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Trabajo Original

Epidemiología y dietética

Design and validity of the Spanish version of two questionnaires related to adverse reactions to foodstuffs

Diseño y validación de la versión española de dos cuestionarios relacionados con reacciones adversas a alimentos

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Abstract

Introduction: there is an emerging current necessity of valid questionnaires, encompassing most of food, beverages, diseases, signs and symptoms currently related to the pathogenesis of adverse reactions to foodstuffs (ARFS) in the Spanish population.

Objectives: this study aimed to design and validate two questionnaires to assess ARFS in the Spanish population, Food and Beverages Frequency Consumption Questionnaire to Identify Adverse Reactions to Foodstuffs (FBFC-ARFSQ-18); and Pathologies and Symptomatology Questionnaire associated with Adverse Reactions to Foodstuffs (PSIMP-ARFSQ-10).

Methods: both questionnaires were designed adapting questionnaires from the literature; and validated, using the expert judgment method, in five phases: questionnaires development, pilot test and reliability, content validity, face validity, and ethical considerations. Questionnaires were developed using the REDCap™ tool hosted at the Universidad Politécnica de Madrid. A total of 20 Spanish experts evaluated the questionnaires. Cronbach's alpha reliability coefficients were calculated using SPSS version 25.0 (IBM Corp., Armonk, NY-USA) and Aiken's V coefficient values were calculated using ICaiken.exe (Visual Basic 6.0, Lima-Perú).

Results: a final construct of questions was designed, ensuring no overlap, for FBFC-ARFSQ-18 and PSIMP-ARFSQ-10. Cronbach's alpha reliability coefficients were 0.93 and 0.94; and Aiken's V coefficient values were 0.90 (0.78-0.96 CI) and 0.93 (0.81-0.98 CI) for FBFC-ARFSQ-18 and PSIMP-ARFSQ-10, respectively.

Conclusions: both validated questionnaires could be used to analyze the association between certain food and beverages consumption with ARFS, such as food allergies and food intolerances; also, to investigate the link between some specific diseases, signs and symptoms with ARFS.

Keywords:

Adverse effects. Disease management. Food and beverages. Reliability and validity. Surveys and questionnaires. Symptom assessment. Validation study.

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Resumen

Introducción: actualmente, existe una necesidad emergente de cuestionarios validados que abarquen la mayor parte de los alimentos, bebidas, enfermedades, signos y síntomas relacionados con la patogénesis de las reacciones adversas a los alimentos (RAA).

Objetivos: diseñar y validar dos cuestionarios para evaluar las RAA en población española, el Cuestionario de Frecuencia de Consumo de Alimentos y Bebidas para Identificar Reacciones Adversas de Origen Alimentario (CFCAB-RAA-18); y el Cuestionario de Patologías y Sintomatología Asociadas a Reacciones Adversas a Alimentos (PSIMP-RAA-10).

Métodos: ambos cuestionarios se diseñaron adaptando cuestionarios de la literatura y se validaron, utilizando el método de juicio de expertos, en cinco fases: desarrollo de cuestionarios, prueba piloto y confiabilidad, validez de contenido, validez aparente y consideraciones éticas. Los cuestionarios se desarrollaron utilizando la herramienta REDCap™. Un total de 20 expertos evaluaron los cuestionarios. Se calcularon coeficientes de confiabilidad alfa de Cronbach con SPSS versión 25.0 (IBM Corp., Armonk, NY-Estados Unidos) y valores del coeficiente V de Aiken con ICaiken.exe (Visual Basic 6.0, Lima-Perú).

Resultados: se diseñó una construcción final de preguntas, evitando solapamiento entre ambas herramientas. Los coeficientes de confiabilidad alfa de Cronbach fueron 0,93 y 0,94, y los valores del coeficiente V de Aiken fueron 0,90 (IC: 0,78-0,96) y 0,93 (IC: 0,81-0,98) (CFCAB-RAA-18 y PSIMP-RAA-10, respectivamente).

Conclusiones: ambos cuestionarios fueron validados y podrían utilizarse para analizar la asociación entre el consumo de determinados alimentos y bebidas con las RAA, como alergias e intolerancias alimentarias, así como para investigar el vínculo entre algunas enfermedades, signos y síntomas específicos con las RAA.

Palabras clave:

Alimentos y bebidas. Cuestionarios. Fiabilidad. Reacciones adversas. Síntomas y signos. Validez.

INTRODUCTION

The global prevalence of adverse reactions to foodstuffs (ARFS), including components of food and beverages allergy (CFBA) and components of food and beverages intolerance (CFBI), in developed countries is around 30 %, with a female dominance in adults of 60 %, representing an emerging public health concern (1,2). CFBA and CFBI can start at any age; in fact, there is an increased reported incidence of new-onset CFBA in adults (one adult for every four children) (1-3). A detailed record of the consumption of any substance that is used as food and beverages or to make food and beverages (foodstuffs) and a clinical history are essential keys for the diagnosis, management, analysis and the study of ARFS (2,4). The consumption of specific foodstuffs can induce a wide range of adverse reactions ranging from abdominal swelling to life-threatening anaphylaxis (5). The relationship of foodstuffs intake, that may cause ARFS, and the analogous diseases and symptomatology make it challenging for researchers and physicians to establish a proper analysis of ARFS.

Several approaches of tools have been launched to identify food and beverages frequency consumption in the adult population with ARFS, focusing on CFBA and celiac disease (CD): Gluten Food Frequency Questionnaire (G-FFQ) (6), the Global Allergy and Asthma European Network (GA2LEN) FFQ (7) and the Pregnancy FFQ (8). Similarly, various tools have been designed to screen a CFBA such as the CFBA Screening Questionnaire (9), the Food Allergy Questionnaire (FAQ) (10), the Allergy Questionnaire for Athletes (AQUA©) (11), the Lahey Health Allergy Questionnaire (12) and the Weill Cornell Medicine Adult Allergy Questionnaire (13). There are also separate tools available to identify specific groups of symptoms by system, such as the Gastrointestinal Symptom Rating Scale (GSRS), the self-reported Skin Complaints Questionnaire (14), the Sensitive Skin Questionnaire (15) or the UCLA Dizziness Questionnaire (UCLA-DQ) (16).

Health professionals can frequently confuse non-adverse reactions to food and beverages with ARFS, especially when using only one of the tools available without considering a group of appropriate questionnaires, or their adaptation, for the population or patient of interest (17). The diagnosis of CFBA can be confirmed with a physical exploration, clinical history, oral food challenge (OFC) or by evidence of sensitization to the culprit using, for example, skin prick test (SPT) or serologic testing measuring food-specific immunoglobulin E (IgE) by a physician. However, it has been highly suggested by previous studies (18,19), specially by the European Academy of Allergy and Clinical Immunology (EAACI) (20), to support any of the clinical tests using adequate questionnaires, to report both, foodstuffs consumption and symptomatology, as the strongest predictors of a probable CFBA (20). Nowadays, food behavior, the expansion and management of diseases and the relationship between them is evolving in developing countries (21,22). There are extensive new foodstuffs consumed in the Mediterranean Spanish area besides those belonging to the Mediterranean diet (MD); diets are becoming highly processed and several fad diets are appearing (22,23). In addition, various pathologies and diseases are currently being investigated for their potential to have a direct or indirect relationship to ARFS: atopic dermatitis (24), irritable bowel syndrome (IBS) (25), and other diseases (26,27). In this sense, to identify all the main food consumption, pathologies and symptomatology that influence ARFS, focusing on CFBA and CFBI characteristics, designing and validating a specific tool should be a priority for an efficient diagnosis, analysis and study of ARFS.

However, there is no consensus or validated questionnaire to measure, in the Spanish population, up-to-date food and beverages consumption, including current available food groups, diets, new foodstuffs and all types of possible diseases, symptoms and signs that may have a current, potential and direct relation to ARFS (not only to CFBA). Therefore, as part of a broader investigation, the objectives of this study were to design and validate, through the expert judgement method, two questionnaires to assess ARFS for the Spanish population: the Food and Beverages Frequency Consumption Questionnaire to identify Adverse Reactions to Foodstuffs (FBFC-ARFSQ-18) (*Cuestionario de Frecuencia de Consumo de Alimentos y Bebidas para Identificar Reacciones Adversas de Origen Alimentario*, CFCAB-RAA-18);

and the Pathologies and Symptomatology Questionnaire Associated with Adverse Reactions to Foodstuffs (PSIMP-ARFSQ-10) (*Cuestionario de Patologías y Sintomatología Asociadas a Reacciones Adversas a Alimentos*, PSIMP-RAA-10). Both objectives, as a first step to facilitate the identification of a population with a high probability of having ARFS, are under the umbrella of the subsequent ARFS analysis initiative through a follow-up study.

MATERIALS AND METHODS

This study developed and validated the FBFC-ARFSQ-18 and the PSIMP-ARFSQ-10 questionnaires using the expert judgement method over the following phases: a) questionnaires development; b) pilot test and reliability; c) content validity; d) face validity; and e) ethical considerations (Fig. 1).

PHASE 1: QUESTIONNAIRES DEVELOPMENT

Both questionnaires were previously adapted with available tools found in the literature to the particularities of ARFS. The FBFC-ARFSQ-18 questionnaire used a basis-format of the semiquantitative Fernández-Ballart JD et al. FFQ (28) and the International Statistical Classification of Diseases and Related Health Problems (ICD-10) was followed for the PSIMP-ARFSQ-10 questionnaire (29). Tools were designed and structured according to the researchers' insights (authors of this study). Items of FBFC-ARFSQ-18 were intended as food groups and items of PSIMP-ARFSQ-10 were designed as diseases and symptomatology of a human body system. Food groups of the FBFC-ARFSQ-18 consisted in foodstuffs with possible causative food allergens proposed by Lyons et al. (20) (Annex I; https://www.nutricionhospitalaria.org/anexos/04631-01.pdf). Initially, there were 21 items for the FBFC-ARFSQ-18 tool, however, "vegetables, garden vegetables and legume" were consolidated as a single item. Similarly, olive oil was added to item 15 "other food groups", acquiring 18 items. Likewise, there were initially five items as five human body systems as a starting point for the PSIMP-ARFSQ-10 (each item was separated into two categories, "diseases or pathologies" and "symptoms and signs", acquiring ten items in accordance with the researchers' insights). The items of FBFC-ARFSQ-18 were classified into three sections (eating habits; frequency of consumption of food and beverages; and frequency of consumption of food supplements) to identify the eating patterns of interest in diets "free of" or "containing" allergens, components and/or foodstuffs related to ARFS that can possibly cause CFBA or CFBI. The items of PSIMP-ARFSQ-10 followed the ICD-10 classification (29) to stablish the human body systems

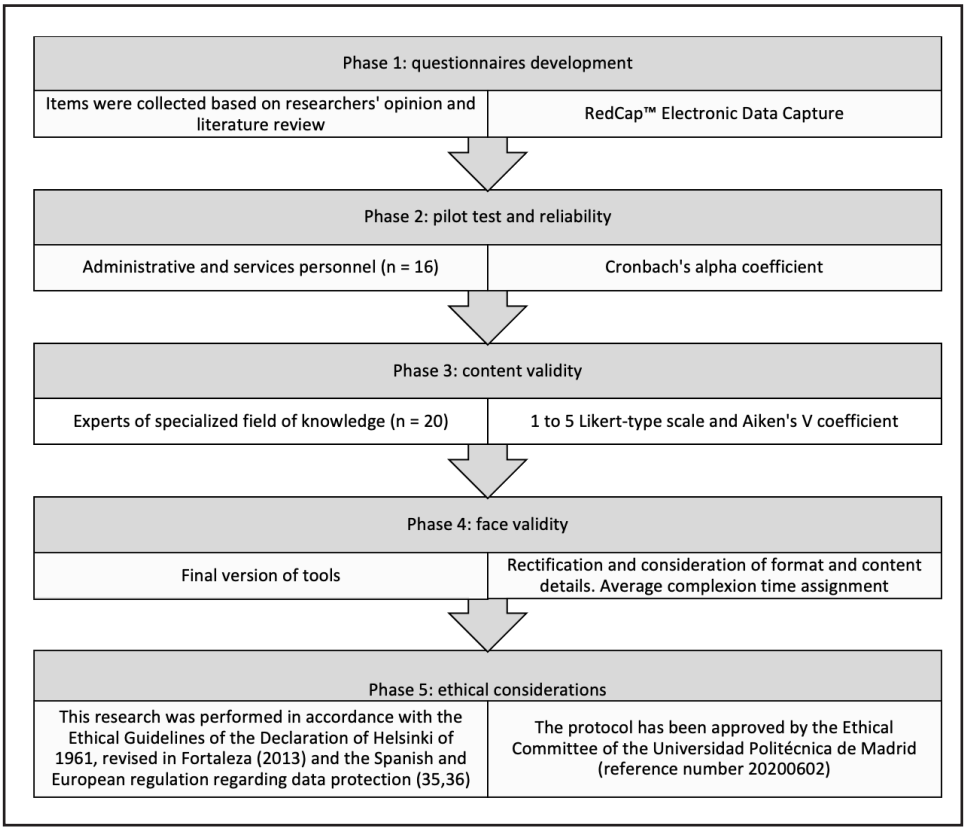

Figure 1.

Flow diagram of the phases involved in the design and validity using the expert judgement method of the FBFC-ARFSQ-18 and PSIMP-ARFSQ-10 questionnaires to assess ARFS.

and the EAACI guidelines (30) for the identification of the specific diseases, signs and symptoms related to ARFS (five sections: digestive system; skin and subcutaneous tissue; nervous system [NS]; respiratory system [RS]; and other human body systems [other diseases/pathologies, symptoms and signs, not elsewhere classified]). Both tools were hosted using RedCap™ (Research Electronic Data Capture), an electronic data capture program specifically designed for research and a secure web platform hosted at the Supercomputing and Visualization Center of Madrid (CESVIMA) of the Universidad Politécnica de Madrid (UPM). RedCap™ was also used to build and manage the online databases for both questionnaires.

Annex I.

PHASE 2: PILOT TEST AND RELIABILITY

Tools were evaluated by a pilot sample with similar characteristics to the target population to obtain qualitative assessments such as the identification of semantic errors, writing and comprehension. Inclusion criteria were: to be Spanish, living in the Region of Madrid, with age over or equal to 18 years (≥ 18 years), with non-scientific qualification (including students and retired) and presenting at least five diseases or subjective symptoms related to ARFS (Table I). Subjects with scientific background were excluded. Sampling was applied to the administrative and service personnel (ASP) of the Faculty of Physical Activity and Sport Sciences (INEF) of the UPM, to ensure evaluations by individuals who were not familiar with science. The complexion time of both questionnaires was recorded and evaluations of the approach of the items to their ARFS were calculated using the Cronbach's alpha reliability coefficient. Values greater than or equal to 0.80 (≥ 0.80) were considered as acceptable. Statistical analysis was carried out using SPSS Statistics software version 25.0 (31). At the end of the pilot test, the revised version of the tool was then reviewed by the expert judges for validation.

PHASE 3: CONTENT VALIDITY

Experts were recruited from different national research groups, hospitals, scientific institutions and universities using the contacts of the research group conducting this study (academics and practitioners of the intended field of knowledge). The inclusion criteria for being considered as an expert were: with age over or equal to 35 years old (≥ 35 years); over or equal to 15 years of career experience (≥ 15 years); academic background related to food science and/or nutrition (food science and technology professionals, dietitians, nutritionists, pharmacists, nurses and fam-

Table I. Descriptive data of the pilot sample for the adaptation of FBFC-ARFSQ-18 and PSIMP-ARFSQ-10

Evaluators	Age (years)	M/F	Country of birth	Residence	Qualification	Number of diseases, symptoms and signs related to ARFS
1	43	M	Spain	Region of Madrid	IT support	14
2	55	M	Spain	Region of Madrid	Administrative assistant	8
3	24	M	Spain	Region of Madrid	Student	16
4	24	F	Spain	Region of Madrid	Student	9
5	57	F	Spain	Region of Madrid	Administrative assistant	14
6	43	M	Spain	Region of Madrid	Audio-visual technician	7
7	44	F	Spain	Region of Madrid	Concierge	26
8	47	F	Spain	Region of Madrid	Technical assistant	7
9	55	M	Spain	Region of Madrid	Stationer	27
10	62	M	Spain	Region of Madrid	Concierge	19
11	58	F	Spain	Region of Madrid	Administrative assistant	19
12	64	F	Spain	Region of Madrid	Marketing assistant	11
13	33	M	Spain	Region of Madrid	Telecommunications technician	12
14	35	F	Spain	Region of Madrid	Security guard	6
15	64	F	Spain	Region of Madrid	Retired	8
16	66	M	Spain	Region of Madrid	Retired	13

ARFS: adverse reactions to foodstuffs; F: female; IT: information technology; M: male.

ily physicians) for the evaluation of FBFC-ARFSQ-18; and related to medicine and/or nursing (nurses and family physicians) for the evaluation of PSIMP-ARFSQ-10. A group of 33 experts were contacted, 15 experts with a wide experience in food science and/or nutrition for the FBFC-ARFSQ-18 questionnaire; and 18 experts with extensive experience in the field of medicine and/or nursing for the PSIMP-ARFSQ-10 questionnaire. After they received an e-mail invitation or on-line correspondence using a RedCap™ unique Uniform Resource Locator (URL) link, 28 experts consented to participate (15 experts for the FBFC-ARFSQ-18 and 13 experts for the PSIMP-ARFSQ-10). The final number of experts was 20 (eight experts were excluded for not accomplishing the inclusion criteria, not answering the evaluation questionnaire, or sending an incomplete evaluation).

Experts were asked to indicate below each item their opinion using an open box of comments and their degree of agreement, using a 1 to 5 Likert-type scale, where five points indicated the highest agreement and one, the lowest agreement. The standard deviations (SD) of the differences between scores have been established as a viable option for quantifying validity (32); thus, when an expert's evaluation was greater than or equal to 3 (≥ 3) SD different from the mean of the other nine experts in two or more questions (≥ 2), these values were not considered as valid because of the discordance with the rest of experts (33). The content validation coefficient for the final ten experts was calculated using Aiken's V coefficient (95 % confidence interval [CI]) and a minimum Aiken's V coefficient score of ≥ 0.75 was required for each question to be validated (33,34). Aiken's V coefficient and the lower and upper limits of confidence intervals were calculated using the software ICaiken.exe (Visual Basic 6.0, Lima, Perú) (34). Descriptive data of the experts are shown in tables III and IV.

Table II. Descriptive data of experts for the evaluation of FBFC-ARFSQ-18

Expert	Age (years)	M/F	Qualification	Highest degree	Career completion (year)	Career experience (years)
1	47	M	Human Nutrition and Dietetics	Ph.D.	2001	21
2	41	M	Pharmacy and Biochemistry	Ph.D.	2002	20
3	66	F	Nursing	MSc.	1977	45
4	65	F	Nursing	MSc.	1979	43
5	63	M	Medicine	Ph.D.	1982	40
6	71	M	Pharmacy and Nutrition	Ph.D.	1972	50
7	40	F	Human Nutrition and Dietetics, Food Science and Technology	Ph.D.	2004	18
8	49	F	Pharmacy	Ph.D.	1995	27
9	50	F	Pharmacy	Ph.D.	1999	23
10	64	M	Medicine	Ph.D.	1982	40

F: female; M: male; MSc: Master of Science; Ph.D.: Doctor of Philosophy.

Table III. Descriptive data of experts for the evaluation of PSIMP-ARFSQ-10

Expert	Age (years)	M/F	Qualification	Highest degree	Career completion (year)	Career experience (years)
1	66	F	Nursing	MSc.	1977	45
2	60	F	Medicine	Ph.D.	1992	30
3	65	F	Nursing	MSc.	1979	43
4	64	F	Nursing	MSc.	1977	45
5	65	M	Medicine	Ph.D.	1979	43
6	58	F	Medicine	Ph.D.	1985	37
7	57	F	Medicine	BSc.	1988	34
8	62	F	Medicine	Ph.D.	1983	39
9	50	M	Medicine	Ph.D.	1996	26
10	68	M	Medicine	Ph.D.	1979	43

BSc: Bachelor of Science; F: female; M: male; MSc: Master of Science; Ph.D.: Doctor of Philosophy.

Table IV. Likert-type scale values offered by the panel of experts in all FBFC-ARFSQ-18 items for validation

	FBFC-ARFSQ-18 validation									
	Expert 1	**Expert 2**	**Expert 3**	**Expert 4**	**Expert 5**	**Expert 6**	**Expert 7**	**Expert 8**	**Expert 9**	**Expert 10**
Item 1	5	5	5	2	5	5	3	5	4	5
Item 2	5	5	5	2	5	5	2	5	4	5
Item 3	5	5	5	5	5	5	4	5	5	5
Item 4	5	5	5	5	5	5	5	5	5	4
Item 5	5	5	5	5	4	5	5	5	5	5
Item 6	5	5	5	5	5	5	4	5	5	5
Item 7	5	5	5	5	5	4	4	5	5	5
Item 8	5	5	5	5	5	4	4	5	3	5
Item 9	5	5	5	4	5	5	4	5	5	5
Item 10	5	5	5	2	5	4	4	5	5	5
Item 11	5	5	5	2	5	3	5	5	3	5
Item 12	5	5	5	5	5	5	5	5	3	4
Item 13	5	5	5	3	5	4	4	5	4	5
Item 14	5	5	5	5	5	3	5	5	3	5
Item 15	5	5	5	3	5	4	5	5	5	5
Item 16	4	5	5	5	5	4	5	5	5	5
Item 17	4	5	5	5	5	4	4	5	1*	4
Item 18	5	5	5	5	5	3	4	5	2	4

*FBFC-ARFSQ-18: Food and Beverages Frequency Consumption Questionnaire to Identify Adverse Reactions to Foodstuffs. *Values ≥ 3 SD of the mean of the rest of the nine experts.*

PHASE 4: FACE VALIDITY

Open questions after each domain or section of each questionnaire were placed for experts to analyze if the categories of each questionnaire captured the intended concept; and also, to specify what experts thought the questionnaire measured, possible missing items and what they thought in general means. The percentage of experts who commented at least one section was recorded, as well as the mean complexion time of each questionnaire (data described in the Results section, Phase 4 of this document).

PHASE 5: ETHICAL CONSIDERATIONS

This research was performed in accordance with the Ethical Guidelines of the Declaration of Helsinki of 1961, revised in Fortaleza (2013) (35) and following the Spanish and European regulations on data protection (36). The protocol has been approved by the Ethics Committee of the UPM (reference number 20200602).

RESULTS

PHASE 1: QUESTIONNAIRES DEVELOPMENT

The final pool of items was categorized into three sections for the FBFC-ARFSQ-18 (eating habits, food and beverages frequency consumption and food supplement frequency consumption) and five sections for the PSIMP-ARFSQ-10 (digestive system, skin and subcutaneous tissue, nervous system, respiratory system and other human body systems [other diseases/pathologies, symptoms and signs, not elsewhere classified]). Both validated tools followed the recommendations of previous studies (9,14,20,37).

Items 1 and 2 of the FBFC-ARFSQ-18 were based on the timing of food and beverages intake, an aggregation of the number of the individual foods, main meals and food and beverages intake between meals, both to represent more closely the required food and beverages consumption patterns recommended in a previous structural validation European FFQ (37). Items 3 and 4 describe the most reported aspects of concern when it comes to ARFS: type of diet (vegan, gluten-free, fermentable oligosac-

charides, disaccharides, monosaccharides and polyols [FODMAP], biogenic amines, etc.) and type of foodstuff (processed, non-processed and type of preserved products), especially when comparing regular population and athletes (5,26,38). Items 16, 17 and 18 were added to more deeply investigate the whole food intake of the population with possible ARFS including food supplements (probiotics, vitamin D), which are not very common in a FFQ but of high significance in the pathogenesis of ARFS (25,39). Items 5 to 15 corresponded to eleven food groups designed to be answered based on the consumption of a participant or patient in the last six months with a scale describing the monthly, weekly or daily intake of each foodstuff. There is plenty of information on paediatric oral immunotherapies (OIT) and the required time interval, for an ARFS observation, after changing a specific food intake. However, some case studies with adults suggest a minimum observation of three to six months (18,40). Trying to fill in the gaps, the present study proposes the FBFC-ARFSQ-18, describing the food and beverages intake during the last six months, for the Spanish population to support the current clinical tools of diagnosis and to obtain a meaningful approach from a population with possible ARFS.

All items (from 1 to 10) of the PSIMP-ARFSQ-10 included four body categories of diseases and symptomatology (digestive, skin and subcutaneous tissue, nervous system, respiratory system) and one category of other human body systems (other diseases/pathologies, symptoms and signs, not elsewhere classified). All of these items were designed to be answered with a yes or no question with a special annotation for the questions about pathologies and diseases that if the answer is "yes", the pathology may have medical diagnosis. This annotation was made to assess the awareness of a valid relationship with ARFS. The experts agreed with the relevance of this nature of the question and considered it as a reductor of bias in self-perception of discomfort towards ARFS. Finally all pathologies and symptomatology sections have an ending question to select other diseases or symptomatology related to the same body system. There could still be some case studies approaching pathologies such as mononucleosis and CFBA (41). A final construct of questions was designed for both tools, ensuring no overlap (Annex I; https://www.nutricionhospitalaria.org/anexos/04631-01.pdf).

PHASE 2: PILOT TEST AND RELIABILITY

The pilot test was completed by 16 INEF-UPM ASP evaluators, aged 24 to 66 years (50 % women, 48.38 ± 13.96 years), during December 2021 (Table I). Three observations regarding clarity and comprehension were considered for the final version: another level for the frequency scale for food and beverages in the FBFC-ARFSQ-18 tool, "< 1 time per month", between "never" and "1 to 3 times per month"; notification of the approximate complexion time to fill each questionnaire in the instructions section of both tools; and the addition of "with medical diagnostic" after the option "yes" in the PSIMP-ARFSQ-10 tool. The average complexion time for both questionnaires, reported by ASP, was 15:05 and 6:34 minutes for the FBFC-ARFSQ-18 and PSIMP-ARFSQ-10 tools, respectively. Cronbach's alpha reliability coefficient was greater than 0.80 in both cases: 0.93 for FBFC-ARFSQ-18 and 0.94 for PSIMP-ARFSQ-10.

PHASE 3: CONTENT VALIDITY

A total of 20 Spanish experts accomplished the inclusion criteria. Five experts of the FBFC-ARFSQ-18 and three experts of the PSIMP-ARFSQ-10 were excluded; two experts did not accomplish one of the inclusion criteria and the other six, for various reasons, as not answering the evaluation questionnaire, or sending an incomplete evaluation. All experts were different and none of the experts evaluated both questionnaires (ten food science and/or nutrition professionals aged mean ± SD 55.6 ± 11.37 years evaluated the FBFC-ARFSQ-18; and ten medicine and/or nursing professionals aged mean ± SD 61.5 ± 5.38 years evaluated the PSIMP-ARFSQ-10) (Tables II and III).

Resulting values of the Likert-type scale by the ten selected experts for both questionnaires are shown in tables IV and V. Aiken's V coefficient values were greater than 0.75 in both cases: 0.90 (0.78-0.96 CI) for the FBFC-ARFSQ-18 and 0.93 (0.81-0.98 CI) for the PSIMP-ARFSQ-10 (Table VI).

PHASE 4: FACE VALIDITY

Food groups of the FBFC-ARFSQ-18 were organized in ten food groups in section 2 of the FBFC-ARFSQ-18 (Annex I https://www.nutricionhospitalaria.org/anexos/04631-01.pdf). In the FBFC-ARFSQ-18, due to the Spanish diet habits, sunflower (item 6) and olive oil (item 15) were separated, according to the recommendations of expert 7, into independent questions inside their corresponding food group. Each foodstuff represented a single question, and all their common commercial formats or types of packaging were merged in the same question. Foodstuffs that were not listed into each food group (e.g., currant, passion fruit, or any other less common food in the Mediterranean Spanish area) could be described and reported by selecting the option "Other food or beverages of this Group. Specify". Analogously, the diseases recommended by experts 1 and 3 (otitis, short bowel syndrome [SBS] and small-intestinal bacterial overgrowth [SIBO]) and the symptoms recommended by experts 1 and 6 (muscle cramps, sleep apnea, dyspnea and snoring) were included in the PSIMP-ARFSQ-10 questionnaire. Peripheral edema was relocated from item 4 ("Symptoms and signs of the skin and subcutaneous tissue") to item 10 ("Other symptoms and signs"). Nine out of ten experts commented at least one section of the FBFC-ARFSQ-18 and the PSIMP-ARFSQ-10 tool (except for experts number 9 and 5, correspondingly of each questionnaire). The average of complexion time, reported by experts, to complete both questionnaires was 14:18 and 5:52 minutes

for FBFC-ARFSQ-18 and PSIMP-ARFSQ-10 tools, respectively (Annex II and Annex III; https://www.nutricionhospitalaria.org/anexos/04631-02.pdf).

Annex II
Annex III

DISCUSSION

Both RedCap™-designed questionnaires, FBFC-ARFSQ-18 and PSIMP-ARFSQ-10, for the Spanish population with possible ARFS were validated after a previous rigorous investigation about the current causative foodstuffs of ARFS (42), as well as the associated diseases and symptomatology recently reported (30,43). To make progress on science and in response to the demands of the conclusions of the articles of Garcia-Larsen et al. (7) and Cade et al. (44), the FBFC-ARFSQ-18 tool included the evaluation of not only a single food, such as milk or egg consumption to analyze allergy, but instead, it included most of the current investigated causative foodstuffs of ARFS, such as CFBA or CFBI (42). Similarly, it contributed to the improvement of the evaluation of associated diseases and symptomatology related to ARFS; apart from following the recommendations of previous studies by Makatsori et al. (45) and Schafer et al. (46), the PSIMP-ARFSQ-10 tool not only included the assessment of a single disease and its symptoms, but instead conveniently collected the current diseases, signs and symptoms related to ARFS.

Regarding the construction and design of the FBFC-ARFSQ-18, the scientific literature provides clear evidence about the possible causative food and beverages of a CFBA or CFBI. In self-reported studies (42,47), foodstuffs such as milk, apple, tomato, egg, kiwi,

Table V. Likert-type scale values offered by the panel of experts in all PSIMP-ARFSQ-10 items for validation

	PSIMP-ARFSQ-10 validation									
	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Expert 7	Expert 8	Expert 9	Expert 10
Item 1	5	5	5	5	3	4	4	5	5	5
Item 2	5	5	5	5	3	5	5	5	5	5
Item 3	5	5	5	5	2	5	4	5	5	5
Item 4	5	5	5	5	3	5	5	5	5	5
Item 5	5	5	5	5	4	5	5	5	5	5
Item 6	5	5	5	5	4	5	4	5	5	5
Item 7	5	5	5	5	2	4	4	5	5	5
Item 8	5	5	5	5	4	4	5	5	5	4
Item 9	5	5	4	5	4	4	5	5	5	5
Item 10	5	5	5	5	4	5	4	5	5	5

PSIMP-ARFSQ-10: Pathologies and Symptomatology Questionnaire Associated with Adverse Reactions to Foodstuffs.

Table VI. Number of experts pointing to each Likert-type scale value, mean score and Aiken's V coefficient for all items evaluated by experts

	FBFC-ARFSQ-18							PSIMP-ARFSQ-10						
	Likert-type scale*					Mean	Aiken's V (95 % CI) value (lower-upper limit)	Likert-type scale					Mean	Aiken's V (95 % CI) value (lower-upper limit)
	1	2	3	4	5			1	2	3	4	5		
	Number of experts							Number of experts						
Item 1	0	1	1	1	7	4.40	0.85 (0.71-0.93)	0	0	1	2	7	4.60	0.90 (0.77-0.96)
Item 2	0	2	0	1	7	4.30	0.83 (0.68-0.91)	0	0	1	0	9	4.80	0.95 (0.84-0.99)
Item 3	0	0	0	1	9	4.90	0.98 (0.87-0.99)	0	1	0	1	8	4.60	0.90 (0.77-0.96)
Item 4	0	0	0	1	9	4.90	0.98 (0.87-0.99)	0	0	1	0	9	4.80	0.95 (0.84-0.99)

(Continues on next page)

Table VI (Cont.). Number of experts pointing to each Likert-type scale value, mean score and Aiken's V coefficient for all items evaluated by experts

	FBFC-ARFSQ-18							PSIMP-ARFSQ-10						
	Likert-type scale*					Mean	Aiken's V (95 % CI) value (lower-upper limit)	Likert-type scale					Mean	Aiken's V (95 % CI) value (lower-upper limit)
	1	2	3	4	5			1	2	3	4	5		
	Number of experts							Number of experts						
Item 5	0	0	0	1	9	4.90	0.98 (0.87-0.99)	0	0	0	1	9	4.90	0.98 (0.87-0.99)
Item 6	0	0	0	1	9	4.90	0.98 (0.87-0.99)	0	0	0	2	8	4.80	0.95 (0.84-0.99)
Item 7	0	0	0	2	8	4.80	0.95 (0.84-0.99)	0	1	0	2	7	4.50	0.88 (0.74-0.95)
Item 8	0	0	1	2	7	4.60	0.90 (0.77-0.96)	0	0	0	3	7	4.70	0.93 (0.80-0.97)
Item 9	0	0	0	2	8	4.80	0.95 (0.84-0.99)	0	0	0	3	7	4.70	0.93 (0.80-0.97)
Item 10	0	1	0	2	7	4.50	0.88 (0.74-0.95)	0	0	0	2	8	4.80	0.95 (0.84-0.99)
Item 11	0	1	2	0	7	4.30	0.83 (0.68-0.91)	-	-	-	-	-	-	-
Item 12	0	0	1	1	8	4.70	0.93 (0.80-0.97)	-	-	-	-	-	-	-
Item 13	0	0	1	3	6	4.50	0.88 (0.74-0.95)	-	-	-	-	-	-	-
Item 14	0	0	2	0	8	4.60	0.90 (0.77-0.96)	-	-	-	-	-	-	-
Item 15	0	0	1	1	8	4.70	0.93 (0.80-0.97)	-	-	-	-	-	-	-
Item 16	0	0	0	2	8	4.80	0.95 (0.84-0.99)	-	-	-	-	-	-	-
Item 17	1	0	0	4	5	4.20	0.80 (0.65-0.90)	-	-	-	-	-	-	-
Item 18	0	1	1	2	6	4.30	0.83 (0.68-0.91)	-	-	-	-	-	-	-
Total Aiken's V Mean (± SD)							0.90 (± 0.06)							0.93 (± 0.03)

*CI: confidence interval; FBFC-ARFSQ-18: Food and Beverages Frequency Consumption Questionnaire to Identify Adverse Reactions to Foodstuffs; PSIMP-ARFSQ-10: Pathologies and Symptomatology Questionnaire Associated with Adverse Reactions to Foodstuffs. *Likert-type scale ranged from 1 to 5, where the minimum (1) value was based on very poor relevance and the maximum (5) on the highest degree of relevance.*

shrimp, fish, hazelnut, walnut, wheat and peanut were the most reported, although kiwi is not strictly considered as part of a strict MD. However, Telleria-Aramburu et al. (48) proposed an approach of a short FFQ for a Spanish sample of the Basque Country region, located in the north of Spain, with common Spanish food and also differencing proccessed and non-processed food, but still not very detailed regarding types of nuts, seeds, cereals, beverages, food supplements and other food groups of interest for the analysis of ARFS (48). Similarly, a European FFQ (7) has been proposed to assess the relation to allergy and asthma, not specifically CFBA; the Gluten FFQ (6), specifically focused only on cereal allergens; and the Pregnancy FFQ (8), with questions oriented to the gestation period. They are not yet available in the Spanish language and with particular characterisitics of the population of interest and/or allergy in general and not specifically ARFS, CFBA or CFBI.

EAACI and Ogulur et al. already proposed in 2017 and 2021 several diseases and symptomatology associated with CFBA (30,43). In order to improve the range of possibilities and precision of the tool (PSIMP-ARFSQ-10), specific diseases of recent investigations related to ARFS were taken into account (e.g., food protein-induced enterocolitis syndrome [FPIES], SIBO, IBS, atopic dermatitis, dizziness, etc.) (16,24-26,49). Experts who validated the questionnaire agreed with the authors of the present study about this, and other groups of diseases (SBS, hiatal hernia, pytiriasis, alopecia, panic attack) and symptomatology (xerostomia, erythema, sleep apnea, dyspnea, muscle cramps) were added from phase 1 and also following the experience and observations of 20 experts in phase 4.

This study could offer the key point to establish two validated questionnaires to analyze the main aspects of both, food consumption and diseases related to ARFS in a Spanish population under their self-perception, with the intention of being used together with a clinical diagnosis tool of the physician's choice. Furthermore, these tools could be used together with other health promotion studies and future ARFS local research projects.

This study has several strengths: the validation procedure is based on a rigorous qualitative research process, the use of a robust secure web platform for design and hosting, and the difference in the type of expertise that each professional may have towards the Spanish ARFS field, avoiding bias through multidisciplinary knowledge. The main limitation of this study is that questionnaires are designed and validated only for adults.

CONCLUSIONS

The findings of this study allow to conclude that both questionnaires designed to assess food consumption, diseases and

symptomatology in a Spanish population with possible ARFS could be used for clinical applications to analyze the association between certain food and beverages consumption with ARFS, such as, CFBA and CFBI. In addition, they could be used to investigate the link between some specific diseases, signs and symptoms with ARFS due to their optimal validity values. The FB-FC-ARFSQ-18 and the PSIMP-ARFSQ-10 questionnaires should facilitate research projects and be used together (recommended) with the clinical diagnostic tools of CFBA and CFBI.

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