inability to blind participants, experimenters and outcome assessors. Additionally, outcome measures are primarily self-report measures, and an additional source for data (saliva) was only sought for one of the outcome measures. However, authors have attempted to reduce bias where possible, and have reported processes appropriately.	Low/Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Study details

Reference	Baptist, A. P., Dever, S. I., Greenhawt, M. J., Polmear-Swendris, N., McMorris, M. S., & Clark, N. M. (2012). A self-regulation intervention can improve quality of life for families with food allergy. Journal of Allergy and Clinical Immunology, 130(1), 263-265. DOI: https://doi.org/10.1016/j.jaci.2012.03.029

Study design

- ☒ Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias	Food allergy quality of life, self-efficacy
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Table E5-E6

Is the review team's aim for this result…?

- ☒ to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☒ Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)

☐	Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐	Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐	“Grey literature” (e.g. unpublished thesis)
☐	Conference abstract(s) about the trial
☐	Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐	Research ethics application
☐	Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐	Personal communication with trialist
☐	Personal communication with the sponsor

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Description	Response options
1.1 Was the allocation sequence random?	No information about the randomisation process was reported.	PY
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Some differences are observed related to ethnicity however this is not commented on.	PY
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Authors indicate that the study is blind, but provides no further details. It would not have been possible to blind intervention facilitators to the control vs treatment.	PN
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?		PN
2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?		NA
2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA

Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?		PN
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were important co-interventions balanced across intervention groups?		NA
2.4. Could failures in implementing the intervention have affected the outcome?		PN
2.5. Did study participants adhere to the assigned intervention regimen?	Authors do not report on adherence	NI
2.6. If N/PN/NI to 2.3 or 2.5 or Y/PY/NI to 2.4: Was an appropriate analysis used to estimate the effect of adhering to the intervention?		NI
Risk-of-bias judgement		Low /Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Description	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		NI
3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?		N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NI
3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?		NI
3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NI
Risk-of-bias judgement	As authors did not report on missing data it is difficult to ascertain risk of bias in this domain.	Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Description	Response options
4.1 Was the method of measuring the outcome inappropriate?	However one of the measures (self-efficacy) was measured using an unvalidated questionnaire devised by authors.	PY/PN
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?		PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?	Outcomes were self-report.	Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		PN
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA
Risk-of-bias judgement		Low /Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Description	Response options
5.1 Was the trial analysed in accordance with a pre-specified plan that was finalized before unblinded outcome data were available for analysis?		NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		NI
5.3 ... multiple analyses of the data?		NI
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement	The study has some methodological issues, and often fails to report processes which decreases the confidence in reported results.	Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

APPENDIX C: Registered trial protocol on clinicaltrials.gov

Exploring the Effectiveness of Online Self-help for Parents of Children With Food Allergies

ClinicalTrials.gov Identifier: NCT03529747

Recruitment Status : Enrolling by invitation
First Posted : May 18, 2018
Last Update Posted : July 17, 2018

Sponsor:
Canterbury Christ Church University

Collaborator:
Brighton & Sussex Medical School

Information provided by (Responsible Party):
Canterbury Christ Church University

Study Description

Go to

Brief Summary:
This study aims to conduct an initial evaluation of whether online self-help can improve the quality of life of parents of children with food allergies.

Condition or disease	Intervention/treatment	Phase
The Well Being of Parents of Children With Food Allergies	Other: Online self-help	Not Applicable

Detailed Description:
This study is a pilot randomised controlled trial (RCT) comparing online self-help for parents of children with food allergies with a wait-list control. A battery of self-report measures will be administered online at baseline (week 0), post-intervention (week 5) and at follow-up (week 9).

Study Design

Go to

Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	150 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Single (Outcomes Assessor)
Primary Purpose:	Supportive Care
Official Title:	Exploring the Effectiveness of Online Self-help for Parents of Children With Food Allergies
Estimated Study Start Date :	August 2018
Estimated Primary Completion Date :	April 2019
Estimated Study Completion Date :	April 2019

Resource links provided by the National Library of Medicine NIH NLM

MedlinePlus related topics: Allergy Food Allergy

U.S. FDA Resources

Arms and Interventions

Go to

Arm	Intervention/treatment
Experimental: Online self-help A website providing information and psycho-education aimed at parents and carers of children with food allergies.	Other: Online self-help As detailed in experimental arm description.
No Intervention: Wait list control A waiting list control group, who will receive access to the online self-help once the RCT is complete.	

Outcome Measures Go to

Primary Outcome Measures :

1. Change from baseline at 5-weeks on the Food Allergy Quality of Life Parental Burden scale [Time Frame: Post-intervention (5-weeks after baseline)]

   This measures parental burden when caring for a food-allergic child, producing a score between 17 and 119, with higher scores indicating greater burden.

Secondary Outcome Measures :

1. Change from baseline at 9-weeks on the Food Allergy Quality of Life Parental Burden scale [Time Frame: Follow-up (9-weeks after baseline)]

   This measures parental burden when caring for a food-allergic child, producing a score between 17 and 119, with higher scores indicating greater burden.

2. Change from baseline at 5-weeks on the Patient Health Questionnaire depression scale 8 [Time Frame: Post-intervention (5-weeks after baseline)]

   This measures symptoms of depression, producing a score between 0 and 24, with higher scores indicating greater symptomatology.

3. Change from baseline at 9-weeks on the Patient Health Questionnaire depression scale 8 [Time Frame: Follow-up (9-weeks after baseline)]

   This measures symptoms of depression, producing a score between 0 and 24, with higher scores indicating greater symptomatology.

4. Change from baseline at 5-weeks on the Generalised Anxiety Disorder 7 scale [Time Frame: Post-intervention (5-weeks after baseline)]

   This measures symptoms of generalised anxiety disorder, producing a score between 0 and 21, with higher scores indicating greater symptomatology.

5. Change from baseline at 9-weeks on the Generalised Anxiety Disorder 7 scale [Time Frame: Follow-up (9-weeks after baseline)]

   This measures symptoms of generalised anxiety disorder, producing a score between 0 and 21, with higher scores indicating greater symptomatology.

6. Change from baseline at 5-weeks on the Perceived Stress Scale (10 items) [Time Frame: Post-intervention (5-weeks after baseline)]

   This produces a score between 0 and 40, with higher scores indicating higher levels of perceived stress.

7. Change from baseline at 9-weeks on the Perceived Stress Scale (10 items) [Time Frame: Follow-up (9-weeks after baseline)]

   This produces a score between 0 and 40, with higher scores indicating higher levels of perceived stress.

Other Outcome Measures:

1. Change from baseline at 5-weeks on the Food Allergy Self-Efficacy Scale for Parents [Time Frame: Post-intervention (5-weeks after baseline)]

   This measures a parent's confidence in managing their child's food allergy, producing a score between 0 and 100, with higher scores indicating greater confidence.

2. Change from baseline at 9-weeks on the Food Allergy Self-Efficacy Scale for Parents [Time Frame: Follow-up (9-weeks after baseline)]

   This measures a parent's confidence in managing their child's food allergy, producing a score between 0 and 100, with higher scores indicating greater confidence.

3. Change from baseline at 5-weeks on the Intolerance of Uncertainty Scale [Time Frame: Post-intervention (5-weeks after baseline)]

   This measures participants' ability to tolerate uncertainty, producing scores between 27 and 135, with higher scores indicating lower tolerance of uncertainty.

4. Change from baseline at 9-weeks on the Intolerance of Uncertainty Scale [Time Frame: Follow-up (9-weeks after baseline)]

   This measures participants' ability to tolerate uncertainty, producing scores between 27 and 135, with higher scores indicating lower tolerance of uncertainty.

Eligibility Criteria

Go to

Information from the National Library of Medicine NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

- Being a parent of at least one child (under the age of 18) who has a food allergy.
- Adequate understanding of written English.

Exclusion Criteria:

- Having consulted on the design of the self-help website.

Contacts and Locations

Go to

Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03529747***

Locations

United Kingdom

Salomons Centre for Applied Psychology, Canterbury Christ Church University
Tunbridge Wells, Kent, United Kingdom, TN1 2YG

Sponsors and Collaborators

Canterbury Christ Church University

Brighton & Sussex Medical School

Investigators

Principal Investigator:	Naomi Sugunasingha, BSc, PGCert	Canterbury Christ Church University
Study Director:	Fergal Jones, PhD, PsychD	Canterbury Christ Church University
Study Director:	Christina Jones, PhD	Brighton & Sussex Medical School

More Information

Go to

Responsible Party:	Canterbury Christ Church University
ClinicalTrials.gov Identifier:	NCT03529747 History of Changes
Other Study ID Numbers:	NaomiSugunasinghaMRP2017
First Posted:	May 18, 2018 Key Record Dates
Last Update Posted:	July 17, 2018
Last Verified:	July 2018

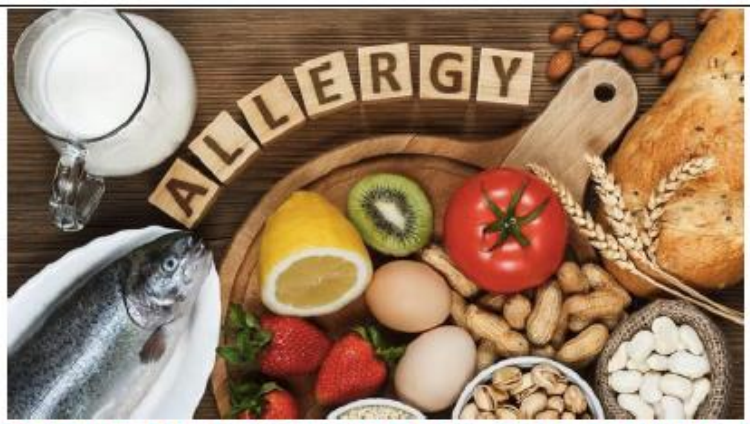
Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: Undecided

Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:
Hypersensitivity
Food Hypersensitivity
Immune System Diseases
Hypersensitivity, Immediate

APPENDIX D: Study Advertisements for recruitment

Picture advertisement used on Facebook



ARE YOU THE PARENT OF A CHILD WITH A FOOD-ALLERGY?

Take part in a new study developing an online self-help resource.

Caring for a child with an allergy can be demanding and, many parents can experience higher levels of stress and worry. As a part of research at Canterbury Christ Church University I am designing a self-help website to support parents of children with food allergies. The website has been created in consultation with an allergy specialist, and we would like your feedback. Our hope is that this website will provide you with information to help you to support your child in their day-to-day lives, and to give you some techniques to cope when you are feeling stressed.

This study will begin in September 2018, and you will be able to get involved from the comfort of your own home. **If you would like to learn more about the study, please follow the link and find out if you are eligible to participate.** PascalStudy

Many thanks for your interest!

APPENDIX D: Study advertisements continued.

Social media recruiting

Facebook summary/advertisement:

Are you the parent of a child with a food-allergy? With the help of an allergy specialist, we are developing a self-help website, that we hope will support the management of stress and worry we know is common in carers of children with allergies. If you are interested in trialling the website, please click the following link to see if you are eligible:
PascalStudy

Twitter advertisement:

Are you a parent of a child with a food allergy? Find out about an online self-help website here: PascalStudy

Lay summary to send to third parties (e.g. Anaphylaxis Campaign, Allergy UK):

We are increasingly aware of the stress and worry associated with caring for a food-allergic child, and the limited amount of support available to these individuals.

This randomised controlled trial (RCT) will explore whether parents of food-allergic children might benefit from online support. This has been registered as a pilot RCT; see https://clinicaltrials.gov/ct2/show/NCT03529747. The study has been peer-reviewed, and ethical approval gained from the Canterbury Christ Church University ethics panel.

Participants will be asked to trial a self-help website, and to feed back whether the website has helped them to manage anxiety or stress. The website content has been developed in consultation with a service user group, as well as professionals specialising in allergies. We expect that the website will provide self-help guidance for managing anxiety and stress related to having a child with a food allergy. Researchers will consult with both service user representatives and an allergy specialist for the duration of the project.

We hope that the study will enable future research in this area and encourage the provision of increased support for food-allergic children.

We would like to recruit participants through the Allergy UK/Anaphylaxis Campaign websites and social media.

APPENDIX E: G* Power output

```
                        [1] -- Sunday, March 03, 2019 -- 15:02:
t tests - Means: Wilcoxon-Mann-Whitney test (two groups)

Options:    A.R.E. method

Analysis:   A priori: Compute required sample size
Input:      Tail(s)                          =   One
            Parent distribution              =   Normal
            Effect size d                    =   0.8
            α err prob                       =   0.05
            Power (1-β err prob)             =   0.95
            Allocation ratio N2/N1           =   1
Output:     Noncentrality parameter δ        =   3.3624942
            Critical t                       =   1.6673493
            Df                               =   68.6647947
            Sample size group 1              =   37
            Sample size group 2              =   37
            Total sample size                =   74
            Actual power                     =   0.9539314


[2] -- Sunday, March 03, 2019 -- 15:02:32
t tests - Means: Wilcoxon-Mann-Whitney test (two groups)

Options:    A.R.E. method

Analysis:   A priori: Compute required sample size
Input:      Tail(s)                          =   One
            Parent distribution              =   Normal
            Effect size d                    =   0.68
            α err prob                       =   0.05
            Power (1-β err prob)             =   0.95
            Allocation ratio N2/N1           =   1
Output:     Noncentrality parameter δ        =   3.3224971
            Critical t                       =   1.6613155
            Df                               =   93.4929659
            Sample size group 1              =   50
            Sample size group 2              =   50
            Total sample size                =   100
            Actual power                     =   0.9508808
```

APPENDIX F: Outcome questionnaires

Food Allergy Quality of Life- Parental Burden (FAQoL-PB) Questionnaire

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Appendix F: Outcome questionnaires continued.

Patient Health Questionnaire-8 (PHQ-8)

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Appendix F: Outcome questionnaires continued.

Generalised Anxiety Disorder Scale-7 (GAD-7)

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Appendix F: Outcome questionnaires continued.

Perceived Stress Scale (PSS)

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Appendix F: Outcome questionnaires continued.

Food-Efficacy Scale for Parents (FASE-P)

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Appendix F: Outcome questionnaires continued.

Intolerance of Uncertainty Scale (IUS)

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APPENDIX G: Demographic Questionnaires

Parent demographics

How do you identify?

- ○ Female
- ○ Male
- ○ Other

How old are you? (years)

In which country do you currently reside?

How would you best describe your ethnic origin?

- ○ Black African
- ○ Black Caribbean
- ○ Black other
- ○ Bangladeshi
- ○ Chinese
- ○ Pakistani
- ○ Indian
- ○ Asian other
- ○ White
- ○ Mixed race
- ○ Other, please specify:

What is your current employment status?

- ○ Full-time employment
- ○ Part-time employment
- ○ Self-employed
- ○ Homemaker/carer
- ○ Unemployed

Education: What is the highest degree or level of school you have completed?

- ○ Primary school
- ○ GCSEs or equivalent
- ○ A-Levels or equivalent
- ○ Specialist trade/apprenticeship
- ○ University undergraduate programme
- ○ University post-graduate programme
- ○ Doctoral degree
- ○ Other, please specify:

Are you currently experiencing any mental or physical health difficulties?

- ○ Yes, please provide more details.
- ○ No
- ○ Prefer not to say

Are you currently accessing psychological support/therapy?

- ○ Yes, please specify what kind of support:
- ○ No
- ○ Prefer not to say

Have you ever accessed psychological therapy/support in the past?

- ○ Yes, please specify what kind of support:
- ○ No
- ○ Prefer not to say

Do you belong to a food allergy or anaphylaxis support group?

- ○ Yes
- ○ No

If you choose to withdraw from the study for any reason, can we still contact you to get your feedback on how helpful (or not helpful) you found the website?

- ○ Yes, you may contact me.
- ○ No, I would not like to be contacted.

0% 100%

← →

Appendix G: Demographic questionnaires continued.

Child demographics

Is child 1:

- ○ Female
- ○ Male
- ○ Other

Currently, how old is child 1:

Years	
Months	

How many food allergies does child 1 have?

Has child 1 seen a doctor about their food allergy/allergies?

- ○ Yes, please specify how many months ago:
- ○ No

If child 1 has seen a doctor, how did the doctor test for food allergy? Please choose all relevant options.

- ☐ Skin prick tests
- ☐ Blood tests
- ☐ Food challenge
- ☐ Other (please state)
- ☐ The doctor didn't test for a food allergy
- ☐ Not applicable

How old was child 1 when their allergy was diagnosed? (Years)

What is child 1 allergic to (please select all that apply)?

- [ ] Peanut
- [ ] Tree nuts (e.g. almonds, cashews, pecans, hazelnuts, brazil nuts)
- [ ] Milk
- [ ] Egg
- [ ] Fish
- [ ] Shellfish
- [ ] Wheat
- [ ] Soya
- [ ] Other, please specify

Does child 1 also have (please select all that apply):

- [ ] Asthma
- [ ] Eczema
- [ ] Hay fever
- [ ] None of these

What medicine does child 1 have for their food allergy (please select all that apply) ?

- [ ] Antihistamines
- [ ] Adrenaline auto-injector (Emerade, Epi-Pen, or Jext).
- [ ] None

Have you used an auto-injector trainer or dummy device for child 1?

- ( ) Yes
- ( ) No

If child 1 has an auto-injector, have you ever received training to use it?

- ◯ Yes, please provide details of who provided training:
- ◯ No
- ◯ Not applicable

If child 1 has an auto-injector, in a typical week how many days would you go out without it?

Have you ever used an auto-injector on child 1?

- ◯ Yes
- ◯ No

Has child 1 had an adrenaline auto-injector administered by someone else (i.e. school, doctor, family member, friend, etc.)?

- ◯ Yes
- ◯ No

Has child 1 ever been to the hospital with an allergic reaction to food?

- ◯ Yes
- ◯ No

Has child 1 ever had an anaphylactic reaction (a severe allergic reaction)?

- ◯ Yes, please tell us the number of anaphylactic reactions:
- ◯ No
- ◯ Unsure

Does child 1 have an anaphylaxis management plan?

- ◯ Yes
- ◯ No

APPENDIX H: Feedback questionnaire

Please let us know how many times you visited the website:

- ○ Multiple times a day
- ○ Once a day
- ○ 1-2 times a week
- ○ Once a month
- ○ Less than once a month
- ○ Never

When you visited the website, how long did you typically spend looking through materials?

- ○ Over an hour
- ○ An hour
- ○ <30 mins
- ○ A few minutes
- ○ I only used it to download materials

During the course of the study, did you receive any other form of support? Please select all that apply.

- ☐ No
- ☐ Yes, psychological therapy. Please provide further details:
- ☐ Yes, through a support group. Please provide further details:
- ☐ Other, please provide further details:

During the course of the study, did you take any medication for your mental health? (e.g. for stress, anxiety, depression, etc.)

- ○ Yes
- ○ No

During the course of the study, have you accessed any additional support/advice around allergy management?

- ○ No
- ○ Yes, please say what:

How much do you agree or disagree with the statement "web-based support for carers/parents is useful"?

- ○ Strongly agree
- ○ Agree
- ○ Somewhat agree
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Disagree
- ○ Strongly disagree

What, if anything, did you gain from the website? Please tick all that apply.

- ☐ New information about allergies and allergy management that I did not have before
- ☐ Simplified information about allergies and allergy management that was easy to understand
- ☐ Information about allergies and allergy management that I could provide to family, friends and/or professionals about my child's allergy
- ☐ New information about anxiety and stress management that I did not have before
- ☐ Simplified information about allergies and allergy management that was easy to understand
- ☐ Information about anxiety and stress management that I could provide to family, friends and/or professionals
- ☐ Links and signposting to other services to access further information (including relevant reading, applications, etc.)
- ☐ I felt supported or reassured
- ☐ Other, please state here:
- ☐ I did not find the website useful at all

What aspect(s) of the website did you find the most useful?

Are there any aspect(s) of the website did you not find useful?

Is there anything you think it would be helpful to change about either the website's content or presentation?

How likely are you to continue to use information that you gained from the website (e.g. stress management strategies, printed out information, allergy management cards etc.) after the completion of the study?

- ○ Very likely
- ○ Likely
- ○ Neither likely nor unlikely
- ○ Not likely
- ○ Very unlikely

Do you have any additional comments about the study or the website?

Would you like to receive information summarising the results of the PASCAL study?

- ○ No
- ○ Yes. If so, please provide an email address below where we can contact you.

APPENDIX I: Patient and Public Involvement (PPI) Terms of Reference

Focus Group: Consultation around the development of an online self-help resource for parents of children with a food allergy.

Information about the study:

Title: Exploring the effectiveness of online self-help for parents of children with food allergies.

Study overview: I am looking to explore whether parents of food-allergic children might benefit from online support. I will be developing a supportive website that I hope will provide information aimed at alleviating stress and anxiety. I am hoping that this study will enable future research in this area and encourage further provision of psychological support for parents of food-allergic children.

Thank you for agreeing to meet with me today. Your input will be invaluable in the development of this resource.

What is Public Patient Involvement (PPI)? The National Institute for Health Research identifies PPI as public involvement in research as "with" or "by" members of the public, rather than "to" or "for" them. In our study, we would like to work with you in the development of materials to be used in our research project. More information about PPI can be found online: http://www.invo.org.uk/find-out-more/what-is-public-involvement-in-research-2/

Purpose of PPI group: At this stage, I would like to consult with you to gather information about your experiences caring for a food allergic child. Although becoming involved in this early part of the study would exclude you from testing the website for the duration of the study, you would be given access to the website following the completion of the study (in approximately X months).

We are hoping that the information and advice you provide us will help guide us in the development of the website. You will be asked to provide your feedback in person at a support-group meeting through the Anaphylaxis Campaign. Alternatively, you might prefer to provide me with feedback via telephone or email.

We are interested to know whether you might be interested in information relating to better understanding medical advice provided to you by specialists following diagnosis, or whether you might benefit more from support to better manage stress and anxiety. We will ask you some loosely structured questions to better understand what information or support you might need.

Membership: You have kindly allowed me to talk with you in this meeting—I will be accompanied by my supervisor, Dr. Chrissie Jones (Lecturer in Paediatrics Brighton & Sussex Medical School, Royal Alexandra Children's Hospital. I will likely only meet with you as a one-off. However, once the website has been created, I may contact you to ask for your feedback on the layout and content.

Additional Information

Will information from or about me from during the PPI phase be kept confidential?
Yes. We hope that information that you provide us will inform the content for our website, however your name will not be attached to this.

Any further information which is collected from or about you during the course of the research will be kept strictly confidential. We are required to break confidentiality and share information with relevant support services only under specific circumstances, which is if we feel your safety or the safety of anyone else is a concern. We would always endeavour to discuss any such concerns with you prior to taking any action.

Any information shared will not include your name, address, or any other identifiers so that you cannot be recognised, and will be saved on a password protected device or computer throughout the duration of the study. Following the completion of the study, as per university guidelines, anonymised data is required to be stored securely for a maximum of 5 years. Electronic data will be stored on an encrypted CD at the university campus, and destroyed after 5 years.

What will happen to the results of the research study? The researchers will seek to publish their findings in an academic journal. Some comments or responses may be quoted in the completed research article. All data will remain anonymous and identifiable information changed or removed to protect your anonymity.

Who is organising and funding the research?
This study is funded and sponsored by the Salomons Centre of Applied Psychology, which is part of Canterbury Christ Church University. Additionally, supervision will be provided by Dr Christina Jones, who is based at the Royal Alexandra Children's Hospital in Brighton.

What if there is a problem?
If you are unhappy with the study or have an unsatisfactory experience, you would be welcome to direct your concerns towards myself or either of my lead supervisors. We would be happy to discuss any concerns with you.

Naomi Sugunasingha: n.sugunasingha449@canterbury.ac.uk
Fergal Jones (Lead Supervisor): fergal.jones@canterbury.ac.uk
Christina Jones (Second Supervisor): C.Jones@bsms.ac.uk

Complaints
If you have a concern about any aspect of this study, you should ask to speak to me (see email above) and I will do my best to address your concerns. If you remain unhappy and wish to complain formally, you can do this by contacting Professor Paul Camic, Research Director, Salomons Centre for Applied Psychology – paul.camic@canterbury.ac.uk.

APPENDIX J: Focus Group Feedback Summary

Public Patient Involvement (PPI) Focus Group Summary

Discussion topics:

The first was allergy-specific anxiety management (with specific focus on worrying and tolerating uncertainty) which would likely be developed using cognitive behavioural theory. The second area queried the benefits of an information-providing website that might offer access to practical management advice and knowledge that is in a single place, which is accessible, accurate and consistent.

A few key themes were identified in the discussion. First, parents stated that there was a lack of psycho-social support currently available for parents of food-allergic children.

Second, although they identified that psychological interventions aimed at reducing anxiety had the potential to be beneficial, parents highlighted that their anxiety was not primarily caused by individual factors. That is, caregivers generally felt confident that they could learn appropriate food allergy management skills and maintain appropriate levels of safety for their child at home. However, group members stressed that a key factor that fuelled anxious cognitions was the concern that others (teachers, extended family, other parents, etc) would not be as vigilant as them, and resultantly place their child at risk.

Third, parents were concerned about receiving conflicting messages on the internet and from health care providers (including general practitioners). These concerns and are commonly cited in the allergy literature (Flokstra de Bok & Dubois, 2009) as an ongoing parental concern.

Example quotes from the group:

One group member stated:

[QUOTES REMOVED FROM ELECTRONIC COPY]

Many of the parents shared experiences where an external caregiver had not heeded their care instructions and caused their children to have allergic reactions. Two other members stated:

[QUOTES REMOVED FROM ELECTRONIC COPY]

Outcome:

Focus group participants had a preference for an intervention that helped them to translate food-allergy management information to others (which would help reduce their anxiety), and requested that this information be downloadable. They also requested a list of services that they could be signposted to (for face-to-face, or online support) so that caregivers could seek additional help if they needed it. Attendees provided a list of "Top Tips" for other parents, that would be credited to the [redacted] support group, and also consulted on the "Frequently Asked Questions", which would be answered by researchers and the allergy specialist.

Attendees reviewed completed website pages and provided feedback, which was accounted for in the final content drafts published online.

APPENDIX K: PASCAL downloadable content and website page examples

Downloadable content from the PASCAL Website (provided as a PDF)

WHAT ARE THE SYMPTOMS OF AN ALLERGIC REACTION?

WHAT IS AN ALLERGY?

An allergy is a serious medical condition that impacts on an individual's immune system. An allergic reaction occurs when the body's immune system identifies a typically harmless substance as a threat. As a result, the immune system releases an antibody which helps to trigger the release of the chemical, histamine. An excess of histamine in the body results in allergy symptoms highlighted below, and in some cases can be life-threatening.

Allergies can impact numerous systems in the body:

- Eyes (e.g. watery, itchy, redness, swelling, redness)
- Nose, throat and ears (e.g. runny nose, itchy or blocked nose, sinus pain, headaches, sore throat, swelling or itchiness in the mouth, blocked ears)
- Airways (wheezing, difficulty breathing, worsening asthma, coughing, shortness of breath)
- Digestion (swollen lips and tongue, stomach ache, nausea, vomiting, diarrhoea, reflux)
- Skin (uticaria, or hives that are bumpy, red and itchy, eczema)

Allergy reactions are usually immediate, however there may also be a delayed reaction up to hours after contact with the allergen.

Eyes
Watery, itchy, redness, swelling

Skin
Urticaria (hives), eczema

Digestive System
Diarrhoea, stomach ache, vomiting, swollen lips & tongue

Nose, throat & ears
Runny, blocked nose, sore throat, sinus pain, headaches, swelling & itchiness in the mouth

Heart
Tachycardia (rapid heart rate), Hypotension (low blood pressure)

Airways
Lightheaded, faint, difficulty breathing, wheezing, coughing, asthma

Anaphylaxis
a potentially fatal, severe reaction to an allergen which requires immediate medical attention. This response can affect numerous systems in the body including airways, heart, gut, circulation and skin. In anaphylaxis, the release of histamine is not localised, but generally into the bloodstream. A reaction can occur within seconds or minutes following exposure to an allergen.

Symptoms of anaphylaxis may include:

- Swelling of the tongue and/or throat
- Difficulty in swallowing or speaking
- Vocal changes
- Wheeze or persistent cough
- Severe asthma
- Stomach cramps or vomiting
- Dizziness/loss of consciousness

A note about severity:
While some individuals experience the same level of reaction whenever they come into contact with an allergen, there is no guarantee that a mild reaction on one occasion cannot lead to a severe reaction on another.

FOOD ALLERGY VS FOOD INTOLERANCE

WHAT'S THE DIFFERENCE?

Although these are often confused, *there is a distinct medical difference.* Allergic reactions can be life-threatening, and should be taken very seriously.

ALLERGY symptoms are caused by a response of the immune system, whereas intolerances are not. FOOD INTOLERANCES are more common than allergies, and although severe intolerance can be harmful for individuals in the long-term, they are not imminently life-threatening.

Ingredients:

Dried and sweetened dried fruit (85%) [sultanas, sweetened dried pineapple (10%) (sugar, pineapple, acid: citric acid, preservative: **sulphur dioxide**), dates, raisins], **barley** flakes, **oat** flakes, **wheat** flakes, toasted and malted **wheat** flakes (**wheat**, **barley** malt extract).

Allergy advice

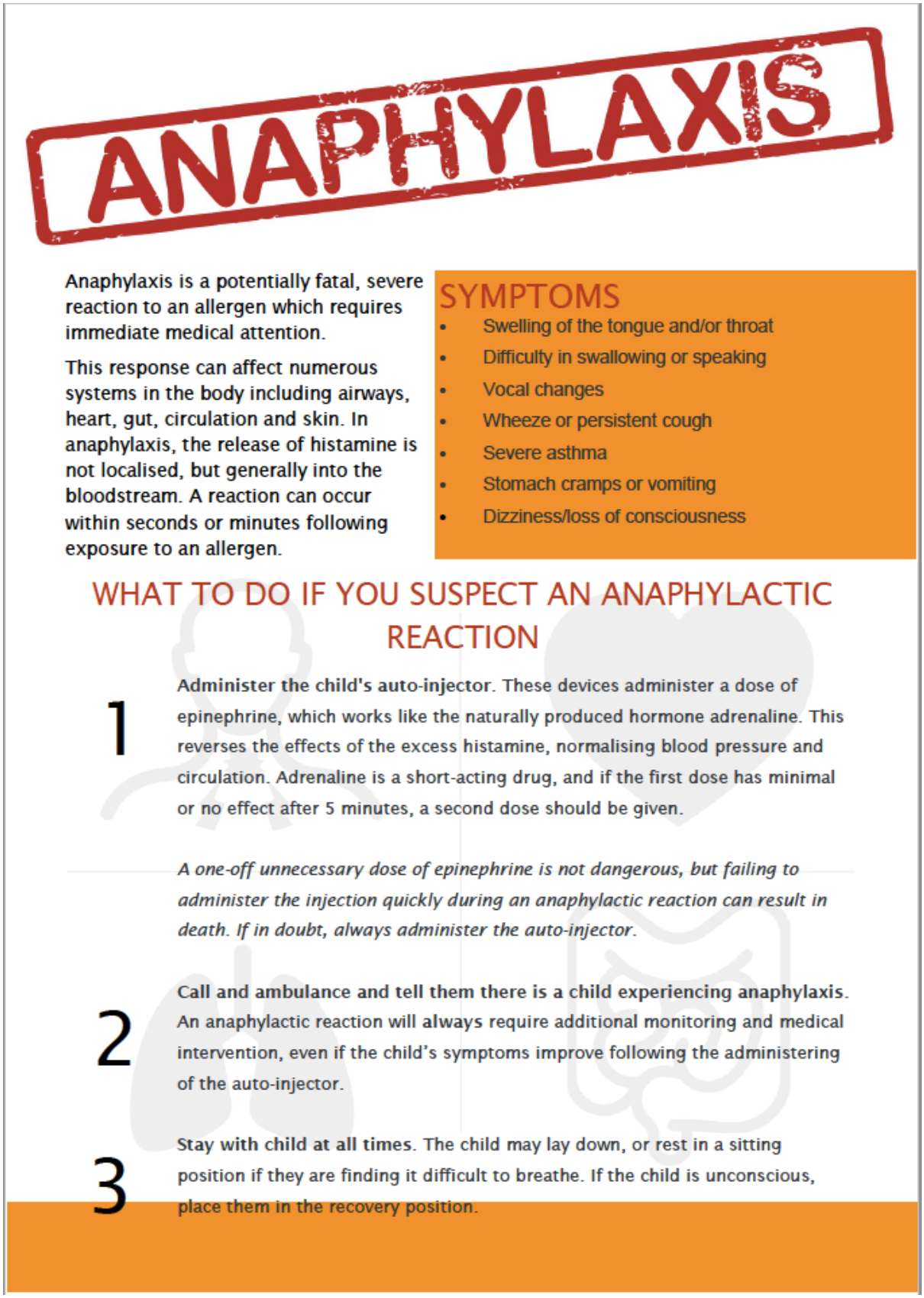
For allergens, see ingredients in bold. May contain nuts and milk.

FOOD LABELLING

Allergens can be identified on the back of a food product, amongst the list of ingredients. Allergens will be highlighted in bold, or highlighted in a separate box at the bottom of the ingredient list.

A useful app "Food Maestro" is currently being developed for parents to identify what brands and foods are safe to eat - "Can I eat this?"

FOODMAESTRO


ANAPHYLAXIS
Anaphylaxis is a potentially fatal, severe reaction to an allergen which requires immediate medical attention.
This response can affect numerous systems in the body including airways, heart, gut, circulation and skin. In anaphylaxis, the release of histamine is not localised, but generally into the bloodstream. A reaction can occur within seconds or minutes following exposure to an allergen.
SYMPTOMS
Swelling of the tongue and/or throat
Difficulty in swallowing or speaking
Vocal changes
Wheeze or persistent cough
Severe asthma
Stomach cramps or vomiting
Dizziness/loss of consciousness
WHAT TO DO IF YOU SUSPECT AN ANAPHYLACTIC REACTION
1
Administer the child's auto-injector. These devices administer a dose of epinephrine, which works like the naturally produced hormone adrenaline. This reverses the effects of the excess histamine, normalising blood pressure and circulation. Adrenaline is a short-acting drug, and if the first dose has minimal or no effect after 5 minutes, a second dose should be given.
A one-off unnecessary dose of epinephrine is not dangerous, but failing to administer the injection quickly during an anaphylactic reaction can result in death. If in doubt, always administer the auto-injector.
2
Call and ambulance and tell them there is a child experiencing anaphylaxis. An anaphylactic reaction will always require additional monitoring and medical intervention, even if the child's symptoms improve following the administering of the auto-injector.
3
Stay with child at all times. The child may lay down, or rest in a sitting position if they are finding it difficult to breathe. If the child is unconscious, place them in the recovery position.

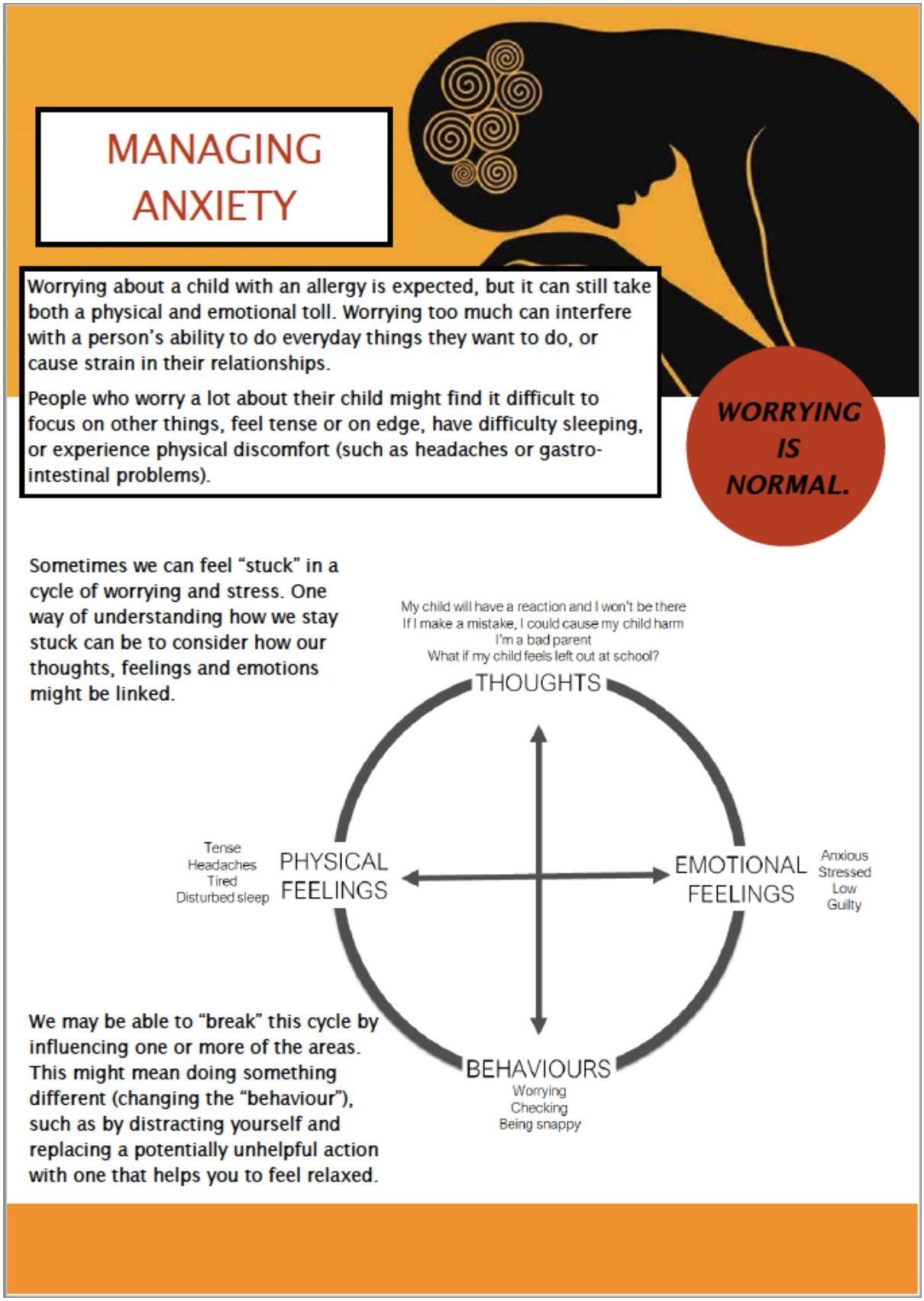
AUTO-INJECTORS

Auto-injectors are prescribed to individuals who are at risk of having a severe allergic reaction. Those prescribed an auto-injector should carry it with them at all times. In the UK, there are three types of auto-injectors available:
Emerade: www.emerade.bausch.co.uk
Epipen: www.epipen.co.uk
Jext: www.jext.co.uk

ADMINISTERING AN AUTO-INJECTOR

Instructions for each injector device is slightly different, and so you should familiarise yourself with the appropriate prescribed device. Training devices are available, and further instructions on administering can be found on the links above.

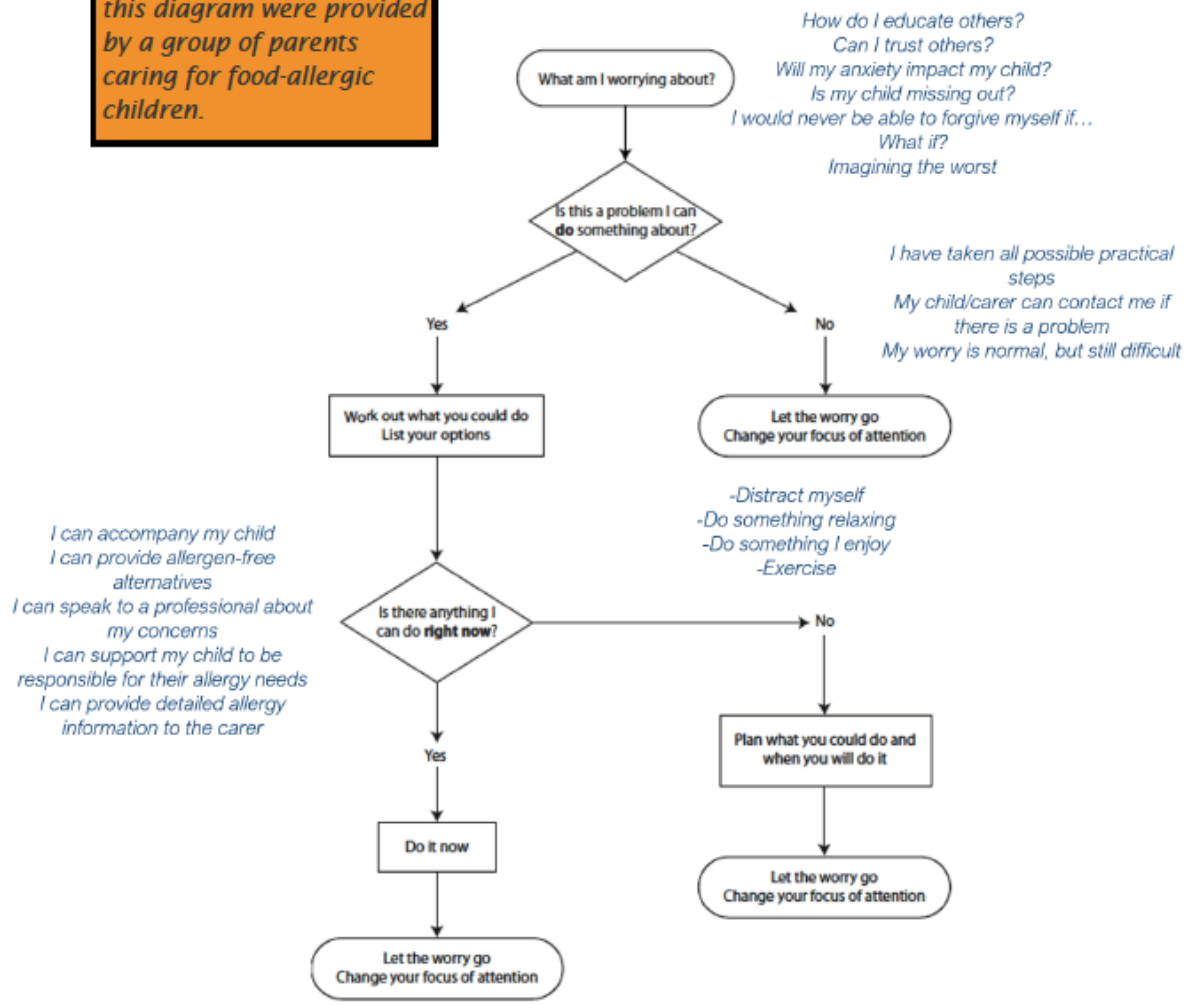
Emerade	Epipen	Jext
1) Remove the safety cap and form a fist around the device (using your dominant hand)	1) Remove the blue safety cap), and form a fist around the device (using your dominant hand)	1) Remove the yellow safety cap, and form a fist around the device (using your dominant hand)
2) Position the injector tip against outer thigh at a 90 angle	2) Position the orange injector tip around 10cm away from the outer thigh.	2) Position the **black** injector tip against outer thigh at a 90 angle
3) Push tip firmly into the thigh until you hear a click, and hold needle in place for 10 seconds.	3) Swing and jab the Epipen at a 90 angle into the outer thigh and hold for 10 seconds.	3) Push tip firmly into the thigh until you hear a click, and hold needle in place for 10 seconds.
4) Remove auto-injector and massage injection site for 10 seconds.*	4) Remove auto-injector and massage injection site for 10 seconds.*	4) Remove auto-injector and massage injection site for 10 seconds.*


MANAGING ANXIETY
Worrying about a child with an allergy is expected, but it can still take both a physical and emotional toll. Worrying too much can interfere with a person's ability to do everyday things they want to do, or cause strain in their relationships.
People who worry a lot about their child might find it difficult to focus on other things, feel tense or on edge, have difficulty sleeping, or experience physical discomfort (such as headaches or gastro-intestinal problems).
WORRYING IS NORMAL.
Sometimes we can feel "stuck" in a cycle of worrying and stress. One way of understanding how we stay stuck can be to consider how our thoughts, feelings and emotions might be linked.
My child will have a reaction and I won't be there
If I make a mistake, I could cause my child harm
I'm a bad parent
What if my child feels left out at school?
THOUGHTS
Tense
Headaches
Tired
Disturbed sleep
PHYSICAL FEELINGS
EMOTIONAL FEELINGS
Anxious
Stressed
Low
Guilty
BEHAVIOURS
Worrying
Checking
Being snappy
We may be able to "break" this cycle by influencing one or more of the areas. This might mean doing something different (changing the "behaviour"), such as by distracting yourself and replacing a potentially unhelpful action with one that helps you to feel relaxed.

THE *WORRY DIAGRAM*

One way of managing worry, can be to separate the worries into two categories—ones that you can influence, and the ones that are out of your control. This can help us to decide what to do.

The ***worries*** *described in this diagram were provided by a group of parents caring for food-allergic children.*



PSYCHOLOGICAL RESOURCES

Even though feeling worried or anxious is a normal response for those caring for a child with an allergy, sometimes some support can be very helpful. Please see the resources below to find out where to get more detailed information on self-help resources, or to find out how to refer yourself for psychological therapy.

1. https://www.nhs.uk/service-search/Psychological-therapies-(IAPT)/LocationSearch/10008 IAPT services provide free short-term therapy through the NHS for individuals struggling with depression and anxiety disorders. Therapists will tailor care to your needs, and provide you with practical tools to better manage your mood. You can self-refer or ask your GP to refer you.

2. https://www.getselfhelp.co.uk Provides some Cognitive Behavioural Therapy (CBT) based resources, which have an established evidence base for supporting those struggling with anxiety and depression.

3. http://www.cci.health.wa.gov.au/resources/consumers.cfm Provides some Cognitive Behavioural Therapy (CBT) based resources, which are evidenced to help support those struggling with anxiety and

FURTHER INFORMATION

- https://www.allergyuk.org
- https://www.anaphylaxis.org.uk
- http://www.bsaci.org/index.htm
- www.emerade.bausch.co.uk
- www.epipen.co.uk
- http://www.foodmaestro.me/home.html
- www.jext.co.uk
- https://www.foodallergy.org
- www.sparepensinschools.uk
- Book recommendation - Food allergy & your child: a practical guide for parents

FREQUENTLY ASKED QUESTIONS

- Can I sit my child next to others eating foods they are allergic to?
ALSO What are the risks where your allergens are present at parties?
Most commonly, reactions occur when an individual comes into physical contact with an allergen (typically by ingestion). Reactions are not likely to occur because they are present in the room, however their presence in a shared space (such as a classroom) can increase the chance of cross-contamination. That is, residue of the allergen may be left behind on a surface and then touched by the child with the allergy. See "are food allergens 'in the air'", below.

- Are food allergens 'in the air'?
Individuals may react to allergens in the air if the food protein has been aerosolized (such as when milk is steaming, or eggs/fish are frying, soup is boiling, etc.). Some foods do not aerosolize, such as peanut butter or cooked fish cooling on a plate.

How likely a reaction is to occur would depend on the amount of protein in the air, and how close this was to the child with the allergy. Risk of exposure would be reduced in a large room or outdoor space (rather than a small, enclosed space). Additionally, the child's sensitivity and whether or not they have asthma may influence the chance of a reaction. Food exposure in the air is not that different to pollen exposure, and is more likely to trigger symptoms such as congestion and itchy eyes. Breathing symptoms may be more likely to occur in individuals with asthma. Reactions (and especially severe reactions such as anaphylaxis) under these circumstances are very uncommon.

- Where can I be trained on auto-injectors?
Training videos for use of auto-injectors can be viewed via brand websites:
http://www.jext.co.uk/jext-video-demonstrations.aspx
http://www.epipen.co.uk/patients/epipenr-user-guide/
https://www.emerade.com/instruction-video

Trainer "dummy" pens, that contain no needle, can also be ordered from these sites to facilitate practicing administering at home.

Further information can be found on the websites listed on the sites reference page, [here-insert hyperlink to website references].

Information about training for managing anaphylaxis can be found here: https://www.anaphylaxis.org.uk/information-training/allergywise-training/

FREQUENTLY ASKED QUESTIONS

- **What is useful to know when eating out?**
Although food businesses are not obligated to provide "safe" options, caterers are required to provide clear and accurate information about the ingredients used in dishes they serve to their customers. Those that do not adhere to this can be reported to the Local Authority, and food standard agency. These rules apply both to packaged (on labels) and unpackaged items.

Allergy UK, a national charity runs an Allergy Aware Scheme. Food outlets who join this scheme have passed a rigorous audit that assessed staff training, supplier information, purchase and delivery of orders, storage of goods, food handling and preparation, and finally front of house "order taking". A list of these vendors can be found on the allergy UK website: https://www.allergyuk.org/get-help/eating-out

Further information can be found on the Anaphylaxis Campaign website (https://www.anaphylaxis.org.uk/young-people/young-people-help-a-guide-to-eating-out/), and the Food Allergy Research and Education (FARE) website (https://www.foodallergy.org/life-with-food-allergies/managing-lifes-milestones/dining-out).

- **How do I cope explaining to school/carers/grandparents who think I am making up the allergies or exaggerating the risks? What strategies can I take with them?**
Try arranging a time to sit down and talk through the risks carefully, when there are no distractions or other obligations. Rather than overloading them with information, try explaining the dangers of anaphylaxis, and what this might look like in your child. Furthermore, emphasise how the risk of serious harm or death can be managed by quick administering of an auto-injector and contacting emergency services. The materials on this website have been designed to help you to communicate these issues with others.

- **What is the consequence of touching (rather than eating) the allergen?**
Research in this area is not extensive. One study suggests that touching an allergen (e.g. peanut butter) would not be likely to cause an anaphylactic reaction (in those with peanut allergy), but that there might be milder symptoms (such as redness or itching). However, it is important that individual cases are discussed with your allergy specialist before you adjust your avoidance of any allergens.

What are the risks of flying on commercial airlines if you have allergies?
See *"Are food allergens in the air?"*

FREQUENTLY ASKED QUESTIONS

- Do baby-wipes get the allergen off? Does washing hands with warm soapy water get the allergen off?
According to FARE (https://www.foodallergy.org/about-fare/blog/how-to-clean-to-remove-food-allergens), washing your hands with bar or liquid soap is an effective way of removing allergens from your hands. They also highlighted that using hand-wipes will also remove the allergen. They urge caution when washing hands without soap, or using hand sanitizer, which may not reliably remove the allergen.

- What practical steps can a school/child-minder/nursery take to keep my child safe?
Exposure to allergens can never be entirely controlled, however, certain environments can be made safer:

- The allergen could be removed from the environment (asking other parents not to give their children peanuts, etc.) however this is not always practical.
- Allergens could be cleaned from areas the child is going to access (e.g. wiping down surfaces with warm soapy water before and after food activities, keeping a "safe sponge" to prevent cross-contamination when washing dishes)
- Agreed communication with you about any activities relating to food (including when food products or packaging are used for play activities).
- Encourage all carers of your child to practice using the auto-injector so that they would feel comfortable to use it in an emergency.
- Checking all food labels for the presence of allergens.

- Do adrenaline pens that are dropped need to be replaced?
Unfortunately, there is not a clear answer here. Most devices are tough, and the needle is protected. The device should be kept in the carry-case, which adds additional protection. However, a dropped device that has cracked or is leaking should always be replaced.

- What are the risks for individuals with animal allergies when visiting others' houses where the animals are present?
It is important to discuss situations that might put your child in the presence of an allergen with their doctor. You may be able to take steps such as communicating with the individual you are visiting, to request that their animal is not permitted into the room that you will be staying in. You can also choose to take anti-histamine medication to reduce allergy symptoms, and carry emergency medication (auto-injectors). It is possible that you may not be able to take your child to visit homes where pets are present if they have reacted poorly in the past. Under these circumstances you may choose to meet somewhere else, or in your own home instead.

FREQUENTLY ASKED QUESTIONS

- Can you keep adrenaline in the fridge? What about near radiators? Are there insulated bags that help temperature control?
Auto-injectors should not be refrigerated or kept in direct sunlight. They should be kept at room temperature in the dark, and should not be exposed to extreme temperatures (too hot or too cold). The mechanism may be hindered if the injector is submerged in water.

Auto-injectors should be replaced regularly prior to their expiration dates. Should only an expired auto-injector be available during an anaphylactic reaction, it may be administered but the labelled dosage may no longer be accurate and this is not recommended. You should never use an auto-injector that have become discoloured, as this indicates that it has come into contact with a foreign object, extreme temperatures, or oxygen. If discoloured, the auto-injector should be disposed of and replaced immediately.

- Will my child "outgrow" their allergy?
Research cannot definitely answer this question, and concerns should be directed to your allergy specialist. However, a study in 2013 analysed data for nine common food allergies (here and summarised on FARE here), across a large sample. They found that a little over a quarter of children outgrew their allergies at an average age of 5.4 years old.

The study highlighted that children allergic to milk, egg or soy were most likely to outgrow their allergies. Conversely, those with allergies to shellfish, tree nuts, and peanuts were outgrown far less frequently. Other factors that were associated with outgrowing allergies were a history of only mild-moderate reactions, being allergic to only one food, and having eczema as the only symptom.

More information can be found on Anaphylaxis Campaign website.

-Should I take "may contain" warning seriously?
Manufacturers include this warning on their products to highlight the possibility of cross-contamination in their products even if the allergen is not an intended ingredient in the product. These warnings should not ignored—you may eat these products numerous times without a reaction but this does not mean that you cannot have a reaction in the future.

MYTH BUSTING

MYTH: Food allergies aren't serious. An allergic reaction can range from a runny nose and hives, to difficulty breathing and loss of consciousness. If a reaction is severe, it can cause anaphylaxis, which is life-threatening. Food allergies must be taken seriously, and those with allergies must remain vigilant to ensure they avoid a reaction.

MYTH: Eating a little bit won't hurt. For some individuals, exposure to even a small amount of an allergen can trigger a severe reaction. Exposure is usually through consumption, but can also be through touch or even breathing it in. For this reason, cross-contact between safe foods and allergens must always be avoided.

MYTH: Each allergic reaction will get worse and worse. Food allergy reactions are unpredictable, and you won't be able to tell if a reaction will be mild, moderate or severe. You should always be prepared with emergency medication, just in case.

MYTH: A food allergy that has only caused a mild reaction is a mild allergy. There are no mild or severe food allergies. Something that caused a mild reaction could still cause a severe reaction in the future (and vice versa).

MISCONCEPTION: All allergy-inducing ingredients must be listed on food labels.

MISCONCEPTION: If food doesn't traditionally contain an allergen or if you don't see the allergen listed in the menu description, the food is safe to eat. Allergens can appear in unexpected places, so you should never assume anything about how a food has been made or served. Always read food labels and ask about ingredients before eating a food that you have not prepared yourself.

TOP TIPS FOR PARENTS OF FOOD-ALLERGIC CHILDREN

Parents in the Anaphylaxis Campaign [redacted] Support Group had these top tips to share:

"The allergy and gluten free show at the Olympia is great. You can attend lectures with top specialists, and I found it really informative."

"Join a support group- we learn from each other"

"There are good resources on Facebook and the allergy websites"

" Remember that you have the right to go to any hospital or specialist that you want. Take your child to the place you feel they are getting the best support. The best ones are university hospitals or ones that have been approved by the BSACI. If you call the BSACI helpline number, they will be able to tell you what hospitals these are."

"Anxiety is perfectly normal- you're not mad!"

"Trust your instincts. You are the authority on your child's allergy, and it is ok to complain if you don't think they are receiving appropriate care."

"Remember that GP's and nurses are not specialists."

"Perseverance and good communication with others is really important when you come up against resistance (e.g. from schools)."

"You will feel more confident if you train and train others (family, other parents, school staff) on the administering of auto-injectors. The thought of injecting your child in an emergency is scary, so it's good to have practice knowing what it feels like."

"Check what your child's school allergy management plan is well before they start-- this can help you to have things in place well in advance."

"You might feel crazy sitting outside the house after you have dropped your child off for a party, but it's ok to take steps that help you to give your child independence, while also keeping them safe."

MY ALLERGY PROFILE

Picture

My name is _____

I am allergic to:

_____

_____

_____

_____

_____

If I have consumed an allergen, I might say:

_____

_____

_____

_____

You might notice changes in me, including:

_____

_____

_____

_____

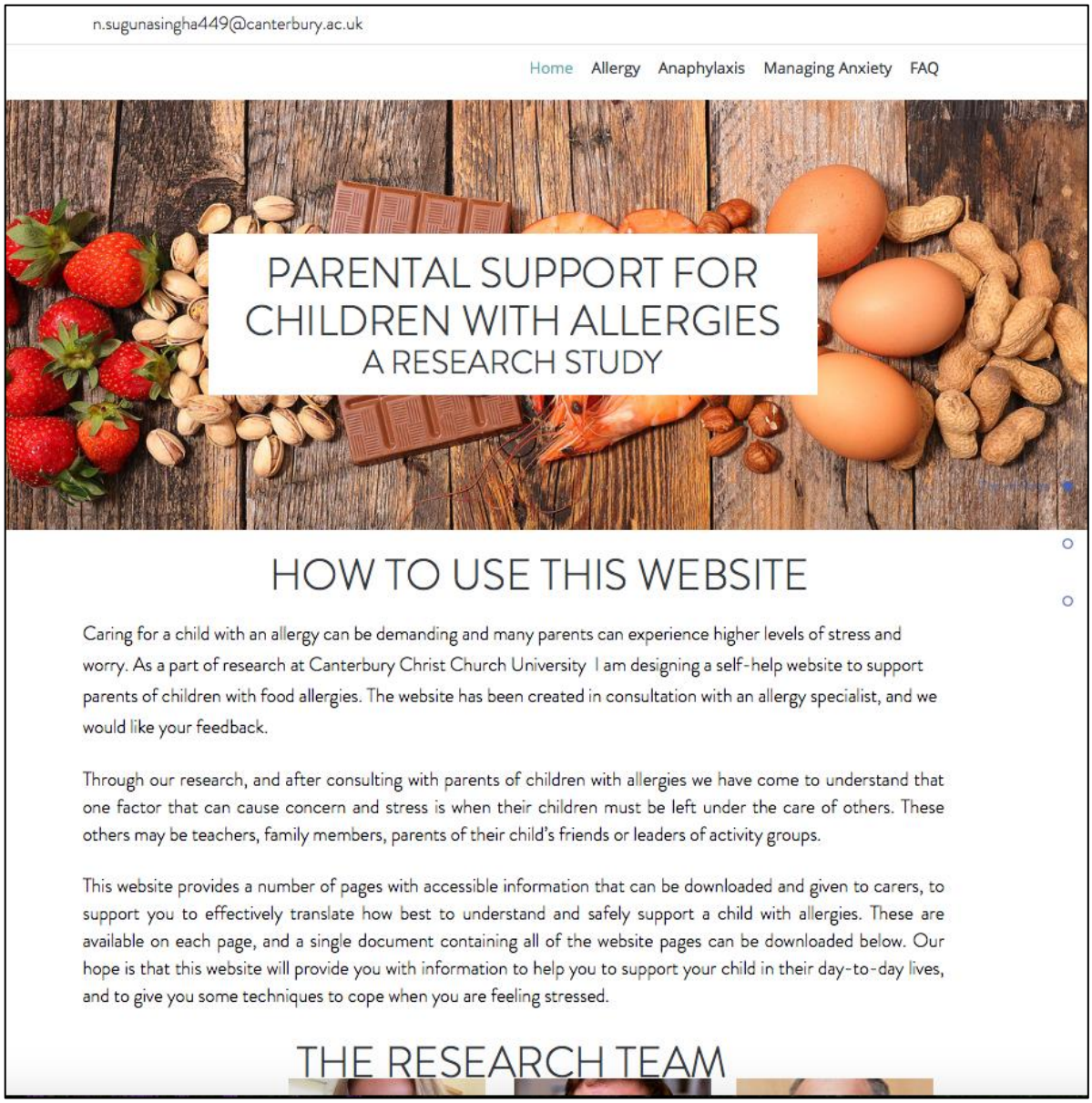
If this happens, please:

- ☐ Give me an anti-histamine (e.g. piriton)
- ☐ Administer my auto-injector
- ☐ Call an ambulance
- ☐ Call my mum/dad/caregiver

Additional notes:

APPENDIX K: PASCAL downloadable content and website page examples continued.

Webpage examples (content mirrors downloadable PDG pages above). The website can be viewed in full at www.pascalstudy.co.uk with the password Pascal2018.



1 - **Administer the child's auto-injector**. These devices administer a dose of epinephrine, which works like the naturally produced hormone adrenaline. This reverses the effects of the excess histamine, normalising blood pressure and circulation. Adrenaline given this way is safe, and giving a child an unnecessary one-off dose will not harm them.
Adrenaline is a short-acting drug, and if the first dose has minimal or no effect after 5 minutes, a second dose should be given.

A one-off unnecessary dose of epinephrine is not dangerous, but failing to administer the injection quickly during an anaphylactic reaction can result in death. If in doubt, always administer the auto-injector.

2 - **Call and ambulance and tell them there is a child experiencing anaphylaxis**. An anaphylactic reaction will ***always*** require additional monitoring and medical intervention, even if the child's symptoms improve following the administering of the auto-injector.

3 - **Stay with child at all times**. The child may lay down, or rest in a sitting position if they are finding it difficult to breathe. If the child is unconscious, place them in the recovery position.

Analphylaxis
What to do....

AUTO-INJECTORS

Auto-injectors are prescribed to individuals who are at risk of having a severe allergic reaction. Those prescribed an auto-injector should carry it with them at all times. In the UK, there are three types of auto-injectors available:

Emerade: www.emerade.bausch.co.uk
Epipen: www.epipen.co.uk
Jext: www.jext.co.uk

MANAGING ANXIETY

WORRYING IS NORMAL

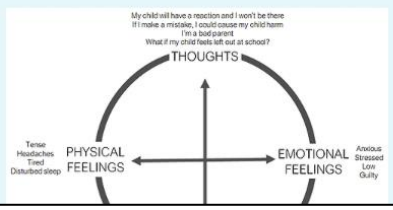
Worrying about a child with an allergy is expected, but it can still take both a physical and emotional toll. Worrying too much can interfere with a person's ability to do everyday things they want to do, or cause strain in their relationships.

People who worry a lot about their child might find it difficult to focus on other things, feel tense or on edge, have difficulty sleeping, or experience physical discomfort (such as headaches or gastro-intestinal problems).

Top of Page
Worry Diagram

THE VICIOUS CYCLE

Sometimes we can feel "stuck" in a cycle of worrying and stress. One way of understanding how we stay stuck can be to consider how our thoughts, feelings and emotions might be linked linked.
We may be able to "break" this cycle by influencing one or more of the areas. This might mean doing something different



APPENDIX L: Participant information sheet and consent form

Participant information sheet

Information about the research

Study Title: Exploring the effectiveness of online psycho-education for parents of food allergic children.

Hello. My name is Naomi Sugunasingha and I am a trainee clinical psychologist at Canterbury Christ Church University. I would like to invite you to take part in a research study. Before you decide if you would like to be involved it is important that you understand why the research is being done and what it would involve for you. We would like you to read the following information carefully and take note of any questions you may have (if any). Talk to others about the study if you want to as it may help you to decide whether it is a good idea to take part.

Part 1 tells you the purpose of this study and what will happen to you if you take part.
Part 2 gives you more detailed information about the conduct of the study. Please ask us if anything is unclear or if you have any further questions.

Part 1

What is the purpose of the study?

I am looking to explore whether parents of food-allergic children might benefit from online support. I will be developing a supportive website that I hope will provide information aimed at alleviating stress and anxiety. I am hoping that this study will enable future research in this area and encourage further provision of psychological support for parents of food-allergic children.

Why have I been invited?

We are inviting parents of children (under the age of 18) who suffer with food allergy of varying severity to participate.

Do I have to take part?

You do not have to take part and it is up to you to decide to join the study. If you agree to take part, I will then ask you to complete an online consent form. You are free to withdraw at any time, without giving a reason.

What will I be asked to do?

The study will take three months from start to finish. As the study will be conducted online, you will not be required to attend any meetings, and you may access the website at times that work best for you. However, you will be able to contact me via email if you have any questions.

- ***Randomised Trial***

  Sometimes we don't know which form of treatment is the most effective. In order to find out, we need to compare different treatments. At the start of a study, we put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same to start with, each participant is put into a group by chance (randomly). You may be placed in a group that does not have immediate access to the website, but will be given full access to the website after 8 weeks.

- ***Questionnaires***
  All participants across both groups will be asked to complete a series of questionnaires, which will give me information about your experiences and levels of stress. These questionnaires should take around 20-25 minutes, and you will be asked to complete them three times throughout the course of the study (at the start, after four weeks and again after 8 weeks); this will let us follow any changes to how you are feeling. Finally, you will also be asked to complete a feedback questionnaire after 12 weeks, which will give you the opportunity to let me know if you found the website helpful.

This information is summarised in the table below:

Time-points to complete questionnaires	**Start**	**Middle**	**End**	**Post-intervention**
Group 1: Immediate Access	0 Weeks	4 Weeks	8 Weeks	Feedback questionnaire 12 Weeks
Group 2: Access after 8 weeks	0 Weeks	4 Weeks	8 Weeks	Feedback Questionnaire 12 Weeks

- ***The website:***
  This website will provide you with specialist information about how best to support your food allergic child, and may suggest some stress-management and coping strategies.

Should you decide to take part in the study, you will be given a copy of this information sheet.

What are the possible disadvantages and risks of taking part?
We do not expect that you will experience any distress or discomfort when taking part in the study. However, it is possible that by discussing your difficulties you might recall previous experiences of stress and anxiety. Should this happen, you will be advised to discuss this with your general practitioner/primary care physician. You will also be given information about where you can seek additional support. You should consider this when deciding to take part in the study.

What are the possible benefits of taking part?
We cannot promise the study will help you but we are hoping that website will give you information and support that may have previously been lacking. Additionally, the information we get from this study may encourage further research in this area. Finally, it may help improve the provision of psychological support for parents of food-allergic children.

Will information from or about me from taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes part 1.
If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?
You have the right to withdraw from the study at any point. If you decide that you do not want to continue with the study, we would like to use the data collected up to your withdrawal. We may ask if you would be willing to be contacted at our follow up time; this will allow us to find out more information about your withdrawal, however you also have the right to decline being contacted for this follow up.

What if there is a problem?
If you are unhappy with the study or have an unsatisfactory experience, you would be welcome to direct your concerns towards myself or either of my lead supervisors. We would be happy to discuss any concerns with you.

Naomi Sugunasingha: n.sugunasingha449@canterbury.ac.uk
Fergal Jones (Lead Supervisor): fergal.jones@canterbury.ac.uk
Christina Jones (Second Supervisor): C.Jones@bsms.ac.uk

Complaints
If you have a concern about any aspect of this study, you should ask to speak to me (see email above) and I will do my best to address your concerns. If you remain unhappy and wish to complain formally, you can do this by contacting Professor Paul Camic, Research Director, Salomons Centre for Applied Psychology – paul.camic@canterbury.ac.uk.

Will information from or about me from taking part in the study be kept confidential?
All information that is collected from or about you during the course of the research will be kept strictly confidential. We are required to break confidentiality and share information with relevant support services only under specific circumstances, which is if we feel your safety or the safety of anyone else is a concern. We would always endeavour to discuss any such concerns with you prior to taking any action.

Any information shared will not include your name, address, or any other identifiers so that you cannot be recognised, and will be saved on a password protected device or computer throughout the duration of the study. Following the completion of the study, as per university guidelines, anonymised data is required to be stored securely for a maximum of 5 years. Electronic data will be stored on an encrypted CD at the university campus, and destroyed after 5 years.

What will happen to the results of the research study?
The researchers will seek to publish the findings in an academic journal. Some comments from feedback questionnaires may be quoted in the completed research article. All data will remain anonymous and identifiable information changed or removed to protect your anonymity.

Who is organising and funding the research?
This study is funded and sponsored by the Salomons Centre of Applied Psychology, which is part of Canterbury Christ Church University. Additionally, supervision will be provided by Dr Christina Jones, who is based at the Royal Alexandra Children's Hospital in Brighton.

Who has reviewed the study?
All research in the University is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by The Ethics Panel at Salomons Centre for Applied Psychology, Canterbury Christ Church University.

APPENDIX L: Participant information sheet and consent form continued.

Online consent form

Study Consent Form

Title of Project: Exploring the effectiveness of online psycho-education for parents of food allergic children.

Name of Researcher: Naomi Sugunasingha

Please select all of the relevant boxes.

- ☐ 1. I confirm that I have read and understand the information sheets for the above study. I have been given the opportunity to consider the information, ask questions and have had any questions answered satisfactorily.
- ☐ 2. I understand that my participation is voluntary and that I am free to withdraw myself at any time without giving any reason.
- ☐ 3. I understand that relevant sections of my data collected during the study may be looked at by the lead supervisors [Fergal Jones and Christina Jones]. I give permission for these individuals to have access to my data.
- ☐ 4. I agree that anonymous quotes from my feedback questionnaire may be used in published reports of the study findings
- ☐ 5. I am aware that the information provided on the website is not intended to replace the a guidance given to me by my child's regular healthcare professional.
- ☐ 6. I agree to take part in the above study.

0% 100%

← →

APPENDIX M: Qualtrics messages to participants

Start of study messages to intervention and control groups

CONTROL GROUP Edit Select Language

Thank you for agreeing to take part in this study.

Delayed access:
You have been randomly chosen to access the website in 8 weeks from now.

A reminder for why we have a delayed access group:
Sometimes we don't know which form of intervention is the most effective. In order to find out, we need to compare our intervention with the support already in place. At the start of a study, we put people into groups and give each group a different intervention (e.g. immediate vs delayed access to the website). The results are compared to see if one is better. To try to make sure the groups are the same to start with, each participant is put into a group by chance (randomly). You have been placed in the group that does not have immediate access to the website, but will be given full access to the website after 8 weeks. This can help us to see if the website is a useful resource relative to support services already in place.

Questionnaires
You have just completed the first set of questionnaires, which are designed to give me some information about your experiences and levels of stress. You will be asked to complete these questionnaires twice more-- in a month, and again after 8 weeks. This will let us follow any changes to how you are feeling. Finally, you will also be asked to provide feedback after 12 weeks, which will give you the opportunity to let me know if you found the website helpful.

What happens next?
The study will take three months from start to finish. *For the first 8 weeks, you will not need to do anything.*After 8 weeks, you will be sent a link and password to access the website. As the study will be conducted online, you will not be required to attend any meetings, and you may access the website at times that work best for you. We may send you emails to remind you to look at the website. If you have any questions you will be able to contact me via email (n.sugunasingha449@canterbury.ac.uk). Finally, you will also be asked to provide feedback after 12 weeks, which will give you the opportunity to let me know if you found the website helpful.

Extra support
If you experience any distress as a result of these questionnaires, or at any point during the study, we would recommend that you access support through your general practitioner (GP). There is also an attached document highlighting further resources for psychological support. Please note that these additional resources are primarily based in the United Kingdom. If you are accessing the study from another location, we would ask that you seek further guidance from your primary care physician or family doctor.

Attachments
Participant Information Sheet
Support Resources

This information will be sent to you via email, so that you may review it at your convenience.

EXPERIMENTAL GROUP

Edit Select Language

Thank you for agreeing to take part in this study. You have been allocated to the group that is given immediate access to the website.

Please follow the link below to access website Guest Area. You will be asked to enter a password for full access to the study website.

Website: https://www.pascalstudy.co.uk
Password: Pascal2018

We would please request that users do not share their password or the website content with anyone else, especially others who are involved in the study.

What happens next?
Please take some time to read through the website content and download anything you might find useful. The study will take three months from start to finish. As the study will be conducted online, you will not be required to attend any meetings, and you may access the website at times that work best for you. We may send you emails to remind you to look at the website. If you have any questions you will be able to contact me via email (n.sugunasingha449@canterbury.ac.uk).

Questionnaires
You have just completed the first set of questionnaires, which are designed to give me some information about your experiences and levels of stress. You will be asked to complete these questionnaires twice more-- in a month, and again after 8 weeks. This will let us follow any changes to how you are feeling. Finally, you will also be asked to provide feedback after 12 weeks, which will give you the opportunity to let me know if you found the website helpful.

Extra support
If you experience any distress as a result of these questionnaires, or at any point during the study, we would recommend that you access support through your general practitioner (GP). There is also an attached document highlighting further resources for psychological support. Please note that these additional resources are primarily based in the United Kingdom. If you are accessing the study from another location, we would ask that you seek further guidance from your primary care physician or family doctor.

Attachments
Participant Information Sheet
Support Resources

This information will be sent to you via email, so that you may review it at your convenience.

APPENDIX M: Qualtrics messages to participants continued.

Ending messages at post-intervention (Time 2), follow-up (Time 3) and following feedback

TIME 2 ENDING

Edit

Select Language

Thank you for completing the second round of questionnaires. Please note you will be contacted again in another 4 weeks.

TIME 3 Ending

Edit

Select Language

Thank you for your continued participation in the study. All participants will now have access to the website--please see information below about how to log in.

Website
Please follow the link to access the website Guest Area. You will be asked to enter the password below for full access to the study website.

Website: https://www.pascalstudy.co.uk
Password: Pascal2018

What happens next?
Please take some time to read through the website content and download any useful information. You may access the website at times that work best for you. If you have any questions you will be able to contact me via email (n.sugunasingha449@canterbury.ac.uk).

Questionnaires
You have just completed the third set of questionnaires, which are designed to give me some information about your experiences and levels of stress over the past 8 weeks. We will contact you a final time 4 weeks from now with a short feedback questionnaire where you can let us know what you think about the website. We look forward to hearing your thoughts then.

Extra support
If you experience any distress as a result of these questionnaires, or at any point during the study, we would recommend that you access support through your general practitioner (GP). There is also an attached document highlighting further resources for psychological support. Please note that these additional resources are primarily based in the United Kingdom. If you are accessing the study from another location, we would ask that you seek further guidance from your primary care physician or family doctor.

Dear participant,

Thank you for your feedback of the PASCAL study! You have now completed the study, and we are very grateful for your invovlement.

If you consented to an update of research findings, a summary of the results will be sent out to the email you provided in due course.

Additional Support:
Further information about support services are attached below. Please note that the PASCAL study is based in the United Kingdom and suggested services are primarily accessible in this region. Should you feel in need of additional support and you are not in the UK, we would advise that you speak with your doctor (general practitioner [GP], primary care physician, etc.)

Support Resources

Thank you!

APPENDIX N: Ethics committee approval letter

THIS HAS BEEN REMOVED FROM THE ELECTRONIC COPY

APPENDIX O: Data exploration

Baseline descriptive statistics

Statistics

treated			t1_qol	t1_phq	t1_gad	t1_pss
Control	N	Valid	93	93	93	93
		Missing	0	0	0	0
	Mean		85.4409	4.4409	6.0215	17.1720
	Std. Error of Mean		2.00505	.43013	.56320	.68692
	Median		90.0000	4.0000	5.0000	18.0000
	Std. Deviation		19.33597	4.14798	5.43135	6.62443
	Skewness		-.693	.992	.862	-.242
	Std. Error of Skewness		.250	.250	.250	.250
	Kurtosis		-.077	.206	-.227	-.613
	Std. Error of Kurtosis		.495	.495	.495	.495
	Range		83.00	16.00	19.00	28.00
	Percentiles	25	72.5000	1.0000	1.5000	13.0000
		50	90.0000	4.0000	5.0000	18.0000
		75	100.0000	7.0000	10.0000	21.5000
Treatment	N	Valid	112	112	112	112
		Missing	0	0	0	0
	Mean		84.1607	4.9643	5.6964	17.5000
	Std. Error of Mean		1.80124	.46550	.46600	.68515
	Median		86.0000	4.0000	5.0000	17.5000
	Std. Deviation		19.06251	4.92636	4.93168	7.25097
	Skewness		-.381	1.400	.975	.142
	Std. Error of Skewness		.228	.228	.228	.228
	Kurtosis		-.673	1.684	.347	-.084
	Std. Error of Kurtosis		.453	.453	.453	.453
	Range		78.00	21.00	20.00	35.00
	Percentiles	25	73.0000	1.0000	2.0000	13.2500
		50	86.0000	4.0000	5.0000	17.5000
		75	99.7500	7.0000	8.0000	21.7500

Baseline normality tests

Tests of Normality

		Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	treated	Statistic	df	Sig.	Statistic	df	Sig.
t1_qol	Control	.111	93	.007	.954	93	.002
	Treatment	.079	112	.081	.968	112	.009
t1_phq	Control	.187	93	.000	.885	93	.000
	Treatment	.185	112	.000	.849	112	.000
t1_gad	Control	.166	93	.000	.894	93	.000
	Treatment	.154	112	.000	.900	112	.000
t1_pss	Control	.085	93	.097	.978	93	.109
	Treatment	.071	112	.200*	.987	112	.358

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

APPENDIX O: Data exploration continued.

Post-intervention descriptive statistics

Statistics

treated			t2_qol	t2_phq	t2_gad	t2_pss
Control	N	Valid	56	56	56	56
		Missing	37	37	37	37
	Mean		80.5536	5.3393	6.4286	17.4821
	Std. Error of Mean		2.71216	.64931	.77955	.96799
	Median		82.0000	4.0000	5.0000	18.5000
	Std. Deviation		20.29592	4.85902	5.83362	7.24378
	Skewness		-.609	.816	.959	-.478
	Std. Error of Skewness		.319	.319	.319	.319
	Kurtosis		-.034	-.316	.036	-.351
	Std. Error of Kurtosis		.628	.628	.628	.628
	Range		89.00	17.00	21.00	29.00
	Percentiles	25	66.0000	1.2500	2.0000	13.2500
		50	82.0000	4.0000	5.0000	18.5000
		75	95.7500	8.7500	9.0000	22.7500
Treatment	N	Valid	47	47	47	47
		Missing	65	65	65	65
	Mean		78.3191	5.4468	5.5532	16.8723
	Std. Error of Mean		2.78693	.75904	.80574	1.16994
	Median		79.0000	3.0000	4.0000	16.0000
	Std. Deviation		19.10623	5.20371	5.52389	8.02067
	Skewness		-.284	.985	1.234	.192
	Std. Error of Skewness		.347	.347	.347	.347
	Kurtosis		-.613	.155	.636	-.208
	Std. Error of Kurtosis		.681	.681	.681	.681
	Range		74.00	19.00	19.00	36.00
	Percentiles	25	65.0000	2.0000	1.0000	13.0000
		50	79.0000	3.0000	4.0000	16.0000
		75	95.0000	9.0000	8.0000	23.0000

Post-intervention normality tests

Tests of Normality

		Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	treated	Statistic	df	Sig.	Statistic	df	Sig.
t2_qol	Control	.108	56	.158	.962	56	.077
	Treatment	.070	47	.200*	.972	47	.325
t2_phq	Control	.167	56	.000	.897	56	.000
	Treatment	.192	47	.000	.874	47	.000
t2_gad	Control	.140	56	.008	.887	56	.000
	Treatment	.191	47	.000	.840	47	.000
t2_pss	Control	.116	56	.057	.960	56	.061
	Treatment	.087	47	.200*	.985	47	.793

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

APPENDIX O: Data exploration continued.

Follow-up descriptive statistics

Statistics

treated			t3_qol	t3_phq	t3_gad	t3_pss
Control	N	Valid	49	49	49	49
		Missing	44	44	44	44
	Mean		79.3878	6.2857	7.3469	18.2245
	Std. Error of Mean		2.69870	.78788	.88041	1.10050
	Median		83.0000	5.0000	6.0000	20.0000
	Std. Deviation		18.89093	5.51513	6.16290	7.70353
	Skewness		-.556	.998	.576	-.391
	Std. Error of Skewness		.340	.340	.340	.340
	Kurtosis		-.327	.068	-.777	-.551
	Std. Error of Kurtosis		.668	.668	.668	.668
	Range		75.00	20.00	21.00	32.00
	Percentiles	25	66.5000	2.0000	2.0000	12.5000
		50	83.0000	5.0000	6.0000	20.0000
		75	94.0000	8.0000	11.5000	24.0000
Treatment	N	Valid	43	43	43	43
		Missing	69	69	69	69
	Mean		72.7674	4.7442	4.3953	15.7674
	Std. Error of Mean		3.23478	.72535	.71462	1.17176
	Median		72.0000	4.0000	4.0000	16.0000
	Std. Deviation		21.21190	4.75641	4.68605	7.68374
	Skewness		-.085	1.187	1.303	-.102
	Std. Error of Skewness		.361	.361	.361	.361
	Kurtosis		-.911	1.314	1.534	-.022
	Std. Error of Kurtosis		.709	.709	.709	.709
	Range		77.00	20.00	17.00	31.00
	Percentiles	25	53.0000	1.0000	.0000	11.0000
		50	72.0000	4.0000	4.0000	16.0000
		75	90.0000	8.0000	7.0000	20.0000

Follow-up normality tests

Tests of Normality

		Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	treated	Statistic	df	Sig.	Statistic	df	Sig.
t3_qol	Control	.107	49	.200*	.955	49	.061
	Treatment	.085	43	.200*	.965	43	.217
t3_phq	Control	.153	49	.006	.881	49	.000
	Treatment	.159	43	.008	.876	43	.000
t3_gad	Control	.134	49	.028	.916	49	.002
	Treatment	.174	43	.002	.834	43	.000
t3_pss	Control	.122	49	.067	.971	49	.254
	Treatment	.104	43	.200*	.971	43	.332

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

APPENDIX P: Baseline comparisons

Comparison on baseline measures between participants allocated to the PASCAL intervention compared to the waitlist control (randomisation check).

Test Statistics[a]

	t1_qol	t1_phq	t1_gad	t1_pss
Mann-Whitney U	4971.500	5000.000	5159.000	5207.000
Wilcoxon W	11299.500	9371.000	11487.000	11535.000
Z	-.559	-.495	-.116	-.002
Asymp. Sig. (2-tailed)	.576	.621	.907	.998

a. Grouping Variable: treated

Comparison on baseline measures for participants who completed post-intervention measures and those who did not

Test Statistics[a]

	t1_qol	t1_phq	t1_gad	t1_pss
Mann-Whitney U	4689.000	4713.500	4786.500	4296.500
Wilcoxon W	10045.000	10069.500	10142.500	9652.500
Z	-1.328	-1.278	-1.103	-2.255
Asymp. Sig. (2-tailed)	.184	.201	.270	.024

a. Grouping Variable: attrition t1t2

Comparison on baseline measures for participants who completed follow-up measures and those who did not

Test Statistics[a]

	t1_qol	t1_phq	t1_gad	t1_pss
Mann-Whitney U	4598.000	5183.000	4938.500	4870.000
Wilcoxon W	8876.000	11624.000	9216.500	9148.000
Z	-1.421	-.036	-.617	-.777
Asymp. Sig. (2-tailed)	.155	.971	.537	.437

a. Grouping Variable: attrition_t1t3

Comparison on baseline measures for participants who completed both post-intervention and follow-up measures and those who did not

Test Statistics[a]

	t1_qol	t1_phq	t1_gad	t1_pss
Mann-Whitney U	4290.000	4766.500	4607.500	4207.000
Wilcoxon W	6991.000	7467.500	7308.500	6908.000
Z	-1.298	-.127	-.520	-1.504
Asymp. Sig. (2-tailed)	.194	.899	.603	.133

a. Grouping Variable: attrition_any

Comparison on baseline measures for differences in the treatment versus control group for participants that completed post-intervention measures (Intervention group N= 47; Control group N = 56)

Test Statistics[a]

	t1_qol	t1_phq	t1_gad	t1_pss
Mann-Whitney U	1276.000	1275.000	1169.000	1205.500
Wilcoxon W	2404.000	2403.000	2297.000	2333.500
Z	-.265	-.274	-.978	-.733
Asymp. Sig. (2-tailed)	.791	.784	.328	.464

a. Grouping Variable: treated_att_t2

Comparison on baseline measures for differences in the treatment versus control group for participants that completed follow-up measures (Intervention group N= 43; Control group N = 49)

Test Statistics[a]

	t1_qol	t1_phq	t1_gad	t1_pss
Mann-Whitney U	849.000	1039.500	886.000	970.000
Wilcoxon W	1795.000	1985.500	1832.000	1916.000
Z	-1.601	-.110	-1.317	-.654
Asymp. Sig. (2-tailed)	.109	.912	.188	.513

a. Grouping Variable: treated_att_t3

Comparison on baseline measures for differences in the treatment versus control group for participants that completed both post-intervention and follow-up measures (Intervention group N= 32; Control group N = 41)

Test Statistics[a]

	t1_qol	t1_phq	t1_gad	t1_pss
Mann-Whitney U	540.500	647.000	548.000	578.000
Wilcoxon W	1068.500	1175.000	1076.000	1106.000
Z	-1.285	-.101	-1.206	-.868
Asymp. Sig. (2-tailed)	.199	.920	.228	.385

a. Grouping Variable: treated_att_any

APPENDIX Q: Sub-group analysis comparisons

Ranks

phq_hi		treated	N	Mean Rank	Sum of Ranks
Low	diff_t1t2_qol	Control	47	43.98	2067.00
		Treatment	41	45.10	1849.00
		Total	88		
	diff_t1t2_phq	Control	47	44.16	2075.50
		Treatment	41	44.89	1840.50
		Total	88		
	diff_t1t2_gad	Control	47	44.78	2104.50
		Treatment	41	44.18	1811.50
		Total	88		
	diff_t1t2_pss	Control	47	45.33	2130.50
		Treatment	41	43.55	1785.50
		Total	88		
High	diff_t1t2_qol	Control	9	9.94	89.50
		Treatment	6	5.08	30.50
		Total	15		
	diff_t1t2_phq	Control	9	8.06	72.50
		Treatment	6	7.92	47.50
		Total	15		
	diff_t1t2_gad	Control	9	7.89	71.00
		Treatment	6	8.17	49.00
		Total	15		
	diff_t1t2_pss	Control	9	7.67	69.00
		Treatment	6	8.50	51.00
		Total	15		

Test Statistics[a]

phq_hi		diff_t1t2_qol	diff_t1t2_phq	diff_t1t2_gad	diff_t1t2_pss
Low	Mann-Whitney U	939.000	947.500	950.500	924.500
	Wilcoxon W	2067.000	2075.500	1811.500	1785.500
	Z	-.205	-.136	-.110	-.327
	Asymp. Sig. (2-tailed)	.837	.892	.912	.743
High	Mann-Whitney U	9.500	26.500	26.000	24.000
	Wilcoxon W	30.500	47.500	71.000	69.000
	Z	-2.068	-.059	-.119	-.355
	Asymp. Sig. (2-tailed)	.039	.953	.905	.722
	Exact Sig. [2*(1-tailed Sig.)]	.036[b]	.955[b]	.955[b]	.776[b]

a. Grouping Variable: treated

b. Not corrected for ties.

APPENDIX R: Google analytics data for website access

Descriptive statistics including data points at 00:00

Statistics

duration_minutes

N	Valid	108
	Missing	0
Mean		2.6535
Std. Error of Mean		.56255
Median		.0000
Std. Deviation		5.84614
Skewness		2.905
Std. Error of Skewness		.233
Kurtosis		8.317
Std. Error of Kurtosis		.461
Range		28.10
Minimum		.00
Maximum		28.10
Percentiles	25	.0000
	50	.0000
	75	1.8542

Descriptive statistics excluding data points at 00:00

Statistics

duration_minutes_nz

N	Valid	48
	Missing	60
Mean		5.9705
Std. Error of Mean		1.09528
Median		2.3083
Std. Deviation		7.58835
Skewness		1.696
Std. Error of Skewness		.343
Kurtosis		2.026
Std. Error of Kurtosis		.674
Range		27.82
Minimum		.28
Maximum		28.10
Percentiles	25	1.2125
	50	2.3083
	75	9.5833

APPENDIX S: Content analysis sample coding frame

Do you have any additional comments about the study or the website?
Useful- attention to the area
Useful- new to allergies
Thanks for the study
No time to review the website
More psychological support
Local support

Do you have any additional comments about the study or the website?	**Coder 1**	**Coder 2**
Useful- new to allergies	2	2
Useful- attention to the area	2	2
Thanks for the study	2	2
No time to review the website	2	2
More psychological support	1	1
Local support	1	1
No further comments		

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APPENDIX T: Update to ethics committee

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APPENDIX U: Feedback summary to participants

Thank you for your interest in the PASCAL study- a research study looking to explore the effectiveness of an online self-help intervention for parents of food-allergic children. This is a summary of our results.

Development:
The website was created in consultation with expert parents and users of services, as well as allergy specialists.

Study:
Parents were allocated into one of two groups at random – one group had access to the website straight away and the other group received access to the website 8 weeks later. This helped us to know how helpful our website was in supporting parents. The study ran from October 2018 until February 2019. As the website is no longer running, a copy of the downloadable content is also attached to this summary.

Current research has highlighted that there are very few interventions which support parents caring for children with food allergies. The research also suggests that a particular worry for some parents is "handing over" care to others, as well as having limited accessible information about how to manage food-allergies. The website aimed to offer parents and caregivers easy and accessible information about allergies, which could be handed out to other individuals who might look after your children (e.g., teachers, other parents, etc.).

The content covered general information about allergies, allergic reactions, emergency preparedness (e.g., how to correctly use an auto-injector), stress and worry management techniques and supportive comments from other parents ("top tips").

Results:
Our analysis of the questionnaire results did not show that the website had a big effect on quality of life, anxiety, stress or feelings of low mood between the start and the end of the study.

We found that many parents were interested in the study, and completed our questionnaires at each time point. However, analysis showed that very few people spent time on the website. We wondered whether this might mean that the website was not useful for participants which is important information for us to consider. The feedback we received from participants

agreed that the information was very easy to understand, but for many was not new information as the parents involved reported caring for a child with food allergies for a number of years. Many of you suggested that the website would be better suited to parents who are new to allergy management.

What does this tell us?

We found that our particular website was potentially not aimed at the right subgroup of people, and think that the research needs to tailor studies to the needs of individual groups. This website with basic allergy management information may be better suited to parents of newly diagnosed children. Further research needs to be completed to add to this study and better understand how best to support parents of children with allergies.

APPENDIX V: Author guideline notes for the Journal of Allergy and Clinical Immunology: In Practice (JACI-In Practice)

The Journal of Allergy and Clinical Immunology: In Practice covers the spectrum of conditions treated by allergy-immunologists in their practice. The emphasis of the journal is to provide practical information for clinicians that they can use in their everyday practice.

As JACI-In Practice require an accurate word count of 3,500, this thesis will be edited to meet this criteria.

More detailed criteria can be viewed on: https://www.elsevier.com/journals/the-journal-of-allergy-and-clinical-immunology-in-practice/22132198/guide-for-authors