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ORIGINAL ARTICLE

Food Allergy and Gastrointestinal Disease

Core Outcome Set for IgE-mediated food allergy clinical trials and observational studies of interventions: International Delphi consensus study 'COMFA'

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Abstract

Background: IgE-mediated food allergy (FA) is a global health concern with substantial individual and societal implications. While diverse intervention strategies have been researched, inconsistencies in reported outcomes limit evaluations of FA treatments. To streamline evaluations and promote consistent reporting, the Core Outcome Measures for Food Allergy (COMFA) initiative aimed to establish a Core Outcome Set (COS) for FA clinical trials and observational studies of interventions.

Methods: The project involved a review of published clinical trials, trial protocols and qualitative literature. Outcomes found as a result of review were categorized and classified, informing a two-round online-modified Delphi process followed by hybrid consensus meeting to finalize the COS.

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Results: The literature review, taxonomy mapping and iterative discussions with diverse COMFA group yielded an initial list of 39 outcomes. The iterative online and in-person meetings reduced the list to 13 outcomes for voting in the formal Delphi process. One more outcome was added based on participant suggestions after the first Delphi round. A total of 778 participants from 52 countries participated, with 442 participating in both Delphi rounds. No outcome met a priori criteria for inclusion, and one was excluded as a result of the Delphi. Thirteen outcomes were brought to the hybrid consensus meeting as a result of Delphi and two outcomes, 'allergic symptoms' and 'quality of life' achieved consensus for inclusion as 'core' outcomes.

Conclusion: In addition to the mandatory reporting of adverse events for FA clinical trials or observational studies of interventions, allergic symptoms and quality of life should be measured as core outcomes. Future work by COMFA will define how best to measure these core outcomes.

KEYWORDS
allergic symptoms, core outcome set, food allergy, outcome assessment, quality of life

Abbreviations: COMFA, Core Outcome Measures for Food Allergy; COMET, Core Outcome Measures in Effectiveness Trials; COS, Core Outcome Set; FA, Food allergy; GRADE, Grading of Recommendations, Assessment, Development, and Evaluations); HCP, Healthcare professionals delivering care to patients with food allergy; IgE, Immunoglobulin E; PFA, People with lived experience of food allergy including adult caregivers of people <18 years old; QoL, Quality of life; RS, Researchers involved in studies of food allergy.

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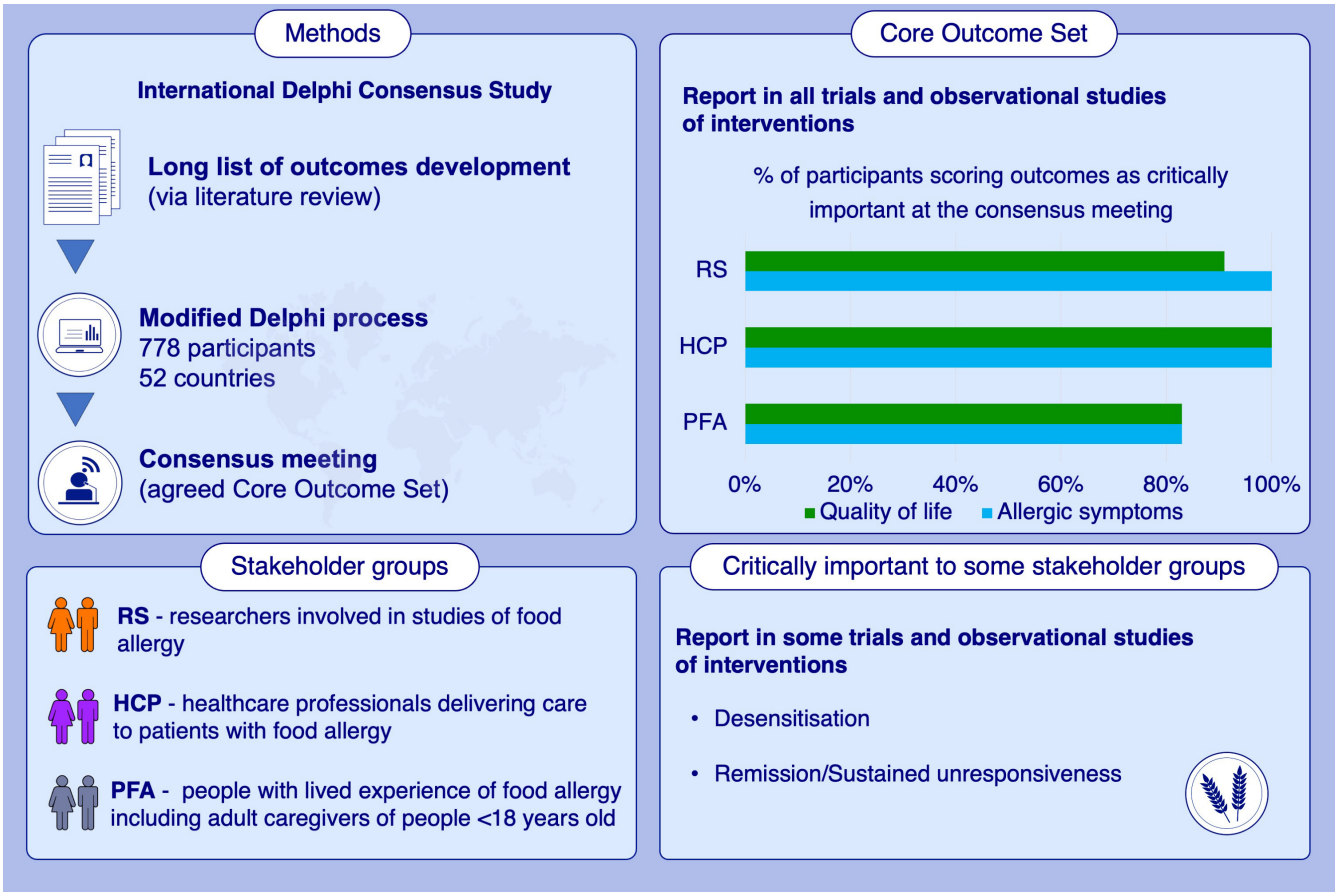

GRAPHICAL ABSTRACT

Core Outcome Measures for Food Allergy (COMFA) initiative, through international modified Delphi consensus process, has established a Core Outcome Set (COS) for IgE-mediated food allergy measured in clinical trials and observational studies of interventions. 'Allergic symptoms' and 'quality of life' achieved consensus for inclusion in the final COS. 'Desensitisation' and 'remission/sustained unresponsiveness' were considered important but did not reach a predefined threshold for inclusion in all three stakeholder groups. Abbreviations: COMFA, Core Outcome Measures for Food Allergy COS, Core Outcome Set; IgE, immunoglobulin E.

1 | INTRODUCTION

Food allergy (FA) is associated with significant morbidity, risk of life-threatening reactions and reduced quality of life.[1] While avoidance of culprit foods remains the predominant approach to managing FA, there is increasingly intense research, such as with food immunotherapy or biological treatments, addressing potential alternative intervention strategies.[2]

The synthesis of evidence becomes challenging due to variable outcomes reported in studies by different research teams, making it difficult to compare and contrast findings, hindering evidence-based decision-making.[3]

Core Outcome Set (COS), a harmonized selection of critically important outcomes, has proven beneficial in diverse health fields (e.g. atopic eczema[4] and rheumatoid arthritis[5]) to addressing such challenges.[6] A COS is an agreed set of outcomes which should be measured and reported, at a minimum, in relation to a specific condition. It is important to note that a recommended COS does not prohibit researchers from including other outcomes, but rather ensures that a 'core' selection of outcomes is always measured and reported. A COS can be developed for research studies, for clinical practice, or for both settings.

The gold-standard approach to COS development has been outlined by the Core Outcome Measures in Effectiveness Trials (COMET) handbook[7] and usually consists of two stages to achieve agreement on: (1) 'what to measure'—the set of core outcomes that should be measured and reported; and (2) 'how to measure'—the instruments that are most appropriate to measure those outcomes. Consensus is crucial as key stakeholders have a vested interest in the agreed outcomes and this decision may shape the field in the years to come and ensures the most important outcomes are included in the COS. Although some initiatives developed COS for non-immunoglobulin (IgE)-mediated FA, such as eosinophilic oesophagitis,[8] no COS is available for IgE-mediated FA.

In the absence of an agreed COS for IgE-mediated FA, the Core Outcome Measures for Food Allergy (COMFA) initiative was launched as an international, multidisciplinary group of relevant stakeholders with the primary goal to establish a COS for FA clinical trials and observational studies of interventions. This article outlines the first phase of an international COS development project

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and describes a Delphi consensus process to identify what outcomes should be measured in trials and observational studies of interventions for IgE-mediated FA.[9]

2 | METHODS

This first phase of the COMFA study was comprised of three stages: (1) generation of a 'long list' of outcomes via extensive literature review of quantitative research and using available evidence from qualitative research; (2) a two-round online-modified Delphi process to score the importance of the selected outcomes for a COS; and (3) a hybrid interactive consensus meeting to review results of the Delphi process and agree upon the final COS. The study protocol was developed a priori (https://osf.io/2qk4d/) and approved by the Ondokuz Mayıs University Research Ethics Committee OMUKAEK (REC number 2023000083-1). The project was registered on the COMET database (https://www.comet-initiative.org/Studies/Details/1423). The core group of six people (AD, KPD, PK, RJB, CA and DMu) responsible for the day-to-day management of the process was formed. Members of the core group had combined expertise in clinical allergy, COS development methodology, clinical research and clinical trial methodology. Throughout each stage of the process, the core group engaged in consultations with people with lived experience of FA.

2.1 | Literature review and long list of outcomes development

A long list of outcomes was informed by comprehensive literature review of outcomes reported in published clinical trials, clinical trial protocols and published qualitative individual studies and a systematic review.[10,11]

The unique outcomes were categorized into domains via Dodd et al.[12] taxonomy, initially reviewed by a core group through email and Zoom discussions. Subsequently, a hybrid 2.5-day meeting, involving researchers, health professionals, people with lived experience and carers, took place in Porto, Portugal, in October 2022 to present and deliberate the initial list of outcomes and descriptions. The core group subsequently invited stakeholders (researchers, health professionals, people with lived experience and carers) from around the world to review these outcomes. The core group upon approval by the COMFA Consortium members, finalized the candidate outcomes for the first round of the Delphi process.

2.2 | Delphi process and definitions

Consensus building included a two-round online-modified Delphi process. The study team invited potential Delphi participants from published studies, professional organizations (e.g. World Allergy Organization; American Academy of Allergy, Asthma and Immunology; American College of Allergy, Asthma and Immunology; Canadian Society of Allergy and Clinical Immunology; European Academy of Allergy and Clinical Immunology) and patient organizations. International and local professional and patient organizations also distributed open calls for participation and the public COMFA study website (https://comfa.eu/) provided additional details.

Participants represented three main stakeholder groups: (a) people with lived experience of FA and family members/caregivers (including adult caregivers of people less than 18 years old) (PFA); (b) healthcare professionals delivering care to patients with FA (HCP); and (c) researchers involved in studies of FA (RS).

2.3 | Delphi Round 1

Delphi materials and all participant information were provided in English, German, Russian, French, Italian, Portuguese and Spanish. The Delphi survey was delivered using Welphi software ('Premium plan', Decision Eyes LDA, Rua Mouzinho da Silveira, 1250-166 Lisbon, Portugal).

In Round 1, participants provided basic demographic information (stakeholder group, age, gender, ethnicity and geographic location). During Round 1, participants were shown a list of outcomes along with plain language descriptions and were asked to score them on a 9-point Likert scale ranging from 1 to 9 based on the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) framework. Participants could also provide comments on existing outcomes, or add suggestions for additional outcomes. These suggestions were assessed by the core group for inclusion in the second Delphi round (we had predefined a priori criteria for the inclusion of any new outcome suggested by ≥1% of the participants).

2.4 | Delphi Round 2

Participants who rated 50% or more of the outcomes in the Round 1 of the Delphi process were invited to take part in Round 2 as agreed a priori. The second Delphi round included all outcomes from Round 1 and additional suggested outcomes.

In Round 2 of the Delphi process, for each outcome, participants were shown their original rating from the first round alongside distribution of ratings within each stakeholder group; they were then asked to again rate each outcome.

We defined a priori consensus for inclusion of an outcome into the COS as 80% or more of participants in each stakeholder group rating the outcome as critically important (GRADE rating 7–9). We prespecified consensus for exclusion of an outcome from the COS as 50% or less of respondents in each stakeholder group rating the outcome as critically important. Outcomes receiving voting scores between 50% and 80% were brought into discussion at the hybrid consensus meeting.

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2.5 | Consensus meeting

Similar to the initial invitation process, any interested participant could join the consensus meeting. Individuals who participated in the second round of the Delphi process could self-express their interest in joining the consensus meeting while completing the survey.

The consensus meeting was conducted in a hybrid format, combining both in-person and online participation. The in-person part took place in London, United Kingdom, while the online component was facilitated through the Zoom platform (Version 5.13, Zoom Video Communications Inc., San José, USA), allowing for simultaneous participation from remote locations. The meeting, chaired by a skilled and impartial facilitator (CA), was conducted in English.

The discussions were organized in facilitated break out groups with a balanced composition of stakeholders. Break out groups reported back to the whole group and the meeting proceeded with the presentation of arguments supporting the inclusion of specific outcomes, followed by arguments against their inclusion.

After the presentation of the arguments, in-person participants and only those online participants present for the entire duration of the meeting, received invitations to confidentially rate the outcomes using the GRADE scale on eduVote (SimpleSoft, Braunschweig, Germany). Industry representatives, and those who declared significant conflict of interest, were excluded from voting. The consensus thresholds followed those prespecified earlier for the Delphi processes.

2.6 | Statistical analysis

For all outcomes considered at each stage of the consensus process (the two Delphi rounds and the consensus meeting), descriptive statistics of the voting was used to show the overall scores of each stakeholder group for the three GRADE categories and to determine whether the outcomes met the predefined criteria for inclusion or exclusion. Free-text comments were translated from the French, Russian, Spanish, Portuguese, German and Italian surveys into English, collated and reviewed by the core group.

Graphs displaying the distribution of ratings for each outcome, stratified by stakeholder group, were produced using R (Version 4.0.2, package 'ggplot2') and shown to participants in the second Delphi round.

3 | RESULTS

An extensive list of outcomes initially contained 39 entries (Data S1—Table S1) distributed across three distinct domains[12]: 19 represented 'physiological/clinical' outcomes, 17 represented 'functioning' and 3 were classified as 'resource use'. After comprehensive deliberations described in Section 2, the COMFA Consortium approved the revised list. As a result, the initial list of 39 outcomes was considerably condensed to a more focused set of 13 outcomes (four 'physiological/clinical', eight 'functioning' and one 'resource use'). These were presented in the subsequent Delphi process (Table 1). Figure 1 summarizes the steps taken in the development of the COS.

3.1 | Delphi process

The first round of the online-modified Delphi process took place from 10 to 31 March 2023. In total, 1066 individuals registered to take part in this study. Seven hundred and seventy-eight out of 1066 (73%) participants from 52 countries completed the first round (i.e. they rated 50% or more of the 13 outcomes).

Of the 778 invited to participate, 422 (54%) scored the outcomes in the second round. Response rates in the second round varied between the stakeholder groups with 208/446 (47%) PFA, 79/138 (57%) HCP and 135/194 (70%) RS scoring the outcomes. Demographic characteristics, by Delphi round, are presented in Table 2. Further details about the Delphi participants can be found in Data S1—Table S2.

At the end of the first round of the Delphi process, no outcomes met predefined criteria for either 'exclusion' or 'inclusion' in the COS (Table 3).

The first round of Delphi yielded a total of 111 free-text comments addressing existing outcomes and 156 free-text responses regarding additional outcomes that the core group reviewed. One outcome met a priori defined criteria for inclusion in the second round of the Delphi process: 'quality of life' suggested by 10 (1.3%) participants. This outcome was added to the 13 original outcomes, yielding a total of 14 outcomes for rating in the second round of the Delphi.

The second suggested outcome 'adverse effects/severe adverse effects' was mentioned by nine (1.2%) participants but was not included in the second round as this outcome assessment is mandatory in clinical trials anyway. Only 'quality of life' advanced to the list of outcomes for deliberation in the second Delphi round.

In the second Delphi round, one outcome, 'work, studies or recreational activities', met predefined 'exclusion' criteria and the other 13 outcomes did not meet either criteria for 'inclusion' or 'exclusion'. At least 80% of participants in one stakeholder group, but not all groups, considered the following three outcomes critical: 'allergic symptoms', 'quality of life' and 'remission/sustained unresponsiveness' (Data S1—Table S3). A total of 13 potential outcomes advanced to the final consensus meeting. Results from the Delphi process and the consensus meeting are presented in Data S1—Table S4, and a full report of the consensus meeting is provided in Data S2.

3.2 | Consensus meeting

The hybrid consensus meeting took place on 11–12 May 2023 in London, United Kingdom, comprised 66 registrants, of whom 43 attended the meeting (30 attended in person and 13 joined online).

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TABLE 1 The list of outcomes presented to the Delphi participants.

Domain	Outcome	Description
Physiological/clinical	Desensitization	The ability to consume (as a result of an intervention) a prespecified amount of food containing the trigger allergen as a result of intervention, without allergic symptoms which are bothersome to the person with food allergy (FA) (this outcome can be assessed either at a particular time point or at multiple time points, continuous)[a]
	Remission/sustained unresponsiveness	The ability to safely consume (without restriction) a food containing the trigger allergen (this outcome should be assessed at prespecified point(−s) after ceasing an intervention)[a]
	Allergic symptoms	Occurrence and frequency of allergic symptoms (e.g. tingling or itching; a raised, itchy red rash [hives]; swelling of the face, mouth [angioedema], throat or other areas of the body; difficulty swallowing; wheezing or shortness of breath; hoarse voice; feeling dizzy and lightheaded, fainting; feeling sick [nausea] or vomiting, dysphagia; abdominal pain or diarrhoea; anaphylaxis; hay fever-like symptoms, such as sneezing or itchy eyes [allergic conjunctivitis]) due to intended or unintended consumption of a food containing the trigger allergen
	Allergic comorbidities	Occurrence of new allergic comorbidities or a change in degree of control of existing allergic co-morbidities, such as eosinophilic oesophagitis, eczema, asthma, allergic rhinitis, etc., with or without exposure to food containing the trigger allergen
Functioning	Satisfaction with intervention	The degree to which intervention/services fulfilled the expectations of the person with FA and/or their carers
	Meet initial expectations from an intervention	The degree to which the expectation (anticipation or the belief) about what is to be encountered in an intervention or in the healthcare system will be met
	Food allergy-related psychological distress	Anxiety (including phobias), distress or worries related to FA
	Personal and family-related aspects	Including, but not limited to food consumption, sharing/preparing food, impact on connecting with others, including people living with a person with FA and friends, maintaining and creating new friendships and personal/romantic relationship and social activities. FA impact on people living with a person with FA and friends. Relationships between the family members and friends
	Food allergy management behaviour	Degree to which confidence, competence and motivation exists to manage FA (e.g. being able to communicate about allergies at restaurants, carrying and using auto-injectors and other medicines [e.g. antihistamines, inhaled steroids])
	Adherence	The extent to which a person follows the agreed FA management (e.g. taking medication, following a diet, and/or executing lifestyle changes)
	Work, studies or recreational activities	Impact of FA on work, study, attendance, engagement/ participation in recreational activities
	Stigma	Fear or experiences of being discriminated against, bullied, excluded from activities, ignored, including by employer/school/nursery/university, medical professionals, social groups, family/friends/neighbours or others
	Quality of life[a]	Individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a multi-domain construct and usually encompasses at least a physical, a mental and a social health dimension
Resource use	Economic impact	Financial impact resulting from the costs of medications, food and non-health related costs due to FA. Frequency of seeing healthcare professionals (e.g. doctor, psychotherapist, psychologist), taking rescue medications, returning to the hospital or emergency care, including complementary/alternative medicine (e.g. acupuncturists, naturopaths); indirect costs (time loss, lost productivity and opportunity costs due to FA); the costs to the healthcare system

[a]Outcome suggested by Round 1 participants, and rated during Round 2.

Seven participants (two online and five in-person) participated in consensus meeting discussions, but, due to conflicts of interest, proved ineligible to vote. Six participants were not able to stay during the whole discussion and voting process and also proved ineligible to vote. In total, 30 meeting participants voted: 6 PFA, 13 HCP and 11 RS (Data S2—Table S1).

Meeting participants were informed that the 'work, studies or recreational activities' outcome was excluded as it had met

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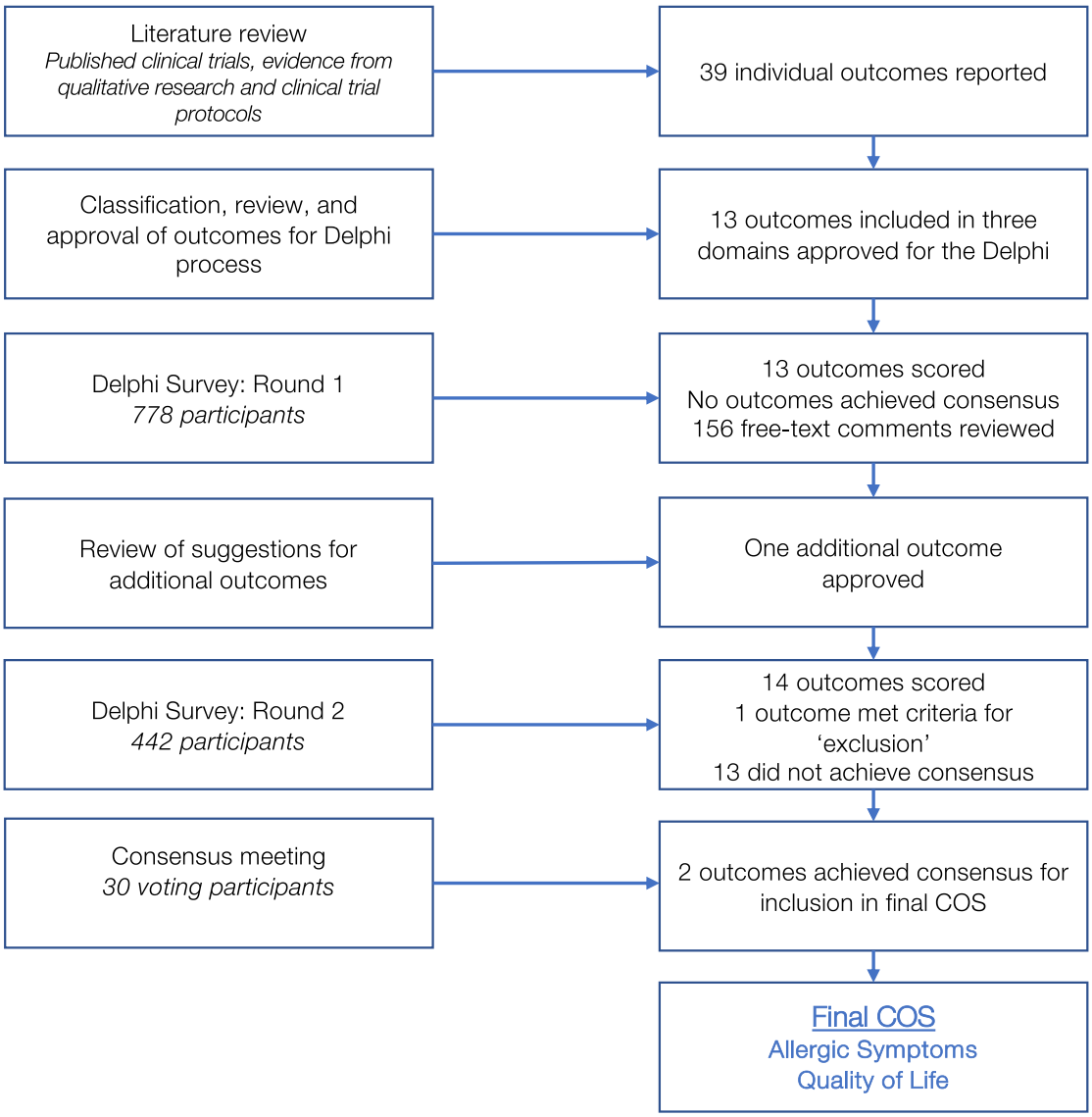

FIGURE 1 Overview of the Core Outcome Set development process.

predefined criteria (Data S2—Table S2). The outcomes discussed included: 'desensitisation', 'remission/sustained unresponsiveness', 'allergic symptoms', 'allergic comorbidities', 'adherence', 'satisfaction with intervention', 'meet initial expectations from an intervention', 'food allergy management behaviour', 'economic impact', 'quality of life', 'personal and family related aspects', 'food allergy related psychological distress' and 'stigma' (Data S2—Tables S3–S7).

After discussion and voting, two outcomes met the predefined consensus definition for inclusion. 'Allergic symptoms' with 5/6 (83%) PFA, 13/13 (100%) HCP and 11/11 (100%) RS rating it as critically important (Data S2—Tables S4 and S8). 'Quality of life' with 5/6 (83%) PFA, 13/13 (100%) HCP and 10/11 (91%) RS rating it as critically important (Data S2—Tables S6 and S8). Additionally, it was agreed upon that 'quality of life' should be more specifically defined in the future at the 'how to measure' phase of the project (Data S2—Table S5). Apart from included outcomes, It is worthy to note that adverse events are mandatory to report in clinical trials. Table 3 summarizes the results of the two Delphi rounds and consensus meeting. Additionally, a comprehensive report of the consensus meeting is available in Data S2.

4 | DISCUSSION

We report the findings of an international consensus process, which reached agreement regarding the critically important outcomes to be measured in all clinical trials and observational studies of interventions for IgE-mediated FA. Through an online-modified Delphi process, followed by a hybrid consensus meeting involving stakeholder groups from around the globe, 'allergic symptoms' and 'quality of life' achieved consensus for inclusion in the final COS (Figure 2).

Out of all outcomes from the physiological/clinical domain, 'allergic symptoms' was the only one that reached the necessary threshold

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TABLE 2 Delphi and consensus meeting voting participants demographics.

	Delphi Round 1 ($n=778$)	Delphi Round 2 ($n=422$)	Consensus meeting ($n=30$)
Stakeholder group, *n* (%)			
People with lived experience of food allergy (FA) including adult caregivers of people <18 years old	446 (57)	208 (49)	6 (20)
Healthcare professionals delivering care to patients with FA	138 (18)	79 (19)	13 (43)
Researchers involved in studies of FA	194 (25)	135 (32)	11 (37)
Gender			
Women	583 (75)	298 (71)	17 (57)
Men	161 (21)	108 (26)	13 (43)
Non-binary	2 (<1)	1 (<1)	
Prefer not to answer	3 (<1)	1 (<1)	
Unknown[a]	29 (4)	14 (3)	
Ethnicity			
Black or African American	3 (<1)	2 (<1)	
Hispanic or Latino or Spanish origin	43 (6)	26 (6)	
Indigenous peoples	3 (<1)	2 (1)	
Middle Eastern or N. African	11 (1)	5 (1)	
South Asian	9 (1)	6 (1)	
South East Asian or Pacific Islander	11 (1)	8 (2)	
White	524 (67)	296 (70)	
Prefer not to say	36 (5)	16 (4)	
Another ethnicity not reported above	42 (5)	21 (5)	
Unknown[a]	96 (12)	40 (10)	30
Geographical area			
Asia	32 (4)	22 (5)	2 (7)
Africa	4 (1)	2 (1)	
Australia	8 (1)	5 (1)	
Europe	532 (68)	276 (65)	23 (77)
North America	79 (10)	57 (14)	5 (17)
South America	10 (1)	6 (1)	
Central America	5 (1)	5 (1)	
Unknown[a]	108 (14)	49 (12)	
Age group (years)			
<18	27 (4)	9 (2)	
18–29	51 (7)	28 (7)	
30–39	218 (28)	114 (27)	
40–49	226 (29)	115 (27)	
50–59	144 (19)	89 (21)	
60–69	86 (11)	51 (12)	
70–79	21 (3)	12 (3)	
80–90	3 (<1)	2 (1)	
Unknown[a]	2 (<1)	2 (1)	30

Note: Some participants did not specify their gender, ancestry, location or age group.

[a]Not all percentages add up to 100% owing to rounding.

to be included in the COS. This result aligns with prior expectations, as past COS initiatives focused on other conditions have also recognized the crucial importance of symptoms. Regrettably, despite considerable efforts to redirect attention towards prioritizing 'patient-important' outcomes, in certain medical fields, over 75% of outcomes were not identified as patient-important, indicating a preference for surrogate outcomes.[13] This highlights the ongoing challenge in truly prioritizing patient-oriented outcomes in healthcare in general. While 'allergic

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TABLE 3 Summary of Delphi voting on outcomes stratified by domain.

Outcome	Delphi Round 1	Delphi Round 2	Consensus meeting
Physiological/clinical domain			
Desensitization	No consensus	No consensus: brought to consensus meeting	Exclude[c]
Remission/sustained unresponsiveness[a]	No consensus	No consensus: brought to consensus meeting	Exclude[c]
Allergic symptoms[a]	No consensus	No consensus: brought to consensus meeting	Include
Allergic comorbidities	No consensus	No consensus: brought to consensus meeting	Exclude[c]
Functioning domain			
Satisfaction with an intervention	No consensus	No consensus: brought to consensus meeting	Exclude[c]
Meet initial expectations from an intervention	No consensus	No consensus: brought to consensus meeting	Exclude[c]
Food allergy-related psychological distress	No consensus	No consensus: brought to consensus meeting	Exclude[c]
Personal and family-related aspects	No consensus	No consensus: brought to consensus meeting	Exclude[c]
Food allergy management behaviour	No consensus	No consensus: brought to consensus meeting	Exclude[c]
Adherence	No consensus	No consensus: brought to consensus meeting	Exclude[c]
Work, studies or recreational activities	No consensus	Exclude[c]	Exclude[c]
Stigma	No consensus	No consensus: brought to consensus meeting	Exclude[c]
Quality of life[a,b]	NA	No consensus: brought to consensus meeting	Include
Resource use			
Economic impact	No consensus	No consensus: brought to consensus meeting	Exclude[c]

Note: All outcomes from Round 1 were included in Round 2, regardless of ratings in Round 1.

Abbreviations: FA, food allergy; NA, not applicable.

[a]Outcome was given an overall GRADE rating of 7–9 by at least one, but not all, stakeholder group and was therefore prioritized for discussion at the consensus meeting.

[b]Outcome was added after the first Delphi round.

[c]Outcome did not reach the required threshold for inclusion in all stakeholder groups and was therefore excluded.

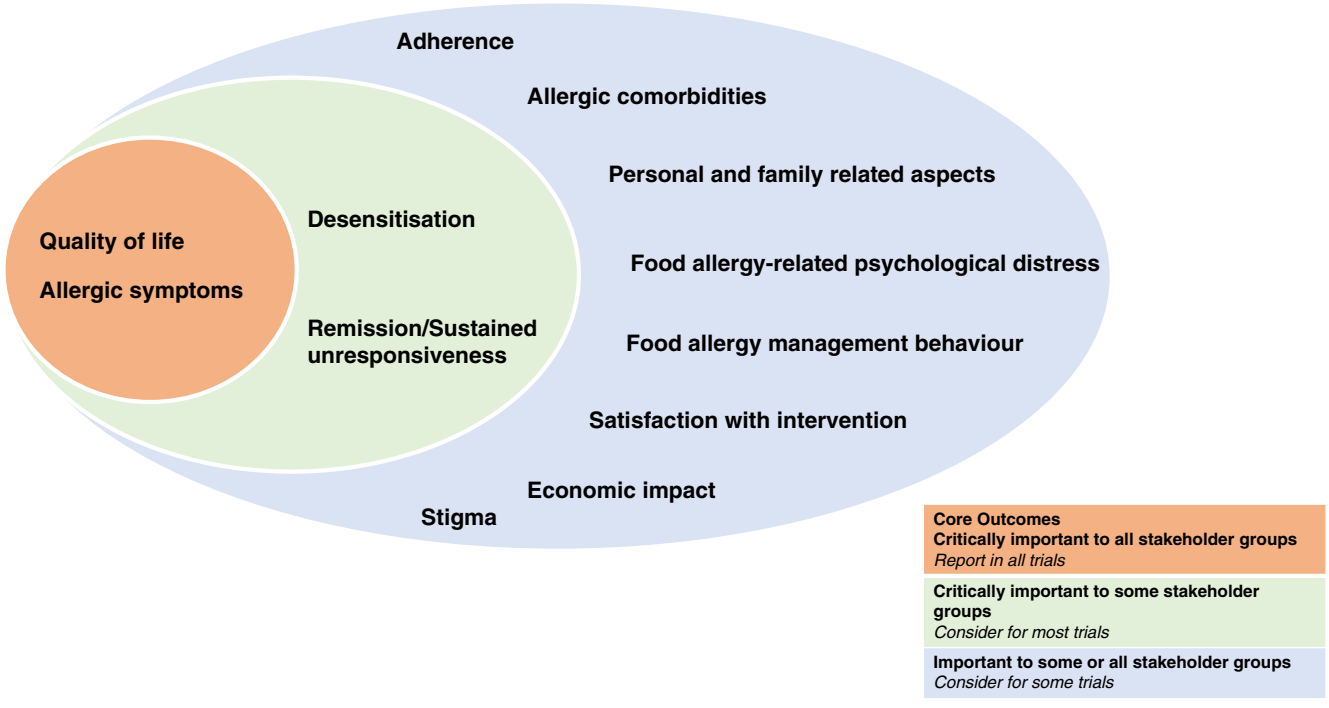

FIGURE 2 Core Outcome Set for Food Allergy clinical trials and observational studies of interventions.

symptoms' has been chosen as a core outcome, there are no widely accepted validated tools to measure this outcome and developing such tools may be one of the priorities moving forward. There is also an unmet need in harmonization and detailed classification of severe allergic reactions, including anaphylaxis in the research context, which is reserved to the second phase of this project.

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Most clinical trials including increasingly popular methods of intervention such as oral immunotherapy and epicutaneous immunotherapy frequently report desensitization or sustained unresponsiveness as primary outcomes.[14–16] Both outcomes were considered important but surprisingly did not reach a predefined threshold for inclusion due to the reluctance of the PFA group. These outcomes were the subject of detailed discussions, and several reasons may explain the lack of agreement on their critical importance. Firstly, both outcomes rely on measuring allergic symptoms, as both 'desensitisation' and 'remission' are constructs based on the reduction or complete elimination of FA symptoms. Additionally, concerns were shared about perception of remission with people with lived experience feeling insecure if they would be told in the clinical settings that long-term remission is achieved. It was highlighted that there is no reliable way to predict that achieving a remission during or shortly after an intervention will guarantee a life-long freedom from FA as symptoms may reoccur at some point in the future.

In the functioning domain, only 'quality of life' (QoL) met the established threshold for inclusion, echoing a familiar trend observed in various health conditions where this outcome is often ranked among the most critical.[17]

During the Delphi process, QoL subdomains were not prioritized. However, when the overarching QoL term was introduced, it gained preference and was voted in. QoL is a complex concept; many do not fully grasp its meaning due to lack of universal definition[18] but inherently see its importance. When divided into subdomains, its perceived significance seems to diminish. Grouping QoL as a whole might better capture diverse opinions on available interventions. The broader QoL outcome was chosen over subdomains like 'food allergy-related psychological distress', 'personal and family-related aspects' and 'food allergy management behaviour' for several reasons (Data S2—Table S8). Firstly, QoL is a comprehensive term that likely encompasses these subdomains, promoting a holistic view of health. This approach ensures all vital aspects of a patient's experience are addressed. Secondly, QoL is universally recognized with standardized tools, making it a top pick in health studies. The subdomains might lack standard definitions or tools, complicating their use and result interpretation. Lastly, there might have been redundancy concerns. Including both QoL and its subdomains could seem repetitive if the subdomains are effectively covered by the broader QoL measure. Excluding these subdomains simplifies the COS without omitting key information.

Nevertheless, the inclusion of the QoL outcome plays a pivotal role in acknowledging the patients' perspective and allows us to consider the chronic nature of the condition and its long-term implications. Interventions focusing on symptom management may not only be beneficial for the patient, but may also potentially lead to undesirable consequences, potentially impairing the overall QoL. This consideration highlights the importance of evaluating this outcome. During consensus meeting discussions, participants agreed that the general concept of QoL needed to be further refined in a more specific fashion when deciding on the instruments to measure it in the next stage of the COS development.

Our study had several strengths, such as implementation of a robust and comprehensive methodology, beginning with a review of existing literature and a rigorous refinement process, involving both in-person and online dialogues with a diverse group of stakeholders from a wide range of geographic locations, thus increasing the likelihood that a broad range of perspectives was considered. The Delphi process, a well-regarded method for achieving consensus, demonstrated flexibility and responsiveness to participant feedback, with the inclusion of an additional outcome after the first round of the Delphi. At the same time, our study has several limitations that need to be acknowledged and considered for a comprehensive understanding of the findings. Firstly, while we made efforts to ensure a diverse participant pool by translating our Delphi process into seven languages and by including individuals from different geographical locations, it is important to note that the majority of participants resided in developed countries.[19] This may introduce a bias towards perspectives and experiences that are specific to these regions. However, these are also the countries where FA is most common and has a broader expression. Additionally, overall underrepresentation of male participants in the Delphi process, should be acknowledged, although it is commonly observed in online surveys.[20,21] Secondly, the consensus meeting involved a relatively small number of participants, and it was conducted in English without simultaneous translation, due to resource limitations. However, the outcomes discussed at the consensus meeting were based entirely on the Delphi survey responses and feedback, in which there were many more participants. It is important to recognize that this limitation of lower representation at the consensus meeting is common in studies utilizing the Delphi methodology. It should also be noted that in the second round of our study, all participants who accessed the outcome scoring page with the previous results from the first round of Delphi were included. Due to the settings of the Delphi system, it was impossible to differentiate between participants who chose to keep their ratings unchanged from the first round and those who did not complete the scoring for the second round. However, out of the 422 participants in the second round, only 18 individuals did not modify their ratings for any of the outcomes and did not provide a rating for QoL. To prevent any potential selection bias, these participants were still included in the final analysis. Finally, our study employed a predefined threshold of 80% for including outcomes in the COS, as stated in the protocol. Use of a different threshold may have resulted in different core outcomes—for example, a higher 90% threshold would have resulted in no core outcomes and a lower 70% threshold would have resulted in additional outcomes. We recommend that in addition to using the essential core outcomes arising from this project, investigators take into consideration the 'recommended outcomes' which did not reach our predefined 80% threshold but were considered important by the Delphi participants. These include 'desensitisation' and 'remission/sustained unresponsiveness' that reached 70% threshold in all stakeholder groups in the second round of Delphi.

In summary, this first formal core outcome development process for IgE-mediated FA, which involved a large number of stakeholders

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from around the globe, including people with lived experience and their carers, has identified two core outcomes which we recommend should be included in all clinical trials and observational studies of FA interventions. By measuring allergic symptoms and QoL in all such studies, investigators and those evaluating the results of the studies can have increased confidence in the findings and comparative efficacy between interventions can more easily be established. Future work will identify optimal measurement tools for assessing symptoms and QoL in studies of IgE-mediated FA.

AUTHOR CONTRIBUTIONS

RJB and CA conceived the idea for the study. CA and DMu led the methods group. RJB, DMu, CA, NN, NS, DKC and JG designed the study protocol. IC, RJB, DMu and NN reviewed the outcomes used in previous quantitative studies, while MAG and JLPP provided expertize regarding outcomes assessed in the qualitative research, AMMS and WV led on the process outlining immunological outcomes used in the studies of IgE-mediated food allergy: all above-mentioned activities resulted in the development of the initial long list of outcomes. MME, SS, EEC, ES, NB, JC, MGi, FG, EB, MJM, AFS, JG, PK, KPD, AD, PRR, JG, RJB, CA and DMu conducted multiple meetings to discuss the long list of outcomes and generated descriptions. DMu coordinated the data revision process. IM, JC, DMu, KPD and VB prepared meetings where the initial long list of outcomes was discussed. AD, PK, KPD and DMu developed the online Delphi surveys and together with CA contributed to the day-to-day management of the project. MSMÇ developed the ethics application for the research ethics committee. RB, DM, CA, KPD, AD, PK, JG, NN and NS participated in discussions about project methods throughout the duration of the project. EP performed the statistical analysis. JLPP, IM, PRR, JC, MGi and AFS coordinated the translation of study materials. EB, AFS and MJM led on people with lived experience engagement throughout this study. RJB, DMu, KPD, JG, AD, PK, NB, EB, MAC, PC, JC, ADG, MGi, FG, MGr, DI, CJJ, EK, RCK, DPM, IM, MJM, DMi, CÖ, NP, JLPP, PRR, JR, PS; AFS, FS, NS, IS, MHS, JU and WV participated in the consensus meeting. CA facilitated the consensus meeting. AD, DMu, CA, RJB, JG and KPD drafted this article. All authors reviewed and approved the final article. All authors were able to access the study data. DMu and AD accessed and verified all the data in the study and had final responsibility for the decision to submit the article for publication.

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CONFLICT OF INTEREST STATEMENT

DMu is a Co-Chair of International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC) Global Paediatric Long COVID Working Group, member of ISARIC working group on long-term follow-up in adults and lead of PC-COS project. CA reports grants or contracts from Dr Wolff Group and Bionorica. He also acknowledges consulting fees from the Dr Wolff Group, Bionorica, Sanofi and LEO Pharma. He serves as a Co-Chair Harmonising Outcome Measures for Eczema (HOME) initiative and Co-Chair Hand Eczema Core Outcome Set (HECOS) initiative and is the core principal investigator of the KUNOKids Health Study (Regensburg, Germany). JG is the project manager of unrestricted research grants from Danone Nutricia Research to Leipzig University for research into human milk composition within the Ulm Birth Cohort Studies. This work is not related to the present publication. RJB declares consultancy payment from Cochrane, Wiley and the British Society for Allergy and Clinical Immunology for editorial work, and payment for expert witness work in cases involving food anaphylaxis and a disputed infant formula health claim. KPD is part-time employed by the IVDK, which systematically collects and analyses data on contact allergies from over 50 partner healthcare facilities. It is partly sponsored by the cosmetic industry or associations as well as by public funds. DPM has provided consultation and speaker services for DBV, ALK, and Alladapt, and is an investigator for DBV and ALK-Abello. JLPP is Section Head, Allied Health; and Co-Lead, Research Pillar for the Canadian Society of Allergy and Clinical Immunology, and is on the steering comittee for Canada's National Food Allergy Action Plan. She reports consulting from Ajonomoto Cambrooke, Novartia, Nutricia and ALK Abelló. EEC is on the board of the patient organization NPO Atopicco Chikyu no Ko Nettowa-ku which deals with allergic disease in Japan. She is a patient representative on Novartis' Global Food Allergy Patient Council. EK is an author of the EAACI guideline: Preventing development of food allergy in infants and young children (2020 update) and Managing food allergy: GA2LEN 2022. RK's work involves the development of psychometric scales for allergy and asthma, and she has published a number of psychometric scales in the field. PRR reports research grants from FAES and Aimmune Therapeutics; speaker honoraria from DBV, GSK, FAES, Novartis, ALK-Abelló, LETI Pharma, Aimmune Therapeutics, Sanofi, Stallergenes; and conslutant fees from FAES, Miravo outside the submitted work. AMMS is on the advisory board for ALK and a paid speaker for Thermo Fisher Scientific. MS reports being a speker at seminars arranged by Thermo Fisher Scientific. JU is an associate editor of AACI and she is on the board of directors of CSACI.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available in the supplementary material of this article.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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