Mental Health of Children with Food Allergy and their Parents

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Thesis Portfolio Abstract

The psychological impact that food allergy may have for both children and their parents has received increased interest in recent years. This portfolio aims to offer a timely and novel contribution to this field, through firstly presenting a systematic review with meta-analysis assessing the prevalence of anxiety, depression, and post-traumatic stress in children with food allergy. An original piece of empirical research is subsequently presented, assessing worry, anxiety, and post-traumatic stress symptoms in a relatively large sample (*N*=104-105) of parents of children with food allergy.

The systematic review found pooled prevalence estimates of 12.6% (95% CIs 6.0%-19.3%) for anxiety and 6.9% (95% CIs 1.3%-12.5%) for depression in children with food allergy. Compared to their peers without food allergy, the review found a small but significant increase in anxiety (*d*=0.21; 95% CIs 0.16-0.26) and depression (*d*=0.30; 95% CIs 0.14-0.45) in children with food allergy. However, due to high degrees of heterogeneity and relatively small sample sizes, these results remain tentative. Additionally, only one pilot study was found assessing post-traumatic stress.

The empirical study used an online questionnaire to assess mental health in parents of children with food allergy. The study found 81.0% of parents reported clinically significant worry, 42.3% met the clinical cut-off for post-traumatic stress symptoms, and 39.1% reported moderate-extremely severe anxiety. Regression analyses were conducted including allergy severity, intolerance of uncertainty, and food allergy self-efficacy, which were significant for all three psychological outcomes. However, intolerance of uncertainty was the most consistent predictor of poorer mental health.

Overall, the portfolio highlights the need for further consideration of the psychological impact of food allergy. In particular, the potential for post-traumatic stress in this population, which had not previously been assessed in a large-scale study. Theoretical and clinical implications, as well as recommendations for future research are discussed.

Table of Contents

Thesis Portfolio Abstract **2**

Acknowledgements **9**

Introduction to Portfolio **10**

Chapter 1: Systematic Review **13**

Abstract 14

Introduction 15

Method 17

Results 20

Discussion 32

References 35

Supplementary Material 1: Details of Search Strategy 42

Supplementary Material 2: Quality Assessment Rating Tool 43

Chapter 2: Bridging Chapter **46**

Chapter 3: Empirical Research Project **51**

Abstract 52

Introduction 53

Method 57

Results 64

Discussion 72

References 75

Chapter 4: Extended Methodology 81

Ethical Considerations 81

Demographic and Allergy Questionnaire 83

Power Analysis 84

Chapter 5: Extended Results 85

Statistical Assumptions 85

Relationship Between Allergy Severity Variables 88

Exploratory Data Analysis 90

Chapter 6: Discussion 101

Summary of Results 101

Links to Previous Research 103

Theoretical Implications 111

Clinical Implications 117

Strengths and Limitations 120

Future Research 123

Conclusion 126

Bibliography 127

Appendices 140

List of Tables

Table 1. Review Inclusion and Exclusion Criteria 18

Table 2. Overall Quality Assessment Ratings of Included Studies 22

Table 3. Summary of Studies Included in Prevalence Synthesis.....23

Table 4. Summary of Studies Included in Difference Synthesis 28

Table 5. Child Food Allergy(s) and Symptoms Reported by Parents 62

Table 6. Mean Scores and Correlations Between Intolerance of Uncertainty, Food Allergy Self-Efficacy, Worry, Anxiety, and Post-Traumatic Stress Symptoms 66

Table 7. Differences in Worry, Anxiety, and Post-Traumatic Stress Symptoms in Parents Whose Children do and do not Have Indicators of More Severe Food Allergies.....67

Table 8. Hierarchical Multiple Regression Model for Parental Worry (PSWQ).....68

Table 9. Logistic Regression Model of Anxiety in Parents of Children with Food Allergies.....69

Table 10. Classification Table for Logistic Regression Model of Anxiety 70

Table 11. Logistic Regression Model of PTSS in Parents of Children with Food Allergies.....71

Table 12. Classification Table for Logistic Regression Model of PTSS.....71

Table 13. Correlations Between All Continuous Variables Assessed in Empirical Study 92

Table 14. Differences in Worry, Anxiety, and PTSS Scores with all Possible Dichotomous Demographic and Allergy Variables.....93

Table 15. Exploratory Logistic Regression Model for Anxiety in Parents of Children with Food Allergies 97

Table 16. Classification Table for Exploratory Logistic Regression Model of Anxiety 98

Table 17. Exploratory Logistic Regression Model of Parental PTSS in Food Allergies.....99

Table 18. Classification Table for Exploratory Logistic Regression Model of PTSS 99

List of Figures

Figure 1. PRISMA Diagram showing studies included and excluded from review with reasons. 21

Figure 2. Cognitive Model of Anxiety, replicated from Clark, D.A., & Beck, A.T. (2010). Cognitive Therapy of Anxiety Disorders: Science and Practice. New York: Guildford Press. 50

Figure 3. Histogram showing parents' PTSS scores. 87

Figure 4. Histogram showing parents' anxiety scores. 88

Figures 5-9. Forest plots of prevalence syntheses. 158

Figures 10-15. Forest plots of difference syntheses. 159

List of Appendices

Appendix A: Allergy Author Guidelines 140

Appendix B: Forest Plots for all Meta-Analysis Syntheses 158

Appendix C: Journal of Pediatric Psychology Author Guidelines 162

Appendix D: REC and HRA Letters Confirming Ethical Approval 170

Appendix E: Participant Information Sheet (Clinic Version).....178

Appendix F: Appendix E: Consent to Contact Form 180

Appendix G: Participant Information Sheet (Online) 181

Appendix H: Consent Form 184

Appendix I: Participant Pre-Brief 186

Appendix J: Participant Debrief Information 187

Appendix K: Demographic and Allergy Questionnaire 189

Appendix L: Penn State Worry Questionnaire (Meyer, Miller, Metzger, & Borkovec, 1990) 197

Appendix M: Depression Anxiety Stress Scales 21 - Anxiety subscale (Lovibond & Lovibond, 1995) 198

Appendix N: Impact of Events Scale – Revised (Weiss & Marmar, 1997) with adapted instructions 199

Appendix O: Intolerance of Uncertainty Scale – Short Form (Carleton et al., 2007) 201

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Introduction to Portfolio

Food allergy is a relatively common chronic health condition in childhood, with prevalence around 6-8%, and suggestions of rising prevalence over recent years (Luyt, Ball, Kirk, & Stiefel, 2016). Food allergy also presents some largely unique challenges for children and those caring for children with food allergy. Medical management of food allergy currently focuses on reducing the risk of exposure (i.e. avoiding allergens) and managing symptoms where accidental exposure occurs (Boyce et al., 2011). As well as being a necessity, food is often social and, albeit to varying degrees, dependent on others (e.g. shops/food suppliers), which is a notable difference to most other forms of allergy (e.g. venom). Successful avoidance can therefore be challenging, and relies on the understanding and caution of not only themselves but also other individuals (e.g. teachers, those working in the food industry) and large food companies (i.e. for accurate allergen labeling).

Over recent years, there has been an increased awareness of the possible impact food allergy could have for the psychological wellbeing of children and their parents/carers (e.g. Cummings, Knibb, King, & Lucas, 2010). However, as the field remains in its relative infancy, there are substantial gaps in the psychological literature. This portfolio aims to offer a timely contribution to this field: firstly, offering a systematic review of the current evidence base assessing the prevalence of mental health problems in children with food allergy; secondly, presenting an original piece of empirical research that assesses anxiety and post-traumatic stress symptoms in parents of children with food allergy. Additional information on the methodology and results of the empirical paper is also provided, and the thesis concludes with a summary and discussion of the results and implications of the

portfolio. However, it is first useful to provide an overview of information and terminology relevant to the remainder of this portfolio: firstly through outlining how 'children' is defined within this portfolio; and secondly defining food allergy, and overviewing allergy symptoms and management.

The age range to which 'children' refers is variable across the literature. For example, in some instances 'children' is used to refer to the pre-adolescence period ending around the age of 12 years (e.g. Hardin & Hackell, 2017). This portfolio takes a wider definition of 'children' referring to the period between birth and adulthood, which is in keeping with legal definitions (e.g. United Nations, 1989) and much of the paediatric psychology literature (e.g. Bennett, Shafran, Coughtrey, Walker, & Heyman, 2015; Lau et al., 2014; Roberts, Maddux, & Wright, 1984). The age at which 'adulthood' is considered to begin is variable, but often refers to a time between the ages of 16 and 19 years (e.g. European Union Agency for Fundamental Rights, 2017; World Health Organisation, 2013). As the systematic review within this portfolio aims to synthesise the wider literature, an internationally relevant definition of children from the United Nations is used, which defines a child as someone below the age of 18 years (United Nations, 1989). In contrast, the empirical paper is limited to the United Kingdom (UK). Whilst the legal definition of a child in the UK is below 18 years (Children Act 1989), the paediatric service where recruitment occurred, and many health services, transition children to adult care at 17 years. As such, the slightly younger age range of 0-16 years is used for the purpose of the empirical paper within this portfolio.

Food allergies involve adverse immune reactions to specific allergens, with symptoms affecting the skin, respiratory and/or gastrointestinal systems (NICE, 2011a). Food allergies can be broadly categorized as immunoglobulin E (IgE)-

mediated and non-IgE mediated. IgE-mediated allergies are typically characterized by rapid reactions and can in the most severe instances lead to anaphylaxis. Anaphylaxis is a potentially life threatening reaction, involving rapid changes to breathing, airways, and/or circulation (Resuscitation Council (UK), 2008). Non-IgE mediated allergies typically involve delayed reactions and symptoms such as eczema, diarrhea or constipation (NICE, 2011a). However, mixed IgE and non-IgE reactions are possible.

Diagnosis of food allergy involves taking a clinical history. Where IgE-mediated allergy is suspected, blood tests and/or skin prick tests should be used to aid diagnosis, whereas suspected non-IgE allergies typically involve trial elimination and reintroduction of the suspected allergen (NICE, 2011a).

If exposure to food allergen(s) occurs, for milder allergic reactions, management of symptoms typically involves the use of anti-histamines (Boyce et al., 2011). Where anaphylaxis is suspected, the focus is on administering epinephrine at the earliest possible opportunity (Boyce et al., 2011); as such, individuals at risk of anaphylaxis should carry an adrenaline auto injector (AAI; e.g. EpiPen, Emerade). If anaphylaxis is suspected, emergency services should be contacted and children suspected of experiencing anaphylaxis should be admitted to hospital under the care of a paediatric medical team (NICE, 2011b).

Overall, children with food allergy and their parents face a number of additional challenges and risks, which is important context for understanding psychological wellbeing in this population, as discussed throughout the remaining portfolio. The following chapter presents a systematic review with meta-analysis assessing the prevalence of mental health conditions in children with food allergy.

Chapter 1: Systematic Review

The following paper has been written in accordance with the guidelines of the journal *Allergy*. Author guidelines for *Allergy* are displayed in Appendix A. For the purpose of the thesis portfolio, tables and figures have been included in position. Information that would be submitted as supplementary material is indicated in text and included immediately following the paper. Forest plots included for the purpose of the thesis portfolio only are displayed in Appendix B.

Word count (UEA guidelines): 4998

What is the prevalence of anxiety, depression, and post-traumatic stress in children with food allergies? A meta-analysis.

Short title: Mental health in paediatric food allergy: A review

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Abstract

Introduction: Paediatric food allergy has been suggested to impact on children's psychological wellbeing. This review evaluates the prevalence of anxiety, depression, and post-traumatic stress in children (aged 0-17 years) with food allergy, and compares this to children without food allergy. *Method:* A systematic search of three databases (Medline, CINAHL and PsycINFO) found 14 studies that met the review inclusion criteria. Risk of bias was assessed, and where sufficient data was available random effects meta-analyses were used to synthesise the data. *Results:* The review found pooled prevalence estimates of 12.6% (95% CIs 6.0%-19.3%) for anxiety and 6.9% (95% CIs 1.3%-12.5%) for depression in children with food allergy. Compared to their peers without food allergy, the review found a small but significant increase in anxiety (d=0.21; 95% CIs 0.16-0.26) and depression (d=0.30; 95% CIs 0.14-0.45) in children with food allergy. However, these results differed between anxiety disorders, with evidence of increased separation and generalized anxiety but no significant increase in social anxiety in children with food allergy. Only one pilot study was identified assessing post-traumatic stress in children with food allergy. *Conclusion:* This review indicates that children with food allergy may be at a small but significant increased risk of experiencing mental health problems. However, there is a high degree of heterogeneity in the current evidence base, and the total sample sizes remain small, therefore the conclusions drawn are tentative.

Key words: anxiety, depression, food allergy, post-traumatic stress, review

Introduction

It has been suggested that children with chronic health conditions may be at greater risk of experiencing mental health problems, for example due to needing to manage symptoms of illness and medical procedures.[1] Meta-analyses support an overall small increase in anxiety and depression in children with chronic health conditions.[1,2] However, substantial variance in the effect sizes between health conditions was found, demonstrating the importance of considering mental health in specific health problems rather than general paediatric populations. Food allergy was not included in these previous reviews, despite being a common health condition in childhood,[3] likely due to the paucity of available research at the time.

Food allergy has been suggested to impact on children's psychological wellbeing both directly and indirectly. Direct impact of food allergy may include increased anxiety due to the risk of accidental exposure,[4] or the emotional impact for children who have experienced severe, potentially life-threatening allergic reactions, which would meet ICD-11[5] and DSM-5[6] definitions of a stressful event as required in the diagnosis of post-traumatic stress disorder. Indirectly, food allergy has been suggested to impact on child mental health through mechanisms such as indications of increased incidence of bullying in children with food allergy,[7] which in turn has well-established links with anxiety and depression.[8,9]

All the factors outlined above demonstrate how food allergy presents additional risks and threats for children to manage, which is a common feature across psychological models of anxiety.[10] Whilst there is a lack of literature exploring health related beliefs in food allergy, the nature of the threat in food allergy involves a degree of uncertainty (i.e. due to the inability to completely control exposure to allergens), which is one factor suggested to increase anxiety in the wider literature.[10–

[12] Furthermore, if avoidance of allergens leads to withdrawal from certain activities (e.g. social activities involving food), this would be suggested to impact on mood[13] as well as anxiety.[10] Therefore, on the basis of psychological models and theory, one may reasonably predict that children with food allergy could be at elevated risk of experiencing mental health difficulties. Better understanding the presence and nature of mental health problems in children with food allergy is important for assessing the psychological needs and for adapting psychological interventions in this population.

A review of the psychosocial impact of food allergy was previously conducted in 2010.[14] However, at the time of this review the majority of research had focused on quality of life rather than specific mental health problems. Only two studies were found using a validated measure of anxiety in a child food allergy population,[15,16] no papers were found assessing depression in children with food allergy, and trauma was not included within the search terms of the review. Since this time, there has been a significant increase in research in the field; as such, there is a clear need for an updated synthesis. Furthermore, it is now possible to consider psychosocial impact in more detail, through the differentiation of broader quality of life and more specific mental health problems. The present review focuses on anxiety, depression, and post-traumatic stress due to the paucity of mental health research at the time of the previous systematic review.

Therefore, the present review addresses two questions:

1. What is the prevalence of anxiety, depression, and post-traumatic stress in children with food allergy?
2. Do the levels of anxiety, depression, and post-traumatic stress symptoms in children with food allergy differ from normative samples?

Method

This review was registered on PROSPERO (ID: CRD42018096212), an international prospective register of systematic reviews.

Search Strategy

The search included three databases: Medline, CINAHL and PsycINFO. The search included research from the start date of each database up to the 13th June 2018. The full search strategy is available is Supplementary Material 1; search terms included variants of anxiety, depression, or post-traumatic stress, and variants of allergy or anaphylaxis, as well as relevant index terms.

Inclusion and Exclusion Criteria

The inclusion criteria for the present review are summarised in Table 1. For all studies, food allergy could be self-reported, confirmed by a paediatrician/other relevant healthcare professional, or indicated by medical tests. Mental health could be assessed through self-report measures or diagnostic interview. The approaches used to identify the food allergy and assess mental health were considered in the subsequent quality assessment and synthesis of the data. Where studies used a methodology that could meet inclusion criteria, but the required data were not reported in such a way that could be reliably extracted from the original paper, authors were contacted to attempt to obtain the relevant information. Where no response was provided by 2nd February 2019 these studies were excluded from the review.†

†Any information received from authors after this date will be incorporated prior to submission to a journal; as of the 2nd February information from two studies was outstanding.

Table 1. Review Inclusion and Exclusion Criteria

Inclusion	Exclusion
• Anxiety, depression, and/or trauma symptoms assessed in children (age 0-17 years) with food allergy For prevalence: • Proportion of children with a diagnosis or clinically significant symptoms of above mental health conditions reported For difference: • Mean and N or proportion diagnosed for above mental health conditions reported for food allergy and comparison group • Comparison group aged 0-17 years, general or healthy population, and same mental health assessment as food allergy group	• Non-English Language • Non-peer reviewed studies • Adult population (over 17 years) • Non-allergic food reactions (e.g. coeliac disease) • Non-food allergy • Studies reporting no new data or only qualitative data For prevalence: • Measures of general mental health symptomology with no defined clinical cut-off For difference: • Comparison to previously published norms • Comparison groups that may include children with food allergy

Study Selection and Data Extraction

The titles and abstracts were screened by the first author (KR) for potential eligibility. All full text articles were then screened by KR and a second reviewer (HE), blind to the other's ratings. Any disagreements were discussed in relation to the outlined inclusion criteria, and where needed resolved by a third reviewer (JY). Data extraction was completed by KR using a pre-defined data extraction form. Where both parent and child rated mental health, but no aggregated measure was available, children's self-report was extracted and included in the synthesis.

Quality Assessment

Due to the lack of a single recommended approach to the assessment of quality in systematic reviews of non-randomised control trials,[17,18] a quality assessment tool

was developed for the purpose of the review (Supplementary Material 2). The tool was primarily based on the Joanna Briggs Institute Checklist for Prevalence Studies[19] and the Newcastle-Ottawa Quality Assessment Scale,[20] incorporating relevant items from these measures adapted to the food allergy population being reviewed. The assessment was used to guide an informed categorical judgment of each study as high, medium, or low risk of bias. An additional criterion was included on the basis of a critique of meta-analyses in the paediatric psychology literature,[21] whereby any study with a sample size less than 35 per group were considered high risk of bias. All studies were quality assessed by KR, with approximately one third also reviewed by another individual (HC), and any disagreements resolved by a third reviewer (JY).

Synthesis Approach

For the first review question, meta-analysis of prevalence was conducted using OpenMeta. For the second review question, all between group differences were converted to Cohen's d effect sizes. These effect sizes were then pooled using MAVIS v1.1.3. Both OpenMeta and MAVIS make use of the metafor package for R. In all cases, random-effects model meta-analyses were used, and 95% confidence intervals are reported. All analyses were re-run removing studies considered to be at high risk of bias. Meta-analyses were run where there was a minimum of two studies after the removal of those considered high risk of bias. Where this criterion was not met, results were tabulated and synthesized narratively. Due to the small numbers in each synthesis, it was not considered appropriate to explore moderators statistically, where high degrees of heterogeneity were observed, possible reasons for this are discussed.

Results

Figure 1 shows a PRISMA diagram summarising study selection. After removing duplicates 2597 studies were found in the search. The reference list of the previous systematic review[14] was also checked but did not lead to the inclusion of any additional studies. Two reviewers screened the full-text of 98 articles, with seven articles (7.1%) also discussed with a third reviewer. 14 studies were included in the synthesis, 11 for the prevalence synthesis and seven for the difference synthesis. Broad exclusion reasons are listed in Figure 1. A subset of studies assessed food related anxiety,[22–29] most often using the Food Allergy Quality of Life – Parent Form subscale.[25] While food related anxiety is important to consider, these studies were not included in the present review as there is currently no agreed threshold for clinically significant food related anxiety to establish prevalence, and it is not possible to meaningfully compare this in non-food allergy populations. Two studies were excluded due to comparing outcomes to previously established norms.[15,30] Additionally, as only one study reported lifetime mental health[31] in food allergy, and this study used a self-disclosure of diagnosis rather than a validated measure, a decision was made to only include studies that assessed *current* anxiety, depression, or post-traumatic stress within the prevalence analysis. Two additional studies were included on the basis of additional information received from authors.[32,33]

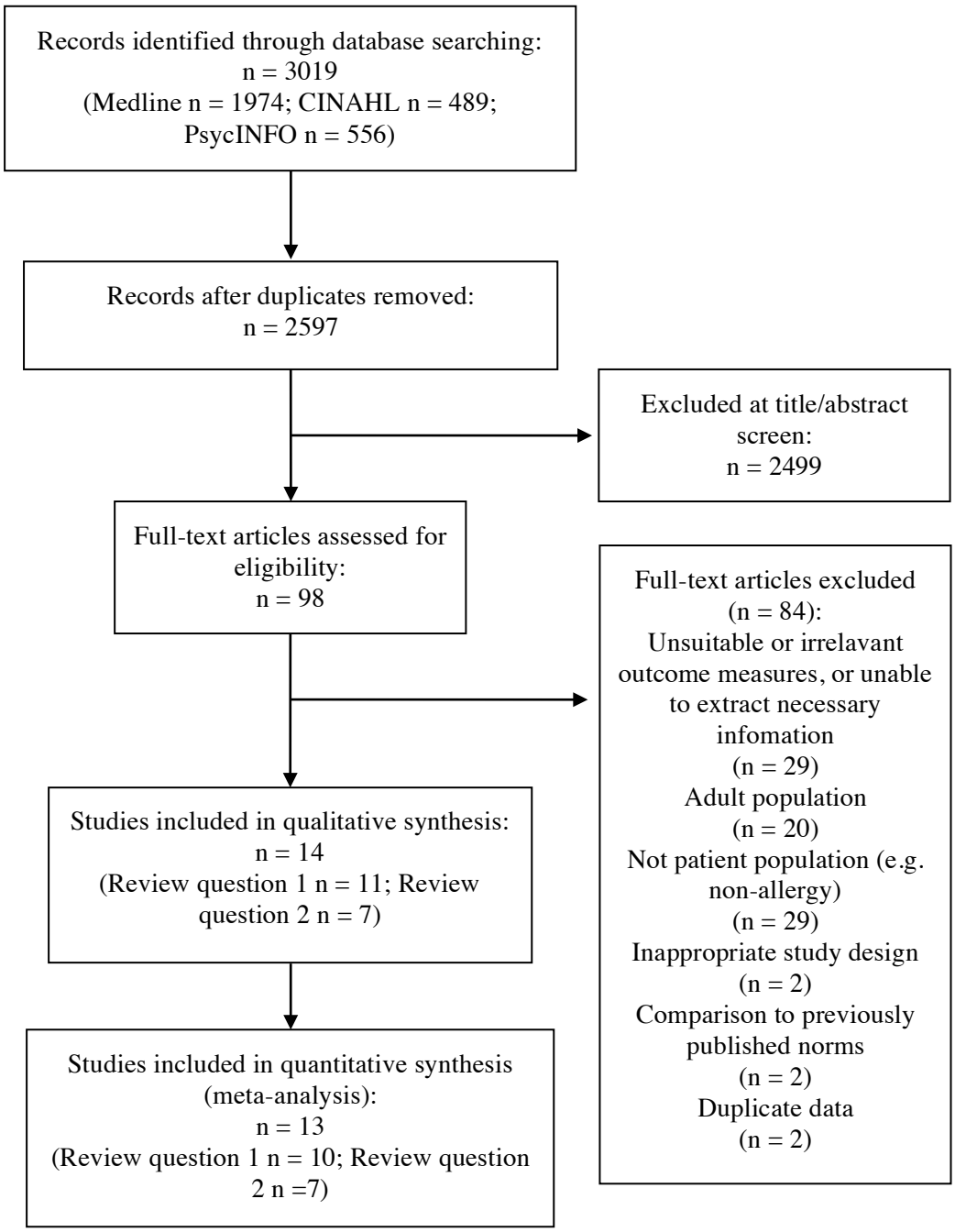

Figure 1. PRISMA Diagram showing studies included and excluded from review with reasons.

Quality assessment ratings of all studies included in the synthesis are displayed in Table 2. Five studies were second rated, with one disagreement (Cohen's κ=.71) between low and medium risk of bias resolved by a third reviewer. Four studies were considered to be high risk of bias, in all cases this was due to small sample sizes.

Table 2. Overall Quality Assessment Ratings of Included Studies

Risk of Bias	**Study (First author (year))**
Low	Brew (2018) Fedele (2016) Ferro (2016) Lau (2014) LeBovidge (2009) King (2009)
Medium	Annunziato (2015) Fox (2017) Rubes (2014) Shanahan (2014)
High	Butler (2018) Goodwin (2017) LeBovidge (2014) Weiss (2016)

Review Question 1: Prevalence

Details of the studies included in the prevalence synthesis are displayed in Table 3. The 11 studies included in the prevalence synthesis included a total of 2228 children with food allergy, and reported 26 estimates of prevalence covering eight specific mental health conditions and measures of non-disorder specific anxiety. Twenty-one of these prevalence estimates were included in quantitative synthesis.

Table 3. Summary of Studies Included in Prevalence Synthesis

First Author, year	Study Setting [a]	Design [b]	Food Allergy Diagnosis [c]	Age Range (years)	% Male	Food Allergy N	Mental Health Measure(s) (parent/ child report) [d]	% Clinically Significant Symptoms or Diagnostic Criteria Met [d]								
								Any Anx	Sep	Phobia	Panic	GAD	Soc	Dep	PTSS	PTSD
Annunziato, 2015[34]	Clinic	C	M	8-17	61	249	MASC-10 (C) t score 61+	14	-	-	-	-	-	-	-	-
Brew, 2018[33]	Community	L	S	9	47	1330	SCARED (anx; P), SMFQ (dep; P)	16	-	-	-	-	-	2	-	-
Butler, 2018[35]	Clinic (ND)	P	M	6-16	-	8	MINI-KID (P)	-	0	38	-	25	-	13	-	-
Fedele, 2016[32]	Clinic	C	M (IgE)	6-12	65	60	MASC (C) t score 70+	2	5	-	-	-	3	-	-	-
Ferro, 2016[36]	Community	L	S	14	55	268	YSR (C)	22	-	-	-	-	-	19	-	-
Fox, 2017[37]	School	C	S	13-17	-	87	MASC Social anxiety subscale (C)	-	-	-	-	-	19	-	-	-
Lau, 2014[38]	Clinic	C	M (IgE)	8-16	68	40	SCARED (P)	20	23	-	13	23	10	-	-	-
LeBovidge, 2014[39]	Clinic (OIT)	P	T (Peanut)	7-15	60	13	SCARED – generalized and panic subscales (P)	-	-	-	0	8	-	-	-	-

First Author, year	Study Setting [a]	Design [b]	Food Allergy Diagnosis[c]	Age Range (years)	% Male	Food Allergy N	Mental Health Measure(s) (parent/ child report)[d]	% Clinically Significant Symptoms or Diagnostic Criteria Met[d]								
								Any Anx	Sep	Phobia	Panic	GAD	Soc	Dep	PTSS	PTSD
LeBovidge, 2009[40]	Clinic and Non-Profit Organisation	C	M	8-17	60	70	MASC (anxiety t score 70+; C), BASC-2 (depression; C)	5	14	-	-	-	-	0	-	-
Rubes, 2014[41]	Clinic	I	S	8-17	52	78	SCARED – generalized anxiety subscale (C)	-	-	-	-	15	-	-	-	-
Weiss, 2016[42]	Clinic (PFC)	P	M (Ana)	7-13	56	25	Child PTSD Symptom Scale (C)	-	-	-	-	-	-	-	36	8

[a]PFC = post food challenge; OIT = after consenting to Oral Immunotherapy Trial; ND=newly diagnosed (within 6 months), if not specified time point not controlled for in study.

[b]C=cross-sectional, L=longitudinal, I=intervention (baseline data used), P=pilot study (baseline data used where intervention pilot).

[c]M=medical records or confirmed by healthcare professional, S=self or parent report, T=recognised allergy testing completed in study. IgE = reaction was required to be confirmed IgE-mediated; Ana = anaphylaxis plan or history of anaphylaxis required. Unless specified, any food allergens were included.

[d]MASC-10 = Multidimensional Anxiety Scale for Children-10; SCARED = Screen for Child Anxiety Related Disorders; SMFQ = Short Mood and Feelings Questionnaire; MINI-KID = Mini International Neuropsychiatric Interview for Children and Adolescents; MASC = Multidimensional Anxiety Scale for Children; YSR = Youth Self-Report; BASC-2 = Behavior Assessment System for Children Second Edition

[d]Sep = separation anxiety; Soc = social anxiety; Dep = depression

Anxiety (non-disorder specific)

Six studies reported on the number of children experiencing clinically significant anxiety on non-disorder specific measures. Meta-analysis of these studies yielded a pooled estimated prevalence of clinically significant anxiety of 12.6% (CIs 6.0% - 19.3%; n=2017). However, estimates of heterogeneity indicated high levels of variance between the studies (I^2=94.0%). No studies were considered to have a high risk of bias.

Social Anxiety

Three studies reported on the number of children experiencing clinically significant social anxiety; none of these studies were considered to be high risk of bias. Pooling these studies generated an estimated prevalence of 10.1% (CIs 0.1% - 19.6%; n=187). Again, estimates of heterogeneity indicate a high level of variance between studies (I^2=80.7%), and as the pooled sample size was small particular caution is therefore needed in interpreting this result.

Separation Anxiety

Four studies reported the prevalence of separation anxiety in children with food allergy, one of which was considered high risk of bias.[35] Estimated prevalence of separation anxiety is 11.2% (CIs 3.4%-19.0%; n=178). Estimates of heterogeneity indicate a moderate-high level of variance (I^2=62.5%). Removing the study considered to be high risk of bias resulted in a very small increase in the estimated prevalence and increased the heterogeneity (12.6%, CIs 3.0-22.2%; I^2=74.2%).

The differences in estimated prevalence may reflect differences in methodology. Whilst all four studies reported on children with medically diagnosed

food allergy, three different anxiety measures were used, including different timeframes (one-month, three-month, recently) and informants (child/parent). Although interestingly, of the two most closely comparable studies,[32,40] higher prevalence of separation anxiety was observed in the study with a slightly older sample[40] contrary to what would be expected from the wider anxiety literature.[43]

Generalized Anxiety Disorder/Worry

Four studies investigated generalized anxiety disorder or clinically significant worry in children with food allergy, two of which were considered to be high risk of bias.[35,39] Estimated prevalence was 16.0% (CIs 9.9%-22.0%; n=139), with heterogeneity estimates indicating little variance (I^2=0.0%). Removing the studies considered to be high risk of bias resulted in a small increase in estimated prevalence (17.4%, CIs 10.5%-24.2%; I^2=0.0%).

Panic and Phobia

Two studies reported on panic, but as one of these studies was considered high risk of bias[39] the results were not combined statistically. One additional study assessed specific phobia. Given the heterogeneity, small number of studies, and generally small sample sizes, it is not possible to draw conclusions on prevalence for these conditions.

Depression

Current rates of depression were reported by four studies, one of these studies was considered to be a high risk of bias.[35] Including all studies, prevalence was estimated as 6.9% (CIs 1.3%-12.5%; n=1676). A high degree of variance between studies was

found (I^2=94.2%). Removing the study considered to be high risk of bias, made little difference to the results (6.6%, CIs 0.8%-12.4%; I^2=96.1%).

PTSS/PTSD

Only one study was found assessing PTSS or PTSD in children with food allergy, finding 36% of participants to report clinically significant PTSS and 8% to meet PTSD criteria. However, this was a pilot study, and therefore had a small N. Moreover, post-traumatic stress was also assessed immediately following a food challenge, which may have affected the results.

Review Question 2: Difference

The studies included in the synthesis for the second review question are outlined in Table 4. The studies provided 23 estimated effect sizes for difference, covering six specific mental health conditions and studies using measures of any anxiety. Twenty-two of these comparisons were included in statistical synthesis. For all meta-analyses, funnel plots were inspected for indications of publication bias. Whilst the small numbers of studies in each synthesis reduce how interpretable these plots are, no clear indicators of publication bias were observed for any of the following analyses.

Table 4. Summary of Studies Included in Difference Synthesis

First Author, year	Study Setting (Design)[a]	Food Allergy (FA) Diagnosis[b]	Comparison Group	Age Range, years	Food Allergy N (% male)	Comp Group N (% male)	MH Measure (parent/ child report)[c]	Cohen's d [95% CIs][d]						
								Any Anx	Sep	GAD	Panic	Soc	OCD	Dep
Brew, 2018[33]	Community (L)	S	No current or historic atopic disease	9	1330 (47%)	8392 (full cohort 50.4%)	SCARED (anx; P), SMFQ (dep; P)	0.22 [0.16, 0.27]	-	-	-	-	-	0.45 [0.39, 0.51]
Ferro, 2016[36]	Community (L)	S	Same birth cohort with no FA or other health condition	14	268 (55%)	1035 (53%)	YSR (C)	0.15 [0.01, 0.28]	-	-	-	-	-	0.19 [0.06, 0.33]
Fox, 2017[37]	School (C)	S	No self-reported FA	13-17	87 (-)	762 (-)	MASC Social anxiety subscale (C)	-	-	-	-	0 [-0.22, 0.22]	-	-
Goodwin, 2017[44]	Clinic (C)	M	Paediatric outpatients with no history of FA	4-12	16 (anx); 20 (dep). (48%)	27 (anx); 31 (dep). (53%)	MASC (anx: C); CDI (dep; C)	0.94 [0.27, 1.57]	0.46 [-0.17, 1.08]	-	-	0.83 [0.17, 1.46]	-	0.16 [-0.41, 0.72]
King, 2009[16]	Clinic (C)	M (Peanut)	Older siblings without FA	FA: 8-12; Comp: 8-15	46 (65%)	46 (37%)	SCAS (C)	0.19 [-0.22, 0.60]	0.52 [0.10, 0.93]	0.07 [-0.34, 0.48]	0.20 [-0.21, 0.61]	-0.11 [-0.52, 0.30]	0.11 [-0.3, 0.53]	-

First Author, year	Study Setting (Design)[a]	Food Allergy (FA) Diagnosis[b]	Comparison Group	Age Range, years	Food Allergy N (% male)	Comp Group N (% male)	MH Measure (parent/ child report)[c]	Cohen's d [95% CIs][d]						
								Any Anx	Sep	GAD	Panic	Soc	OCD	Dep
Lau, 2014[38]	Clinic (C)	M (IgE)	Hospital outpatients with no chronic atopic or non-atopic disease	8-16	40 (68%)	38 (68%)	SCARED (P)	0.16 [-0.29, 0.60]	0.05 [-0.40, 0.49]	0.50 [0.04, 0.94]	0.52 [0.06, 0.97]	-0.17 [-0.61, 0.28]	-	-
Shanahan, 2014[45]	Community (L)	S	Same population with no parent reported FA	10-16	136 (46.3%)	5029 (-)	CAPA (P&C)	-	0.41 [0.24, 0.58]	0.38 [0.21, 0.55]	-	-	-	0.24 [0.07, 0.41]

[a]C=cross-sectional, L=longitudinal

[b]M=medical records or confirmed by healthcare professional, S=self or parent report. IgE = reaction was required to be confirmed IgE-mediated. Unless specified, any food allergens were included.

[c]SCARED = Screen for Child Anxiety Related Disorders; YSR = Youth Self-Report; MASC = Multidimensional Anxiety Scale for Children; SCAS = Spence Children's Anxiety Scale; CDI=Children's Depression Inventory; CAPA= Child and Adolescent Psychiatric Assessment

[d]Sep = separation anxiety; Soc = social anxiety; Dep = depression

Anxiety (Non-disorder specific)

The combined effect size for the five studies assessing non-disorder-specific anxiety was 0.21[0.16, 0.26], $p<.001$ (food allergy n=1700; comparison n=9538). This indicates a small but significant increase in anxiety reported for children with food allergy. There was no significant heterogeneity between studies, $Q(4) = 5.57$, $p=0.234$, $I^2=0.05\%$. Removing the one study considered to be a high risk of bias,[44] did not notably change these results (0.20[0.15, 0.26], $p<.001$).

Social Anxiety

The combined effect size for four studies comparing social anxiety in children with food allergy to those without did not find a significant difference, 0.06[-0.26, 0.38], $p=.711$ (food allergy n=189; comparison n=873). There was a moderate degree of variability between studies, $Q(3) = 6.99$, $p=.072$. $I^2=59.98\%$. The variability decreased when the high risk of bias study[44] was removed, $Q(2) = 0.55$, $p=0.759$, $I^2=0.00\%$. However, there remained no significant difference between the groups, -0.05[-0.23, 0.13], $p=0.598$.

Separation Anxiety

The combined effect size for separation anxiety (k=4) was 0.39[0.24, 0.53], $p<.001$ (food allergy n=238; comparison n=5140). This indicates significantly higher separation anxiety in children with food allergy with a small effect size. There was not significant variability between the studies, $Q(3) = 2.74$, $p=0.434$. $I^2=0.00\%$. These results were maintained when the one high risk of bias study[44] was removed (0.38[0.23, 0.53], $p<.001$). The smallest effect size was observed for the only study to use exclusively parent reported anxiety.[38]

Generalized Anxiety

Three studies compared generalized anxiety disorder or worry in children with and without food allergy, finding significantly higher anxiety in children with food allergy with a small effect size, 0.35[0.20, 0.50], $p<.001$ (food allergy n=222; comparison n=5113). No studies were considered to be high risk of bias, and there was no significant heterogeneity between studies, $Q(2) = 2.32$, $p=0.314$, $I^2=0.00\%$. The smallest effect size was reported by the only study using exclusively child report,[16] however this study also had an older comparison group, which may affect results.[43]

Panic

Two studies compared panic in children with and without food allergy, finding significantly higher panic with a small effect size, 0.34[0.03, 0.65], $p=.030$ (food allergy n = 86; comparison n = 84). Neither study was considered high risk of bias, and the heterogeneity was not significant, $Q(1) =1.04$, $p=.307$, $I^2=4.19\%$. However, the confidence intervals were wider than for both separation and generalized anxiety, with the lower confidence interval indicating no difference in panic disorder.

Obsessive Compulsive Disorder

One study assessed obsessive compulsive disorder finding an effect size of 0.11, which indicates no clear difference between children with and without food allergy.

Depression

The combined effect size for the four studies assessing depression was 0.30[0.14, 0.45], indicating significantly higher depression in children with food allergy with a small effect size ($p<.001$). There was significant variation between studies, $Q(3) = 15.73$, $p=.001$, $I^2=76.00\%$. Removing the one study considered high risk of bias[44] did not notably change the combined effect size, 0.31[0.14, 0.47], $p<.001$. The variation between the studies appears largely due to the larger effect size found by the only study to use exclusively parent report.[33] However, as there were further differences between all three studies (e.g. in the depression measure used), there may be different factors responsible for this heterogeneity.

Discussion

The present review synthesised the research assessing anxiety, depression, and post-traumatic stress in children with food allergy. The estimated prevalence rates for current overall anxiety and depression were 12.6% (95% CIs 6.0-19.3%) and 6.9% (95% CIs 1.3-12.5%) respectively. However, there was a high degree of heterogeneity in the methodology and prevalence estimates between studies, meaning caution is needed in interpreting these results. There was also relatively little consistency in the anxiety disorders reported in research, and notably only one pilot study assessed post-traumatic stress in children with food allergy.

Prevalence estimates for any anxiety and depression were both higher than general child population estimates of 6.5% and 2.9% respectively.[46] Although general population reviews have been able to use stricter inclusion criteria due to the wider literature available, which limits the comparability of these estimates.

Small but significant increases in anxiety (d=0.21) and depression (d=0.30) were found in children with food allergy compared to children without food allergy. This compares to average effect sizes of 0.18 (anxiety) and 0.19 (depression) previously found for children with and without any chronic health condition.[1,2] Whilst, the effect size for depression calculated in the current review is larger than the previous estimates for any health condition, the heterogeneity in the depression synthesis limits the robustness of this finding.

Despite the variability in methodologies and prevalence estimates, relatively little heterogeneity was observed in the synthesis of studies comparing anxiety in children with and without food allergy, adding confidence to these the results. However, differences were found between anxiety disorders, with small effects found for generalized anxiety (0.35) and separation anxiety (0.39), but no significant difference found for social anxiety (0.06), demonstrating the utility of assessing different forms of anxiety. This pattern of results appears in keeping with the nature of food allergy. In particular, as the management of food allergy includes avoidance of allergens, children with food allergy may find it harder to be away from home or parents (separation anxiety) and/or worry more (GAD). Whilst it has been suggested that a degree of anxiety may be adaptive for allergy management,[22] if this anxiety is negatively impacting on wellbeing, it is important to consider ways to offer support for anxiety whilst maintaining the necessary caution surrounding allergen exposure.

There has been substantial growth in the literature exploring mental health in children with food allergy in recent years (all studies meeting review inclusion criteria were published between 2009 and 2018); however, the overall body of evidence remains relatively small, limiting the present review. Firstly, it was not considered meaningful to statistically explore any moderators, which would have

been particularly beneficial given the wide range of methodologies used. Furthermore, additional variables that may act as moderators between food allergy and mental health outcomes, such as bullying or the time since allergic reaction, were rarely reported in research. This is particularly concerning given the majority of research uses a solely cross-sectional design, which is not able to establish causality.

As is typical in paediatric psychology literature, the review was also limited by the sample size within studies. Nearly a third of studies (4/14) had a food allergy sample size of less than 35, and were considered to be high risk of bias. Within the prevalence syntheses, even pooled sample sizes were at times smaller than would be ideal for a single prevalence study. For feasibility reasons, the current review also excluded non-English language studies and grey literature. It is possible that this would have led to the inclusion of additional studies, which may have reduced issues associated with the small k and N.

Finally, the current study focused on mental health measures thereby excluding food related anxiety, due to the lack of an established clinical cut-off for these measures. Future research exploring food allergy related anxiety may help to distinguish whether elevated anxiety is an adaptive response or of greater concern and therefore warranting intervention.

Despite these limitations, the review utilized a systematic approach to synthesize the current literature. This also highlights areas that warrant further consideration. Firstly, there is a clear need for research investigating post-traumatic stress in children with food allergy. Post-traumatic stress has been reported in children with other health conditions, e.g. asthma[47] and diabetes.[48] However, despite being a common health condition, which can sometimes cause a life-threating reaction, there has been only one attempt to assess post-traumatic stress in food allergy. It would be

beneficial for this research to include longitudinal assessments, e.g. following diagnosis and/or allergic reactions, to allow greater consideration of causality and adaptation over time. Secondly, the review highlights the need for further larger scale studies that include sub-types of anxiety, depression and possible moderators.

Overall, this review provides a systematic summary of the current evidence base for anxiety, depression, and post-traumatic stress in children with food allergy. Whilst it is positive to note the substantial growth in literature in this field, there are significant limitations in the evidence base due to generally small sample sizes, differences in methodology, and limited consistent reporting of possible moderators. The synthesis indicates children with food allergy may experience a small but significant increase in anxiety and depression compared to their peers without food allergy. The most consistent results were found for studies assessing differences in anxiety, but the review highlighted the importance of considering different forms of anxiety rather than using only non-disorder specific measures. The synthesis indicates children with food allergy may experience greater separation anxiety and generalized anxiety compared to their peers, but no greater social anxiety. However, until research is available addressing the current limitations in the field, any conclusions drawn on the relative prevalence of mental health in children with food allergy remain tentative.

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Supplementary Material 1: Details of Search Strategy

The following search terms were used for all three databases (Medline, CINAHL, PsychINFO):

anxi* OR panic OR phobi* OR worry OR depress* OR "posttraumatic stress" OR "post-traumatic stress" OR "post traumatic stress" OR mental health index terms (see below)

AND

allergy OR allergies OR allergic OR allergen OR allergens OR anaphylaxis OR anaphylactic OR "food hypersensitivity" OR "adverse food reaction" OR food allergy index terms (see below)

Relevant exploded index terms were included for each database. For Medline, this included the MeSH terms: "Anxiety" "Anxiety Disorders" "Depression" "Depressive Disorder" "Psychological Trauma" "Trauma and Stressor Related Disorders" and "Food Hypersensitivity". For CINAHL, the CINAHL headings: "depression" "anxiety" "anxiety disorders" "trauma" "stress disorders, post-traumatic" and "food hypersensitivity". For PsycINFO, the PsycINFO thesaurus terms: "anxiety" "anxiety disorders" "depression (emotion)" "major depression" "trauma" and "food allergy".

Supplementary Information 2: Quality Assessment Rating Tool

Quality Assessment Tool

For all studies:

1. How was the food allergy identified?
    - **a.** Medical records/Physician confirmed
    - **b.** Confirmed by recognized tests/approach by qualified professional
    - **c.** Self-diagnosed or other
2. Was mental health assessed using a validated tool?
    - **a.** Yes – validated diagnostic interview
    - **b.** Yes – validated self-report questionnaire
    - **c.** No
3. Was mental health measured reliably?
    - **a.** If relevant, was researcher trained in the use of the tool?
    - **b.** Was the measure completed as intended (e.g. self vs parent vs professional report)?
    - **c.** Was the measure completed in the same way for all participants?
4. Was the response rate adequate (50%+)? If not were steps taken to account for this?

    Yes

    No
5. Were participants and the setting described in detail?

    Yes

    No
6. Was the sample size at least N=35 (per group where relevant)?

    Yes

    No

For comparison:

1. Was the comparison group recruited from the same community as the allergy group?

a. Yes – another clinical group recruited from same setting and approximate time period, with the same inclusion criteria used (other than health status)
b. Yes – healthy controls recruited from same region and approximate time period, with the same inclusion criteria used (other than health status)
c. No

2. How was the comparison group defined:
    a. No current or historic food allergy (medical records)
    b. No current or historic food allergy (self-report)
    c. No current food allergy (medical records or recognized tests by qualified professionals)
    d. No current food allergy (self-report)

AND:

    e. No current long term health condition (medical records)
    f. No current long term health condition (self-report)
    g. Included on basis of having another condition (medical records)
    h. Included on basis of having another condition (self-report)
    i. General population sample other than exclusion of food allergy

3. Was the same method of data collection used for the allergy and comparison groups?
    Yes
    No
4. Was the comparison group comparable to the allergy group on other (e.g. demographic) factors? If not, was this adequately controlled for?
    Yes
    No
5. Was the response rate similar for both groups?
    Yes
    No

Overall Judgment: _____

Guidance

Low Risk of Bias

Study generally well designed, with possible limitations (e.g. differences in demographics between groups) adequately controlled for in the analysis. All relevant measures/diagnostic interviews were valid and reliable. To be considered low risk of bias studies must have an adequate sample size.

Medium Risk of Bias

There may be some concerns over the quality of the study, which may include, but are not limited to:

- Representativeness of the sample (e.g. bias in sampling/recruitment method)
- Food allergy diagnosis based exclusively on self-report
- Differences between the allergy and control groups (that are not adequately controlled for in the analysis)

However, overall the study is considered to be of adequate quality, given the practicalities of research, with no cause for significant concern (e.g. very small sample sizes, non-validated outcome measures).

High Risk of Bias

Significant concerns about the quality of the study, including very small sample sizes (N less than 35 per group), non-validated outcome measures, or an accumulation of medium risk factors.

Unable to rate

Insufficient information was available to judge the quality of the study.

Chapter 2: Bridging Chapter

The previous chapter summarised the literature assessing mental health in children with food allergy. However, when considering the psychological impact of paediatric health conditions it is also important to consider those surrounding the child, particularly those with main caring responsibility (i.e. parents/guardians, from here on in parents is used to refer to any adult with this responsibility). In the wider paediatric literature, increased anxiety has been found in mothers of children with any chronic illness (van Oers et al., 2014), as well as parents of children with various specific health conditions including diabetes (e.g. Streisand et al., 2008) and epilepsy (Jones & Reilly, 2016). Furthermore, parents have been reported to experience post-traumatic stress symptoms (PTSS), in relation to paediatric medical events (e.g. burns; Hawkins, Centifanti, Holman, & Taylor, 2019) and health conditions (including asthma, Kean, Kelsay, Wamboldt, & Wamboldt, 2006; and cancer, Sharkey et al., 2018).

Arguably, it is of particular importance to consider the psychological impact for parents in conditions such as food allergy that are most commonly diagnosed in infancy or early childhood (Sicherer & Sampson, 2010). In infants and very young children, parents initially hold responsibility for managing a condition that the child is unlikely to have awareness of. In food allergy this can mean that children can grow up with allergy management being a normal part of their routine, and may not have any recollection of allergic reactions. Where this is the case, parent's experience and perception of food allergy could be expected to be more notably different from their child's (e.g. Akeson, Worth, & Sheikh, 2007). Furthermore, due to difficulties with assessing anxiety or other mental health problems in young children (Carpenter,

Sprechmann, Calderbank, Sapiro, & Egger, 2016), assessing parent mental health allows the inclusion of a wider proportion of the food allergy population in research.

As well as the clear importance for parents' own wellbeing, consideration of parent mental health is also important due to the possible knock on effects for child wellbeing. A recent meta-analysis (Lawrence, Murayama, & Creswell, 2019) found evidence for elevated anxiety and depression in children of parents with anxiety disorders. Interestingly, whilst there was no evidence of specificity (i.e. children being more likely to experience the same anxiety disorder as their parent), children of parents with an anxiety disorder were found to be at increased risk of experiencing generalized anxiety and separation anxiety. However, children of parents with an anxiety disorder were not found to be significantly more likely to experience social anxiety. This is the same pattern of results observed in the meta-analysis chapter within this portfolio. A better understanding of the mental health of parents of children with food allergy may therefore also contribute to a better understanding of the psychological impact for children.

The following chapter reports on an original piece of empirical research assessing anxiety and post-traumatic stress in parents of children with food allergy. It is first useful to give additional consideration to the models available to guide this research.

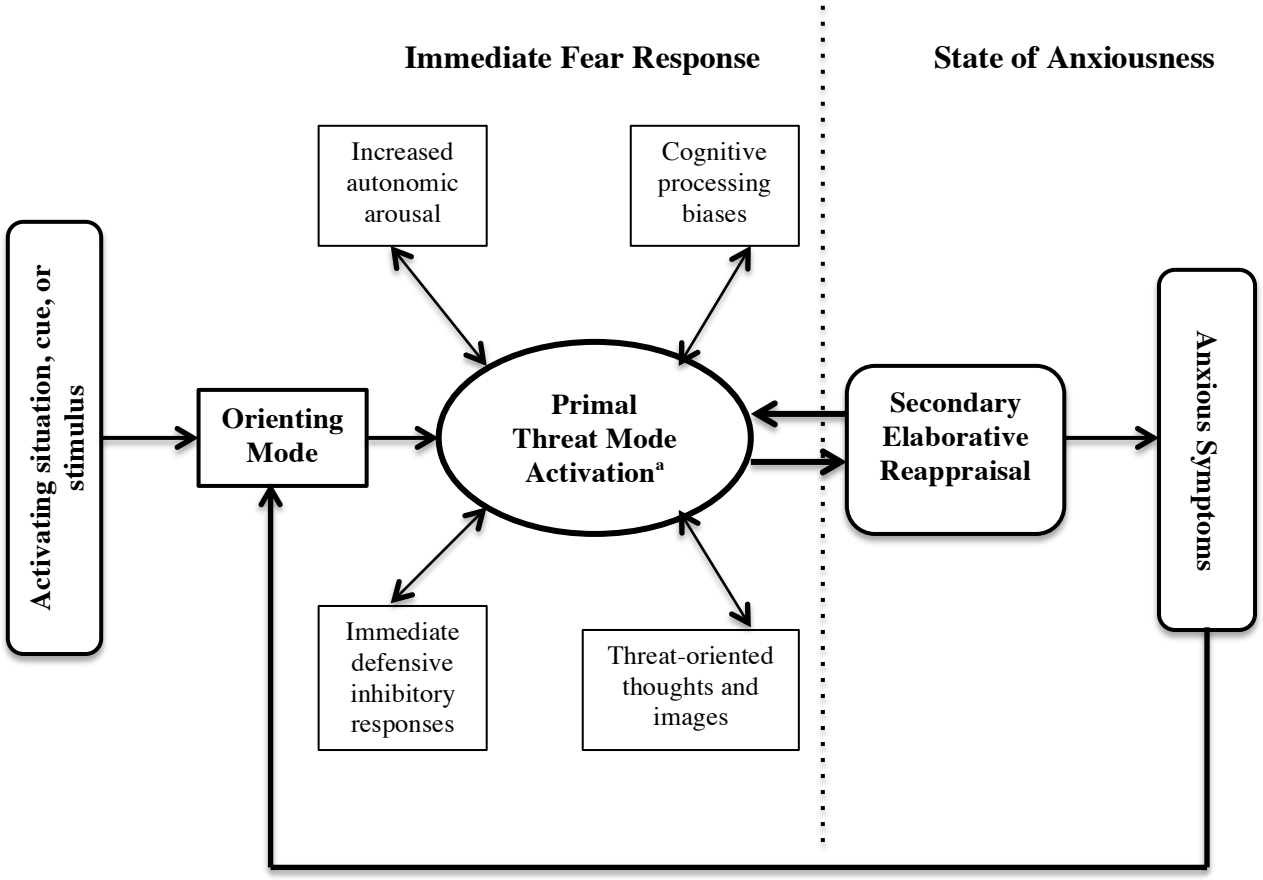
Despite the growing evidence base exploring the psychological impact of physical health problems for children and their parents, few attempts have been made to develop psychological models specific to this population, a notable exception being the integrative model of paediatric traumatic stress. Kazak et al. (2006) developed the integrative model of paediatric medical traumatic stress, which was subsequently updated by Price, Kassam-adams, Alderfer, Christofferson, & Kazak

(2016) to reflect the growing evidence base. The model considers patterns of psychological response to a potentially traumatic medical event over three stages: peri-trauma (the initial potentially traumatic event and immediate responses), acute medical care (demands associated with period of active treatment), and ongoing care or discharge from care (time following active treatment). The model highlights the importance of the interactions between medical events and individual and family responses, in doing so the model focuses on commonalities across health conditions (e.g. in terms of psychological risk factors for the development of PTSS) whilst acknowledging differences between conditions, for example in terms of the nature of the potentially traumatic event, and length and invasiveness of treatment. The model places particular emphasis on an individual's perception of the potentially traumatic event as threatening (e.g. perceived risk of death), as this has consistently been found to be a good predictor of significant PTSS across the literature (Price et al., 2016). However, due to the lack of available research, the model offers limited specificity regarding broader individual or social factors that may increase risk of PTSS.

As a model of traumatic stress, Price et al.'s (2016) model is also not designed to assess the broader psychological impact of paediatric health. In particular, while it is apparent how the model could be applied following a severe allergic reaction, it is less clear if or how the model would be applied in situations where there is neither a single acute medical emergency (e.g. as in burns) nor ongoing active treatment (e.g. as in diabetes), as somewhat unusually the main management of food allergy is avoidance rather than the addition of medication or medical procedures. As the aim of the research presented in the following chapter was to assess anxiety more generally as well as PTSS, and was interested in including the full spectrum of food allergy severity, the research drew more heavily on a general model of anxiety, given

the possible limitations of applying the integrated model of paediatric medical traumatic stress in this instance.

Clark and Beck's (2010) transdiagnostic CBT model of anxiety (replicated below in Figure 2 and discussed further in the following chapter), shows commonality with the integrated model of paediatric medical traumatic stress in considering the nature and perception of a potential threat and an individual's responses to this. However, Clark and Beck's model is much broader in nature, being developed on the basis of the much wider anxiety literature; as such, it provides more suggestion of individual factors that impact on anxiety responses. Furthermore, through focusing on the similarities across, rather than differences between, anxiety disorders it offers a useful framework for approaching areas with limited pre-existing research, as is the case in food allergy. Cross-referencing the available food allergy literature, experience of clinicians working in food allergy, and suggestions from the Clark and Beck model, was therefore considered the most appropriate way to determine variables that could be of particular interest to explore in the following study.



[a]Activation of threat-related schemas e.g. a need to minimise uncertainty

Figure 2. Cognitive Model of Anxiety, replicated from Clark, D.A., & Beck, A.T. (2010). *Cognitive Therapy of Anxiety Disorders: Science and Practice*. New York: Guildford Press.

Chapter 3: Empirical Research Project

The following paper has been prepared in accordance to the *Journal of Pediatric Psychology*, author guidelines can be found in Appendix C. Tables have been included in position for the purpose of the portfolio. Due to the differing requirements for margins and page formatting for the thesis portfolio, the paper appears to exceed the journal page limit. Additional documents included for the purpose of the thesis portfolio only are included in the appendices and indicated in text, the Food Allergy Self-Efficacy Scale for Parents (Knibb, Barnes, & Stalker, 2015) is not included in the appendices for copyright reasons.

Word count: 5876

Do parents of children with food allergy report anxiety, worry, and post-traumatic stress symptoms, and what predicts this?

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Abstract

Objective The purpose of this study was to explore anxiety, worry, and post-traumatic stress symptoms (PTSS) in parents of children with food allergies, and to evaluate whether these three psychological outcomes could be predicted by allergy severity, intolerance of uncertainty, and food allergy self-efficacy. **Methods** Participants were 105 parents who reported their children to have medically diagnosed food allergies. Participants were recruited to a study on parent wellbeing through an allergy clinic and social media advertisements. Participants completed online questionnaires assessing anxiety, worry, PTSS, intolerance of uncertainty, food allergy self-efficacy, and demographic and allergy information. **Results** 81.0% parents reported clinically significant worry, 42.3% met the clinical cut-off for PTSS, and 39.1% reported moderate-extremely severe anxiety. Regression models including allergy severity, intolerance of uncertainty, and food allergy self-efficacy were significant for all three psychological outcome measures. However, intolerance of uncertainty was the only variable to consistently be significantly predictive in these models. **Conclusions** This study highlights the need for greater awareness of mental health in parents of children with food allergy. The study also indicates that factors impacting on parents' perception of threat may be most strongly predictive of psychological outcomes, warranting further research. Finally, the study indicates that intolerance of uncertainty may be a promising target for psychological interventions within this population.

Key words: food allergy, paediatric, parental anxiety, worry, post-traumatic stress

Introduction

Food allergies have become increasingly common in recent years, with prevalence in children of around 6-8% (Luyt, Ball, Kirk, & Stiefel, 2016). Food allergies can vary widely in severity, but all will involve an adverse immune reaction to a particular allergen, with symptoms including changes to the skin, gastrointestinal, and respiratory systems, with the most severe cases leading to anaphylaxis (National Institute for Health and Clinical Excellence; NICE, 2011a). The medical management of food allergies is primarily avoidance, this can be challenging as even with careful management exposure to allergens can occur (Boyce et al., 2010), for example through accidental exposure or cross-contamination during food preparation.

Research has started to explore the impact that living with a food allergy could have for an individual's mood and quality of life (e.g. Cummings, Knibb, King, & Lucas, 2010). As food allergies are most prevalent in childhood (Boyce et al., 2010), this research has included the psychosocial impact that caring for a child with food allergy may have for their parents, as initially caregivers often have the primary responsibility for allergy management. Previous research has typically found increased anxiety and stress in parents, particularly mothers, of children with food allergy (e.g. Cummings, Knibb, King, & Lucas, 2010; Lau et al., 2014). However, there has been little focus on the nature of anxiety experienced by parents or predictors of psychological wellbeing. Better understanding of the nature of anxiety experienced by parents of children with food allergies may help with the development of models and better treatment options for this population.

In qualitative research, parents of children with food allergy have described experiencing increased worry (e.g. Akeson, Worth, & Sheikh, 2007; Sanagavarapu,

Wainstein, Children, & Katelaris, 2016). Worry was also a common difficulty amongst participants in a recent case series study of cognitive behavior therapy (CBT) for parents of children with food allergies (Knibb, 2015), with a large proportion of participants scoring over the clinical cut-off for generalized anxiety disorder (GAD). It may be that parents identify more strongly with worry than other more somatic aspects of anxiety. However, larger studies assessing anxiety in parents of children with food allergy have typically used general measures (such as the HADS; Zigmond & Snaith, 1983), which are not suitable for exploring different forms of anxiety. This study will therefore include both a worry measure, and a measure of more physical symptoms of anxiety typical in panic presentations.

Furthermore, both qualitative research (e.g Akeson et al., 2007; Rouf, White, & Evans, 2012) and a review of food allergy literature (Kelsay, 2003) have highlighted the need for post-traumatic stress symptoms (PTSS) to be investigated in parents of children with food allergies. Evidence of PTSS has also been found in parents of children with various other health conditions, including cancer (Kazak, Boeving, Alderfer, Hwang, & Reilly, 2005) and asthma (Kean, Kelsay, Wamboldt, & Wamboldt, 2006). Despite this, PTSS has remained unaddressed within food allergy literature. This study will therefore also assess whether parents report experiencing PTSS in relation to food allergy events.

It is also important to consider factors that may predict psychological outcomes, as these can help both with the identification of more at risk parents and the development of psychological models and treatments. The majority of NICE recommended treatments for anxiety disorders are CBT-based (e.g. panic and GAD, NICE, 2011b; PTSD, NICE, 2018). There are common features across CBT-based anxiety disorder models, which are also incorporated in Clark and Beck's (2010)

transdiagnostic cognitive model of anxiety. In particular, the nature of the anxiety-provoking event, individuals' perception of an event as threatening, and individuals' perceived capacity to cope. As research examining the psychological impact of food allergies is in relative infancy, one factor from each of these three categories will be included in the present study.

Firstly, allergy severity, allergy factors have been included in some past research, with inconsistent findings. For example, Cummings, Knibb, Erlewyn-Lajeunesse et al. (2010) found mothers of children at risk of anaphylaxis experienced significantly greater anxiety, whilst Marklund, Ahlstedt, and Nordström (2006) found the lowest emotional wellbeing in parents of children who primarily experience gastrointestinal symptoms, typically a less severe allergy. As the current study includes psychological outcomes that have not previously been assessed in this population, allergy factors will be retained despite these past mixed results. However, the study will also incorporate parental factors that may impact on perception of food allergies and their ability to cope, that have not received as much attention in past research, and may help to explain the inconsistencies in the previous literature.

One belief that Clark and Beck (2010) propose can increase an individual's perception of threat is intolerance of uncertainty. Intolerance of uncertainty is also suggested to be an important factor in individuals' experience of worry (Dugas, Gosselin, & Ladouceur, 2001), and, as previously outlined, parents have described experiencing worry in relation to food allergy (Akeson et al., 2007; Sanagavarapu et al., 2016). Furthermore, in qualitative research, parents have described anxiety relating to the impossibility of completely controlling their child's exposure to food allergens, and the associated need for calculated risk taking (Rouf et al., 2012). This

demonstrates the requirement for parents to frequently manage a degree of uncertainty relating to their child's health, and therefore an intolerance of uncertainty may be particularly pertinent in this population.

Finally, parents' food allergy related self-efficacy will be assessed, as a factor that may impact on their perceived ability to cope, which in turn would be expected to reduce anxiety (Clark & Beck, 2010). It has been suggested that self-efficacy could help to explain inconsistent results found between allergy severity and anxiety in past research, as parents of children with more severe allergies could receive more medical support or be more likely to develop family management plans (Cummings, Knibb, King, & Lucas, 2010). This may lead to greater confidence in food allergy management, in turn reducing anxiety. Providing parents with more knowledge, with a view to increasing confidence, has also been suggested as an intervention for improving parent wellbeing (Quach & John, 2018), it is therefore important to investigate whether a relationship between self-efficacy and psychological outcomes is found to support this recommendation.

In summary, this study aims to address significant gaps in the literature by investigating PTSS and the nature of anxiety experienced by parents of children with food allergy. The study will also contribute to the current understanding of psychological outcomes in this population by exploring three factors that may be expected to be related to parents' experience of anxiety, worry and PTSS.

Research Questions

The present study has two primary research questions:

1. Do parents of children with food allergy report clinically significant levels of worry, anxiety, and/or PTSS?

2. Are parents' experiences of anxiety, worry and PTSS predicted by intolerance of uncertainty, food allergy self-efficacy, and/or severity of allergy?

Method

Design and Inclusion Criteria

The study had a cross-sectional design using an online survey. Inclusion criteria were having main caring responsibility for a child (age 0-16 years) with a medically diagnosed food allergy. Participants were also required to be residents of the United Kingdom and to have sufficient understanding of English language to be able to complete the questionnaires.

Procedure

Ethical approval for the study was sought and granted by the NRES Committee East of England – Essex (Appendix D).

Potential participants were invited to take part in a study investigating parent wellbeing in paediatric food allergy, with recruitment occurring through both social media advertisements and a paediatric allergy clinic. All participants completed the study online. Participants recruited through the allergy clinic were given information about the study (Appendix E) and completed a consent to contact form (Appendix F), which gave permission for the researcher to send potential participants two emails with information about the study and a link to the online survey. Social media advertisements were shared through Twitter and Facebook groups relevant to food allergy in the UK.

At the start of the online survey participants were given study information (Appendix G), asked to provide consent for participation (Appendix H), and informed of sources of further information and support for any issues raised in the study (Appendix I). Participants then completed the questionnaires outlined below. At the end of the study participants were reminded of sources of further information and support (Appendix J), and had the opportunity to enter a prize draw to win one of ten £20 Amazon gift vouchers and to request a summary of the study's results.

Measures

Demographic and allergy questions (Appendix K). For the purpose of the study a questionnaire was developed to gather information about the participant and their child(ren) with food allergy. Where participants had more than one child with food allergy, they were asked to complete the questions for each child. The questionnaire included five questions pertaining to the severity of each child's food allergy: having an adrenaline auto-injector (AAI) prescribed, an AAI having been administered during an allergic reaction, history of anaphylaxis reaction, parent reported anaphylaxis symptoms (in line with action plans endorsed by the Royal College of Paediatrics and Child Health and the British Society for Allergy and Clinical Immunology, 2013), and having attended A&E with an allergic reaction. The questionnaire was developed based on past research and consultation with allergy clinicians.

Penn State Worry Questionnaire (PSWQ; Meyer, Miller, Metzger, & Borkovec, 1990; Appendix L). The PSWQ is a 16-item measure of worry, scored on a five-point Likert scale. Total scores range from 16-80 (a higher score indicating greater levels of worry). The PSWQ has been found to have good reliability and

validity in both general and clinical populations, both for measuring worry as a transdiagnostic construct and for identifying GAD (Meyer et al., 1990; Brown, Antony, & Barlow, 1992) . As such, the PSWQ has two previously established cut-offs, a score of 45 has been shown to discriminate clinical from non-clinical samples, whilst a score of 64 has been found to have discriminative validity for GAD compared to other anxiety and mood disorders (Behar, Alcaine, Zuellig, & Borkovec, 2003; Chelminski & Zimmerman, 2003). Within the current study Chronbach's Alpha was 0.92, indicating good reliability.

Depression Anxiety Stress Scales 21 (DASS-21) - Anxiety subscale (Lovibond & Lovibond, 1995; Appendix M). The DASS-21 anxiety subscale is a seven-item measure of anxiety experienced in the past week, predominantly focused on somatic symptoms. Responses are given on a four-point Likert scale, responses are totaled and doubled, resulting in a score from 0-42 with a higher score indicating greater anxiety. Based on a general population sample, five categories of scores have been developed to indicate increasing severity (Lovibond & Lovibond, 1995). In a large general population sample (Henry & Crawford, 2005), the DASS-21 anxiety subscale has been found to have good reliability and convergent validity with the anxiety subscale of the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983). Within the current study Chronbach's Alpha was 0.89, indicating good reliability.

Impact of Events Scale – Revised (IES-R; Weiss & Marmar, 1997; Appendix N). The IES-R is a 22-item measure of trauma symptoms experienced over the past seven days, with responses scored on a five-point Likert scale, scores vary from 0-88 with a higher score indicating more trauma symptoms. A score of 33 or more has been suggested to have the best diagnostic accuracy for PTSD (Creamer,

Bell, & Failla, 2003); however, a score of 24 or more has been suggested as indicative of clinically significant PTSS (Asukai et al., 2002). Participants were asked to complete the IES-R in reference to the most stressful experience they could recall related to their child's allergy, and were asked to briefly indicate what this event was and when it occurred. The IES-R has been found to have good reliability (Weiss & Marmar, 1997), and has been used in much research exploring PTSS in parents of children with health conditions, including asthma (Kean et al., 2006). Reliability in the present study population was good, Chronbach's alpha = 0.96.

Intolerance of Uncertainty Scale – Short Form (IUS-S; Carleton, Norton, & Asmundson, 2007; Appendix O). The IUS-S is a 12-item measure of an individual's attitudes towards uncertainty. The IUS-S is scored on a five-point Likert scale, with total scores ranging from 12-60, higher scores indicating less tolerance of uncertainty. The IUS-S has been found to have good reliability and validity in clinical and non-clinical samples (e.g. Khawaja & Yu, 2010).

Food Allergy Self-Efficacy Scale for Parents (FASE-P; Knibb, Barnes, & Stalker, 2015). The FASE-P is a 21-item scale designed to measure parents' confidence in managing their child's food allergy. Parents rate their confidence in their ability to do each item from 0-100 (a higher score indicating greater confidence), an average confidence rating is then calculated. A score under 70 indicates further support with allergy management is needed. The FASE-P's psychometric properties have been assessed using an online survey of parents of children with food allergy, and found the scale to have good reliability and construct validity (Knibb et al., 2015).

Participants

Parents. Participants were 106 parents (103 mothers, 3 fathers) who reported having a child(ren) with medically diagnosed food allergies. However, one mother was excluded from the analyses as no psychological outcome measures were completed. The age of the remaining 105 participants ranged from 23-55 years (mean=38.96, *SD*=6.53). Seventeen participants (16.2%) had more than one child with a medically diagnosed food allergy, of whom 16 had two children with food allergy and one had three children with food allergies. Ten participants (9.5%) also had a food allergy themselves.

Participants predominantly found out about the study through social media advertisements (88.6%), with eight participants (7.6%) recruited through a paediatric allergy clinic, and 2.9% hearing about the study through other means (word of mouth and allergy charities). Consent to contact was taken from 13 parents at allergy clinics; however, no information is available for the number of eligible parents approached about the study.

Children. The 123 children with food allergies reported on by parents were 67 boys and 55 girls (1 gender not reported). Child age ranged from 6-months to 16 years 10 months (mean=6.13years, *SD*=4.23). The most commonly reported food allergens were peanuts, milk, and egg, for all allergens see Table 5. The total number of different foods participants' children were allergic to varied from 1-15 (mean=4.07, *SD*=3.05).

Parents reported that their child's food allergies had been diagnosed mainly by specialist allergy clinics (79.7%, *N*=98), but also GPs (7.3%, *N*=9), and other healthcare professionals including paramedics, dieticians, gastroenterologists, private consultants, general paediatricians, and dermatologists (13.0%, *N*=16). The method of diagnosis included skin prick testing (74.0%), medical history (56.1%), blood tests (42.3%), and other (primarily food challenges or elimination diets; 11.4%).

Antihistamines had been prescribed for 85.4% (*N*=105) of children, and adrenaline auto-injectors (AAIs) for 67.5% (*N*=83). Sixty children (48.8%) had been taken to A&E because of an allergic reaction, with 50.4% reported to have experienced at least one anaphylactic reaction. Symptoms parents reported their children experiencing during an allergic reaction are displayed in Table 5.

Table 5

Child Food Allergy(s) and Symptoms Reported by Parents

Allergen	*N*
Peanut	69 (56.1%)
Milk	68 (55.3%)
Egg	63 (51.2%)
Tree Nut	53 (43.1%)
Soy	28 (22.8%)
Sesame	24 (19.5%)
Wheat	21 (17.1%)
Shellfish	8 (6.5%)
Fish	6 (4.9%)
Other	42 (34.2%)
Symptom	***N***
Runny or congested nose	77 (62.6%)
Bloated stomach	48 (39.0%)
Abdominal pain	83 (67.5%)
Diarrhoea	62 (50.4%)
Vomitting	82 (66.7%)
Hives or itchy skin rash	107 (87.0%)
Itchy/tingling mouth	78 (63.4%)
Persistent cough[a]	52 (42.3%)
Swollen lips, face, or eyes	84 (68.3%)
Swollen tongue[a]	31 (25.2%)
Difficulty swallowing[a]	37(30.1%)
Breathing difficulties[a]	51 (41.5%)
Dizziness[a]	31 (25.2%)
Sudden tiredness[a]	54 (43.9%)
Collapse[a]	20 (16.3%)
Sudden change in behaviour	56 (45.5%)

[a]included as anaphylaxis symptom

Data Treatment

Where parents had more than one child with food allergy, the five dichotomous allergy severity factors were included as 'yes' if at least one child met the criteria. An approximate median split was used to dichotomise anaphylaxis symptoms, resulting in a cut-off of having at least one child with at least three anaphylaxis symptoms. Where dummy coding of dichotomous variables was required for analyses, 0 represented 'no' and 1 represented 'yes'.

Missing Data. One participant was excluded from the PTSS analyses, as the event they answered the IES-R in relation to was not food allergy related. As the PSWQ, IES-R, and DASS-21 Anxiety Subscale were all found to be reliable, and there were no notable patterns in missing data (e.g. more sensitive questions being missed), individual mean substitution was used up to a maximum of 30% of missing items. This approach has been found to lead to less distortion of the dataset than alternative methods of missing data imputation, while minimizing data wastage (Roth, Switzer, and Switzer, 1999). Less than 1% of data was replaced using this approach. There was no missing data for the IUS-S or FASE-P.

Data Analysis

Data analysis was conducted using IBM SPSS Statistics v25. Regression analyses were used to address the second research question, for the PSWQ the assumptions of multiple linear regression were adequately met. However, for the DASS-21 and IES-R linear regression assumptions were violated, therefore logistic regression was used for these two analyses. For the IES-R the data was split using the PTSS cut-off score of 24. As the DASS-21 uses five levels of severity rather than a single cut-off the

data was split into scores indicating no-mild anxiety (scores of 0-9) or moderate-extremely severe anxiety (scores of 10-42).

As five dichotomous indicators of food allergy severity were included in the current study, initially differences in the three mental health outcome measures were assessed (using t-tests or non-parametric alternatives) with the aim of using the strongest predictors in the main regression analysis. Where more than one allergy severity variable was found to be significant, the relationship between these variables was explored further to assess whether they would offer unique contributions to a multiple regression model.

Regression analyses were run including food allergy severity variable(s) at step 1, and parent self-efficacy (FASE-P) and intolerance of uncertainty (IUS-S) in step 2 of the models. Due to the small number of fathers who completed the study, it was not possible to control for gender in the analysis, regression analyses were therefore re-run excluding male participants, and controlling for maternal age.

Results

Do Parents of Children with Food Allergy Report Clinically Significant Levels of Worry, Anxiety, and/or PTSS?

On the PSWQ, the mean score was 56.77(*SD*=12.69), 85 parents (81.0%) scored over the cut-off of 45 (found to distinguish clinical to non-clinical samples), and 37 parents (35.2%) scored above 64 (found to have good discriminatory validity for generalized anxiety disorder). On the DASS-21 Anxiety Subscale, the mean score was 9.42(*SD*=9.54), 46.7% showed 'normal' levels of anxiety, 14.3% 'mild', 14.3% 'moderate', 8.6% 'severe', and 16.2% 'extremely severe'. On the IES-R, the mean score was 22.28(*SD*=20.34), 44 parents (42.3%) scored above 24, the recommended

cut-off for clinically significant PTSS, with 33.7% (*N*=35) scoring over 33, the suggested clinical cut-off for PTSD. The stressful events reported by parents for the IES-R included witnessing anaphylactic reactions in their child (51.0%), witnessing non-anaphylactic allergic reactions in their child (39.4%), and other events (9.6%) such as hearing about an allergic reaction in their child or finding out their child was exposed to allergens. This was similar amongst parents who scored over the cut-off for PTSS (56.8% anaphylaxis, 36.4% non-anaphylactic allergic reaction, and 6.8% other). For parents who reported clinically significant PTSS, time since the traumatic event varied from less than one week to ten years, with a median of 11 months.

Overall, 86.7% of participants reached the clinical cut-off on at least one of the three psychological outcome measures, with 48.6% showing clinical significant levels on at least two measures, and 25.7% reaching the clinical threshold on all three psychological outcome measures.

Are Parents' Experiences of Worry, Anxiety, and PTSS Predicted by Intolerance of Uncertainty, Food Allergy Self-Efficacy, and/or Severity of Allergy?

Greater intolerance of uncertainty and lower food allergy self-efficacy were significantly correlated with anxiety, worry, and post-traumatic stress symptoms (Table 6); however the correlations were consistently stronger for intolerance of uncertainty.

Differences in worry, anxiety, and trauma symptoms between food allergy severity groups are shown in Table 7. A significant difference in anxiety, worry and PTSS was observed for parent reported anaphylaxis symptoms, a significant difference in worry and PTSS was also observed for an AAI having been

administered, and in PTSS for A&E having been attended for an allergic reaction. Whilst the relationship between the significant allergy severity variables did not appear strong enough to warrant concerns of multicollinearity (Cramer's phi=0.31-0.41), inclusion of multiple allergy factors in regression analyses appeared to mask the effect of the individual variables. Further exploration indicated that this appeared to be due to an AAI having been administered mediating the relationship between parent reported anaphylaxis symptoms and A&E attendance with worry and PTSS. As an AAI having been administered was also found to have the largest effect size for both worry and PTSS, a decision was made include an AAI having been administered as the only marker of allergy severity in worry and PTSS regression analyses. For the anxiety regression, parent reported anaphylaxis symptoms was included as the only severity marker found to have a significant difference.

Table 6

Mean Scores and Correlations Between Intolerance of Uncertainty, Food Allergy Self-Efficacy, Worry, Anxiety, and Post-Traumatic Stress Symptoms

	Mean(*SD*)	1	2	3	4	5
1. IUS-S	34.30(10.66)	-				
2. FASE-P	72.11(14.10)	-.42**[a]	-			
3. PSWQ	56.76(12.63)	.66**[a]	-.22*[a]	-		
4. DASS-21 Anxiety Subscale	9.50(9.53)	.45**	-.24*	.51**	-	
5. IES-R	22.28(20.34)	.47**	-.33**	.37**	.58**	-

Note. IUS-S = Intolerance of Uncertainty Scale – Short Form; FASE-P = Food Allergy Self-Efficacy Scale for Parents; PSWQ = Penn State Worry Questionnaire; DASS-21 = Depression Anxiety Stress Scales 21; IES-R = Impact of Events Scale Revised.

[a]Pearson's correlation coefficient, all other correlations using non-parametric Spearman's rank correlation coefficient

*p<.05 **p<.01

Table 7

Differences in Worry, Anxiety, and Post-Traumatic Stress Symptoms in Parents Whose Children do and do not Have Indicators of More Severe Food Allergies

			PSWQ		DASS-21 Anxiety		IES-R	
		N	Mean(SD)	p^a	Mean(SD)	p^b	Mean(SD)	p^b
AAI Prescribed	Yes	78	57.90(11.27)	.191	9.43(9.62)	.751	23.48(21.09)	.545
	No	26	53.38(16.00)		9.92(9.54)		19.20(18.24)	
AAI Given	Yes	21	61.76(11.85)	.042*	11.71(10.03)	.134	36.29(19.16)	<.001**
	No	84	55.51(12.57)		8.94(1.23)		18.74(19.16)	
Anaphylaxis History	Yes	60	57.54(11.74)	.467	10.34(1.33)	.315	23.97(20.87)	.476
	No	45	55.72(13.78)		8.23(1.23)		20.07(19.64)	
A&E Attended	Yes	57	56.96(12.49)	.923	10.79(10.10)	.189	27.33(21.65)	.022*
	No	47	56.72(12.97)		8.05(8.73)		16.75(17.11)	
Anaphylaxis Symptoms	Yes	45	59.81(11.43)	.031*	12.29(10.91)	.020*	29.36(23.40)	.016*
	No	60	54.48(13.08)		7.41(7.79)		17.09(16.07)	

Note. PSWQ = Penn State Worry Questionnaire; DASS-21 = Depression Anxiety Stress Scales 21; IES-R = Impact of Events Scale Revised; AAI prescribed = At least one child with an adrenaline auto-injector prescribed for food allergy; AAI Given = AAI administered at least once during an allergic reaction; Anaphylaxis History = At least one previous parent-reported anaphylactic reaction to food; A&E attended = Accident and Emergency attended at least once due to food allergy; Anaphylaxis Symptoms = Parent reports having at least one child who has experienced at least three symptoms indicative of anaphylaxis during allergic reactions.

[a]independent samples t-test [b]Mann-Whitney U test

Worry. Hierarchical multiple regression was used to predict parental worry (PSWQ score), with an AAI having been administered at the first step, and food allergy self-efficacy (FASE-P) and intolerance of uncertainty (IUS-S) entered at step 2. The first model was significantly predictive of parental worry, $F(1,103) = 4.25$, $p=.042$, but explained only 4.0% of variance. When self-efficacy and intolerance of uncertainty were added to the model, it remained significantly predictive of worry, $F(3,101) = 29.66$, $p<.001$, and was a significantly better fit of the data, $\Delta F(2,101)=40.74$, $p<.001$. The second model explained an additional 42.9% of variance. Within this model, an AAI having been administered and intolerance of uncertainty were significant predictors of worry, but food allergy self-efficacy was not (Table 8), the strongest predictor in the model was intolerance of uncertainty ($\beta = .69$). This pattern of results was maintained when fathers were excluded from the analysis, but when controlling for maternal age only intolerance of uncertainty remained a significant predictor.

Table 8

Hierarchical Multiple Regression Model for Parental Worry (PSWQ)

	B	*SE B*	β	*p*
Step 1 (R^2=.04)				
AAI given	6.25	3.03	.20	.042*
Constant	55.51	1.36		<.001**
Step 2 (R^2=.47)				
AAI given	4.79	2.29	.15	.038*
IUS-S	0.81	0.10	.69	<.001**
FASE-P	0.07	0.07	.08	.316
Constant	22.71	7.25		.002*

Note. AAI Given = Adrenaline auto-injector administered at least once during an allergic reaction; IUS-S = Intolerance of Uncertainty Scale – Short Form; FASE-P = Food Allergy Self-Efficacy Scale for Parents.

Anxiety. Binary logistic regression was used to predict parental anxiety (no-mild or moderate-extremely severe anxiety on the DASS-21 Anxiety Subscale). The first model, including only parent reported anaphylaxis symptoms, did not lead to a significant improvement in the classification of clinical cases, $\chi^2(1) = 3.20$, p=.074. When intolerance of uncertainty and food allergy self-efficacy were added to the model, there was a significant improvement in the number of participants correctly classified, $\chi^2(3)$=12.65, p=.005. A Hosmer and Lemeshow Test indicated that the model was a good fit of the data, $\chi^2(8) = 6.99$, p=.538. Within this model, intolerance of uncertainty was the only variable that was individually significantly predictive (Table 9). The model correctly classified 69.5% of participants, with superior specificity than sensitivity (Table 10). When fathers were excluded from the analysis and controlling for maternal age, intolerance of uncertainty remained the only individually significant predictor of anxiety.

Table 9

Logistic Regression Model of Anxiety in Parents of Children with Food Allergies

Predictor	β	*SE* β	*p*	OR (e^{β}) [95% confidence intervals]
Step 1				
Anaphylaxis Symptoms	-.73	.41	.075	0.484 [0.22, 1.10]
Constant	-.04	.30	.882	0.96
Step 2				
Anaphylaxis Symptoms	-.78	.43	.073	0.46[0.20, 1.08]
IUS-S	.05	.02	.031*	1.05[1.01, 1.10]
FASE-P	-.02	.02	.320	0.98[0.95, 1.02]
Constant	-0.53	1.72	.759	.589

Note. Anaphylaxis Symptoms = Parent reports having at least one child who has experienced at least three symptoms indicative of anaphylaxis during allergic reactions; IUS-S = Intolerance of Uncertainty Scale – Short Form; FASE-P = Food Allergy Self-Efficacy Scale for Parents.

Table 10

Classification Table for Logistic Regression Model of Anxiety

Observed	Predicted		Percentage Correct
	No-Mild Anxiety	Moderate-Severe Anxiety	
No-Mild Anxiety	54	10	84.4
Moderate-Severe Anxiety	22	19	46.3
Overall Correct			69.5

PTSS. Binary logistic regression to predict whether parents experienced clinically significant PTSS symptoms (i.e. IES-R above 24), found a model including only an AAI having been administered led to a significant improvement in the classification of clinical cases, $\chi^2(1) = 12.53$, $p<.001$. However, when intolerance of uncertainty and food allergy self-efficacy were added to the regression model, there was a significant improvement in the number of participants correctly classified, $\chi^2(3)=31.24$, $p<.001$, and a Hosmer and Lemeshow test indicated the model was a good fit of the data, $\chi^2(8) = 8.29$, $p=.406$. Within this model an AAI having been administered and intolerance of uncertainty were individually significantly predictive of PTSS (Table 11). The model correctly classified 76.9% of participants, although the model's specificity was superior to its sensitivity (Table 12). This pattern of results was maintained when removing fathers from the analysis, and controlling for maternal age.

Table 11

Logistic Regression Model of PTSS in Parents of Children with Food Allergies

Predictor	β	*SE* β	*p*	OR (e^{β}) [95% confidence intervals]
Step 1				
AAI given	-1.84	.56	.001**	0.16 [0.05, 0.48]
Constant	1.16	.51	.023*	3.20
Step 2				
AAI given	-2.00	.61	.001**	0.14 [0.04, 0.45]
IUS-S	.07	.03	.006**	1.07 [1.02, 1.13]
FASE-P	-.03	.02	.089	0.97 [0.94, 1.00]
Constant	1.04	1.87	.579	2.82

Note. AAI Given = Adrenaline auto-injector administered at least once during an allergic reaction; IUS-S = Intolerance of Uncertainty Scale – Short Form; FASE-P = Food Allergy Self-Efficacy Scale for Parents.

Table 12

Classification Table for Logistic Regression Model of PTSS

Observed	Predicted		Percentage Correct
	IES-R below 24	IES-R above 24	
IES-R below 24	50	10	83.3
IES-R above 24	14	30	68.2
Overall Correct			76.9

Note. IES-R = Impact of Events Scale – Revised.

Discussion

This study found a large proportion of parents of children with food allergies reported clinically significant worry, anxiety, and/or PTSS. This varied from 39.0% of participants reporting moderate-extremely severe anxiety (DASS-21 Anxiety Subscale) to 81.0% of parents reporting clinically significant worry (PSWQ). Clinically significant levels of PTSS were observed in 42.3% of participants, including parents of children with both life-threatening and milder allergies. Within regression analyses, greater intolerance of uncertainty was a consistent significant predictor of worry, anxiety, and PTSS. In contrast, whilst food allergy self-efficacy was significantly correlated with all three mental health outcome measures, it did not remain significant in any of the planned regression analyses. Finally, mixed results were found for the relationship between allergy severity and parent mental health.

These findings supplement previous qualitative studies in the field, which have indicated worry (e.g. Akeson et al., 2007; Sanagavarapu et al., 2016) and trauma symptoms (e.g. Akeson et al., 2007; Rouf et al., 2012) in parents of children with food allergy. The rates of anxiety found in the current study, are also comparable to past research that has used general measures of anxiety, such as the HADS (e.g. Knibb & Semper, 2013). However, the disparity between the rates of clinically significant anxiety and worry found in the present study highlight the benefit of considering different types of anxiety rather than exploring anxiety as a unitary construct.

The strong relationship found between intolerance of uncertainty and mental health outcomes is congruent with the high rates of worry in the sample, a presentation where intolerance of uncertainty has been suggested to play a central role (Dugas et al., 2001). This finding is also in keeping with qualitative parent

reports (e.g. Rouf et al., 2012) and the nature of food allergy, due to the impossibility of guaranteeing non-exposure to allergens. However, contrary to anxiety models (Clark & Beck, 2010), and suggestions in past research (e.g. Quach & John, 2018), food allergy self-efficacy was not a significant predictor in any of the regression analyses. It may be that parents' perception of threat was too great to be moderated by their confidence in allergy management. This is an important clinical finding, as whilst confidence is important for medical management, the present study indicates that psychological interventions may be more effective if they focus on factors that impact on parents' threat perception (e.g. intolerance of uncertainty).

The mixed results for allergy severity are also in keeping with the previous literature (e.g. Cummings, Knibb, Erlewyn-Lajeunesse et al., 2010; Marklund et al., 2006); however, the study raised interesting novel findings particularly for having an AAI administered, which was a significant predictor of worry and PTSS. While an AAI having been administered has been discussed in some previous research (e.g. Ogg, Wong, Wan, Davis, & Arkwright, 2017; Williams, Parra, & Elkin, 2009), it has been considered less frequently than an AAI having been prescribed, particularly in relation to anxiety. In the wider paediatric psychology literature, parents of children with Type I diabetes have reported giving injections to be the second most distressing diabetes related event, with the most distressing being having their child rushed to hospital (Horsch, McManus, Kennedy, & Edge, 2007). Given AAI administration involves giving an injection during a potentially life-threating reaction, likely to lead to A&E admission, it is in keeping with this research that parents may find this particularly distressing. If this finding is supported by future research, it may be beneficial to introduce targeted brief psychological assessments

for parents whose children have had an AAI administered; however, at this stage caution is needed due to the limitations of the current study.

Firstly, the study used a cross-sectional design, and therefore it is not possible to establish causality between food allergy and psychological outcomes. Whilst PTSS was measured in relation to the most stressful food allergy event parents could recall, inferring a degree of causality, the time since this event took place was not controlled for and as the IES-R only considers symptoms over the past week it does not account for the potential of resolved PTSS. It would be beneficial for future research to take a longitudinal approach, better suited to establishing causality between food allergy events and psychological distress.

A further limitation of the study is the gender split of participants. While inclusion criteria were any adult with the main caring responsibility for a child with food allergy, only three fathers participated. In the future, a paired design may be helpful allowing both parents to report. This may be more feasible using clinic based recruitment, which would also be better suited to drawing conclusions on prevalence, as it is more possible to assess the representativeness of the study sample.

Finally, while the regression models in the present study were significant, a large proportion of variance in psychological outcomes remained unexplained. Whilst this is to be expected, it could be beneficial for future research to include alternative predictors that were not assessed in the present study. In particular, given the positive findings for intolerance of uncertainty, it may be beneficial to examine additional parental factors that influence threat perception (e.g. food allergy related locus of control, or attitudes towards risk). A better understanding of these factors, could help lead to the development of a psychological model for the impact of food allergy, which in turn could guide treatment.

Despite its limitations, this study addresses a significant gap in the literature through assessing PTSS in parents of children with food allergies, a need highlighted in a 2003 review (Kelsay, 2003) that had remained unaddressed. The study also considered different types of anxiety, and to the best of the authors' knowledge was the first study to include a worry specific measure in a large study within this population. The differences in prevalence and regression results between the three mental health outcomes highlight the utility of taking this approach. This may help to explain inconsistent findings in past research, which has typically used general measures of anxiety (e.g. the HADS), which may have masked different patterns of psychological response. The study also provides useful information for the development of models and the psychological treatment of anxiety and PTSS in parents of children with food allergy, through highlighting a strong relationship between intolerance of uncertainty and greater psychological distress in this population. Overall, the study highlights the importance of greater awareness of parents' mental health in paediatric food allergy, and offers direction for future research in this comparatively new field.

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Chapter 4: Extended Methodology

The following chapter provides additional information concerning the methodology of the empirical research paper, including ethical considerations, the allergy demographic questionnaire, and power analysis.

Ethical Considerations

Public and Patient Involvement

Prior to the application for ethical approval feedback on both the ethics application and participant facing documents was sought from a parent of a child with allergies through a public and patient involvement group (PPIRes). Revisions were made in response to this feedback, for example the inclusion of support information at the start as well as the end of the survey.

Clinic Recruitment

The decision for clinic recruitment to involve consent to contact, rather than allowing full consent and participation at clinic appointments, was both ethical and methodological. Ethically, the decision was made to reduce the risk of coercion, as it was not possible to inform potential participants about the project in advance of their clinic appointments, to allow greater time to consider participation. Methodologically, it also allowed all participants to complete the survey in the same format, to reduce methodological differences that may impact responses.

Participants who were recruited through the paediatric allergy clinic were initially approached by a member of the allergy team. When the researcher was not present, the allergy team would briefly introduce the project, provide the information

sheet, and if interested ask the potential participant to complete the consent to contact form. When the researcher was available in clinic, potential participants gave verbal consent to the food allergy team to speak to the researcher about the project. The researcher then discussed the project, answered any questions, and if interested provided the participant with an information sheet (Appendix E) and consent to contact form to complete (Appendix F). In all instances, consent to contact forms were transported in a locked case, and subsequently stored in a locked cabinet at the University of East Anglia.

Confidentiality

The survey was completed anonymously, which helps maintain participant confidentiality. However, due to this it was not possible to follow-up with participants who scored highly on any of the measures of psychological distress. All participants were therefore signposted to sources of information and were advised to contact their GP if they felt they would benefit from additional support with any of the issues raised in the study. In response to PPI feedback, participants were also advised to complete the survey at a time when they had support available if they felt the topics covered in the research could be distressing for them.

The only identifiable information collected during the online survey was for the purpose of administering the prize draw and the option for participants to receive a summary of the results of the study. Bristol Online Surveys was used to host the survey, which is compliant with UK and EU data protection laws, including the updated General Data Protection Regulations (GDPR; Regulation (EU) 2016/679). The survey data was downloaded on the university server and identifiable

information was immediately removed and saved in separate password protected spreadsheets.

Prize draw

Within the budget of the thesis and recruitment targets, it was not possible to reimburse all participants. A decision was made to offer a prize draw as a token of appreciation for participation. Multiple smaller prizes were offered rather than one large prize, as this was considered less coercive and allowed a greater proportion of participants to receive a prize. To ensure the prizes were fairly distributed, all participants that chose to enter the prize draw were allocated a participant number, and a random number generator was used to select prize draw winners. The winners were emailed, and it was explained that if no response was received within three weeks the prize would be reallocated, using the same process.

Demographic and Allergy Questionnaire

The questionnaire regarding the participants' child(ren) and their allergy was developed on the basis of past research, and discussion with an allergy paediatrician (AB) and the primary supervisor (JY) who has clinical psychology experience working with food allergy.

Although specific food allergies are usually not hereditary, there is evidence for a genetic propensity towards allergic conditions (Marenholz et al., 2017), and it was therefore considered particularly important to account for the fact that parents may have more than one child with food allergy. Different approaches to manage this were considered. No strong rationale was apparent for asking parents to respond in relation to a particular child, a decision was therefore made to allow parents to

respond in relation to multiple children with food allergy. This provided more detailed information, and allowed the researchers to make the decision on assimilating this during the results. In particular, if any allergy variable were a risk factor for poorer psychological wellbeing in parents, one would expect to observe this if any of their children shared this allergy characteristic or experience, asking parents to respond in relation to a specific child risked losing some of this information.

Power Analysis

A priori power analyses were conducted to determine recruitment targets. On the basis of a multiple regression with three predictors (intolerance of uncertainty, food allergy self-efficacy, and allergy severity), with a medium effect size and alpha level of .05, G*Power (Erdfelder, Faul, Buchner, & Lang, 2009) generates a target sample size of 77 (for power at the 0.8 level). Alternatively, using Green's (1991) rule of thumb for regression analyses, a sample size of 74 would be considered necessary with a sample of 107 preferable for also considering the contribution of individual predictors. If all five allergy severity factors were included in regression analyses (total of seven predictors), G*Power recommends a sample size of 103. Recruitment targets were set for this range, and the study successfully recruited to the upper end of this target allowing more power and flexibility in the analyses. However, due to assumption violations, logistic rather than multiple regression was used for some analyses. There is a lack of clear consensus regarding the most appropriate approach for calculating necessary sample sizes for logistic regression analyses (e.g. Demidenko, 2006); however, as the models in the main paper were significant it can be assumed that the study was sufficiently powered.

Chapter 5: Extended Results

The following chapter provides additional results for the empirical research project: firstly, outlining the statistical assumptions that were checked and where these were violated; secondly, providing additional information regarding the decision of which allergy severity factors were included in the main regression analyses; and finally presenting an exploratory analysis to evaluate additional demographic and allergy variables that may predict psychological outcomes.

Statistical Assumptions

Multiple linear regression is dependent on the following statistical assumptions being met (the approach used to test each assumption is included in brackets): normal distribution of the standardized residuals (visual inspection of histogram), absence of outliers/points having an undue influence on the regression line (large standardized residuals, Cook's distance values), homoscedasticity (inspection of scatter plot of standardized residuals against standardized predicted values), absence of multicollinearity (size of relationship between predictor variables), no indications of a non-linear relationship between continuous predictor and outcome variables (inspection of scatterplots). For the worry regression analysis each of these assumptions were adequately met.

Neither the IES-R (PTSS measure; Weiss & Marmar, 1997) nor the DASS-21 Anxiety Subscale (Lovibond & Lovibond, 1995) were normally distributed, with the former approaching a bimodal distribution with a positive skew (Figure 3) and the latter showing a positive skew (Figure 4). Whilst non-normally distributed outcome variables are not always inherently problematic in regression analyses, it can be more

likely that the main statistical assumptions are violated. This was the case in the empirical paper analyses, where plots to assess homoscedasticity for both PTSS and anxiety showed a cone/wedge shape, indicating the data to be heteroscedastic (Clark-Carter, 2010). There are two main alternatives to managing this form of assumption violation: use a data transformation or use an alternative statistical test.

While performing data transformations can allow the planned statistical analysis to be conducted, it can also lead to the results being less clearly interpretable, and where the assumption violations are caused by what could be considered meaningful patterns in the data, rather than spurious results of a particular sample, important results and meaning can be lost. This is notable in the case of PTSS, where one could theoretically predict to see a bimodal distribution, as a large proportion of the population would not be expected to experience PTSS, but a more normal distribution could be expected amongst those scoring in the clinical range (i.e. in those who are experiencing distress in relation to a traumatic event). This is broadly what can be observed in the histogram of PTSS scores in the present sample (Figure 3), and it is particularly notable that the dip in the distribution approximately coincides with the previously established PTSS cut-off score of 24 (Asukai et al., 2002). As such, even if statistical assumptions could be met through data transformation, multiple linear regression would mask this data pattern and the results could therefore be considered to have less explanatory power. It was therefore considered more appropriate to use logistic regression for these analyses. There is a less clear rationale for preferring data transformation or logistic regression for anxiety, as theoretically anxiety could be expected to approximate a normal distribution. However, as transformed data is less immediately interpretable, and would have resulted in using a different analytic approach for all three psychological

outcomes (which in turn makes comparisons across models more difficult), it was considered more appropriate to also use logistic regression for this analysis.

Logistic regression has fewer statistical assumptions than multiple linear regression, but still requires variables to be independent of each other, a lack of multicollinearity, and a linear relationship between the predictors and log odds (tested using the Box-Tidwell method; Osborne, 2015). All of these assumptions were met for the anxiety and PTSS analyses.

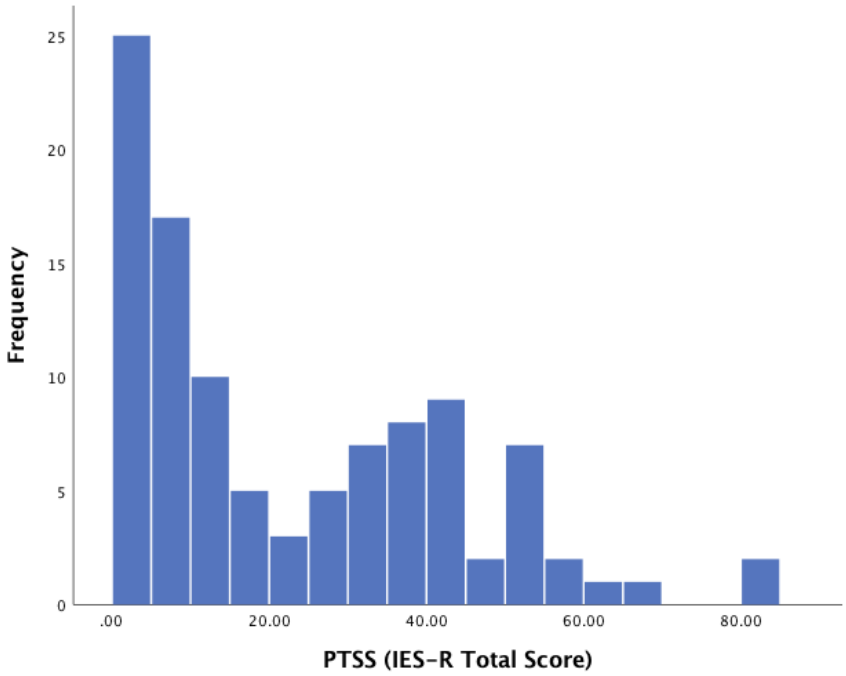

Figure 3. Histogram showing parents' PTSS scores.

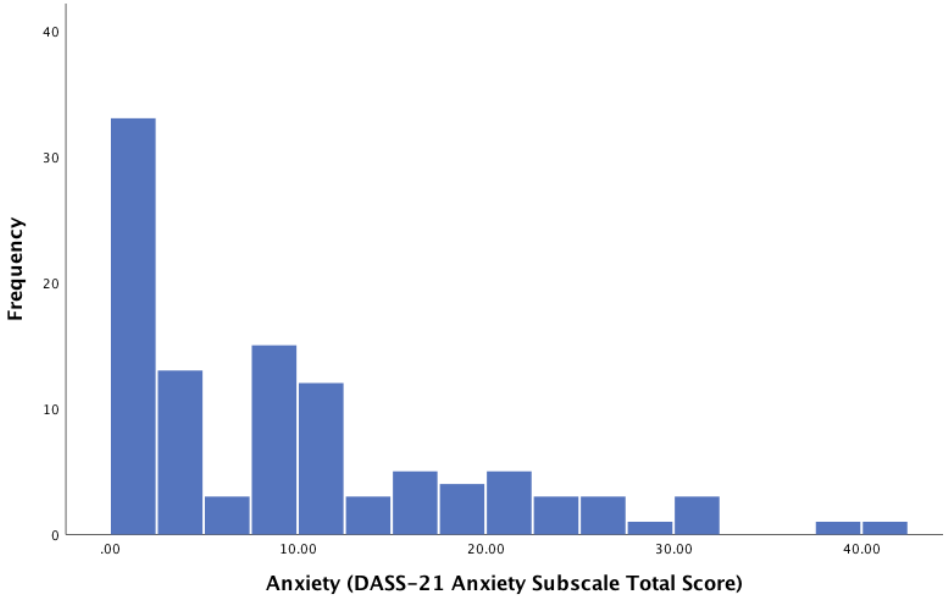

Figure 4. Histogram showing parents' anxiety scores.

Relationship Between Allergy Severity Variables

As outlined in the previous chapter, prior to conducting regression analyses, the relationships between the significant allergy severity factors were assessed to check for potential issues with multicollinearity. For worry this included parent reported anaphylaxis symptoms and an AAI having been administered, and for PTSS this included these two variables as well as A&E having been attended for an allergic reaction. As the effect size of the relationship between these variables did not present cause for concern (largest Cramer's Phi = 0.41), initially regression analyses were conducted including all significant severity factors for each psychological outcome. However, when multiple allergy severity factors were included in a regression model, no variable remained individually significantly predictive, and as this was not readily explained by collinearity it raised concern of possible interaction effects, which could mask the contribution of allergy severity in the final analyses. As such, possible moderations and mediations that were considered to make clinical and

theoretical sense were explored, which indicated that an AAI having been administered may mediate the relationship between the remaining allergy severity factors and psychological outcomes.

As all allergy severity variables as well as PTSS were dichotomous variables, the syntax and spreadsheet developed by Herr (n.d.) was used to conduct the mediation analyses which calculates the proportion of effect mediated based on Mackinnon and Dwyer's (1993) methodology. For PTSS, an AAI having been administered mediated 63.9% of the relationship between A&E attendance and PTSS, and 58.5% of the relationship between anaphylaxis symptoms and PTSS. The mediation effect for worry was smaller, with an AAI having been administered explaining 29.8% of the relationship between anaphylaxis symptoms and PSWQ score. While much smaller, this mediation is still accounting for a notable proportion of the relationship between anaphylaxis symptoms and worry. An AAI having been administered also showed a larger effect size for difference in worry than anaphylaxis symptoms. It was therefore considered most appropriate to include only an AAI being administered in the worry and PTSS analyses.

As an additional check that overall explanatory power was not being lost through the omission of the additional severity variables, a comparison was made in the total variance explained in worry and PTSS regression models including all significant allergy severity variables and those including only an AAI having been administered. For worry, the additional inclusion of anaphylaxis symptoms explained an additional 1% of variance, and for PTSS the inclusion of anaphylaxis symptoms and A&E attendance improved classifications by 1.7%. As this represents only a very small overall improvement, and the significance of the individual variables is lost, the model including only one severity variable was considered to have the best

explanatory power whilst also minimizing the risk of over fitting the regression models.

Exploratory Data Analysis

Given the early stage of research in this field, an additional exploratory analysis was conducted to include additional allergy and demographic factors, with a view to guiding future research. For this exploratory analysis, all possible variables were analysed against the three mental health outcomes (anxiety, worry, and post-traumatic stress), using correlations for continuous variables, and t-tests or non-parametric alternatives for dichotomous variables. Regression analyses were then re-run including all variables that showed a significant relationship, with demographic/allergy factors included in step 1, and parent factors added in step 2. As the purpose of this additional analysis is to guide future research, rather than draw firm conclusions, no steps were taken to account for multiple testing, as in the context of an exploratory analyses this can be overly harsh and result in overlooking potentially valuable results (e.g. Althouse, 2016).

Data Treatment

Where parents had more than one child with food allergy, child age was averaged, total number of different food allergens was summed, and dichotomous items (e.g. whether an AAI was prescribed) were included as 'yes' if at least one child met the criteria (as per main analysis). For analyses including child gender, parents were excluded if they had both male and female children with food allergies. Anaphylaxis symptoms were included as per the main analysis, but two further groups of allergy symptoms were explored. Firstly, mild-moderate symptoms, i.e.

symptoms not considered to be indicative of anaphylaxis (British Society for Allergy and Clinical Immunology, 2013). Secondly, gastrointestinal symptoms (bloated stomach, abdominal pain, diarrhea, vomiting), these form a subset of the mild-moderate symptoms that have previously been suggested to be particularly concerning for parents (Marklund, Ahlstedt, & Nordström, 2006). An approximate median split resulted in a cut-off of having at least one child with at least six mild-moderate symptoms or three gastrointestinal symptoms.

Results

Table 13 shows the correlations between all continuous variables and the three mental health outcome measures, with Table 14 showing the results of between group comparisons for dichotomous variables and mental health outcomes. The significant variables for each mental health measure were then included in regression analyses; however, as per the regression analyses presented in the empirical paper, due to relationships between the different measures of allergy severity, parent reported anaphylaxis symptoms were omitted from the worry and PTSS analyses, and A&E attendance was also excluded from the PTSS analysis. Furthermore, as gastrointestinal symptoms formed a subset of the mild-moderate symptoms these variables could not be considered independent. As such, only gastrointestinal symptoms were included in regression analyses as the effect size was larger for this variable suggesting it to be a stronger predictor.

Table 13

Correlations Between All Continuous Variables Assessed in Empirical Study

	1	2	3	4	5	6	7	8	9	10
1. Child Age	-									
2. Parent Age	.69**	-								
3. Number of Food Allergies	-.07	.001	-							
4. Time for Diagnosis	-.02	-.07	.27**	-						
5. Time Since Diagnosis	.88**	.64**	.05	-.07	-					
6. IUS-S	-.03	-.19[a]	.07	.23*	-.08	-				
7. FASE-P	.25*	.29**	-.001	-.08	.23*	-.44**	-			
8. PSWQ	.09	-.01[a]	.13	.10	.07	.66**[a]	-.22*	-		
9. DASS-21 Anxiety Subscale	.09	-.04	.19	.22*	.16	.45**	-.24*	.51**	-	
10. IES-R	-.01	-.12	.14	.12	-.03	.47**	-.33**	.37**	.58**	-

Note. IUS-S = Intolerance of Uncertainty Scale – Short Form; FASE-P = Food Allergy Self-Efficacy Scale for Parents; PSWQ = Penn State Worry Questionnaire; DASS-21 = Depression Anxiety Stress Scales 21; IES-R = Impact of Events Scale Revised.

[a]Pearson's correlation coefficient, all other correlations using non-parametric Spearman's rank correlation coefficient

*p<.05 **p<.01

Table 14

Differences in Worry, Anxiety, and PTSS Scores with all Possible Dichotomous Demographic and Allergy Variables

			PSWQ		DASS-21 Anxiety		IES-R	
		N	Mean(SD)	*p*[a]	Mean(SD)	*p*[b]	Mean(SD)	*p*[b]
Child Gender	Male	50	55.44(13.29)	.580	10.25(11.32)	.828	25.56(23.24)	.373
	Female	42	56.95(12.66)		7.93(7.50)		18.83(18.23)	
Other health	Yes	87	57.13(11.95)	.518	9.53(9.37)	.891	23.00(20.03)	.227
condition	No	18	55.00(15.76)		9.35(10.55)		18.84(22.02)	
More than one child	Yes	17	58.18(10.22)	.616	10.24(7.34)	.289	23.41(16.37)	.391
with food allergy	No	88	56.49(13.07)		9.36(9.92)		22.06(21.10)	
AAI Prescribed	Yes	78	57.90(11.27)	.191	9.43(9.62)	.751	23.48(21.09)	.545
	No	26	53.38(16.00)		9.92(9.54)		19.20(18.24)	
AAI Given	Yes	21	61.76(11.85)	.042*	11.71(10.03)	.134	36.29(19.16)	<.001**
	No	84	55.51(12.57)		8.94(9.38)		18.74(19.16)	
Anaphylaxis History	Yes	60	57.54(11.74)	.467	10.34(1.33)	.315	23.97(20.87)	.476
	No	45	55.72(13.78)		8.23(1.23)		20.07(19.64)	
A&E Attended	Yes	57	56.96(12.49)	.923	10.79(10.10)	.189	27.33(21.65)	.022*
	No	47	56.72(12.97)		8.05(8.73)		16.75(17.11)	
Anaphylaxis	Yes	45	59.81(11.43)	.031*	12.29(10.91)	.020*	29.36(23.40)	.016*
Symptoms	No	60	54.48(13.08)		7.41(7.79)		17.09(16.07)	
Mild-moderate	Yes	58	56.82(11.73)	.960	11.78(10.35)	.007**	26.35(21.97)	.049*
symptoms	No	47	56.69(13.78)		6.69(7.60)		17.35(17.13)	
Gastrointestinal	Yes	50	56.74(13.18)	.987	12.78(10.55)	.001**	27.82(22.25)	.012*
Symptoms	No	55	56.78(12.21)		6.51(7.40)		17.35(17.23)	
Parental Food	Yes	10	55.50(11.57)	.741	3.80(4.05)	.045*	8.90(12.84)	.016*
Allergy	No	95	56.89(12.78)		10.10(9.75)		23.71(20.52)	

Table 14 (Continued)

			PSWQ		DASS-21 Anxiety		IES-R	
		N	Mean(SD)	p^a	Mean(SD)	p^b	Mean(SD)	p^b
Currently taking	Yes	10	63.70(12.23)	.065	18.60(10.54)	.001**	33.80(24.44)	.050
mood medication	No	93	55.91(12.59)		8.10(8.50)		20.49(19.36)	
Food Allergens:								
Milk	Yes	58	57.83(11.90)	.339	10.57(9.16)	.077	25.11(20.71)	.134
	No	47	55.45(13.48)		8.17(9.89)		18.85(19.55)	
Egg	Yes	56	57.57(12.27)	.485	10.02(8.68)	.229	22.22(20.44)	.913
	No	49	55.84(13.09)		8.90(10.46)		22.36(20.44)	
Peanut	Yes	67	58.13(11.73)	.140	9.01(8.87)	.614	22.24(21.15)	.870
	No	38	54.34(13.90)		10.37(10.65)		22.35(19.34)	
Tree Nut	Yes	51	58.50(11.87)	.171	10.41(9.36)	.314	29.23(21.75)	.002**
	No	54	55.12(13.12)		8.64(9.68)		15.85(16.72)	
Soy	Yes	24	57.17(12.86)	.859	9.06(7.36)	.625	20.70(16.64)	.997
	No	81	56.64(12.63)		9.63(10.11)		22.73(21.35)	
Wheat	Yes	20	58.60(10.34)	.472	9.15(10.19)	.863	26.80(22.12)	.337
	No	85	56.33(13.12)		9.58(9.42)		21.21(19.88)	
Fish	Yes	5	61.60(5.13)	.383	12.00(11.05)	.606	27.20(24.39)	.746
	No	100	56.52(12.85)		9.37(9.49)		22.03(20.23)	
Shellfish	Yes	7	61.14(4.85)	.057	10.57(8.22)	.560	28.00(22.06)	.572
	No	98	56.45(12.96)		9.42(9.64)		21.93(20.30)	
Sesame	Yes	23	57.13(13.93)	.884	8.26(8.03)	.626	24.23(21.21)	.673
	No	82	56.66(12.33)		9.85(9.92)		21.67(20.18)	

Note. PSWQ = Penn State Worry Questionnaire; DASS-21 = Depression Anxiety Stress Scales 21; IES-R = Impact of Events Scale Revised; AAI prescribed = At least one child with an adrenaline auto-injector (AAI) prescribed for food allergy; AAI Given = AAI administered at least once during an allergic reaction; Anaphylaxis History = At least one previous parent-reported anaphylactic reaction to food; A&E attended =

Accident and Emergency attended at least once due to food allergy; Anaphylaxis Symptoms = Parent reports having at least one child who has experienced at least three symptoms indicative of anaphylaxis during allergic reactions; Mild-Moderate Symptoms = Parent reports having at least one child who has experienced at least six mild-moderate symptoms during allergic reactions; Gastrointestinal Symptoms = Parent reports having at least one child who has experienced at least three gastrointestinal symptoms during allergic reactions.
[a]independent samples t-test [b]Mann-Whitney U test

For worry, the regression analysis presented in the empirical paper included the only variables with a significant correlation with or difference in scores on the PSWQ (Meyer, Miller, Metzger, & Borkovec, 1990). Therefore no further regression analysis was conducted.

For anxiety, a binary logistic regression was conducted with anaphylaxis symptoms, gastrointestinal symptoms, parent food allergy, parent currently taking mood medication, and wait time for diagnosis included in the first step, and intolerance of uncertainty and food allergy self-efficacy added in the second step (Table 15). This model led to a significant improvement in the classification of clinical cases, $\chi^2(7) = 29.20$, $p<.001$, and was found to be a good fit to the data, Hosmer-Lemeshow $\chi^2(8) = 6.068$, $p=.640$. Within this model, only gastrointestinal symptoms remained individually significantly predictive. The model correctly classified 76.2% of participants (Table 16), with improvements in both sensitivity and specificity compared to the regression model presented in the empirical paper.

Table 15
Exploratory Logistic Regression Model for Anxiety in Parents of Children with Food Allergies

Predictor	β	*SE* β	p	OR (e^{β}) [95% confidence intervals]
Step 1				
Anaphylaxis Symptoms	-0.49	.48	.300	0.61[0.24, 1.55]
Gastrointestinal Symptoms	-1.59	.49	.001**	0.20[0.08, 0.53]
Time for diagnosis	-0.01	.02	.331	0.99[0.96, 1.02]
Parent Food Allergy	1.40	.88	.112	4.05[0.72, 22.75]
Parent Mood Medication	-1.88	.88	.032*	0.15[0.03, 0.86]
Constant	1.15	1.25	.357	3.15
Step 2				
Anaphylaxis Symptoms	-0.54	.50	.274	0.58[0.22, 1.54]
Gastrointestinal Symptoms	-1.68	.51	.001**	0.19[0.07, 0.51]
Time for diagnosis	-0.02	.02	.250	0.98[0.96, 1.01]
Parent Food Allergy	1.37	.91	.130	3.94[0.67, 23.26]
Parent Mood Medication	-1.79	.91	.050	0.17[0.03, 1.00]
IUS-S	0.05	.03	.064	1.05[1.00, 1.10]
FASE-P	-0.01	.02	.487	0.99[0.95, 1.02]
Constant	0.47	2.31	.838	1.60

Note. Anaphylaxis Symptoms = Parent reports having at least one child who has experienced at least three symptoms indicative of anaphylaxis during allergic reactions; Gastrointestinal Symptoms = Parent reports having at least one child who has experienced at least three gastrointestinal symptoms during allergic reactions; IUS-S = Intolerance of Uncertainty Scale – Short Form; FASE-P = Food Allergy Self-Efficacy Scale for Parents.

Table 16
Classification Table for Exploratory Logistic Regression Model of Anxiety

Observed	Predicted		Percentage Correct
	No-Mild Anxiety	Moderate-Severe Anxiety	
No-Mild Anxiety	54	8	87.1
Moderate-Severe Anxiety	16	23	59.0
Overall Correct			76.2

For PTSS, a binary logistic regression was completed with an AAI having been administered, gastrointestinal symptoms, having a child with tree nut allergy, and parent food allergy included in step 1, and intolerance of uncertainty and food allergy self-efficacy added in step 2 (Table 17). This model led to a significant improvement in the classification of clinical cases, $\chi^2(6) = 43.43$, $p<.001$, and was found to be a good fit of the data, Hosmer-Lemeshow $\chi^2(8) = 5.60$, $p=.692$. Within this model, an AAI having been administered, gastrointestinal symptoms, and intolerance of uncertainty remained significantly predictive. The model correctly classified 75.0% of participants (Table 18), which is a slight reduction in overall correct classifications and specificity but an improvement in sensitivity compared to the main regression model.

Table 17
Exploratory Logistic Regression Model of Parental PTSS in Food Allergies

Predictor	β	*SE* β	*p*	OR (e^{β}) [95% confidence intervals]
Step 1				
AAI given	-1.76	.63	.005**	0.17[0.05, 0.59]
Gastrointestinal Symptoms	-1.14	.49	.019*	0.32[0.12, 0.83]
Tree Nut Allergy	-0.81	.48	.092	0.45[0.18, 1.14]
Parent Food Allergy	1.68	1.14	.138	5.39[0.58, 49.96]
Constant	0.52	1.28	.683	1.69
Step 2				
AAI given	-1.92	.68	.005**	0.15[0.04, 0.56]
Gastrointestinal Symptoms	-1.20	.54	.027*	0.30[0.10, 0.87]
Tree Nut Allergy	-0.90	.54	.093	0.41[0.14, 1.16]
Parent Food Allergy	1.58	1.21	.190	4.87[0.46, 51.75]
IUS-S	0.06	.03	.018*	1.07[1.01, 1.13]
FASE-P	-0.04	.02	.068	0.97[0.93, 1.00]
Constant	1.04	2.26	.646	2.83

Note. AAI Given = Adrenaline auto-injector administered at least once during an allergic reaction; Gastrointestinal Symptoms = Parent reports having at least one child who has experienced at least three gastrointestinal symptoms during allergic reactions; IUS-S = Intolerance of Uncertainty Scale – Short Form; FASE-P = Food Allergy Self-Efficacy Scale for Parents.

Table 18
Classification Table for Exploratory Logistic Regression Model of PTSS

Observed	Predicted		Percentage Correct
	IES-R below 24	IES-R above 24	
IES-R below 24	46	14	76.7
IES-R above 24	12	32	72.7
Overall Correct			75.0

Note. IES-R = Impact of Events Scale – Revised.

Overall, these exploratory analyses highlight some additional variables that could warrant consideration in future research. In particular, gastrointestinal symptoms, which remained significant in both anxiety and PTSS regression models. However, as an exploratory exercise, it is not appropriate to draw conclusions from this data.

Chapter 6: Discussion

This portfolio presented a systematic review with meta-analysis that aimed to estimate the prevalence of anxiety, depression, and post-traumatic stress symptoms (PTSS) in children with food allergy, and compare this to children without food allergy. An original piece of empirical research was subsequently presented to assess whether parents of children with food allergy report clinically significant anxiety, worry and PTSS, and whether these psychological outcomes could be predicted by allergy severity, intolerance of uncertainty, and food allergy self-efficacy. Finally, an exploratory analysis was conducted with the aim of identifying additional food allergy or demographic variables that could warrant further exploration in future research assessing psychological wellbeing in parents of children with food allergy. This chapter offers a summary of results, before discussing the theoretical and clinical implications of the portfolio, offering a critical evaluation of the work, and ending with suggestions for future research in the field.

Summary of Results

The systematic review highlighted the heterogeneity in the current evidence base for anxiety, depression and PTSS in children with food allergy. Whilst this limits the robustness of the results of the review, there are indications of a small but significant increase in anxiety (d= 0.21, 95% CIs 0.16-0.26) and depression (d=0.30, 95% CIs 0.14-0.45) in children with food allergy compared to their peers without food allergy. However, these results were not consistent across anxiety disorders, with evidence of increased separation anxiety and generalized anxiety, but no significant difference in social anxiety. Only one paper was identified assessing PTSS in a child food allergy

population (Weiss & Marsac, 2016); as a pilot study this study had a small sample size, and was also conducted immediately following a food challenge; as such, it was not possible to draw any conclusions on the prevalence or difference in PTSS within this population.

The empirical paper found high rates of worry (81.0%), anxiety (39.1%) and food allergy related PTSS (42.3%) in parents of children with food allergy. Increased intolerance of uncertainty was significantly positively correlated with all three psychological outcomes, and increased food allergy self-efficacy was significantly negatively correlated with all three outcomes, as expected. Mixed results were found for allergy severity variables, with higher scores on all three psychological outcome measures observed in parents that reported their children to have experienced more anaphylaxis symptoms. For worry and PTSS significantly higher scores were also found in parents that reported an adrenaline auto-injector (AAI) to have been administered during an allergic reaction, and PTSS was also significantly higher in parents whose children had attended A&E due to an allergic reaction. However, no significant differences were observed for an AAI being prescribed or for parents that reported their children to have previously experienced an anaphylactic reaction.

Regression analyses were conducted including an AAI having been administered for worry (multiple linear regression) and PTSS (logistic regression), and parent reported anaphylaxis symptoms for anxiety (logistic regression), in addition to intolerance of uncertainty and food allergy self-efficacy for all psychological outcomes. In these analyses, intolerance of uncertainty was the only variable to consistently remain individually significantly predictive within the models. For worry and PTSS, an AAI having been administered was also

significantly predictive. However, food allergy self-efficacy did not remain a significant predictor in any of the three regression analyses.

The exploratory analysis presented in Chapter 5 offered additional significant variables that may warrant further exploration in relation to anxiety and PTSS, but not worry. For anxiety this included parent reported child gastrointestinal symptoms during allergic reaction (higher anxiety), parents having a food allergy themselves (lower anxiety), longer waiting time to receive food allergy diagnosis (higher anxiety), and parents currently taking medication for their mood (higher anxiety). For PTSS the additional significant variables were parent reported child gastrointestinal symptoms (higher PTSS), child tree nut allergy (higher PTSS), and parents having a food allergy themselves (lower PTSS). Exploratory logistic regression analyses including these variables in addition to those included in the empirical paper, for anxiety found gastrointestinal symptoms to be the only variable to remain individually significantly predictive, whilst for PTSS gastrointestinal symptoms, an AAI having been administered, and intolerance of uncertainty all remained individually significantly predictive.

Links to Previous Research

Anxiety

Although conclusions on prevalence and difference compared to non-food allergy populations cannot be drawn (due to the extent of heterogeneity in the meta-analysis, and self-selecting sample and lack of comparison group in the empirical paper), the papers within this portfolio do provide an indication of elevated levels of anxiety in children with food allergy and their parents.

In children, the overall estimated anxiety prevalence rate of 12.6% was higher than general population estimates of 6.5% (Polanczyk, Salum, Sugaya, Caye, & Rohde, 2015). However, particular caution is needed with interpreting this difference as Polanczyk et al. were able to use far more stringent inclusion criteria, and a high degree of heterogeneity was observed in the portfolio's meta-analysis. The estimated pooled effect size for difference between children with and without food allergy (d=0.21) was comparable to the pooled effect size found in a meta-analysis of anxiety in children with and without any chronic health condition (d=0.18; Pinquart & Shen, 2011), although in both instances a high degree of heterogeneity was observed.

Within anxiety disorder specific syntheses, there was a mixed pattern of results for children with food allergy. Interestingly, these results appear to mirror suggestions in previous literature assessing factors that may impact on the mental health of children with food allergy, as well as the medical management of allergy. For example that children with food allergy may find it harder to be away from home and parents (e.g. Sanagavarapu, 2012), or that a degree of anxiety may be needed for children to be sufficiently vigilant in their allergy management (Mandell, Curtis, Gold, & Hardie, 2005).

In parents, the most notable results were for worry, with 81.0% of participants scoring above the Penn State Worry Questionnaire's (PSWQ; Meyer et al., 1990) clinical cut-off for worry as a transdiagnostic mental health symptom (Behar, Alcaine, Zuellig, & Borkovec, 2003), and 35.2% scoring above the higher threshold previously found to have good discriminative validity for generalized anxiety disorder (GAD; Chelminski & Zimmerman, 2003). These results are in keeping with previous qualitative research that has suggested increased worry in

parents of children with food allergy (e.g. Akeson et al., 2007; Sanagavarapu, Wainstein, Children, & Katelaris, 2016). The rate of clinically significant worry found in the empirical paper sample is also substantially higher than general population estimates for GAD, with 12-month prevalence estimates of 1.3-3.1% for those meeting full diagnostic criteria (Wittchen, 2002), and 2.1%-7.7% when sub diagnostic GAD is included (Haller, Cramer, Lauche, Gass, & Dobos, 2014). However, these prevalence estimates have not used the PSWQ. The mean score found on the PSWQ in the empirical paper (56.77) is also substantially higher than general population norms (mean = 42.2; Gillis, Haaga, & Ford, 1995), with both the mean and median (59) score found in the empirical paper falling in the 80th-90th percentile of general population scores for the 18-44 years age range (the most closely comparable to the present study population).

Whilst worry was relatively pervasive in the empirical paper sample, anxiety was also elevated compared to general population norms. The mean score on the Depression Anxiety Stress Scales 21 (DASS-21) Anxiety subscale (Lovibond & Lovibond, 1995) in the empirical paper was 9.42, whereas in a large British general population sample a mean score of 3.76 has been found (Henry & Crawford, 2005). The median score in the present study population was also notably higher than the median general population score, eight and two respectively. This indicates a pattern of more general increased anxiety, rather than a small number of particularly anxious parents increasing the mean scores within the study. Using the more detailed normative data available for the full DASS (which has good convergent validity and comparable scoring to the DASS-21; Henry & Crawford, 2005), similarly to the results for worry, the median anxiety score found in the empirical paper was within the 80th-90th percentile of general population norms (Crawford & Henry, 2003).

Whilst the DASS-21 is not designed as a diagnostic tool, the items within the anxiety subscale are typical of panic type anxiety, which was the rationale for the additional inclusion of this measure alongside the PSWQ.

Overall, while a greater proportion of participants in the empirical paper scored in the clinical range for worry, comparison to previously published norms indicate that parents in the study were reporting notably elevated levels of both worry and panic type anxiety symptoms, with median scores falling in the 80th-90th percentile range. Therefore, while conclusions on prevalence cannot be drawn, it seems unlikely that these results could be explained exclusively by the use of a self-selected sample in the empirical research project.

Post-Traumatic Stress

As only one pilot study was found assessing PTSS in children, no meaningful comparisons or conclusions can be drawn from this data. However, the empirical study was the first study to assess PTSS in parents of children with food allergy, and with a relatively large sample size, it is useful to consider these results in relation to previous literature.

Firstly, the presence of PTSS found in the empirical paper is congruent with qualitative research exploring parents' experience of caring for a child with food allergy (Abdurrahman et al., 2013; Rouf, White, & Evans, 2012). For example, Rouf et al. includes quotes of parents describing what sounds like re-experiencing symptoms. The results of the empirical study support these previous suggestions, and highlight the need for further research assessing PTSS in this population.

In the wider paediatric literature, Price et al.'s (2016) review of paediatric medical traumatic stress research reported a rough prevalence estimate of PTSS as

30% across potentially traumatic medical events and conditions, with a trend in declining symptoms over time. However, they observed a high degree of heterogeneity in estimates. The largest numbers of PTSS studies were found for paediatric injury and cancer, with generally higher rates of PTSS observed in the cancer literature. The rates of clinically significant PTSS observed in the empirical study (42.3%) were comparable to the lower end of the prevalence estimates observed in parents in the first month following cancer diagnosis (40-83%; Price et al., 2016), with prevalence of PTSS in the cancer literature at 10 months having dropped to 7-20%. Within the empirical paper, time since the stressful event was reported but not controlled for, and PTSS symptoms were assessed over the past week, as such resolved PTSS was not accounted for. However, amongst those reporting clinically significant PTSS the median time since the stressful event was 11 months. Given this, the rates of PTSS observed in the empirical study are surprisingly high.

Whilst the results of the empirical study need to be interpreted with caution given the cross-sectional design and self-selecting sample, the PTSS measure was completed specifically in relation to a food allergy related event, and given this has not previously been researched the presence of PTSS in this population is an important and valuable finding.

Depression

Depression was not assessed in parents with food allergy. However, the meta-analysis indicated increased rates of depression in children with food allergy. For prevalence, the meta-analysis generated a pooled prevalence of 6.9%, compared to general child prevalence estimates of 2.9% (Polanczyk et al., 2015), although the

same caution is required as in the anxiety comparison due to heterogeneity and differences in inclusion criteria. The pooled effect size for difference calculated in the portfolio's meta-analysis (d=0.30) was higher than that found in a meta-analysis of children with any chronic health condition compared to healthy child populations (d=0.19; Pinquart, Shen, & Sych, 2011). Whilst a particularly high degree of heterogeneity was observed in the depression synthesis, limiting the robustness of this finding, it is nevertheless an interesting result that warrants further exploration.

Predictors of Psychological Outcomes

Within the empirical paper, intolerance of uncertainty being a consistently strong predictor of mental health outcomes is consistent with the wider literature. While intolerance of uncertainty is widely considered in relation to generalized anxiety disorder (e.g. Dugas, Gagnon, Ladouceur, & Freeston, 1998; Buhr & Dugas, 2006), more recently, research has suggested that intolerance of uncertainty may be a transdiagnostic maintaining factor across both anxiety disorders and depression (e.g. Carleton et al., 2012; Mahoney & McEvoy, 2012). It is congruent with this literature that whilst the largest effect size was found for worry, intolerance of uncertainty also showed medium-large correlations with anxiety and PTSS.

More surprisingly, parents' food allergy related self-efficacy was not a strong predictor of psychological outcomes. Self-efficacy (Bandura, 1988; Cramm, Strating, Roebroeck, & Nieboer, 2013), and particularly domain specific self-efficacy (e.g. Rezendes & Scarpa, 2011; Streisand et al., 2008) have been widely suggested to be protective factors for anxiety and psychological wellbeing. Self-efficacy is one component of an individual's perceived capacity to cope in the secondary reappraisal phase of Clark and Beck's (2010) model of anxiety. Within

food allergy it has also been suggested that confidence in allergy management may help to explain inconsistent findings between allergy severity and psychological outcomes (Cummings, Knibb, King, & Lucas, 2010). While significant correlations between food allergy self-efficacy and worry, anxiety, and PTSS were found, the effect size was generally small, and self-efficacy did not remain significant in any of the regression models. As there was a reasonable spread of scores on the measure used to assess food allergy self-efficacy in the empirical research project (Food Allergy Self-Efficacy Scale for Parents, FASE-P; Knibb, Barnes, & Stalker, 2015), with no indications of a ceiling effect, these results cannot be readily explained through potential measurement issues. As such, it is useful to consider possible reasons a true small effect size may be found for self-efficacy.

Firstly, the FASE-P (Knibb et al., 2015) assesses parents' own confidence in allergy management. While the FASE-P does include items relating to having confidence in making plans with others to ensure their child's safety, it does not explicitly consider their confidence in their child's own allergy management, or confidence in the ability of other adults with caring responsibility (e.g. teachers) to recognize and respond to allergic reactions. As the potential threat is to the child and not directly to the parent themselves, it is possible that parents' confidence in other individuals to whom they need to delegate responsibility would be equally important as their own confidence in terms of the psychological impact of food allergy (e.g. Sanagavarapu et al., 2016). However, there is currently no standardized way to assess this.

Additionally, confidence in the practical management of food allergy is only one facet to an individual's overall perception of their capacity to cope, other variables such as perceived emotional resilience of themselves and their child, could also be

considered in the secondary appraisal phase of Clark and Beck's (2010) transdiagnostic model of anxiety. The relatively small effects found for food allergy self-efficacy cannot infer that these additional factors would not be important.

As per previous food allergy literature (e.g. Cummings, Knibb, Erlewyn-Lajeunesse et al., 2010; Marklund et al., 2006), mixed findings were found for the relationship between allergy factors and psychological outcomes. While any attempts to explain these differences are tentative, some of the main results for allergy factors are broadly in keeping with suggestions from previous literature. For example, parents of children with Type I diabetes have reported giving injections and emergency hospital attendance as the two most distressing diabetes related events (Horsch, Mcmanus, & Edge, 2007). These factors may help to explain why an AAI having been given was a significant predictor of worry and PTSS, whereas having an AAI prescribed was not. However, this cannot explain why an AAI being administered was not a significant predictor of anxiety symptoms or why A&E attendance was only significantly related to PTSS.

Within the exploratory analysis, the finding that gastrointestinal symptoms were a good predictor of anxiety and PTSS is broadly in keeping with the results of Marklund et al. (2006), and the suggestion that these symptoms may be more distressing due to the lack of available treatment (Cummings, Knibb, King, & Lucas, 2010). However, Marklund et al.'s (2006) study used a quality of life measure with a general item regarding the worry or concern that child health causes parents. While parents experiencing food allergy related PTSS might reasonably be expected to score more highly on this type of question, it is less congruent that the empirical project found differences on the anxiety but not worry questionnaire for parents of children with more gastrointestinal symptoms.

Overall, while there are some suggestions for the direct impact particular allergy symptoms or events could have on psychological wellbeing, these are not consistently supported in the empirical project or wider literature. As such, while they may warrant further consideration in future research, no firm conclusions can currently be drawn on the predictive power of allergy factors for mental health.

Theoretical Implications

Presence of Mental Health Difficulties in Children with Food Allergy and their Parents

While neither the meta-analysis nor the empirical paper can draw firm conclusions on the prevalence of mental health difficulties in children with food allergy or their parents, the indication of increased anxiety that they provide lends support to suggestions that this population may be at increased risk of anxiety due to factors such as the need to tolerate the risk of accidental exposure and/or the potentially distressing nature of allergic reactions (e.g. Abdurrahman et al., 2013; Lau et al., 2014; Sanagavarapu, 2009; Sanagavarapu et al., 2016).

Within the anxiety results, a consistent finding across the meta-analysis and empirical paper was higher rates of worry. Previous research has theorised that increased worry may be an adaptive response in food allergy (e.g. Avery, King, Knight, & Hourihane, 2003; Mandell et al., 2005) as it could help with being more vigilant in the avoidance of allergens, in turn improving allergy management. However, when considering the items included in the PSWQ (Meyer et al., 1990; Appendix L), the measure used in the empirical research project, there is an emphasis on worry being pervasive and overwhelming, which is similar in alternative measures of clinically significant worry. As such, it seems reasonable to

suggest that scoring highly on these measures would indicate an extent of worry that goes beyond an adaptive response to a health condition, and would be expected to have a negative impact on an individual's psychological wellbeing. Theoretically, this highlights a need to distinguish normative adaptive responses, from a longer-term negative psychological impact. To help achieve this, it would be useful for future research to focus on refining assessments of food allergy specific anxiety (e.g. FAQLQ-PF food anxiety subscale; DunnGalvin, de BlokFlokstra, Burks, Dubois, & Hourihane, 2008), in particular working towards developing a clinical cut-off for these measures. As an anxiety measure specific to food allergy is likely to have better discriminative power for assessing more and less helpful forms of worry.

The portfolio also indicates that it is possible for both parents (empirical paper) and children (Weiss & Marsac, 2016) to experience significant PTSS in response to food allergy related events. Whilst this is not theoretically surprising, given allergic reactions can cause physical harm and at their most severe risk to life, and the presence of literature showing PTSS in similar health conditions (e.g. asthma; Kean et al., 2006), this was the first study to confirm this in parents of children with food allergy using a validated trauma measure. Furthermore, in line with Price et al.'s (2016) model of pediatric medical traumatic stress, within the empirical paper significant PTSS was in some cases reported in response to less severe allergic reactions or food allergy related events. This supports the suggestion that within paediatric literature it is important to consider PTSS more broadly than those who would meet the full criteria for PTSD (Kazak et al., 2006).

Possible Mechanisms Between Food Allergy and Anxiety and PTSS

Although the aim of the portfolio was not to generate theory, or a model of the psychological impact of food allergy, the empirical paper did aim to contribute to an understanding of possible risk factors of anxiety and PTSS in this population, and as such can offer some theoretical suggestions.

Individual Factors. Individual factors that increase an individual's perception of threat and/or risk are widely theorised to increase anxiety. This is included in Clark and Beck's (2010) transdiagnostic model of anxiety, Price's model of pediatric medical traumatic stress (Price et al., 2016), and Dugas's model of GAD (Dugas et al., 1998). The empirical paper supports this suggestion, as intolerance of uncertainty was found to be a good predictor of all three psychological outcomes, and was the most consistent predictor included in the study.

Intolerance of uncertainty is thought to stem from an individual's negative beliefs relating to the implications of uncertainty, resulting in finding uncertain situations stressful and/or upsetting (Buhr & Dugas, 2009). This can lead individuals to unhelpful attempts to control or avoid uncertainty (Buhr & Dugas, 2009). As discussed throughout this portfolio, avoidance of food allergens is reliant on a number of factors that cannot be readily controlled for (e.g. human error in food preparation). Therefore, parents of children with food allergy are required to either manage a relatively high degree of uncertainty surrounding allergen exposure (likely to be highly anxiety provoking for those who hold negative beliefs around uncertainty), or alternatively take relatively drastic measures to control for accidental exposure, likely to have a profound impact on quality of life. As such, it makes theoretical sense that within food allergy a disposition for intolerance of uncertainty could be particularly challenging.

The strong relationship between an individual's threat perception and psychological outcomes may also provide an alternative theoretical reason for the relatively small effect sizes observed for self-efficacy. As if parents have an especially high sense of threat, particularly one that exceeds the objective medical threat posed by allergy (e.g. Ogg, Wong, Wan, Davis, & Arkwright, 2017), it may not be feasible for parents' confidence to moderate this sufficiently to be a strong protective factor.

Allergy Factors. Similarly to the wider food allergy literature, mixed results were found for the relationship between allergy factors and psychological outcomes. Whilst the possibility of spurious findings cannot be ruled out, it is possible that these mixed findings could be theoretically explained. It was not the aim of the present research to explore these theoretical pathways, but initial tentative hypotheses are offered below.

While, as previously discussed, it is possible that particular allergy symptoms or events are inherently more distressing, the mixed results may be due to indirect pathways between allergy factors and psychological outcomes. It may be that particular allergy variables are associated with higher presence of different individual or environmental risk factors, which in turn are predictive of poorer psychological outcomes. For example, one potential hypothesis could be that parents of children with milder allergies (e.g. as represented by primarily gastrointestinal symptoms) may receive less understanding or caution from others, which in turn could increase parents' perception of social threat and perceived likelihood of allergic reaction. Furthermore, parents of children with milder symptoms may need to tolerate more uncertainty surrounding reactions, due to delayed allergic reactions (NICE, 2011a), and more ambiguity of allergic symptoms (i.e. there are many possible causes of

gastrointestinal and skin symptoms). In contrast, for children at greater risk of anaphylaxis, the greatest threat may be physical, for example an increased perceived risk of the likelihood of death from an allergic reaction (Ogg et al., 2017). Given in the wider anxiety literature one of the key distinguishing factors between disorder specific models is the content of threat related cognitions (Clark & Beck, 2010), these types of differences may help to explain the different pattern of results observed for allergy factors between psychological outcomes and studies.

The exploratory analysis raised an additional interesting allergy related result, in the potential protective impact of parents having a food allergy themselves. This was observed for both anxiety and PTSS. Particular caution is needed in interpreting this result as no adjustments were made for multiple testing within the exploratory analysis, and only 10 participants (9.5%) had a food allergy themselves, limiting the power and generalisability of these analyses. However, it could be beneficial for future research to explore this further both quantitatively and qualitatively to understand whether there is something about parents' own experience of food allergy which is protective for psychological responses to their child's allergy. As if this finding is supported, a better understanding of how parents' own experience has a protective effect could help facilitate the development of interventions for parents who are experiencing difficulties with the psychological impact of food allergy.

Relationship between parent and child mental health. Although the portfolio did not aim to directly compare the psychological outcomes for parents and children, the results of the two papers in combination with the wider anxiety literature raise an additional possible theoretical pathway for child psychological outcomes. As highlighted in the bridging chapter, the patterns of elevated mental health problems (increased separation anxiety, generalized anxiety, and depression, but no increased

social anxiety) found in the meta-analysis in the present portfolio, mirror the results found in Lawrence et al.'s (2019) meta-analysis exploring the impact of parent anxiety disorders on child anxiety. Interestingly, whilst Lawrence et al.'s meta-analysis did not find evidence of increased risk of children experiencing the same anxiety disorder as their parents, they generally found the largest effect sizes for children of parents who met diagnostic criteria for GAD. Given the high rates of clinically significant worry found in the empirical paper, with 35.2% also reaching a cut-off found to have discriminative validity for GAD (Chelminski & Zimmerman, 2003), it is possible that the elevated mental health difficulties observed in children with food allergy, may at least in part be an indirect influence of the psychological impact food allergy has for their parents.

This is particularly notable, as the only study within the systematic review presented in this portfolio that did not find a significant difference in GAD between children with and without food allergy was King, Knibb, and Hourihane (2009) whose comparison group comprised of older siblings without food allergy. This was the only study using this design, and in this instance parental factors would be shared. While a medium effect was still found in separation anxiety in King et al.'s study, as the children without food allergy were required to be *older* siblings, increased separation anxiety in the food allergy group could be expected irrespective of health status (Spence, Zubrick, & Lawrence, 2018). Whilst at this stage this is a very tentative hypothesis, this potential pathway does warrant further exploration as, if it were supported, it would have important clinical implications for successful management of the psychological impact of food allergy.

Clinical Implications

Clinically, one of the most notable implications of the portfolio is the need for greater awareness of the potential impact of food allergy on both child and parent's mental health. For those working in allergy settings, in the short term it would be useful for clinicians to have awareness of the anxiety that children and parents can experience, and that some individuals experience PTSS in relation to food allergy related events. It could be beneficial for allergy clinicians to ask about psychological wellbeing at allergy appointments, and consider making a referral to local psychological services if either parents or children are experiencing difficulties, and no specialist psychological provision is available. This is particularly notable as the results of the empirical paper suggest working to improve confidence in allergy management is unlikely to be sufficient for improving mental health.

In the longer term, it may be beneficial to more formally include a brief screen for psychological wellbeing in children and parents during allergy diagnosis or review, with an established onwards pathway to psychological support, such as is currently recommended in paediatric diabetes (NICE, 2016). However, the feasibility of this form of widespread programme is likely dependent on further research assessing the more direct impact of food allergy on psychological wellbeing, such as assessing PTSS longitudinally after diagnosis/allergic reactions, and further research evaluating food allergy specific anxiety.

For psychologists and other mental health professionals, the portfolio highlights some factors that may be useful to consider in the assessment and treatment of mental health in parents of children with food allergy. Firstly, although mixed results were found for the relationship between allergy factors and psychological outcomes, the results of the PTSS measure in the empirical paper

identify that some parents do find specific allergy related events highly distressing. The regression analyses also suggest certain factors such as an AAI having been administered may be significantly predictive of worry and PTSS. These allergy related events therefore warrant consideration in the assessment and formulation of psychological distress in food allergy. The strong relationship found between intolerance of uncertainty and psychological outcomes also indicates that this may be a promising target for intervention in this population, and warrants consideration in the formulation of psychological distress.

Within the GAD literature, cognitive behavioural therapy (CBT) treatment programmes directly focused on intolerance of uncertainty have been developed (Dugas & Ladouceur, 2000). These interventions typically involve distinguishing worries that can and cannot be problem solved, increasing tolerance of unsolvable worries (through exposure), and developing positive beliefs about worry (van der Heiden, Muris, & van der Molen, 2012). However, within the empirical paper intolerance of uncertainty was found to be a good predictor across psychological outcomes, and this intervention may not be appropriate where worry is not the primary presenting problem.

In more recent years, intolerance of uncertainty has been considered transdiagnostically as well as in relation to GAD (e.g. (Mahoney & McEvoy, 2012). This has led to the consideration of intolerance of uncertainty in transdiagnostic CBT. A randomized control trial of transdiagnostic CBT for anxiety (Boswell, Thompson-Hollands, Farchione, & Barlow, 2013), found decreases in intolerance of uncertainty, which in turn was associated with improved mental health outcomes at the end of treatment. This trial used the Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders (Barlow et al., 2011), which does not explicitly

address intolerance of uncertainty, but focuses more broadly on common features across anxiety disorders and depression. The results of this trial therefore suggest that CBT may be an effective approach for targeting intolerance of uncertainty, including where intolerance of uncertainty is not the sole focus of the intervention, and where worry is not the primary presenting problem. These are promising findings for the potential psychological treatment for parents of children with food allergy.

Two previous studies have also reported on CBT-based interventions with mothers of children with food allergy. Firstly, Boyle et al. (2017) assessed a brief CBT-based intervention (single session with two follow-ups) designed to primarily target mothers' perception of risk of anaphylaxis, compared to a standard care control group. Although maternal state anxiety did not significantly improve following the intervention, there was a significant improvement in those who completed the interventions perception of risk of anaphylaxis and fatal reactions, and improved stress response to a simulated anaphylaxis reaction maintained at a 1-year follow-up. Given the brevity and specificity of the intervention, these generally appear to be positive results. However, the lack of significant difference for maternal anxiety may highlight the need to consider broader factors (e.g. intolerance of uncertainty) as well as allergy specific risks in psychological treatment, going beyond a brief intervention.

A case series of CBT for mothers with food allergy (Knibb, 2015), whereby 12 sessions of target statement driven CBT was offered to five mothers of children with food allergy, found significant reductions in anxiety, worry, and depression at the end of treatment. While this is a very small sample size, it suggests that CBT may

be an effective intervention for psychological distress in mothers of children with food allergy.

Overall, the results of the empirical study in combination with previous anxiety and food allergy literature indicate that CBT may be a promising approach for treating the psychological impact of food allergy, and intolerance of uncertainty may warrant particular attention in therapy.

Strengths and Limitations

A notable strength of the thesis portfolio is the consideration of PTSS in both the systematic review and empirical paper. The need for this research has been repeatedly highlighted (e.g. Kelsay, 2003; Akeson et al., 2007), but as further evident in the systematic review has remained largely unaddressed. The empirical research project, and the one pilot study found assessing PTSS within the systematic review (Weiss & Marsac, 2016), indicate that both parents and children can experience significant trauma symptoms in relation to food allergy related events. With these initial results, further research in this area is clearly warranted to add more depth to these initial findings.

A further strength was the consideration of different forms of anxiety. While in the wider anxiety literature, it is mostly accepted that it is valuable to consider anxiety in a disorder specific as well as in a transdiagnostic or unitary way (e.g. McManus, Shafran, & Cooper, 2010), within physical health psychology literature anxiety, particularly parental anxiety, is often measured as a unitary construct (e.g. Cortes, Castillo, & Sciaraffia, 2018; Lau et al., 2014). Considering different types of anxiety is useful in providing more detailed understanding of the psychological impact health conditions can have for both parents and children, as well as leading to

recommendations for interventions. This is evident in the different rates of forms of anxiety observed in both the meta-analysis and empirical paper, as well as differences in the patterns of some predictors across psychological outcomes in the empirical paper.

Whilst a strength of the portfolio is considering both child and parent wellbeing, the portfolio is limited by considering this separately. While the review and research questions did not require both parent and child mental health to be assessed within the individual chapters, doing so might have improved the explanatory power of the results. This is particularly notable given the patterns of mental health in children appeared to mirror the results of Lawrence et al.'s (2019) meta-analysis reviewing the impact of parent anxiety for child mental health. Within the systematic review, there was insufficient literature to assess potential moderators such as parent mental health. For the empirical paper, whilst the inclusion of a child anxiety measure, as well as allowing two parents to respond, was considered, it was not thought to be feasible. Including a child anxiety measure within the online design would have been complex, as appropriate measures are dependent on the age of the child, and no appropriate measure is available for very young children (Carpenter et al., 2016), and therefore would not have been relevant for all participants. Allowing multiple respondents (e.g. mother, father, child) more generally relies on a mechanism to group responses together, and would therefore be more feasible in a solely clinic based study. However, within the timeframe available for the thesis, online recruitment was considered necessary to allow sufficient recruitment to answer the primary research questions. As such, whilst future research would benefit from considering the psychological wellbeing of multiple family members, the

approach taken in the portfolio is considered to be the most appropriate within the scope of the thesis.

A further limitation of the online design was the reliance of parent reported food allergy and allergy severity, as it was not possible to obtain medical opinions. Whilst parent perception of severity or risk associated with health conditions has been found to be a more consistent predictive of poorer psychological outcomes than medical opinion (Price et al., 2016), it would be theoretically interesting and clinically useful to be able to compare parent and clinician ratings. In particular, for healthcare professionals working in food allergy, any risk factors based on medical information would be easier to screen for, as they would not typically involve gathering additional information. Alternatively, if there was low consensus between parent and medic opinions, this may highlight the importance of checking parents understanding of their child's allergy, as this could have both psychological and medical implications.

Both the empirical paper and systematic review were also limited to cross-sectional designs, which are not equipped for establishing causality. Furthermore, it was not possible to control for factors such as time since most recent allergic reaction, or significant life transitions (such as children starting or changing schools). These factors may reasonably impact on anxiety directly and indirectly (e.g. parents with higher intolerance of uncertainty may find it more difficult to transfer responsibility to new adults or the child themselves). This could also help to explain why no significant relationship was found between time since allergy diagnosis and psychological outcomes within the exploratory analysis, despite reports that the psychological impact of food allergies improves with time (Cummings, Knibb, King, & Lucas, 2010).

Another possible limitation of the empirical paper, which it was not possible to control for, is the wider context in which recruitment occurred. During the recruitment phase of the research, food allergy received substantial interest in the general media, being the focus of numerous news reports (e.g. BBC, 2018; Davies, 2018; Saner, 2018) and television programmes (e.g. Raddings, 2018). Unfortunately, this increased media attention primarily followed the death of teenagers with food allergy. Whilst a raised public awareness of food allergy may have a positive impact for the wider social support parents receive with managing their child's food allergy, hearing of the worst case allergy scenario may also reasonably be anxiety provoking for parents. It would be interesting to explore the impact that this focus on food allergy is having for parents, particularly given the current review and consultation of food allergen labeling laws occurring in the UK (Department for Environmental Food & Rural Affairs, 2019). While these factors were not a direct focus of the portfolio, and more generally quantitative research is often not the most appropriate design for considering experiences of this type of event, all research is situated in a particular context. This was part of the rationale for limiting recruitment to the UK, despite the online methodology, as awareness and laws surrounding food allergy differ nationally, and the research aimed to be applicable to the UK healthcare context. Any notable changes in this wider context are therefore important to consider in the interpretation of the results.

Future Research

While some suggestions of theoretical and clinical implications arising from the portfolio can and have been made, as the field is in its relative infancy arguably the strongest impact the present portfolio can have is in offering guidance for future

research. Many of these suggestions have been presented throughout the portfolio, notably the need for further (ideally longitudinal) research assessing PTSS in food allergy, the potential benefit of research refining measures assessing food allergy specific anxiety, and the need for a larger clinic based study more suitable for assessing prevalence and considering the perspectives of different family members. The following section will therefore focus on some additional suggestions arising from the portfolio.

Firstly, although all the regression models presented in the empirical paper and exploratory analysis were significantly predictive of psychological outcomes, a large proportion of variance remains unexplained. Whilst this is not surprising, it does warrant consideration of additional factors that may be beneficial to consider in future research. One notable area that was not included in the present study is social factors.

Social support has been reported as an important factor in paediatric PTSS literature (e.g. Young et al., 2003) and is included in Price et al.'s (2016) model of pediatric medical traumatic stress. As previously identified, food allergy management is typically particularly reliant on other individuals, both closely (e.g. those to whom parents delegate caring responsibility) and more distantly (e.g. those involved in food production and labeling), it may therefore be expected that social factors could have a significant impact within this population. In past research, many parents of children with food allergy describe experiencing significant social negativity, for example others not taking the allergy seriously (e.g. Mandell et al., 2005; Williams & Hankey, 2015), which could reasonably be a source of anxiety for parents. Both social support and social negativity have also been found to be significantly related to health related quality of life in parents of children with food

allergy (Williams & Hankey, 2015). Therefore, it could be beneficial for future research exploring mental health outcomes in food allergy to include an assessment of these social factors.

Given the results of the meta-analysis, it may also be beneficial for future research to give greater consideration to depression in both children with food allergy and their parents. As demonstrated by the systematic review, there is currently a larger volume of research considering anxiety in this population; however, whilst heterogeneous, the results tentatively indicate a larger effect for depression in children with food allergy compared to their peers. Although not synthesized systematically, there also appears to be a smaller volume of research assessing parental depression compared to anxiety. A decision was made not to include a depression measure in the empirical paper, to minimize participant burden and due to greater theoretical differences in predictors that could warrant exploration. However, it may be useful for future research to expand on this. In particular, the social factors outlined above, especially social negativity, may be expected to impact on mood (Bertera, 2005). For children, the indications of increased incidence of bullying (Muraro et al., 2014) could also be expected to elevate rates of depression. Additionally, some parents may experience self-criticism or guilt following an allergic reaction (Gupta et al., 2008), which could be expected to impact on mood (e.g. Castilho, Pinto-Gouveia, & Duarte, 2017), as well as showing associations with PTSS in paediatric literature (e.g. Hawkins et al., 2019). Overall, the consideration of depression, alongside furthering the anxiety and PTSS literature, could allow a more comprehensive understanding of the psychological impact of paediatric food allergy.

Conclusion

This portfolio aimed to offer a timely and valuable contribution to the literature evaluating the psychological impact of food allergy for children and their parents. A systematic review of mental health in children with food allergy was conducted, providing indications of increased separation anxiety, generalized anxiety, and depression, but not social anxiety compared to their peers without food allergy. However, this review was limited by the high degree of heterogeneity in the current evidence base.

An original piece of empirical research was then presented considering the psychological impact for parents of children with food allergy. Notably, despite relatively longstanding suggestions of the need to assess post-traumatic stress in this population (e.g. Kelsay, 2003), this was the first study to do so using a validated trauma measure, providing useful and novel findings. The study found relatively high rates of anxiety (39.0%), worry (81.0%), and PTSS (42.3%) in a relatively large (*N*=104-105) sample of parents. These outcomes were consistently predicted by intolerance of uncertainty, with less consistent results for allergy severity and food allergy self-efficacy.

Overall, the portfolio highlights the need for greater awareness of the potential impact of food allergy on mental health. Whilst the portfolio is not without limitation, it offers an important contribution to the field, through both novel findings and offering direction for future research.

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Appendix A: *Allergy* Author Guidelines

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Author Guidelines

Sections

1. Submission
2. Aims and Scope
3. Manuscript Categories and Requirements
4. Preparing the Submission
5. Editorial Policies and Ethical Considerations
6. Author Licensing
7. Publication Process After Acceptance
8. Post Publication
9. Editorial Office Contact Details

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2. AIMS AND SCOPE

The aim of *Allergy* is to advance, impact and communicate all aspects of the discipline of Allergy/Immunology including educational, basic, translational and clinical research and maintain contact between basic and clinical Allergy/Immunology.

Allergy is an international journal with contributors and readers from all countries. *Allergy* publishes original articles, reviews, position papers, guidelines, editorials, news and commentaries, letters to the editors and correspondences. Articles are accepted purely on the basis of scientific merit and quality.

3. MANUSCRIPT CATEGORIES AND REQUIREMENTS

i. Editorials

Editorials are commissioned by the Editorial board. Submissions can be considered after consultation with the Editors-in-Chief only.

Title: Should be informative that establishes a link to the article that the Editorial is written for.

Text: Should be strictly limited to 1,000 words. There will not be any abstracts. References: Maximum 9 references are allowed.

Figures and tables: Maximum two display items, figures and/or tables. Figure legends should be concise and should not be more than 100 words.

ii. Position papers

Position papers are written by authors selected by the EAACI Executive Committee.

Title: Should be informative with less than 120 characters.

Short title: Should be less than 50 characters.

Keywords: up to 5, listed in alphabetical order.

Abstract: 200 words of unstructured summary.

Text is limited to:

- less than 4,500 words not including abstracts, figure legends and references (please supply a word count). **Additional unlimited online supporting information can be provided.**
- up to 100 references in the Journal's style (if more, justification should be provided).
- figures and tables are important in position papers and up to 10 figures and/or tables (total) can be included in the text.

iii. Review articles

Reviews should present an update of the most recent developments in a particular field of clinical allergy and immunologic research. We encourage the submission of high quality color pictures and cartoons, which may be selected for the cover of the issue.

Title: should be informative with less than 120 characters.

Short title: Should be less than 50 characters.

Keywords: up to 5, listed in alphabetical order.

Abstract: 200 words of unstructured summary.

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- up to 200 references in the Journal's style.
- figures and tables are important in review papers and up to 10 figures and/or tables (total) can be included in the text.

iv. Original articles

We welcome high quality original publications dealing with innovative aspects of basic and clinical allergy and immunology research.

Title:

- should be informative (example: Prevention of allergy by virus-like nanoparticles delivering shielded versions of major allergens in a humanized murine allergy model) but not descriptive (ex: Use of virus-like nanoparticles in allergy vaccines).
- length less than 100 characters.
- If experiments have been performed in animal models, the species should be specified in the title.

Short title: Should be less than 50 characters

Abstract: 250 words structured as follows:

- background (including the aims of the study).
- methods. For animal models, specify the species.
- results. If space is short, report only the primary outcomes.
- conclusions.

Keywords: up to 5, listed in alphabetical order.

Text: The text is limited to:

- less than 3,500 words not including abstract, figure legends and references (please supply a word count). Informative subtitles should be used in subsections of the results section.
- up to 6 figures and/or tables (total) If longer, reasons for increase in length, figure or table number or reference number should be stated in the cover letter. **Additional unlimited online supporting information can be provided.**

Note: Original articles are limited to 5 printed pages in total. Authors must pay GBP 80 for each additional page.

Figures: up to six figures each with many panels can be included in the original text.

Coloured figures are allowed free of charge for the online version. Colour charges apply for the print version.

The authors should agree to cover additional page and color costs upon submission of a manuscript that will be longer than 5 printed pages; and that has coloured figures of tissue sections and microscopy that will not be understood, if they are only black and white.

v. Letters to the Editor

Letters to the Editor are brief reports that can be preliminary, but may represent original observations that may have a substantial impact within the scope of "*Allergy". They will be subject to peer review and will be indexed in Medline. They should begin with the salutation "To the Editor". There should not be any separate abstract, but rather a conclusion paragraph sums up the Letter. Author names, affiliations, funding sources and conflict of interests should be listed at the end following references. Please note that single case reports will not be considered for publication.

Title: The title should be concise and informative. It should be less than 100 characters.

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- The text is strictly limited to maximum 1000 words.
- Maximum 9 references are allowed of the Journal's style.
- Online supplementary can be used for more references, detailed explanations of methods, sequencing databases, tables and figures.

Figures:

- Up to 2 display items figures and/or tables are allowed.
- Figure legends should be concise and should not be more tan 100 words.

vi. News and Commentaries

Short manuscripts dealing with particular new developments, changes in pradigms, recent patents & innovations, new diagnosis and treatment algorithms, featuring legendary scientists and novel concepts are welcome in this section.

Title: The title should be concise and informative. It should be less than 100 characters.

Text:

- The text is strictly limited to maximum 1000 words.
- Maximum 9 references are allowed of the Journal's style.

Figures:

- Up to 2 display items figures and/or tables are allowed.
- Figure legends should be concise and should not be more than 100 words.

Legends of Allergy

We will feature eminent scientists from our specialty, who have made key discoveries that have substantially changed our understanding and practice in our specialty, in this new series within the

frame of News and Commentaries. This commentary will be written upon invitation and the authors should get the approval of the featured scientist before submission.

Title: The title should be Legends of Allergy: followed by the name of the eminent scientist, who is featured in the article.

Text:

- The text is strictly limited to maximum 1000 words.
- Maximum 5 references are allowed.
- A text box should contain up to 6 major contributions as bullet points including the year of the major discoveries/contributions of the featured scientist.

Figures:

- Up to 2 display items, figures and/or tables are allowed that demonstrate major contributions.
- One of the figures should contain a high-resolution portrait photo of the featured scientist. Figure legends should be concise and not be more than 100 words.

Recent Patents

In this new series, we are going to showcase recent important patents in the allergy/immunology specialty that may have a major impact in the future. These "Recent Patents" articles should contain two sections: one describing the novelty and importance of the invention and the other introducing the story of the invention, including coincidences and luck. Manuscripts for this section will be written upon invitation.

Title: The title should be max 100 characters reflecting the invention.

Text:

- The text is strictly limited to maximum 1000 words.
- Maximum 9 references are allowed.
- The text should not contain an abstract but rather a conclusion paragraph that sums up the discovery and its importance.

Figures:

- Up to 2 display items figures and/or tables are allowed that demonstrate the invention.
- Figure legends should be concise and should not be more than 100 words.
- Online supplementary can be used for more references, detailed explanations of methods, tables and figures.

Algorithms in Allergy & Immunology

In this new series within the News and Commentaries section, we will publish summaries of diagnosis and treatment algorithms on how to approach a patient. These articles will be written upon invitation of authors, who have recently contributed a guideline or a position paper in the area.

Title: The title should be max 100 characters reflecting the disease of interest, such as "Diagnostic algorithms in chronicrhinosinusitis".

Text:

- The text is strictly limited to maximum 600 words.
- Maximum 9 references are allowed.
- The text should not contain an abstract but rather a conclusion paragraph that sums up the discovery and its importance.

Figures:

- Maximum two display items including an algorithm style graph, and additional figure or a table are allowed that demonstrate the algorithm of the approach to patients.
- Figure legends should be detailed and can be as long as 300 words.
- Online supplementary can be used for more references, detailed explanations of methods, tables and figures.

Images in Allergy

We are now inviting our authors to submit interesting images of lesions, microscope images and novel instruments, inventions allowing readers of Allergy to see them perhaps for the first time. These articles will have one image with a text containing a detailed description of the image.

Title: The title should be max 60 characters reflecting the image and related disease.

Text:

- The text is strictly limited to maximum 600 words.
- Maximum 9 references are allowed.
- The text should not contain an abstract but rather a conclusion paragraph should sum up the image and its importance.

Figures:

- One high resolution image (600 Dpi, TIFF file) that has not been previously published should be submitted.
- The legend of the image should be concise and not more than 100 words.

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Correspondences that refer to a previously published original article are welcome to be published in Allergy.

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- up to 6 references in the Journal's style.
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Manuscripts dealing with recombinant allergens will only be considered for external review if they:

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- describe new technological approaches for cloning, production and/or characterization of allergens;
- the sequence has been submitted, accepted and assigned with an official name by the I.U.I.S. Allergen Nomenclature Sub-committee;
- provides a relevant progress with respect to the state of the art of the research in the field of molecular allergy;
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iv. The author's institutional affiliations where the work was conducted, with a footnote for the author's present address if different from where the work was conducted;
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vii. Main text;
viii. References;
ix. Tables (each table complete with title and footnotes);

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Book
2. Voet D, Voet JG. Biochemistry. New York: John Wiley & Sons; 1990. 1223 p.

Internet document
3. American Cancer Society. Cancer Facts & Figures 2003.
http://www.cancer.org/downloads/STT/CAFF2003PWSecured.pdf Accessed March 3, 2003

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Appendix B: Forest Plots for all Meta-Analysis Syntheses

Review Question 1: Prevalence

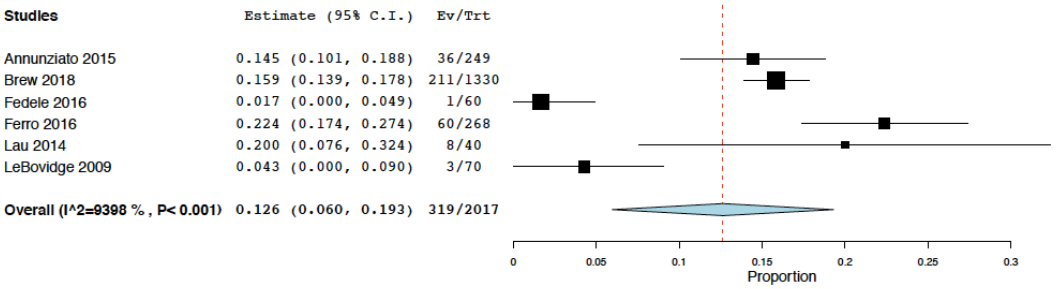


Figure 5. Forest plot of non-disorder specific anxiety (prevalence).

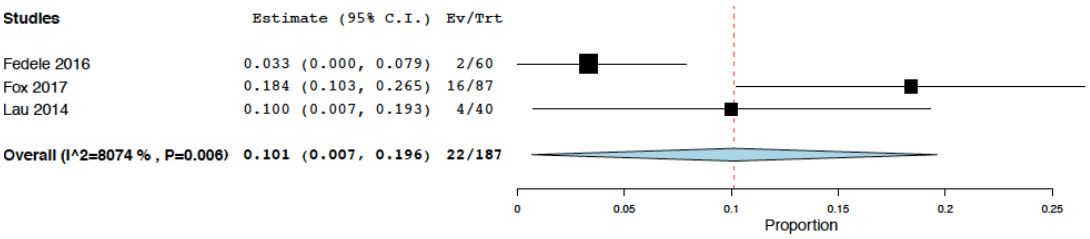


Figure 6. Forest plot of social anxiety (prevalence).

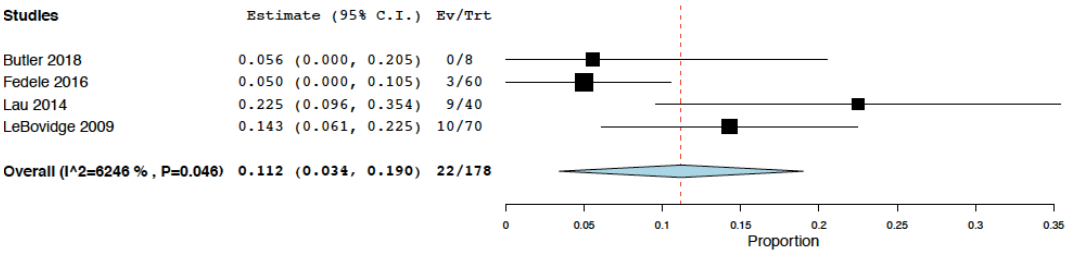


Figure 7. Forest plot of separation anxiety (prevalence)

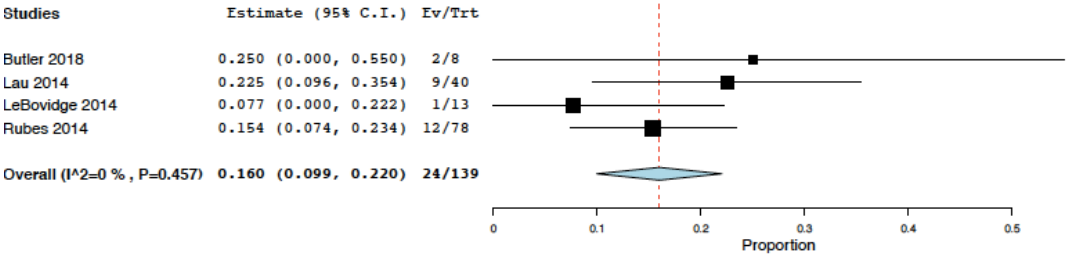


Figure 8. Forest plot of generalized anxiety/ worry (prevalence).

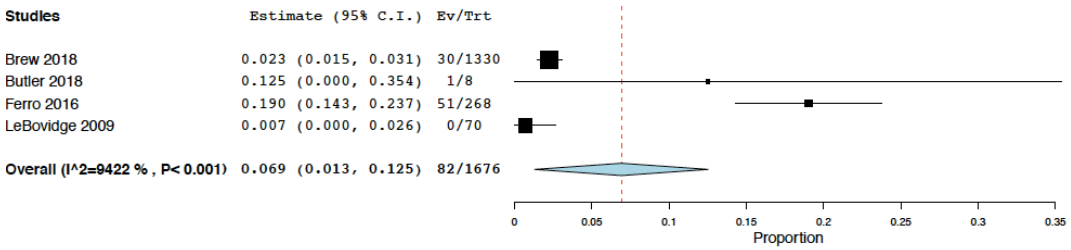


Figure 9. Forest plot of depression (prevalence).

Review Question 2: Difference

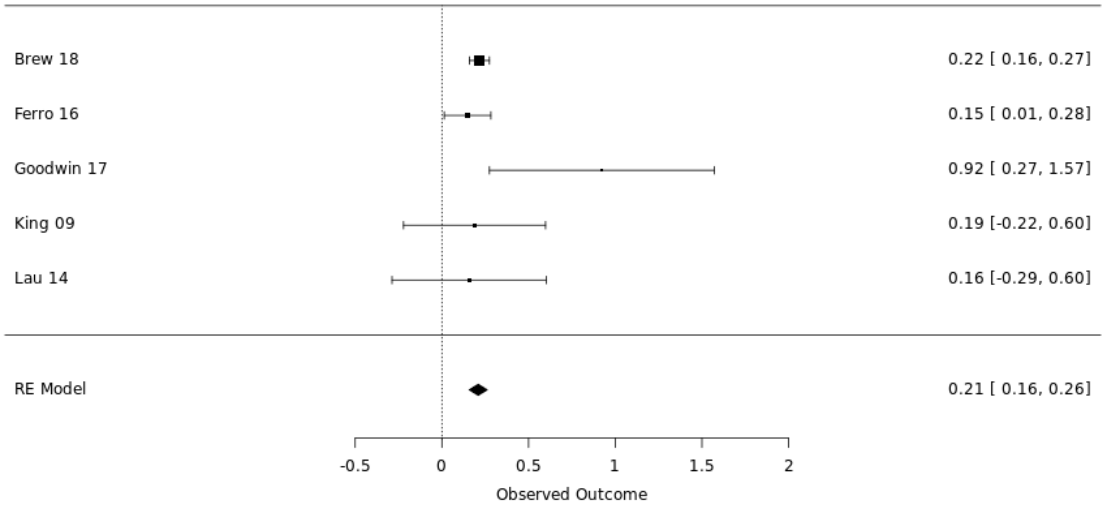


Figure 10. Forest plot of non-disorder specific anxiety (difference).

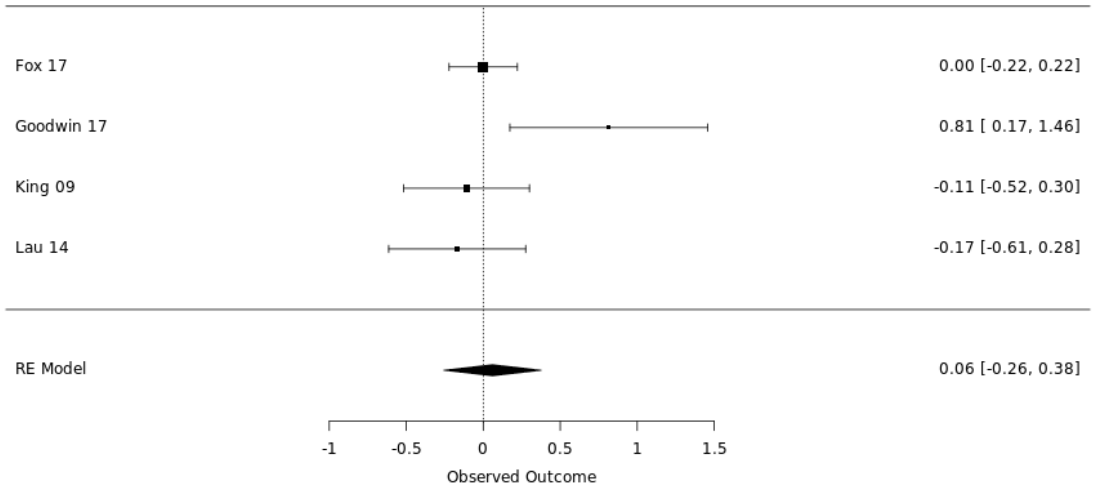


Figure 11. Forest plot of social anxiety (difference).

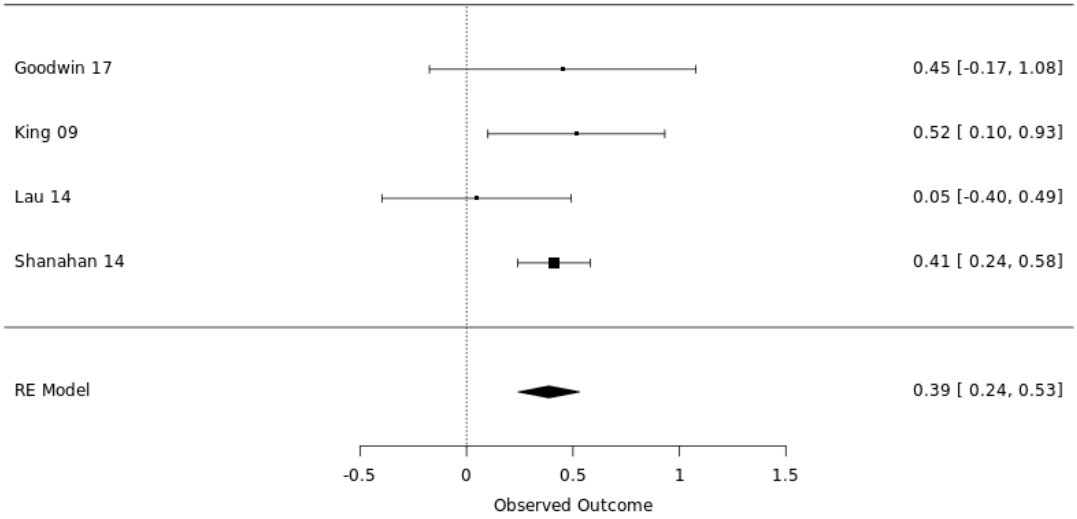


Figure 12. Forest plot of separation anxiety (difference).

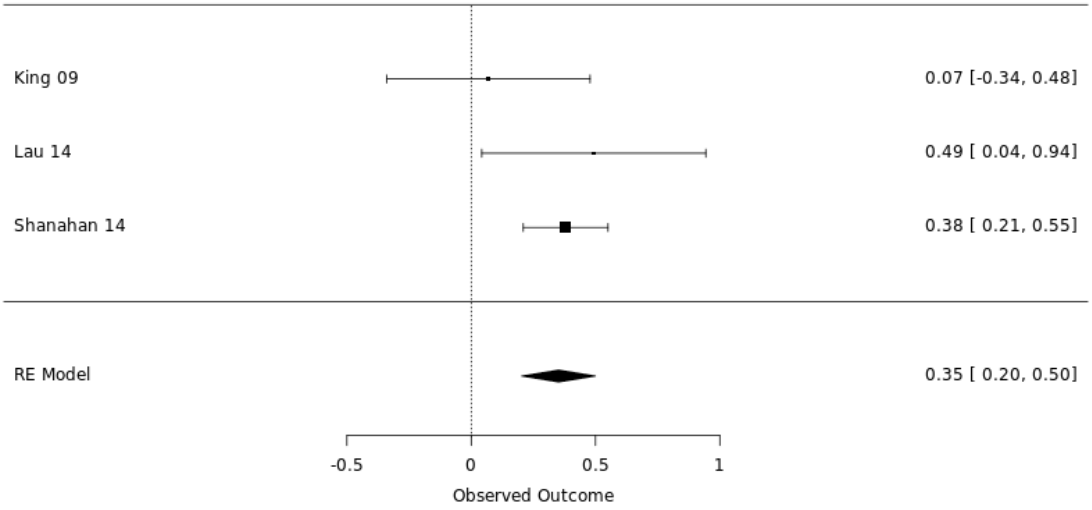


Figure 13. Forest plot of generalized anxiety/worry (difference).

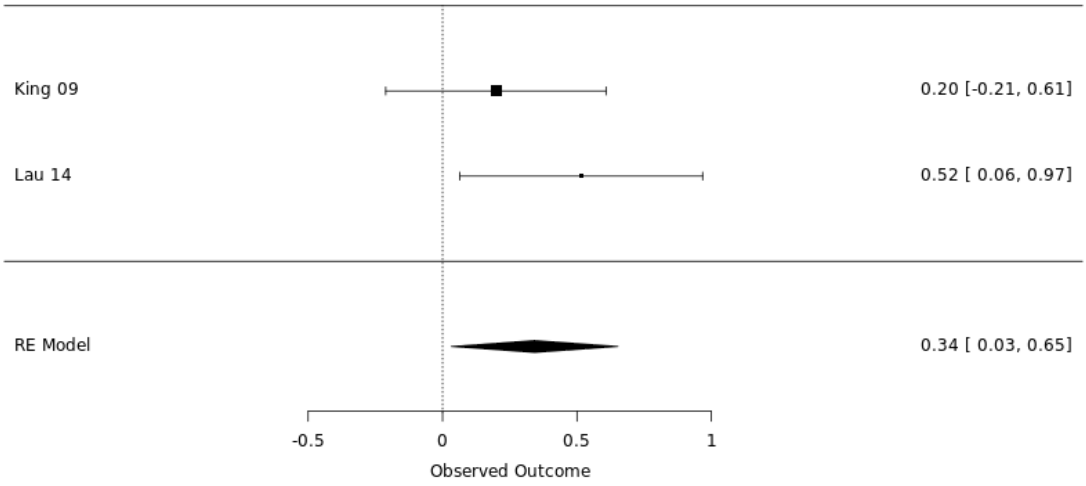


Figure 14. Forest plot of panic (difference).

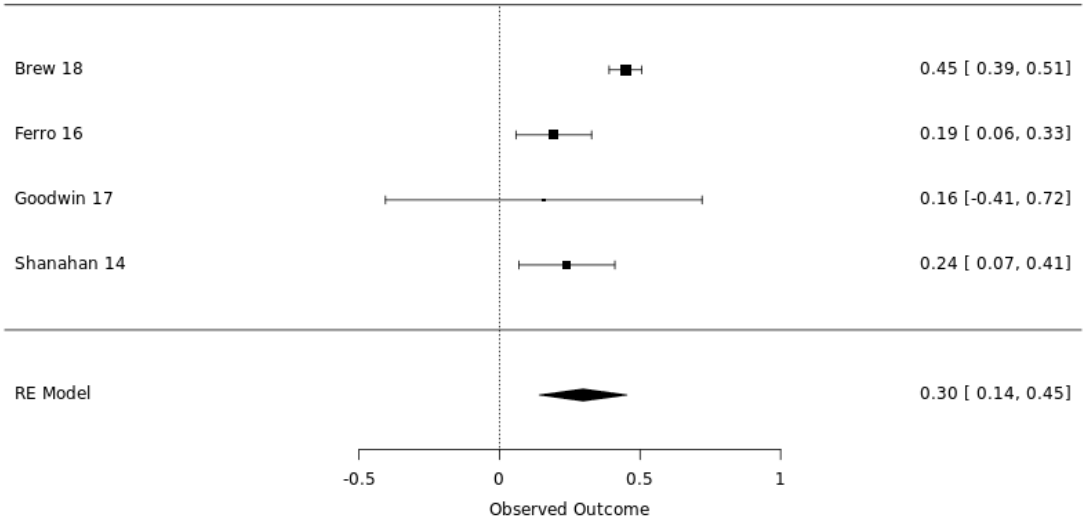


Figure 15. Forest plot of depression (difference).

Appendix C: *Journal of Pediatric Psychology* Author Guidelines

Author guidelines retrieved from:
https://academic.oup.com/jpepsy/pages/author_instructions

Instructions to Authors

The *Journal of Pediatric Psychology* is an official publication of the Society of Pediatric Psychology, Division 54 of the American Psychological Association. *JPP* publishes articles related to theory, research, and professional practice in pediatric psychology.

Author Guidelines

We would like to inform our authors that we now detect plagiarism easily. *JPP* employs the CrossCheck plagiarism screening system. By submitting your manuscript to this journal you accept that your manuscript may be screened for plagiarism against previously published works.

Journal of Pediatric Psychology will not consider papers that have been accepted for publication or published elsewhere. Copies of existing manuscripts with potentially overlapping or duplicative material should be submitted together with the manuscript, so that the Editors can judge suitability for publication. The Editors reserve the right to reject a paper on ethical grounds.

Organization of manuscripts

Manuscript Central will guide authors through the submission steps, including: Abstract, Keyword selection, and the Manuscript. The manuscript must contain an Introduction, Methods, Results, Discussion, Acknowledgements and Reference List.

Length of manuscript: Original research articles should not exceed 25 pages, in total, including title page, references, figures, tables, etc. In the case of papers that report on multiple studies or those with methodologies that necessitate detailed explanation, the authors should justify longer manuscript length to the Editor in the cover letter. Review articles should not exceed 30 pages. Invited commentaries should be discussed with the Editor. The *Journal of Pediatric Psychology* no longer accepts brief reports but will accept manuscripts that are shorter in length.

Manuscripts (text, references, tables, figures, etc.) should be prepared in detailed accord with the Publication Manual of the American Psychological Association (6th ed.). There are two exceptions:

The academic degrees of authors should be placed on the title page following their names, and a structured abstract of not more than 250 words should be included. The abstract should include the following parts:

1. Objective (brief statement of the purpose of the study);
2. Methods (summary of the participants, design, measures, procedure);
3. Results (the primary findings of this work); and
4. Conclusions (statement of implications of these data).

Key words should be included, consistent with APA style. Submissions should be double-spaced throughout, with margins of at least 1 inch and font size of 12 points (or 26 lines per page, 12-15 characters per inch).

Informed consent and ethical treatment of study participants: Authors should indicate in the Method section of relevant manuscripts how informed consent was obtained and report the approval of the study by the appropriate Institutional Review Board(s). Authors will also be asked to sign a statement,

provided by the Editor that they have complied with the American Psychological Association Ethical Principles with regard to the treatment of their sample.

Clinical relevance of the research should be incorporated into the manuscripts. There is no special section on clinical implications, but authors should integrate implications for practice, as appropriate, into papers.

Terminology should be sensitive to the individual who has a disease or disability. The Editors endorse the concept of "people first, not their disability." Terminology should reflect the "person with a disability" (e.g., children with diabetes, persons with HIV infection, families of children with cancer) rather than the condition as an adjective (e.g., diabetic children, HIV patients, cancer families). Nonsexist language should be used.

Special Instructions for Types of Manuscripts

Manuscript types include:

- Original research
- Review articles
- Topical reviews
- Systematic reviews
- Invited commentaries

Original Research

Randomized controlled trials: JPP is committed to enhancing the transparent reporting of all intervention studies. (1) All Randomized Controlled Trials (RCTs) must be registered at or before the time of first patient enrollment in any primary registry of the WHO International Clinical Trials Registry Platform (ICTRP) or in ClinicalTrials.gov, which is a data provider to the WHO ICTRP. Provide the registry name and registry number in the cover letter and methods section. (2) You are required to submit the CONSORT checklist and a flowchart of your research showing the steps found in the Consort E-Flowchart on this checklist for RCTs. You can use CONSORT checklist extensions for different designs and types of data beyond two group parallel trials. Please clearly indicate the page numbers where each checklist item is reported in the manuscript. Please upload this checklist as supplementary material when you submit your manuscript for consideration. Meeting these basic reporting requirements will greatly improve the value of your trial report and may enhance its chances for eventual publication. (3) If you are submitting a secondary data analysis from an RCT, please clearly indicate that it is a secondary data analysis in your manuscript and refer readers to the primary publication of outcomes. Consult with the editorial office if there are questions about reporting.

Non-randomized trials: If you are submitting a non-randomized trial to *JPP,* you are required to follow the reporting elements of the TREND statement and to use this checklist for non-randomized trials. Please clearly indicate the page numbers where each checklist item is reported in the manuscript. Please upload this checklist as supplementary material when you submit your manuscript for consideration.

All intervention studies (RCTs and non-randomized trials) will undergo an additional review for transparent reporting conducted by the *JPP* Assistant Editor for Transparent Reporting. Review comments will be provided on the corresponding checklist. Authors will be required to address any identified reporting issues prior to publication.

Authors are also encouraged to visit the Equator Network for additional information on transparent reporting of all manuscript types.

(2) *Single Subject Studies*: As a journal that encourages submission of intervention studies, the Journal does accept, and encourages submission of, well-conducted single subject studies (N-of-1 designs). Case studies and narrative reports of special cases that are more descriptive will not be considered for review. It is important to note that rigorous single subject designs are considered logical equivalents of Randomized Controlled Trials and include control conditions that support conclusions of causality. Previously published examples can be found in this journal including: Bernard, Cohen, & Moffett (2009); Powers et al. (2006). Authors considering submissions of case reports adopting N-of-1 methodology should consult the following sources within this journal: Cohen, Feinstein, Masuda, & Vowles (2014); Cushing, Walters, & Hoffman (2014); Rapoff & Stark (2008); Case reports that adopt formal N-of-1 methodology should not exceed 20 pages.

References:

Bernard, R. S., Cohen, L. L., & Moffett, K. (2009). A token economy for exercise adherence in pediatric cystic fibrosis: A single-subject analysis. Journal of Pediatric Psychology, 34, 354-365.

Cohen, L. L., Feinstein, A., Masuda, A., & Vowles, K. E. (2014). Single-case research design in pediatric psychology: Considerations regarding data analysis. Journal of Pediatric Psychology, 39, 124-137.

Cushing, C. C., Walters, R. W., & Hoffman, L. (2014). Aggregated N-of-1 randomized controlled trials: Modern data analytics applied to a clinically valid method of intervention effectiveness. Journal of Pediatric Psychology, 39, 138-150.

Powers, S. W., Piazza-Waggoner, C., Jones, J. S., Ferguson, K. S., Daines, C., & Acton, J. D. (2006). Examining clinical trial results with single-subject analysis: An example involving behavioral and nutrition treatment for young children with cystic fibrosis. Journal of Pediatric Psychology, 31, 574-581.

Rapoff, M., & Stark, L. (2008). Editorial: Journal of Pediatric Psychology statement of purpose: Section on single-subject studies. Journal of Pediatric Psychology, 33, 16-21.

(3) Measurement development and validation articles: For additional guidance please read, Holmbeck, G. & Devine, K. (2009) Editorial: An Author's Checklist for Measure Development and Validation Manuscripts.

(4) Historical Analysis in Pediatric Psychology: This is a special series of papers devoted to the history of pediatric psychology. Authors interested in submitting a paper for this series should contact the Editor of *JPP* to discuss potential papers prior to submission. There is no deadline for these papers (they may be submitted anytime). All submissions will be peer reviewed and should comply fully with the *JPP* Instructions to Authors. Papers in this series should be tightly focused contributions that expand our understanding of the roots, evolution, and/or impact of pediatric psychology as a discipline. Manuscripts may focus on the influence of individuals, published works, organizations, conceptualizations, philosophies or approaches, or clinical and professional activities. Successful papers should articulate a clear purpose/question and develop a compelling argument for the topic. Contributions should include a breadth of coverage, such that contradictory data are included and potential biases acknowledged. Historical analysis is more than a recounting of the "facts" and should include a thoughtful and scholarly interpretation of the subject matter. Papers should rely on primary sources and must be clearly and appropriately referenced. Supplemental materials to accompany the article may be posted online.

Review articles:

(a) Topical reviews: Topical reviews summarize contemporary findings, suggest new conceptual models, or highlight noteworthy or controversial issues in pediatric psychology. Topical reviews are

not intended to provide short data summaries or syntheses. Rather they are intended to foster new ways of thinking about a topic area and provide a direction for future research or practice. They are limited to 2,000 words, contain no more than 2 tables or figures, and have an upper limit of 30 references. Supplementary online material (e.g., additional tables) may be considered on a case by case basis.

(b) Systematic reviews: Systematic reviews should not exceed 30 pages. Authors are required to attach the PRISMA checklist and flow diagram as supplementary material for each submission. Authors can find the PRISMA checklist and flow diagram in downloadable templates that can be re-used here. Authors of systematic reviews that do not include a meta-analysis must provide a clear justification in the manuscript explaining why such an analysis is not included for all or relevant portions of the report.

Please consult this editorial (New Guidelines for Publishing Review Articles in *JPP*) which further describes guidelines for review articles, and the Checklist for Preparing and Evaluating Review Articles.

Invited commentaries

- Commentaries are invited on all topics of interest in pediatric psychology, and the page length and scope should be discussed with the Editor. Un-invited commentaries will not be considered.

Additional Guidance

The following links provide additional guidance for authors and reviewers: Editorial Policy, Authors' Checklist, Guidelines for Reviews, Suggestions for Mentored Reviews, "People First," NIH policy, Replication of research, Duplicate and redundant policies, Conflict of interest.

See the following articles for detailed guidance concerning preparation of manuscripts: Editorial: Thoughts in Improving the Quality of Manuscripts Submitted to the *Journal of Pediatric Psychology*: How to Write a Convincing Introduction; Methods: Editorial: How to Report Methods in the *Journal of Pediatric Psychology*; Results and Discussion: Editorial: How to Write an Effective Results and Discussion Section for the *Journal of Pediatric Psychology*.

Funding

Details of all funding sources for the work in question should be given in a separate section entitled "Funding." This should appear before the "Acknowledgements" section.

The following rules should be followed:

- The sentence should begin: "This work was supported by . . ."
- The full official funding agency name should be given, i.e. "the National Cancer Institute at the National Institutes of Health" or simply "National Institutes of Health," not "NCI" (one of the 27 subinstitutions) or "NCI at NIH" (full RIN-approved list of UK funding agencies)
- Grant numbers should be complete and accurate and provided in parentheses as follows: "(grant number xxxx)"
- Multiple grant numbers should be separated by a comma as follows: "(grant numbers xxxx, yyyy)"
- Agencies should be separated by a semi-colon (plus 'and' before the last funding agency)

- Where individuals need to be specified for certain sources of funding the following text should be added after the relevant agency or grant number "to [author initials]."

Oxford Journals will deposit all NIH-funded articles in PubMed Central. See this page for details. Authors must ensure that manuscripts are clearly indicated as NIH-funded using the guidelines above.

Color Figure Charges

Authors are charged for the print reproduction of color figures. The cost is $600 / €525 / £325 per color page. Figures can be published in black and white in the print edition and in color online for free. If you choose this option, please ensure that your figures are clear and readable in both black and white and color.

Permission for Illustrations and Figures

Permission to reproduce copyright material, for print and online publication in perpetuity, must be cleared and if necessary paid for by the author; this includes applications and payments to DACS, ARS, and similar licensing agencies where appropriate. Evidence in writing that such permissions have been secured from the rights-holder must be made available to the editors. It is also the author's responsibility to include acknowledgements as stipulated by the particular institutions. Oxford Journals can offer information and documentation to assist authors in securing print and online permissions: please see the Guidelines for Authors section. Information on permissions contacts for a number of main galleries and museums can also be provided. Should you require copies of this, please contact the editorial office of the journal in question or the Oxford Journals Rights department.

Language Editing

Language editing, if your first language is not English, to ensure that the academic content of your paper is fully understood by journal editors and reviewers is optional. Language editing does not guarantee that your manuscript will be accepted for publication. For further information on this service, please click here. Several specialist language editing companies offer similar services and you can also use any of these. Authors are liable for all costs associated with such services.

PREPARING YOUR MANUSCRIPT

- The *Journal of Pediatric Psychology* offers authors high-quality print and online publication. To ensure rapid and efficient publication, please follow the step-by-step instructions below.
- Follow the journal's instructions to authors regarding the format of your manuscript and references.
- Prepare your manuscript, including tables, using a word-processing program and save it as a .doc or .rtf file. All files in these formats will be converted to .pdf format upon submission.
- Prepare your figures at print publication quality resolution, using applications capable of generating high-resolution .tif files (1200 d.p.i. for line drawings and 300 d.p.i. for color and halftone artwork). The printing process requires your figures to be in this format if your paper is accepted for publication. For useful information on preparing your figures for publication, go to here. For online submission, please also prepare a second version of your figures at low-resolution for use in the

review process; these versions of the figures can be saved in .jpg, .gif, .tif, or .eps format.
- Prepare any other files that are to be submitted for review. The permitted formats for these files are the same as for manuscripts and figures. Other file types, such as Microsoft Excel spreadsheets and Powerpoint presentations, may be uploaded and will be converted to .pdf format. It is also possible to upload LaTeX files, but these will not be automatically converted to .pdf format.
- When naming your files, please use simple file names and avoid special characters and spaces. If you are a Macintosh user you must type the three-letter extension at the end of the file name you choose (e.g. .doc, .rtf, .tif, .pdf).

SUBMITTING YOUR MANUSCRIPT

Note: Before you begin, you should be sure you are using an up-to-date version of Netscape or Internet Explorer. The submission site will not work optimally if you are using a browser other than those recommended by Scholar One:

- Internet Explorer 9
- Internet Explorer 10
- Internet Explore 11
- Firefox 32
- Chrome 37
- Safari 6
- Safari 7

You can download a free upgrade using the icons found at the bottom of the 'Instructions and Forms' section of the online submission web site. If you are using one of the recommended browsers and still experiencing problems, clear your browser cache and try reloading the site. Users should have cookies enabled in their browsers when they access the site.

- First, you will need to log into ScholarOne Manuscripts.
- If you know your login details (i.e., you have submitted or reviewed a manuscript in this journal before), use your User ID and Password to log on. (Your user ID will usually be your email address.)
- If you do not know your login details, check to see if you are already registered by clicking on the 'Forgot your password' button and following the on-screen instructions. If you are not already registered, you can register by clicking on the 'Create account' button on the login screen and following the on-screen instructions.
- If you have trouble finding your manuscripts or have other problems with your account, do not create another account. Instead, please contact the journal's editorial office.
- To submit a new manuscript, go to the 'Author Centre', and click on “Click here to submit a new manuscript', and then follow the on-screen instructions. There are up to 7 steps for you to follow to submit your manuscript. You move from one step to the next by clicking on the 'Next' button on each screen or back to the previous screen by clicking on the 'Previous' button. Please note that if you click on the 'Back' or 'Forward'

buttons on your browser, the information you have entered will not be saved. At any stage you can stop the submission process by clicking on the 'Main Menu' button. Everything you have typed into the system will be saved, and the partially completed submission will appear under 'unsubmitted manuscripts' in your 'Author Centre'. To return to the submission process you will need to click on the button 'Continue Submission' against the relevant manuscript title.

- When submitting your manuscript, please enter your manuscript data into the relevant fields, following the detailed instructions at the top of each page. You may like to have the original word-processing file available so you can copy and paste the title and abstract into the required fields. You will also be required to provide email addresses for your co-authors, so please have these to hand when you log onto the site.
- When you come to upload your manuscript files via the 'File Upload' screen:
- Enter individual files using the 'Browse' buttons and select the appropriate 'File type' from the pull-down menu. The choices may vary from journal to journal but will always include a 'Main Document' (your manuscript text).
- Upload your files by clicking on the 'Upload files' button. This may take several minutes. Click on the SAVE button to confirm the upload. Repeat these steps until you have uploaded all your files.
- If you have uploaded any figures or tables you will be prompted to provide figure/table captions and 'file tags' that will link figures to text in the HTML proof of your main document.
- Once you have uploaded all your files, indicate the order in which they should appear in your paper. This will determine the order in which they appear in the consolidated PDF used for peer review.
- After the successful upload of your text and images, you will need to view and proofread your manuscript. Please do this by clicking on the blue HTML button or a PDF button.
- If the files have not been uploaded to your satisfaction, go back to the file upload screen where you can remove the files you do not want and repeat the process.
- When you are satisfied with the uploaded manuscript proof click on 'Next' which will take you to the 'Review & Submit' screen. The system will check that you have completed all the mandatory fields and that you have viewed your manuscript proof. It will also present you with a summary of all the information you have provided and give you a final chance to edit it. If there is a red cross next to any section this will indicate that not all the fields have been filled in correctly. You may either go back to the relevant page or click the nearest 'edit' button.
- When you have finished reviewing this information press 'Submit'.
- After the manuscript has been submitted you will see a confirmation screen and receive an email confirmation stating that your manuscript has been successfully submitted. This will also give the assigned manuscript number, which is used in all correspondence during peer review. If you do not receive this, your manuscript will not have been successfully submitted to the journal and the paper cannot progress to

peer review. If this is the case your manuscript will still be sitting in the 'Unsubmitted Manuscripts' section of your 'Author Centre' awaiting your attention.

- If you return to your 'Author Centre' you will notice that your newly submitted manuscript can be found in the 'Submitted Manuscripts' area. The 'Status' section provides information on the status of your manuscript as it moves through the review process.

SUBMITTING A REVISED MANUSCRIPT

- Log on to the online submission web site as before and, in the 'Author Centre', click on 'Manuscripts with Decisions'. At the bottom of the screen you will see those manuscripts that require a revision (or that have been revised). Create a revision of this manuscript by clicking on 'create a revision' under Actions. You will now be able to see the editor and reviewer comments and will be able to respond to these.
- You will need to upload the files that constitute your revised manuscript. To facilitate the production process, it is essential that you upload your revised manuscript as a .doc, .rtf, or .tex file, and not in .pdf format. If you wish to finish this another time, you will find the manuscript in your 'Revised manuscripts in draft' list.
- Please be sure to upload a title page with your article containing the title, author group, author affiliations, corresponding author, corresponding author's physical and e-mail address, key words, and any acknowledgments.
- If you click on 'View comments/respond' you will see the editor's letter to you together with the referees' comments. You may cut and paste your responses into the text areas at the bottom of the screen.

IMPORTANT. Your images are required as high-resolution .tif files (1200 d.p.i. for line drawings and 300 d.p.i. for colour and half-tone artwork). For useful information on preparing your figures for publication, go here. Please note that publication of your manuscript will not proceed until figures suitable for reproduction are received.

Getting Help

If you experience any problems during the online submission process, please consult the Author's User Guide which provides more detailed submission instructions and 'movie tutorials' explaining how to submit your paper. You can also email the journal editorial office at jpepsy@gmail.com who will be pleased to assist you with any question/problem you might have.

Crossref Funding Data Registry

In order to meet your funding requirements authors are required to name their funding sources, or state if there are none, during the submission process. For further information on this process or to find out more about the CHORUS initiative please click here.

Appendix D: REC and HRA Letters Confirming Ethical Approval

NHS
Health Research Authority

East of England - Essex Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

18 March 2018

Miss Kate Roberts
Department of Clinical Psychology
University of East Anglia
Norwich
NR4 7TJ

Dear Miss Roberts

Study title:	**Parental Anxiety and Post-Traumatic Stress Symptoms in Paediatric Food Allergy**
REC reference:	**18/EE/0038**
IRAS project ID:	**229968**

Thank you for your letter of 15 March 2018, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Online Advertisement]	Version 1	12 December 2017
Copies of advertisement materials for research participants [Clinic Flyer]	version 1	12 December 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor Insurance]	version 1	19 December 2017
IRAS Application Form [IRAS_Form_04012018]		04 January 2018
Letter from sponsor [Letter confirming UEA sponsorship]	version 1	19 December 2017
Letters of invitation to participant [First Email to Potential Participants]	version 1	12 December 2017
Letters of invitation to participant [Second Email to Potential Participants]	version 1	12 December 2017
Non-validated questionnaire [Questionnaire about parent, child, and allergy]	version 1	12 December 2017
Other [Pre-Survey Support Information Sheet]	version 1	12 December 2017
Other [Online Debrief]	version 1	12 December 2017
Other [Outline of how feedback from attached proposal feedback has been addressed]	version 1	12 December 2017
Other [Letter outlining changes made following REC Review]	version 1	27 February 2018
Other [PDF of Online Survey]	version 1	27 February 2018
Other [Example Screen Shot of Online Survey]	version 1	27 February 2018
Participant consent form [Consent Form]	version 1	12 December 2017
Participant consent form [Clinic Consent to Contact Form]	version 1	12 December 2017
Participant information sheet (PIS) [Clinic Participant Information Sheet]	version 2	22 February 2018
Participant information sheet (PIS) [Online Participant Information Sheet]	version 2	22 February 2018
Referee's report or other scientific critique report [Thesis Proposal Marksheet]	version 1	11 July 2017
Research protocol or project proposal [Project Proposal and Protocol]	version 2	12 December 2017
Summary CV for Chief Investigator (CI) [Kate Roberts CV]	version 1	16 November 2017

Summary CV for supervisor (student research) [Judith Young CV]	version 1	06 October 2017
Summary CV for supervisor (student research) [Richard Meiser-Stedman CV]	version 1	12 December 2017
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Study Flow Chart]	version 1	12 December 2017
Validated questionnaire [Anxiety Subscale of DASS-21 (Lovibond & Lovibond, 1995)]	version 1	12 December 2017
Validated questionnaire [FASE-P (Knibb, Barnes, & Stalker, 2015)]	version 1	12 December 2017
Validated questionnaire [IUS-S (Carleton, Norton, & Asmundson, 2007)]	version 1	12 December 2017
Validated questionnaire [PSWQ (Meyer et al., 1990)]	version 1	12 December 2017
Validated questionnaire [IES-R (Weiss & Marmar, 1997) with additional project-specific instructions]	version 1	12 December 2017

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

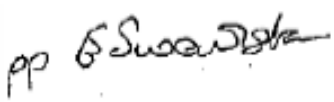
HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

18/EE/0038	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely



Dr Niki Bannister
Chair

Email: NRESCommittee.EastofEngland-Essex@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Sarah Ruthven*
Julie Dawson, Norfolk and Norwich University Hospital NHS Trust

NHS
Health Research Authority

Miss Kate Roberts
Department of Clinical Psychology
University of East Anglia
Norwich
NR4 7TJ

Email: hra.approval@nhs.net

19 March 2018

Dear Miss Roberts

Letter of HRA Approval

Study title:	**Parental Anxiety and Post-Traumatic Stress Symptoms in Paediatric Food Allergy**
IRAS project ID:	**229968**
REC reference:	**18/EE/0038**
Sponsor	**Organization not set**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details

IRAS project ID	228988

and further information about working with the research management function for each organisation can be accessed from the HRA website.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators"*, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found through IRAS.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website.

IRAS project ID	229968

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details on the HRA website.

Your IRAS project ID is **229968**. Please quote this on all correspondence.

Yours sincerely

Thomas Fairman

HRA Assessor

Email: hra.approval@nhs.net

Copy to: *Ms Sarah Ruthven, University of East Anglia, (Sponsor Contact)*
Ms Julie Dawson, Norfolk and Norwich University Hospital NHS Trust, (Lead NHS R&D Contact)

Appendix E: Participant Information Sheet (Clinic Version)

University of East Anglia

Participant Information Sheet:
Parental Anxiety and Post-Traumatic Stress Symptoms in Paediatric Food Allergy

We'd like to invite you to take part in our research study. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. Please feel free to talk to others about the study if you wish. Do ask if anything is unclear.

Purpose and background to the research
Past research has found some parents of children with food allergy experience increased levels of anxiety. There could be many reasons for this, for example having to share your child's needs (e.g. with school), or the unpredictability of allergic reactions. Some parents have also reported experiencing allergy-related events as traumatic, but no previous research has assessed this.

This study is looking to better understand parents'/carers' experience of anxiety, worry and trauma. The study is also interested in factors that might predict whether parents/carers experience these difficulties. We are hoping the survey will be completed by around 100 adults who have the main caring responsibility for a child with food allergy. By understanding their experience, it is hoped that this study can help the development of better ways to support parents/carers. This study is being conducted as part of the Chief Investigator's Doctorate in Clinical Psychology and will be written up as a thesis.

What would taking part involve?
Participation would involve completing an online survey about your child's allergy and your wellbeing. It is anticipated the survey would take approximately 20-25 minutes to complete. There is the option to pause and return to the survey if needed.

If you complete the attached 'consent to contact' form a link to the survey will be emailed to you by the researcher (typically within 1-2 weeks). You will receive a second email around two weeks later to act as a reminder of the study and to thank those that have participated.

What are the possible benefits of taking part?
By participating you can help us to better understand the experience of caring for a child with food allergy. At the end of the online survey you will also have the opportunity to enter a prize draw to win one of ten £20 Amazon gift vouchers.

What are the possible disadvantages of taking part?
Some of the questions in the survey ask about allergy related events and your mood that may make you feel distressed, anxious or upset. If this occurs you may stop the survey at any time. Contact details for support services are also included at the start and end of the online survey.

What will happen if I don't want to carry on with the study?
Participation in the study is completely voluntary, and you may exit the online survey at any time. Leaving the study will not have any impact on the care or treatment you receive. However, as the responses to the online survey are completely anonymous, you are unable to withdraw once you have submitted your responses (by clicking 'finish' at the end of the survey).

Will my information be kept confidential?
Yes – consent to contact forms will be kept securely and will only be accessed by members of the research team or for regulation purposes by the sponsor organisation (University of

East Anglia). Online responses are completely anonymous, and kept securely. If you choose to enter the prize draw or request a study summary, your email address will be kept separately from your study responses on a secure server.

What will happen to the results of the study?
As well as being written up as a thesis, it is anticipated that the results of the study will be written for publication and may be presented at conferences. This allows other researchers and health professionals to learn from and build upon the results from the study. Some data may also be passed on anonymously to other researchers, this is because collecting data from lots of different studies can sometimes help us to learn more than single studies on their own. However, we would *never* share any information that would allow you to be identified. If you wish to receive a summary of the results at the end of the study, there is an option to leave an email address for this at the end of the online survey.

Who is organising this study?
This research is organised by Kate Roberts (see below), Judith Young (see below), and Richard Meiser-Stedman (Reader in Clinical Psychology), and is funded by the University of East Anglia Doctoral Programme in Clinical Psychology

Who has reviewed this study?
Before any research goes ahead in the NHS it needs to be checked by an independent group of people called a Research Ethics Committee. Their job is to ensure that any proposed research is ethical and to protect the safety, rights, wellbeing and dignity of participants. This study has been reviewed and was given a favourable opinion by the NRES Committee East of England – Essex.

What if there is a problem?
If you have any concerns about the study you can contact myself or my supervisor using the details below. If you want to contact someone who is separate from the study, or wish to make a formal complaint, you can contact: Professor Ken Laidlaw, Head of Department, Department of Clinical Psychology, University of East Anglia, NR4 7TJ. Telephone: 01603 593600.

Further information and contact details
Additional information is available at the start of the online survey:
https://uea.onlinesurveys.ac.uk/food-allergy
If you have any questions, or would like more information, please contact the chief investigator, if you then have any further questions please contact the primary supervisor:

Chief investigator: Kate Roberts

Clinical Psychologist In-Training

Department of Clinical Psychology
Norwich Medical School
Elizabeth Fry Building
University of East Anglia
Norwich, NR4 7TJ
Email: K.Roberts1@uea.ac.uk

Primary supervisor: Judith Young
Clinical Senior Lecturer and Honorary Consultant Clinical Psychologist

Department of Clinical Psychology
Norwich Medical School
Elizabeth Fry Building
University of East Anglia
Norwich , NR4 7TJ
Email: Judith.Young@uea.ac.uk

Thank you for taking time to read this information sheet, please keep this information for your records.

Appendix F: Consent to Contact Form

Consent to Contact Form

University of East Anglia

Parental Anxiety and Post-Traumatic Stress Symptoms in Paediatric Food Allergy

Chief investigator: Kate Roberts **Contact Details:** K.Roberts1@uea.ac.uk

Please initial box if you agree:

I confirm I am potentially interested in taking part in the above study and give consent for the researchers to contact me using the following details to provide further information: ☐

Name: _____

Email: _____

_____ _____

Signature Date

Appendix G: Participant Information Sheet (Online)

Parental Anxiety and Post-Traumatic Stress Symptoms in Paediatric Food Allergy

Participant Information Sheet

University of East Anglia

Welcome to our research study. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. Please feel free to talk to others about the study if you wish. If you have any further questions, please use the researcher contact details at the bottom of the page.

Purpose and background to the research

Past research has found some parents of children with food allergy experience increased levels of anxiety. There could be many reasons for this, for example having to share your child's needs (e.g. with school), or the unpredictability of allergic reactions. Some parents have also reported experiencing allergy-related events as traumatic, but no previous research has assessed this.

This study is looking to better understand parents'/carers' experience of anxiety, worry and trauma. The study is also interested in factors that might predict whether parents/carers experience these difficulties. We are hoping the survey will be completed by around 100 adults who have the main caring responsibility for a child with food allergy. By understanding their experience, it is hoped that this study can help the development of better ways to support parents/carers.

This study is being conducted as part of the Chief Investigator's Doctorate in Clinical Psychology and will be written up as a thesis.

Am I eligible to take part?

We are looking for individuals who meet the following criteria to take part in the study:

- At least 18 years old
- Living in the United Kingdom (UK)
- Have main caring responsibility for a child aged 0-16 years with a food allergy
- The food allergy has been diagnosed by a doctor or specialist allergy clinic

What would taking part involve?

The online survey will ask about your child's allergy and your day-to-day mood. It is anticipated the survey would take approximately 20-25 minutes to complete. If you need to pause the survey please click 'finish later' (at the bottom of each page), you will then be given a personal link to allow you to continue the survey later on.

What are the possible benefits of taking part?

By participating you can help us to better understand the experience of caring for a child with food allergy. At the end of the online survey you will also have the opportunity to enter a prize draw to win one of ten £20 Amazon gift vouchers.

What are the possible disadvantages of taking part?

Some of the questions in the survey ask about allergy related events and your mood that may make you feel distressed, anxious or upset. If this occurs you may stop the survey at any time. Contact details for support services will also be provided at the start and end of the survey.

What will happen if I don't want to carry on with the study?

Participation in the study is completely voluntary, and you may exit the online survey at any time. Your responses will only be submitted once you click 'finish' at the end of the survey. As the responses to the online survey are completely anonymous, once your answers have been submitted it is not possible to withdraw from the study.

Will my information be kept confidential?

Yes – online responses are completely anonymous, and kept securely. If you choose to enter the prize draw or request a study summary, your email address will be kept separately from your study responses on a secure server. Identifiable information will be accessed only by the research team, or for regulation purposes by the sponsor organisation (University of East Anglia).

What will happen to the results of the study?

As well as being written up as a thesis, it is anticipated that the results of the study will be written for publication and may be presented at conferences. This allows other researchers and health professionals to learn from and build upon the results from the study. Some data

may also be passed on anonymously to other researchers, this is because collecting data from lots of different studies can sometimes help us to learn more than single studies on their own. However, we would ***never*** share any information that would allow you to be identified. If you wish to receive a summary of the results, there is an option for this at the end of the survey.

Who is organising this study?

This research is organised by Kate Roberts (see below), Judith Young (see below), and Richard Meiser-Stedman (Reader in Clinical Psychology), and is funded by the University of East Anglia Doctoral Programme in Clinical Psychology

Who has reviewed this study?

Before any research goes ahead in the NHS it needs to be checked by an independent group of people called a Research Ethics Committee. Their job is to ensure that any proposed research is ethical and to protect the safety, rights, wellbeing and dignity of participants. This study has been reviewed and was given a favourable opinion by the NRES Committee East of England – Essex.

What if there is a problem?

If you have any concerns about the study you can contact myself or my supervisor using the details below. If you want to contact someone who is separate from the study, or wish to make a formal complaint, you can contact: Professor Ken Laidlaw, Head of Department, Department of Clinical Psychology, University of East Anglia, NR4 7TJ. Telephone: 01603 593600.

Further Information

If you have any questions, or would like more information, please contact the chief investigator or primary supervisor:

Chief Investigator: Kate Roberts

Clinical Psychologist In-Training

Department of Clinical Psychology

Norwich Medical School

Elizabeth Fry Building

University of East Anglia

Norwich, NR4 7TJ

Email: K.Roberts1@uea.ac.uk

Primary Supervisor: Judith Young

Clinical Senior Lecturer and Academic Tutor

Department of Clinical Psychology

Norwich Medical School

Elizabeth Fry Building

University of East Anglia

Norwich, NR4 7TJ

Email: Judith.Young@uea.ac.uk

Appendix H: Consent Form

Consent Form

Please select 'yes' if you agree with the statements below

I confirm that I have read the study information dated 22/02/2018 for the above study. I have had the opportunity to consider the information, and ask questions if I want to and have had these answered satisfactorily

- Yes

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected

- Yes

I understand that relevant sections of the data collected during the study may be looked at by individuals from regulatory authorities. I give permission for these individuals to have access to my records

- Yes

I understand that the information collected about me could be used to support other research in the future, and may be shared anonymously with other researchers

- Yes

I understand that once I submit my answers they cannot be retrospectively removed

Yes

I agree to take part in the above study

Yes

Appendix I: Participant Pre-Brief

Thank you for consenting to participate in our study. The following survey will include some questions relating to allergy related events and your wellbeing. If you feel that this could be distressing for you, we would recommend completing the survey when a family member or other support is around.

If you feel you would benefit from further support with any of the issues raised in the study, we would advise you to discuss this with your GP or another health professional.

Further information about food allergies and anxiety can also be found on the NHS Choices food allergy webpages:

Allergy: http://www.nhs.uk/conditions/food-allergy/Pages/Intro1.aspx

Anxiety: http://www.nhs.uk/Conditions/Anxiety/Pages/Introduction.aspx

Additional information will be provided at the end of the survey.

Thank you for your participation.

Appendix J: Participant Debrief Information

Thank You

Thank you for your participation in the study. We hope that the results of the study can help us to better understand the needs of those caring for a child with food allergy, and to develop ways to support parents and caregivers.

If you feel you would benefit from further support with any of the issues raised in the study, we would advise you to discuss this with your GP or another health professional (e.g. health visitor).

Further information about food allergies can be found on the NHS Choices food allergy web page:

http://www.nhs.uk/conditions/food-allergy/Pages/Intro1.aspx

This page also provides links to the following organisations and charities that can provide further information and advice:

Allergy UK https://www.allergyuk.org

Anaphylaxis Campaign https://www.anaphylaxis.org.uk

BSACI (The British Society for Allergy & Clinical Immunology) http://www.bsaci.org

Further information about anxiety can be found on the NHS Choices web-page which provides information on symptoms, seeking help from your GP, and treatments, including self help:

http://www.nhs.uk/Conditions/Anxiety/Pages/Introduction.aspx

Further support can also be accessed through Samaritans. Samaritans is a charity that provides confidential emotional support for people who are experiencing feelings of distress, despair or suicidal thoughts. The Samaritans operate a free 24/7 helpline in the UK which you can call on 116 123. For more information, including alternative ways to contact Samaritans visit http://www.samaritans.org

If you have any further questions or concerns the researcher contact information can be found

at the bottom of the page. If you wish to make a formal complaint, you can contact: Professor Ken Laidlaw, Head of Department, Department of Clinical Psychology, University of East Anglia, NR4 7TJ. Telephone: 01603 593600.

Chief Investigator: Kate Roberts

Clinical Psychologist In-Training

Department of Clinical Psychology

Norwich Medical School

Elizabeth Fry Building

University of East Anglia

Norwich, NR4 7TJ

Email: K.Roberts1@uea.ac.uk

Primary Supervisor: Judith Young

Clinical Senior Lecturer and Academic Tutor

Department of Clinical Psychology

Norwich Medical School

Elizabeth Fry Building

University of East Anglia

Norwich, NR4 7TJ

Email: Judith.Young@uea.ac.uk

Thank you again for taking time to participate in this study.

Appendix K: Demographic and Allergy Questionnaire

About your child and their allergy:

Do you have more than one child with a medically diagnosed food allergy? (If yes you will be asked to complete the following questions for each child) * *Required*

- ○ Yes
- ○ No

How old is your child? Years:

And months:

Your child's gender:

- ○ Male
- ○ Female

Who diagnosed your child's food allergy?

- ○ GP
- ○ Specialist allergy clinic
- ○ Other

If you selected Other, please specify:

8 / 53

What food(s) is your child allergic to?

Please select at least 1 answer(s).

- [ ] Milk
- [ ] Egg
- [ ] Peanut
- [ ] Tree nuts
- [ ] Soy
- [ ] Wheat
- [ ] Fish
- [ ] Shellfish
- [ ] Sesame
- [ ] Other

If you selected Other, please specify:

How was the food allergy diagnosed?

- [ ] Skin prick testing
- [ ] Blood test
- [ ] Medical history
- [ ] Other

If you selected Other, please specify:

How long ago was your child's allergy diagnosed (please give your best estimate)?

From first seeking medical help for your child's allergy, approximately how long did you wait to receive a diagnosis (please give your best estimate)?

Has your child been prescribed antihistamines for their food allergy?

- Yes
- No

Does your child have an adrenaline auto-injector prescribed (e.g. an EpiPen or Emerade)?

- Yes
- No

Has an adrenaline auto-injector been given to your child during an allergy reaction?

- Yes
- No

Has your child attended Accident and Emergency because of an allergy reaction?

- ○ Yes
- ○ No

Has your child ever experienced an anaphylactic reaction?

- ○ Yes - once
- ○ Yes - more than once
- ○ No

If yes when did this last occur? (please give your best estimate)

Has your child experienced the following symptoms during an allergic reaction?

	Yes	No
Runny or congested nose	○	○
Bloated stomach	○	○
Abdominal pain	○	○
Diarrhoea	○	○
Vomiting	○	○
Hives or itchy skin rash	○	○
Itchy/tingling mouth	○	○
Persistent cough	○	○
Swollen lips, face, or eyes	○	○
Swollen tongue	○	○
Difficulty swallowing	○	○
Breathing difficulties	○	○
Dizziness	○	○
Sudden tiredness	○	○
Collapse	○	○
Sudden change in behaviour	○	○
Other	○	○

If other please specify:

Does your child experience any other allergies or chronic health conditions?

- [ ] No
- [ ] Asthma
- [ ] Eczema
- [ ] Hayfever
- [ ] Other

If you selected Other, please specify:

About yourself:

Your age:

Relationship to child:

- Mother
- Father
- Other

If you selected Other, please specify:

How many children do you currently have caring responsibility for (including your child/children with food allergy)?

Do **you** have any medically diagnosed allergies?

- Yes - food allergy
- Yes - other allergy
- No

If 'yes - food allergy' what food(s) are you allergic to? *Optional*

- [ ] Milk
- [ ] Egg
- [ ] Peanut
- [ ] Tree nuts
- [ ] Soy
- [ ] Wheat
- [ ] Fish
- [ ] Shellfish
- [ ] Sesame
- [ ] Other

If you selected Other, please specify:

If 'other allergy' please specify:

Other than your child does anyone else in your close family have a food allergy?

- ( ) Yes - same allergen as child
- ( ) Yes - different allergen to child
- ( ) No

Are you currently taking any medication for your mood?

- [ ] Yes - anxiety
- [ ] Yes - depression

- [ ] Yes - other
- [ ] No
- [ ] Prefer not to say

How did you find out about the study?

- ( ) NNUH Allergy Clinic
- ( ) Allergy Charity
- ( ) Social Media
- ( ) Other

If you selected Other, please specify:

Appendix L: Penn State Worry Questionnaire (Meyer, Miller, Metzger, & Borkovec, 1990)

Instructions: Rate each of the following statements on a scale of 1 ("not at all typical of me") to 5 ("very typical of me"). Please do not leave any items blank.

	Not at all typical of me				Very typical of me
1. If I do not have enough time to do everything, I do not worry about it.	1	2	3	4	5
2. My worries overwhelm me.	1	2	3	4	5
3. I do not tend to worry about things.	1	2	3	4	5
4. Many situations make me worry.	1	2	3	4	5
5. I know I should not worry about things, but I just cannot help it.	1	2	3	4	5
6. When I am under pressure I worry a lot.	1	2	3	4	5
7. I am always worrying about something.	1	2	3	4	5
8. I find it easy to dismiss worrisome thoughts.	1	2	3	4	5
9. As soon as I finish one task, I start to worry about everything else I have to do.	1	2	3	4	5
10. I never worry about anything.	1	2	3	4	5
11. When there is nothing more I can do about a concern, I do not worry about it any more.	1	2	3	4	5
12. I have been a worrier all my life.	1	2	3	4	5
13. I notice that I have been worrying about things.	1	2	3	4	5
14. Once I start worrying, I cannot stop.	1	2	3	4	5
15. I worry all the time.	1	2	3	4	5
16. I worry about projects until they are all done.	1	2	3	4	5

Appendix M: Depression Anxiety Stress Scales 21 - Anxiety subscale (Lovibond & Lovibond, 1995)

Please read each statement and select a number 0, 1, 2 or 3 which indicated how much the statement applied to you *over the past week.* There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:

0 Did not apply to me at all
1 Applied to me to some degree, or some of the time
2 Applied to me to a considerable degree, or a good part of time
3 Applied to me very much, or most of the time

1	I was aware of dryness of my mouth	0	1	2	3
2	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
3	I experienced trembling (eg, in the hands)	0	1	2	3
4	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
5	I felt I was close to panic	0	1	2	3
6	I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)	0	1	2	3
7	I felt scared without any good reason	0	1	2	3

Appendix N: Impact of Events Scale – Revised (Weiss & Marmar, 1997) with Adapted Instructions

The following questions will refer to your experience of a stressful event. We would like you to complete these questions in reference to the most stressful experience you can recall related to your child's allergy. For example this may be the most severe allergy reaction you can recall your child experiencing, witnessing an allergy reaction in another individual, hearing about a reaction in your child, or being given a food allergy diagnosis.

Please provide a brief indication of what this event is for you below:

- ○ Witnessing an anaphylactic allergy reaction in your child
- ○ Witnessing a non-anaphylactic allergic reaction in your child
- ○ Witnessing an allergic reaction in another individual
- ○ Other

If you selected Other, please specify:

How long ago did this event occur (please give your best estimate)?

At the time of this event was an ambulance called and/or Accident and Emergency visited?

- ○ Yes
- ○ No

	Not at all	A little bit	Moderately	Quite a bit	Extremely
1. Any reminder brought back feelings about it	0	1	2	3	4
2. I had trouble staying asleep	0	1	2	3	4
3. Other things kept making me think about it.	0	1	2	3	4
4. I felt irritable and angry	0	1	2	3	4
5. I avoided letting myself get upset when I thought about it or was reminded of it	0	1	2	3	4
6. I thought about it when I didn't mean to	0	1	2	3	4
7. I felt as if it hadn't happened or wasn't real.	0	1	2	3	4
8. I stayed away from reminders of it.	0	1	2	3	4
9. Pictures about it popped into my mind.	0	1	2	3	4
10. I was jumpy and easily startled.	0	1	2	3	4
11. I tried not to think about it.	0	1	2	3	4
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	0	1	2	3	4
13. My feelings about it were kind of numb.	0	1	2	3	4
14. I found myself acting or feeling like I was back at that time.	0	1	2	3	4
15. I had trouble falling asleep.	0	1	2	3	4
16. I had waves of strong feelings about it.	0	1	2	3	4
17. I tried to remove it from my memory.	0	1	2	3	4
18. I had trouble concentrating.	0	1	2	3	4
19. Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart.	0	1	2	3	4
20. I had dreams about it.	0	1	2	3	4
21. I felt watchful and on-guard.	0	1	2	3	4
22. I tried not to talk about it.	0	1	2	3	4

Appendix O: Intolerance of Uncertainty Scale – Short Form (Carleton et al., 2007)

Please circle the number that best corresponds to how much you agree with each item

	Not at all characteristic of me	A little characteristic of me	Somewhat characteristic of me	Very characteristic of me	Entirely characteristic of me
1. Unforeseen events upset me greatly.	1	2	3	4	5
2. It frustrates me not having all the information I need.	1	2	3	4	5
3. Uncertainty keeps me from living a full life.	1	2	3	4	5
4. One should always look ahead so as to avoid surprises.	1	2	3	4	5
5. A small unforeseen event can spoil everything, even with the best of planning.	1	2	3	4	5
6. When it's time to act, uncertainty paralyses me.	1	2	3	4	5
7. When I am uncertain I can't function very well.	1	2	3	4	5
8. I always want to know what the future has in store for me.	1	2	3	4	5
9. I can't stand being taken by surprise.	1	2	3	4	5
10. The smallest doubt can stop me from acting.	1	2	3	4	5
11. I should be able to organize everything in advance.	1	2	3	4	5
12. I must get away from all uncertain situations.	1	2	3	4	5