Food Sensitive Study: Introduction

Introduction

Background

This report presents findings from research conducted by Aston University on behalf of the Food Standards Agency (FSA). The FSA is an independent government department responsible for protecting public health and consumers' interests in relation to food across England, Wales and Northern Ireland. As part of their function to protect public health, the FSA plays an important role in ensuring that members of the public are protected from potentially life threatening food hypersensitivities, by working with consumers and the food industry to ensure consumers with food hypersensitivities can make safe and informed choices.

Food hypersensitivities (FH) include food allergy, food intolerance and coeliac disease. Eating a food you are sensitive to can result in an adverse reaction with unpleasant and sometimes life-threatening symptoms. Management of FH therefore involves constant vigilance and risk assessment to determine if a food is safe to eat. Research over the last twenty years has demonstrated that this burden, along with the unpredictable nature of FH reactions, has an impact on quality of life (Cummings et al., 2010; Morou et al., 2014). Children, adolescents, adults and parents of children with FH invest a large amount of time and resource in managing the risks associated with an adverse reaction. FH can affect social life, such as eating out; school or work life; relationships with significant others; and can cause anxiety surrounding both eating and the management of a reaction to food (DunnGalvin et al, 2009; Gallagher et al., 2011).

The FSA has a vision to improve the quality of life for people living with FH (footnote 1) and recently commissioned research to explore the impact of legislation which specified that information on specific allergens be provided for foods that are not prepacked (footnote 2) (Begen et al., 2018; Begen et al., 2018). The work was led by the University of Bath and included collecting data on the quality of life of individuals with FH, and parents of children with FH regarding experiences when eating out. They reported on current eating out behaviours, satisfaction with and confidence in information provision about allergens, and preferences for information provision. Greater positivity and adventurousness when eating out was associated with better health-related quality of life (QoL), whereas greater preparation needed for eating out was associated with lower health-related QoL.

Despite the focus of research on the quality of life of those with FH, there are still significant gaps in the literature, as apart from the study conducted by the University of Bath, few studies have focused on food intolerance or adults with FH. Little is known about the factors associated with high or low QoL or how this might change over time. In order to address this, the FSA has commissioned this project to characterise and evaluate the burden caused by living with FH, the day-to-day management of FH, and associated inconveniences.

Aims of the project

The current project, called the FoodSensitive study, was conducted across two linked workstreams. The first workstream aimed to develop and test a survey to collect data on the management, and impacts of FH on daily lives, and the resultant quality of life individuals with FH experience. This information was collected in two waves, one year apart. The second

workstream aimed to produce monetary valuations on the non-tangible elements of food hypersensitivities, including pain, grief and suffering, through eliciting Willingness to Pay (WTP) values (how much someone would be willing to pay to remove the anxiety and day-to-day impact related to having a FH). The sample for this work included, but was not limited to, the sample from workstream one. In line with the FSA's statutory responsibility to protect consumer interests in food, and to enable the FSA to further understand these conditions and seek ways to reduce their burden, samples for both workstreams were drawn from individuals living in the UK.

This report provides the findings for wave 2 of the survey collected for workstream one, published in the Food Sensitive Study Wave 1 Report. The aim of this survey was to collect further data on the management, quality of life and impact of FH on the daily lives of children and adults with FH, as well as parents of children with FH. Comparisons between those that completed the survey at wave 1 and wave 2 were also made. The data for wave 2 were collected between the 10th of October and the 14th of December 2021. (Data for wave 1 were collected between 28th October 2020 and 4th January 2021)

Methods

Study design

This was a cross-sectional online survey. It was administered one year after the previous survey and is also a part longitudinal design for participants who completed both waves. This report provides the findings for the second of these two waves and a comparison of data from wave 1 and wave 2 for those participants that completed both waves. The research approach taken for the second of these two survey waves is the same as that taken for the first wave and is summarised below. More detailed information can be found in the technical report.

Participants and recruitment

Three separate groups of participants were recruited: adults with FH; parents of children with FH (aged 0-17 years); children (aged 8 to 17 years) with FH, living in the UK. FH was defined as experiencing a bad or unpleasant physical reaction after consuming food. The wording of the definition was developed to identify this population in the FSA's Food and You survey, and was based on previous work conducted by Professor Barnett and colleagues at University of Bath, The preferences of those with food allergies and/or intolerances when eating out study. The definition had also been through cognitive testing for the FSA's revised Food and You survey in Summer 2020 (Food and You 2). For recruitment purposes, FH was divided into 3 categories: food allergy, food intolerance and coeliac disease.

Participants from wave one of the survey who consented to be contacted again were sent an email with the study advert and a link to the surveys. As the FH profile of the population in the UK is unknown, a non-probability opportunity sample was also recruited. The opportunity sample consisted of anyone who saw the study advert and was eligible to take part, and participants were recruited through advertising via patient organisations: Allergy UK, the Anaphylaxis Campaign, the Natasha Allergy Research Foundation and Coeliac UK. The survey was also advertised on Twitter. In order to reach children, advertisements were targeted at parents. The project team also advertised through their own networks including university research participation advertising. These methods enabled a rapid and cost-effective way of recruiting the desired cohort. Importantly these methods allowed the study to reach out to those with relatively milder symptoms, in particular people with food intolerance, who may not have sought medical input. It must be noted, however, that these approaches are likely to be affected by respondent biases whereby participants are more highly motivated towards FH issues, particularly those associated with patient organisations, and therefore likely to take part, and are generally of a higher socio-economic status. Using an online platform restricts the survey to people who have access to the internet.

Recruitment rates and the profile of those responding were closely monitored to minimise the risk of under-recruitment in any one group. Initially the numbers of adults, parents and children responding against the overall target numbers for these groups were monitored. The number of respondents reporting food allergy, food intolerance and coeliac disease were then also monitored within each of these groups. Similar to wave one, recruitment was supplemented where needed with the use of online survey panels through Qualtrics to meet the target numbers in each group, and to try and ensure an equal spread of allergy, intolerance and coeliac disease. QualtricsXM is a worldwide company that offers a secure online survey system and the ability to recruit participants with specific inclusion and exclusion criteria to online studies. Qualtrics advertised the study to their UK panel and also advertised to parents in order to recruit children with food hypersensitivities (further information about this can be found in the technical report).

Screening questions at the start of the survey asked individuals if they lived in the UK and had a bad or unpleasant reaction to food. For each survey there was also a specific screening question regarding age or if they were a parent. All participants had to complete the screening questions at the start of the survey to ensure they were eligible for this study.

Measures

In order to capture the data needed for this study, a combination of bespoke questions and a suite of validated psychometric scales were used. The bespoke questions were required to understand impact on day-to-day life that weren't captured by the psychometric scales. This included demographic and FH information as well as questions designed to measure the day-to-day management and impact of food hypersensitivity for each age group and for parents. All measures used in wave 1 were re-used for wave 2, with some minor amendments. Some questions were removed as the FSA had included them in their Food and You 2 survey (particularly around shopping, label reading, reacting in social situations and information sources for FH).

After providing demographic information, respondents were asked to list all foods they reacted to; then provide further details of up to three foods that they perceived had a big impact on their life. Parents were asked to provide details of up to three children and up to three foods per child. This enabled data to be captured on the complexity of FH while not overburdening respondents. For each of the three foods, respondents were asked about specific symptoms, self-reported severity, method of diagnosis, medication and hospitalisation. Respondents were asked to indicate if they thought their reaction to each of these three foods was due to food allergy, food intolerance or coeliac disease. Respondents could also choose to report a different reaction, or to state if they did not know the type of reaction they had. They were then classified in line with what they assessed themselves as being. This ensured that the FH specific QoL scale they were directed to had face validity, as the scale matched with the participant's belief regarding their own reaction. It also allowed for an exploration of misunderstandings regarding food allergy, intolerance of coeliac disease in the sample, based on a comparison with their responses to other questions regarding type of food, symptoms and timing of reactions.

For each of the three foods, respondents were asked to say whether they thought their FH was mild, moderate or severe. This type of self-reported rating of severity has been used in previous published studies (Acaster et al., 2020a; Acaster et al., 2020b) and has been shown to significantly correlate with QoL ratings.

Key data collected included:

- detailed information on foods, symptoms, diagnosis, medication and hospitalisation
- experiences when eating out
- quality of life (measured by valid and reliable questionnaires)

Validated psychometric scales were used to measure FH specific and generic quality of life. A full list of all scales used can be found in the technical report. The specific psychometric quality of life questionnaire respondents completed was based on their own answer to the question regarding the type of FH they perceived they suffered from. For adults, this was for the first food they told us details about. Adults reporting food allergy completed the Food Allergy Quality of Life Questionnaire for Adults (FAQLQ-A) and those reporting food intolerance completed the FIQLQ-A. Adults reporting coeliac disease completed the Coeliac Disease Quality of Life scale for adults (CDQOL).

For parents, the specific quality of life questionnaire they completed was based on their answer regarding the type of FH for the first food of the first child they told us about. For food allergy, parents completed the FAQLQ-Parent proxy for children or for teens, and food intolerance they completed the FIQLQ-Parent proxy for children and teens. Those reporting coeliac disease in their child completed the Coeliac Disease quality of life scale parent-proxy (CDDUX).

Children aged 8-12 years reporting food allergy completed the FAQLQ for children; those aged 13-17 completed the FAQLQ for teens. There was no available validated scale for children or teens with food intolerance, so we adapted the FAQLQ for children and teens using the same methodology that had been used previously to adapt the other FAQLQs for food intolerance. Children reporting coeliac disease completed the Coeliac Disease quality of life scale for child self-report (CDDUX).

A generic quality of life scale - the EQ5D - was used to enable direct comparison across respondent subgroups. The EQ5D generic quality of life scale is a generic, preference-based health status measure. Participants report their current health on dimensions such as mobility, self-care, pain and discomfort, usual activities, anxiety and depression. Responses are converted into a single index value that can be used in cost-effectiveness analyses, where a score of 1 represents full health and a score of 0 represents dead. Participants were also asked to rate their current health on a 0 to 100 visual analogue scale (VAS) with higher scores representing better QoL. The EQ5D is a widely used well-validated scale to measure quality of life in healthy participants and participants with various health conditions. It has also recently been used to measure quality of life in children with peanut allergy (Acaster et al., 2020a; Acaster et al., 2020b) and has been used by the FSA in previous research on foodborne diseases. Adults completed a self-report version, parents completed a parent proxy for their children, and children and teens completed the child version, the EQ5D-Y.

Further information on sampling, the survey measures and the survey methodology can be found in the technical report.

Data analysis and reporting conventions

Sub-groups used within the analysis and reporting were:

1. Respondents with food allergy only
2. Respondents with food intolerance only
3. Respondents with coeliac disease only
4. Respondents with multiple hypersensitivities which included any two (or all three) of allergy, intolerance and coeliac disease.

Participants reporting ‘Other’ or ‘Don’t know’ are not reported on as a subgroup as the key interest in this research was the three main food hypersensitivities. The total number of participants who completed the survey and who were therefore included in the analysis for this report can be found in Table 1. The main data is reported separately for adults with FH, parents of children with FH, and children aged 8-17 years with FH. Descriptive information is provided for all survey questions in the form of text, tables and graphs where appropriate. Comparisons across mean scores for groups were conducted using ANOVAs, which provide an overall F value to tell

you if there is a significant difference. The effect size (np2) was also reported for all ANOVAs. Pearson's correlations were used to examine relationships between pairs of continuous variables. Correlations are used to see if two sets of data are related in some way, so for example to see if higher scores in a variable is related to higher or lower scores in another variable. Where group sizes were big enough regression analysis was then conducted to see what variables might predict QoL.

For the QoL measures, the following comparisons were made for each group where appropriate:

- between clinically diagnosed (footnote 3) and self-diagnosed
- by gender
- by age
- by number of foods/allergens reported
- self-reported severity

For participants who had completed wave 1 and wave 2, answers to survey questions were compared for changes over time where there were sufficient numbers in each group.

Results were reported as significant if $p<0.05$. This indicates that we can be 95% confident that the results did not come about by chance. Where there were multiple comparisons a Bonferroni correction was applied to them, to reduce the risk of stating a difference was significant when it was not. Where this was applied, a corrected ? level was used to determine significance (0.5 divided by the number of comparisons). All tests were two-tailed. Effect sizes were reported for all analyses. Findings were not weighted due to the lack of available food hypersensitivity population information.

Table 1: Number of participants completing wave 2

Participant group	Adults N (%)	Parents of children N (%)	Children N (%)
Respondents with food allergy only	323 (30.3)	399 (53.2)	141 (40.4)
Respondents with intolerance only	330 (31.0)	176 (23.5)	139 (39.8)
Respondents with coeliac only	217 (20.4)	21 (2.8)	29 (8.3)
Respondents with multiple hypersensitivities	131 (12.3)	134 (17.9)	21 (6.0)
Respondent reporting 'other' or 'don't know'	64 (6.0)	20 (2.7)	19 (5.4)
Total	1,065 (100)	750 (100)	349 (100)

1. The FSA's Food Hypersensitivity Strategy, 2019-2025

2. The preferences of those with food allergies and/or intolerances when eating out study.

3. Clinical diagnosis included a health care professional making a diagnosis based on a clinical history, skin prick tests, blood tests and/or food challenge.