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Introduction

Approximately 20% of children and adults avoid particular foods because of perceived food intolerance although prevalence varies according to method of data collection, the population under investigation and the definition of terms (1-2). By the age of 3 years, 6% of children suffer from **Food Hypersensitivity** (FH) confirmed by food challenges; however a much larger proportion of parents report food-related symptoms that lead them to avoid particular foods (3).

‘Food intolerance’ embraces adverse reactions following dietary exposure to foods that most people would not react to. Such reactions may be allergic (immune mechanism) or non-allergic (non-immunological). Allergic reactions may be further sub-divided into IgE-mediated food allergy (FA) and non-IgE-mediated food allergy. For the purposes of this study we include non-allergic and non-IgE allergy under the term food intolerance (FI). Non-allergic reactions to food may be attributable to a variety of mechanisms, some known and some unknown, including enzyme defects and pharmacological reactions. Symptoms of FI most commonly affect the skin or gut, and usually occur some hours following ingestion of the food. Symptoms can range from mild/ moderate (colic, reflux, bloating, constipation) to severe (severe persistent vomiting or diarrhoea, significant blood in stool, faltering growth). Thus, food intolerance is a heterogeneous group of disorders, including coeliac disease, lactose intolerance and symptoms of unknown aetiology, but patients are unified by the fact that they avoid foods that they believe cause adverse effects. Unlike IgE mediated allergy, there is usually no easy test to confirm a diagnosis of food intolerance and patients are frequently self-diagnosed. The impact of food intolerance extends beyond the physical to the social, emotional and financial (4-9) and this is likely to be true for individuals with a well-defined underlying condition as well as those in whom the cause is unclear. Avoidance of the trigger food(s) is the cornerstone in the management of both FA and FI. Although generally asymptomatic, the constant need for vigilance when shopping or eating, and the fear of a reaction impacts on the health related quality of life (HRQL) of affected individuals and their families. As such, HRQL has been argued to be a meaningful outcome measure available for individuals with reactions to food (10).

Disease specific questionnaires have been developed and validated (10-13) for individuals with IgE-mediated food allergy, providing a valuable tool in clinical research settings (14-16). Differences can exist between FI and FA in a number of factors that affect health-related quality of life, including speed of onset of reactions, dose to trigger a reaction, symptoms, availability of 'rescue' medication, and long-term health implications. However, there are no FI-specific questionnaires. This presents a difficulty for health professionals and practitioners, researchers and policy makers in the area of food hypersensitivity. Therefore we sought to develop and validate a sensitive, multi-dimensional self-report measure for adults (>18 years) with FI. We modified the existing validated Food allergy Quality of Life (FAQLQ) questionnaire for adults (13;17) to ensure that the measure was suitable to assess quality of life in those with FI. We then carried out preliminary validation of the instrument in a large cross-sectional study.

Methods

FIQOL was developed by adapting a quality of life measure designed for adults with food allergy; the development included interviews with 14 individuals with food intolerance. Then, 229 adults with food intolerance participated in the psychometric validation of FIQLQ.

The Research Ethics Committee of the School of Applied Psychology, UCC provided approval for the study. Data was stored in compliance with data protection laws.

Participants

A commercial research recruitment company, Acumen Fieldwork-Medical, recruited participants for the cognitive interviews using an online survey, ensuring that we included all regions of the UK.

Participants for the psychometric validation were recruited by the patient organizations Coeliac UK (20.1%), Allergy UK (40.2%) and Anaphylaxis Campaign (1.3%) via their websites and social media. The remainder (38.4%) were recruited by Acumen Fieldwork-Medical.

We screened respondents >18 years to ensure they had symptoms of food intolerance. They needed to avoid foods in their diet in order to prevent adverse reactions to one of the 14 food allergens listed in EU Regulation 1169/2011. We excluded respondents who described symptoms suggestive of IgE mediated allergy, or if they were prescribed treatments indicative of IgE allergy.

Materials and Measures

We used the Food Allergy Quality of Life questionnaire, Adult Form (FAQLQ-AF) as the basis to develop FIQLQ. The FAQLQ is a disease-specific HRQL questionnaire with excellent validity, and reliability for adults with food allergy. It contains 29 items, each scored on a scale from 1 (minimal impairment in HRQL) to 7 (maximal impairment in HRQL).

Since there does not exist a food intolerance specific questionnaire at present, we used the Food Allergy Independent Measure (FAIM) as one of several measures to assess validity. The FAIM assesses perceived risks and expected prognosis of food allergic individuals (18). It has 7 items answered on a 1-7 response scale with a greater score indicating a higher level of perceived risk of adverse outcome. Subjective expectation of outcome is a reliable predictor and correlate of self-reported HRQL in food allergy and in other chronic diseases. For the purposes of this study, we will refer to the measure as the Food Intolerance Independent Measure (FIIM).

Development of FIQLQ and FIIM

We conducted cognitive interviews with 14 adults with food intolerance, using the allergy-specific instruments FAQLQ and FAIM as the starting point for discussions. Before the interview, participants received an information pack by post, including copies of the FAQLQ and the FAIM questionnaires. During the interviews, which we conducted by telephone, participants were asked to reflect on each item in the allergy-specific questionnaires and on the overall instruments. Specifically, they were asked to rate *'how relevant is this question?'* and *'how important is this question to the impact of food intolerance on your health related quality of life?'* on a scale of 0-5 (0 = not at all relevant; 5= very relevant). The interviewer (ADG) also asked *'Are there any questions that are not in the questionnaire which should be added to capture the impact of food intolerance on the quality of life of an*

adult with food intolerance? Are there questions which should be reworded? What wording would you suggest? Interpretation and understanding of items was assessed by asking participants to repeat the question in their own words. The FIIM was assessed in the same way.

Analyses of the interviews were used to develop the FIQLQ questionnaire. We calculated the overall importance (OI) of each item by multiplying the proportion of participants endorsing the relevance of that item with the mean importance score attached to the item. (OI=endorsement x mean importance). Items with the highest OI were retained (cut-off >2.0 (19-20)), **and those below this point were dropped.** We added new questions and amended wording to ensure the new instruments addressed the needs of people with FI.

Psychometric validation of the FIQLQ

Two hundred and twenty nine adults completed the online survey. The first section contained screening questions to ensure participants met the inclusion criteria. The second section contained the FIQLQ; response scores ranged from 1 to 7 and higher scores indicated worse health-related quality of life. The third section contained the Food Intolerance Independent Measure (FIIM). Finally, participants answered independent questions that we used to test whether FIQLQ scales were testing the constructs that we anticipated. For example, *"How would you describe your emotional well-being?"*, *"What level of stress does your adverse food reaction cause you?"* and *"How much is your food intolerance limited the type of activities you partaking?"*

We performed analyses using Statistical Package for Social Sciences (IBM SPSS Statistics version 20). First, we examined the distribution of responses for each item. **Secondly**, we used exploratory factor analysis to identify potential subscales, **which were then named according to the content of the items in each.** An oblique rotation was performed as the subscales were assumed to be correlated. Three widely accepted tests were used to determine the number of factors in the final structure; the Kaiser Guttman criterion, the scree test (to visually assess which components or factors explain most of the variability in the data) and a parallel analysis using Monte Carlo software (19-22).

Factor analysis also assessed the extent to which items correlated with their subscale; we required item-to-subscale correlations ≥ 0.40 . Floor and ceiling effects were considered non-problematic if $<15\%$ of participants had the highest or lowest scores for each subscale. Internal consistency of FIQLQ and its subscales was assessed by Cronbach's α values; a value of >0.07 indicated good internal consistency.

Construct validity was assessed by testing the total score and subscale scores against *a priori* hypotheses. We hypothesized that total FIQLQ scores would be worse for older age groups, for women, for individuals with more symptoms and for people avoiding **more than two** foods. **Concurrent** validity was assessed by the validity coefficient between the FIQLQ, FIIM, and level of stress because of FI. Validity coefficients, unlike reliability coefficients rarely exceed $r=0.4$, particularly where a single test is used (23).

FIQLQ total score, and the other independent variables were not expected to correlate highly with FIIM since they are assumed to measure different, although related, constructs.

We hypothesised:

- Emotional Impact score to be related to (a) "what level of stress does your FI cause you?" and (b) FIIM score
- Social and Dietary Restriction subscale to be related to (a) "how much has food intolerance limited the type of activities you partaking?" and (b) "stress caused to family and friends"
- Reactions and Avoidance subscale to be related to (a) "how safe is eating out or getting takeaway?" and (b) number of symptoms.

Results

Characteristics of participants for the development study and for the preliminary psychometric validation study are in Table 1. The participants all reported symptoms of intolerance, but were excluded if they had IgE mediated allergy. The sample population therefore includes people with self-reported coeliac disease, lactose intolerance and other undefined intolerances.

Development of FIQLQ

The majority of the items in the FAQLQ (> 70%) were rated as 'relevant' or 'very relevant' by participants with FI, and wording was merely modified to make these questions specific for intolerant rather than allergic individuals. Participants considered 11 items to be irrelevant for them (**OI <0.2**), therefore we dropped these items. Four items, which were not in the food allergy-specific measure, were suggested for inclusion in FIQLQ by interviewees; how troublesome do you find it that the quality and clarity of labelling is poor in general?; do you experience physical distress from symptoms during a reaction?; you will be embarrassed by the symptoms of a reaction in social situations?; you are concerned about the impact on your health? This process resulted in 18 items in FIQLQ.

The FAIM had 6 items, 5 of which were endorsed as 'very relevant' by adults with food intolerance. 'Dying from an accidental ingestion' was not considered relevant by FI participants, and this item was removed for the FIIM. This was replaced by the item 'can easily avoid something to which you are intolerant'. One modification to wording was suggested, with the phrase 'effectively manage a reaction' replacing 'effectively deal with a reaction' (Table 2).

Psychometric validation.

Two hundred and twenty nine participants completed the FIQLQ in electronic on-line format. Response scores ranged from 1 to 7 (not at all - extremely). Higher scores indicated higher burden or worse health-related quality of life. **We compared the missing and non-missing cases on variables where information is not missing. Missing scores were negligible (2.2%) and had no impact on results.**

Overall, 26% of participants were self-diagnosed based on their experience of foods which had caused adverse reactions, and the remainder were diagnosed by general practitioners, hospital consultants, complementary therapists or dieticians (Table 3). The majority of participants were intolerant to cereals containing gluten (72%) and/or milk (40%). Allergens not listed in the EU regulations included fruit and vegetables, and chemical additives (Table 3). Gastrointestinal symptoms were the most frequently reported symptoms including, stomach cramps (75%), bloating and constipation (74%), and diarrhoea (69%).

Development of subscales: We used factor analysis to develop subscales. The KMO measure of sampling adequacy was exceeded (>0.60) with Bartlett's test of sphericity $p < 0.0001$, demonstrating that factor analysis was suitable. Oblique rotation resulted in 3 subscales with factor loadings >0.4 , explaining 67% of the variance in the FIQLQ. Parallel analysis using Monte Carlo software supported our decision to retain three factors. Three meaningful subscales emerged: Emotional Impact (EI) had 8 items, Social and Dietary Restrictions (SDR) had 6 items and Reactions and Avoidance (R&A) had 4 items (Table 4). The subscales were scored on a scale ranging from 1-7 with higher scores indicating worse HRQL. Scores were calculated from subscale total/number of Items in subscale: EI 5.6 (SD 1.2); SDR 5.6 (SD 1.3); R&A 4.8 (SD 1.5). The FIQLQ total score was calculated from the sum of all scores/ 18; mean total score 5.4 (SD 1.1). There were no floor or ceiling effects for EI or R&A scales, and no floor effect for the SDR scale (all $<15\%$). A ceiling effect was observed for the SDR scale, with 19.7% of respondents reporting high scores.

Reliability: The FIQLQ subscales had strong internal consistency with Cronbach's α of the total score and sub-scales ranging from 0.81 to 0.94. Subscale to total score correlations were all >0.8 , and subscale to subscale correlations >0.4 , indicating a unitary construct, i.e. all three subscales are useful in evaluating HRQL in food intolerance, but each also makes a unique contribution to the overall score.

Construct Validity of Subscales Score: We had hypothesized that total FIQLQ scores would be worse for older age groups, for women, for individuals with more symptoms and for people avoiding more **than two foods**. Although there was no difference between total FIQLQ scores for women ($M = 5.4, SD 1.2$) in comparison to men ($M = 5.4, SD 0.9$) $p > 0.05$, we confirmed significant correlations for all of these other relationships (Table 5). As predicted EI was related to FIIM and to the item "what level of stress does your FI cause you?"; the SDR subscale correlated moderately with "how much has food intolerance limited the type of activities you partaking?" and to the level of "stress caused to family and friends"; whilst R&A correlated moderately with the item "how safe is eating out or getting takeaway?", and there was a small correlation with the number of symptoms reported (Table 5).

Concurrent validity of the subscales and total score: A test is considered to be 'very beneficial' if validity coefficient values are above 0.35 (23). Moderate significant correlations were found between the FIIM with the three subscales and with Total FIQLQ score (EI $r=0.388$; SDR $r=0.318$; R&A $r=0.448$; Total FIQLQ $r=0.429$). Limitations in social activities with family or friends (EI $r=0.509$; SDR $r=0.519$; R&A $r=0.393$; Total FIQLQ $r=0.544$) was significantly related to the impact of food intolerance. The subscales were negatively correlated with the questions 'how enjoyable do you find eating out/take away' (EI $r=-0.463$; SDR $r=-0.395$; R&A $r=-0.312$; Total FIQLQ $r=-0.448$) and 'how safe is eating out/take away' (EI $r=-0.519$; SDR $r=-0.420$; R&A $r=-0.331$; Total FIQLQ $r=-0.495$). Therefore, as perception of enjoyment and safety decrease, burden on HRQL increases, showing good preliminary construct and concurrent validity of the measure.

Discussion

We have developed and carried out a preliminary validation of the first multi-dimensional self-report questionnaire to measure the impact of food intolerance on HRQL for adults. Valid and reliable instruments are needed to measure any changes in HRQL following clinical, therapeutic or policy interventions. Disease specific questionnaires are routinely used in such a framework and have proved useful both in research and clinical settings for IgE-mediated food allergy. Therefore, we modified the existing validated Food Allergy Quality of Life for Adults questionnaire (FAQLQ AF) to ensure that the measure was suitable to assess quality of life in those with FI. We then validated the instrument in a large cross-sectional study. The process of the modification and development of the questionnaire consisted of cognitive interviews, clinical impact methods and psychometric examination of internal consistency reliability, concurrent and construct validity.

Internal consistency reliability was excellent. Three meaningful factors/subscales emerged from the factor analysis for the FIQLQ: Emotional Impact, Dietary and Social Restrictions, Reactions and Avoidance. As hypothesized, significant moderate correlations were found between the subscale scores of the FIQLQ and relevant independent variables. Therefore, the subscales provide a unique but related contribution to explaining the impact of food intolerance on quality of life. A moderate significant relationship was found

between the total score on the FIQLQ and the Food Intolerance Independent Measure (FIIM). As expected, lower correlations were found between the FIIM and the FIQLQ than were found previously between the FAQLQ and the FAIM (12;17); the consequences for an individual experiencing a reaction in food intolerance are often not as severe or immediate as those experienced by those with IgE mediated food allergy, where life-threatening anaphylaxis may be an outcome. Psychological factors in patients, including the expectation of outcome following a reaction, have been found to be important contributors to the success of many different treatments, and may be an important predictor for treatment outcomes (23-26). If individual's expectation of the likelihood of a reaction is high and the likelihood of managing that reaction is low, then it follows that the individual would be more likely to avoid social events and limit the variety of foods consumed, compared to individuals who expect a less adverse outcome. The moderating effects of other factors, such as number of symptoms experienced, must also be taken into account, for example, those who reported two or more symptoms had worse HRQL than those who report only one.

Coeliac disease is a relatively common food intolerance and 72% of our validation cohort reported intolerance to gluten containing cereals. In previous research, more than one third of the participants with coeliac disease reported feeling angry 'always' or 'most of the time' by having to follow the gluten-free diet. Nearly, 20% reported feeling different from others and misunderstood because of coeliac disease (9). Roma et al (2010) reported that families experienced difficulties detecting gluten from the food label. The authors suggested quality of life could be improved with better labelling of gluten-containing ingredients and more gluten-free foods in supermarkets and restaurants. The effect of coeliac disease continues to have a substantial impact on patient's lives several years after diagnosis with reduced enjoyment of food, less social activity, regular frustration with the dietary restrictions and greater anxiety about general health (8). Although an immediate fatal reaction is not an expected outcome for those with coeliac disease or other food intolerance, factors such as uncertainty around diagnosis, complexity and confusion about which foods are safe to eat and buy, frustration about restrictions, and worries about long-term health confer a significant burden (27). Furthermore, if a food challenge determines

that a patient has food intolerance and not food allergy, the measure will allow for an alternative evaluation of HRQL, and for an appropriate self-care and management protocol to be put in place.

There were limitations in the present study. The FIQLQ and the FIIM were modified from existing instruments rather than developed *de novo*. Preliminary validation suggests that the instrument performs well. Further evaluation with new samples will be carried out, including test/re-test reliability analysis, confirmatory factor analysis and longitudinal analysis in order to confirm and to extend our findings. As in any self-report questionnaires, participants may confuse general adverse impact in their lives with the specific impact of food intolerance. We attempted to minimise this by including the phrase 'because of food intolerance....' after every short series of questions throughout the questionnaire.

The FIQLQ questionnaire is presented in a single short form with 18 questions. The three subscale scores can be calculated simply as the mean of each subscale, and the total score is calculated as the mean of all items. The Food and Drug Administration (FDA) advise calculating and presenting subscale scores particularly in clinical trials, since each subscale may be impacted differently by an intervention (28).

To conclude, our preliminary validation studies demonstrate that the FIQLQ is a reliable and valid tool with good construct validity. The use of patient-reported HRQL measures to better assess clinical and policy outcomes is an important goal of evidence-based medicine and the social sciences. Such measures can form a useful part of clinical decision systems, including guidelines for the management of food related chronic diseases.

Declarations

Ethics approval and consent to participate

The Research Ethics Committee of the School of Applied Psychology, UCC provided approval for the study. Data was stored in compliance with data protection laws. Consent for participation form was provided and signed by all participants in all phases of the study prior to participation.

Consent for publication

Consent for participation and publication form was provided and signed by all participants in all phases of the study prior to participation. Available on request.

Availability of data and material

Data is stored in compliance with data protection laws in School of Applied Psychology, University College Cork, College Rd., Cork City, Ireland; and Department of Psychology, University of Bath, Claverton Down, Bath, North East Somerset BA2 7AY, United Kingdom.

Competing interests

No competing interests for any of the authors, according to BioMed Central criteria.

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Authors' contributions

JB & JL conceived the study and was involved in design and co-ordination of study; ADG drafted the paper and carried out data analysis; KR & FB collected data and assisted in data analysis. All authors helped in final editing of paper and all authors read and approved the final manuscript.

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