Clinical Nutrition ESPEN 66 (2025) 489–496

Contents lists available at ScienceDirect

Clinical Nutrition ESPEN

journal homepage: http://www.clinicalnutritionespen.com

Original article

Developing a core outcome set for nutrition care in adult outpatients with irritable bowel syndrome (COS-RD-IBS study)

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ARTICLE INFO

Article history:
Received 15 October 2024
Accepted 11 February 2025

Keywords:
Irritable bowel syndrome
Nutrition care
Core outcome set
Delphi survey
Clinical practice

SUMMARY

Background and aims: Irritable bowel syndrome (IBS) is a frequent disorder thought to be caused by a disturbance of the gut–brain axis. Nutrition interventions are an essential pillar of its treatment. However, there is no consensus on which outcomes should be applied to assess the effectiveness of nutrition care in IBS. Standardized outcome sets, or "core outcome sets" (COS), have been proposed to harmonize outcomes in clinical research and practice. This project aims to develop a COS for dietitian-provided nutrition care in adults with IBS or food intolerances with intestinal symptoms, to be implemented in routine outpatient practice.

Methods: A comprehensive outcomes list was developed based on quantitative and qualitative studies, COS and guidelines on IBS, and important outcomes named by participants. Health service users, dietitians, gastroenterologists, and health care decision makers rated the outcomes in two Delphi survey rounds on their importance and ranked them in a third round. Data was analyzed by panel to account for the different views and sample sizes.

Results: A total of 192 participants registered for the Delphi process. The following 14 outcomes reached consensus in all panels after two rounds: perception of symptom triggering foods/nutrients, intake of trigger foods/nutrients, practicability of diet, adherence, digestive symptoms overall, abdominal pain, abdominal bloating, stool consistency, stool frequency, physical functioning related QoL, nutrition related QoL, social functioning related QoL, empowerment of self-care.

Conclusions: The Delphi process yielded in a 14 outcomes COS, which exceeds what is typically considered feasible in routine nutrition care. Further work is needed to refine the COS and to identify standardized measurement tools for each outcome.

1. Introduction

Irritable bowel syndrome (IBS) is a frequent disorder thought to be caused by a disturbance of the gut–brain axis, with a global prevalence of about 4.1 % according to the Rome IV criteria [1]. Adults with IBS experience various gastrointestinal and non-gastrointestinal symptoms that reduce their health related quality of life (QoL), cause psychological distress, impair workforce productivity, and increase healthcare utilization [2–4]. Many associate their symptoms with specific foods, potentially leading to self-imposed dietary restrictions [5]. Consequently, nutrition interventions are a key component of IBS treatment and are commonly recommended in IBS management guidelines [6–9].

A recent consensus-based paper on diet and IBS emphasizes that dietitians should tailor nutrition interventions to patient preferences and triggers [10]. However, there is no consensus on which outcomes to assess in nutrition care in IBS. This absence of a consensus necessitates the use of individually defined outcomes, leading to variability in measured outcomes between dietitians but also from patient to patient [11]. This variability complicates

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https://doi.org/10.1016/j.clnesp.2025.02.017

effectiveness research and quality improvement initiatives. For example, our research group found analyzing data in a systematic review and meta-analysis challenging due to the heterogeneous outcomes and outcome measurement methods [12].

To address this issue, standardized outcome sets, or "core outcome sets" (COS), have been proposed to harmonize outcomes not only in research but also in clinical practice, and clinical audits [13,14]. COS propose outcomes to be always measured in the respective setting of nutrition care. As relevant outcomes may differ between different medical conditions (e.g., between diabetes and IBS), the COS should be defined per medical condition. The outcomes should be measured with the most valid and reliable measurement instruments applicable to everyday practice [15]. This project aims to develop a COS for dietitian-provided nutrition care in adults with IBS or food intolerances with intestinal symptoms (IBS-FI), to be implemented in routine outpatient practice as a proof of concept (COS-RD-IBS). This approach could be extended to other conditions in future phases. The scope of the COS-RD-IBS includes IBS and food intolerances as in real-life settings, diagnostics may not always be as strict as in efficacy randomized controlled trials, and symptoms of some food intolerances may considerably overlap with IBS symptoms.

2. Materials & methods

This study employed a modified Delphi technique to develop the COS-RD-IBS. The Delphi technique was used for the consensus process, as it has been successfully used in other projects to develop COS and recommended in guidelines [16]. The project was conducted in accordance with the "Core Outcome Measures in Effectiveness Trials" (COMET) initiative and its handbook [16] as the COMET initiative focuses on effectiveness trials. Several other guidelines have been consulted for additional guidance [17–20]. The project was registered in the COMET database (https://www.comet-initiative.org/Studies/Details/2014). The results are reported in adherence to the Core Outcome Sets-STAndards for Reporting (COS-STAR) criteria [21]. The design did not necessitate ethical approval in the participating countries. In Switzerland, the Health, Social, and Integration Directorate of the Cantonal Ethics Committee for Research in Bern (Switzerland) confirmed non-responsibility for this project on 09 March 2022. (BASEC no: Req-2022-0028).

2.1. Preliminary literature review

Prior to developing the methodology, we conducted a comprehensive search of the COMET database [22], MEDLINE (PubMed interface), CINAHL (EBSCOhost interface), and the U.S. Food and Drug Administration guidance database (https://www.fda.gov/regulatory-information/search-fda-guidance-documents) to identify existing COS relevant to the scope of COS-RD-IBS. Only one COS focusing on IBS in adults [23] was found, but it was deemed unsuitable for the COS-RD-IBS project due to its focus on drug development efficacy studies.

This project was divided into two main phases:

1. Consensus on outcomes to include in the COS-RD-IBS
2. Definition of outcome measurement methods

This paper reports on Phase 1.

2.2. Outcomes list development

A comprehensive, literature-based list of potential outcomes was developed using five sources:

1. Quantitative studies assessing the efficacy or real-world effectiveness of a diet low in fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (LFD) in IBS, extracted from studies included in a recent systematic review and meta-analysis conducted by our group [12].
2. COS and guidelines on IBS [23–27].
3. Qualitative studies assessing the views, perceptions, and experiences of adults. These studies were evaluated to ensure that the patients' perspective was sufficiently included in the outcomes list since the outcomes assessed in trials are often determined without the consultation of IBS patients [28].
4. Patient-reported experience measures based on a dietetic-specific questionnaire currently being developed in Switzerland to supplement the patient-reported experience measures mentioned by a few of the studies of sources 1 to 3.
5. Outcomes suggested by the Delphi process participants during registration.

All outcomes found in the quantitative and the qualitative studies, the COS, and guidelines were translated into German lay terms and discussed with experts (gastroenterologist, psychologist) where needed. Outcomes that appeared too similar to be considered separate outcomes were merged. Finally, the outcomes were grouped into six categories (food/nutrition related and anthropometric measurements, symptoms, bowel movement, QoL & mental health, experiences with nutrition care, financial aspects) and a short lay-term description was developed for each outcome. For round three, the categories symptoms and bowel movement were merged. The resulting questionnaire was pretested for understandability with at least one participant per panel of the Delphi process. The outcomes suggested by the participants were added later on.

2.3. Delphi process

Four stakeholder groups were included: dietitians, health care users with IBS-FI, gastroenterologists, and health care decision makers. The inclusion criteria were: being residents (health care users) or working (other groups) in Austria, Germany, or Switzerland, with sufficient German language proficiency for all groups. Dietitians needed to conduct more than five consultations per month on IBS-FI and/or work in research on IBS-FI. Health care users were required to be at least 18 years old and to suffer from IBS-FI confirmed by a physician (self-reported, no restriction on the diagnostic criteria applied). Gastroenterologists needed to regularly treat people with IBS-FI (more than five consultations per month) and health care decision makers needed to be involved in either health care system policymaking, working for a governmental public health office, a health insurance company or association, or on quality assurance in a dietetic professional organization, with no requirement of their work being associated with IBS.

The four stakeholder groups were divided into three panels: 1) dietitians, 2) health service users with IBS-FI, and 3) gastroenterologists and health care decision makers (others). The panels were based on the OMERACT handbook recommending one panel for the health service users and one for all other participants [20]. As dietitians will mainly be working with the COS-RD-IBS, we were specifically interested in their opinions, which resulted in a separate panel for them. We aimed to recruit 50–100 participants per panel. Purposeful sampling was applied. Recruitment was conducted via email through relevant organizations and direct outreach between January and March 2024. Welphi (https://www.welphi.com/) was used for registration and the Delphi process.

The participants had to register on Welphi's website and to answer demographic questions. Furthermore, they were asked to

list outcomes they considered most important for nutrition care in IBS-FI and to rate how many outcomes could be assessed in every consultation. The Delphi process consisted of two rounds where the participants rated all outcomes on the outcome list for their importance for routine nutrition care (1 March to 2 April, 2024 and 18 April to 2 May 2024) and a ranking exercise in round 3 (3 May to 21 May 2024). In round 1 and 2, the outcomes were rated on a five-point Likert scale from "not important at all" to "very important" with an additional option "Unable to rate". Compared to the study protocol registered in the COMET database (https://www.comet-initiative.org/Studies/Details/2014), we changed the scale used in the Delphi process from a nine-point to a five-point Likert scale as in our pretests, the scale had been criticized as too detailed and cumbersome and, thus, adding to the burden for the participants. Reminders were sent out after 10 days to participants who had not completed the respective round. Participants could also comment on the outcomes. Participants were allowed to participate in subsequent rounds independently of their participation in previous rounds.

The degree of consensus was predefined as a minimum 70 % of the participants, in all panels, rating an outcome as important or very important, and a maximum of 15 % of participants, in all panels, rating the same outcome as not important or not important at all. Because of the high number of outcomes reaching a consensus for importance in all panels in the first round, we decided to apply a stricter consensus definition for round 2. Therefore, a consensus in round 2 required at least 50 % of the participants in all panels to rate an outcome as "very important". In round 2, the results per panel of round 1 were displayed to the participants so that they could decide whether they wanted to keep their answer or change it. In round 3, participants ranked the outcomes reaching consensus in round 2 in all panels on their importance (1 = most important, 2 = second most important …) per outcome category.

2.4. Data analysis

The participants' characteristics were analyzed descriptively. Each outcome mentioned by participants was carefully assessed whether it was already on the outcomes list or needed to be added to it. As Welphi did not support data analysis per panel, data were exported from Welphi and analyzed descriptively to determine consensus yes/no per outcome, per panel. Comments were scanned for a need to change an outcome, outcome label, or outcome description. Round 3 results were analyzed descriptively by panel. The analyses were performed in R version 4.4.1 (R Core Team 2024) using the R packages arsenal version 3.6.3 [29], ggplot2 version 3.5.1 [30], ggstats version 0.6.0 [31], likert version 1.3.5 [32], and xtable version 1.8.4 [33].

3. Results

3.1. Outcomes list

Figure 1 illustrates the process for developing the outcomes list, which began with a literature-based search identifying 168 outcomes and was refined to 72 outcomes for Delphi process round 1. During the process from the literature-based outcomes list to the round 1 outcomes list, a total of 85 outcomes were merged with others due to their similarity, and a total of 25 outcomes were deleted. Two outcomes were added based on pretest feedback and ten based on participants' suggestions during the registration process. Figure 2 lists all the outcomes sorted by category. Definitions of the outcomes can be found in Table S1 in the supplementing materials. Outcomes added based on participant feedback in the registration process included: *meal composition*, *satiety*, *appetite*, *food/nutrition related knowledge*, *physical activity*, *gut microbiota*, *inflammation parameters* (all in the category food/nutrition related and anthropometric measurements), *odor of flatulence* (category symptoms), *odor of stool* (category bowel movement) and *ability to concentrate* (category QoL & mental health).

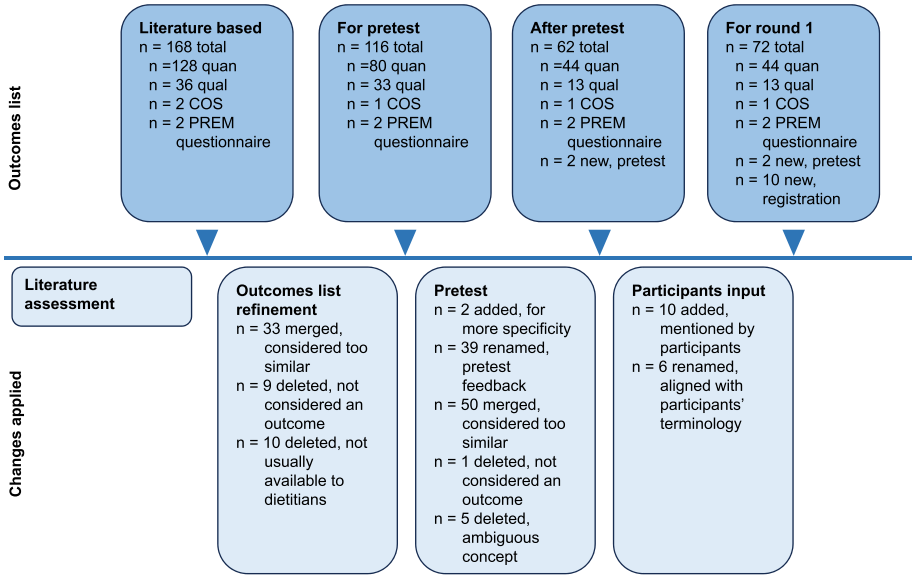

Fig. 1. Outcome selection process from generating a literature-based outcomes list to the start of the Delphi process. COS: core outcome set; PREM: patient-reported experience measures; quan: quantitative studies; qual: quantitative studies.

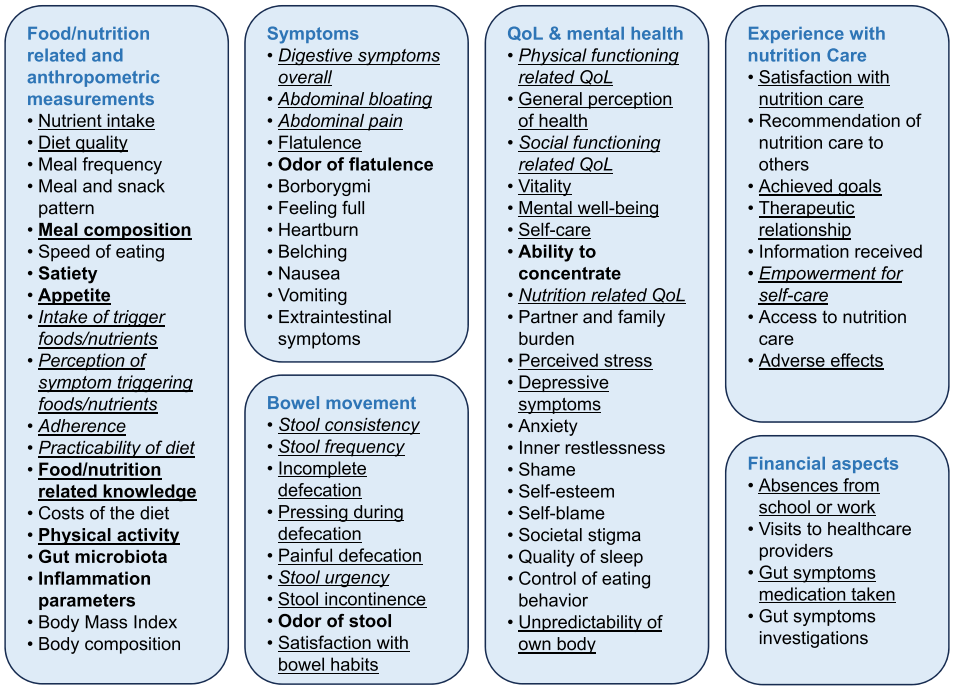

Fig. 2. Outcomes list for the Delphi process. Bold: outcomes added by participants; underlined: reached consensus in all panels in Delphi round 1, italic: reached consensus in all panels in Delphi round 2; QoL: Quality of life.

3.2. Delphi process participants

The characteristics of the Delphi process participants are shown in Table 1. A total of 57 health service users, 104 dietitians, and 34 gastroenterologists and health care decision makers registered for the Delphi process. The rate of participation in the Delphi process was 63 % in round 1, 52 % in round 2 and 3 for the health service users, 74 % in round 1, 66 % in round 2 and 69 % in round 3 for dietitians and 63 % in round 1 and round 3, and 60 % in round 2 for the gastroenterologists and health care decision makers; respectively.

Across all three panels, 3–4 outcomes were rated most frequently as realistic to be routinely assessed in nutrition care (Table 2).

3.3. Delphi process results

An overview of round 1 and 2 of the Delphi process results are shown in Fig. 2. After round 1, 10 of 19 outcomes reached the threshold for consensus in the food/nutrition related and anthropometric measures category, five of 12 in the category symptoms, eight of nine in the category bowel movement, 10 of 20 in the QoL & mental health category, five of eight in the category experience with dietitian and two of four in the financial aspects category. After round 2, this was reduced to four outcomes in the food/nutrition related and anthropometric measures category, three in the categories symptoms, bowel movement and QoL & mental health. One outcome reached consensus in the category experiences with dietitian and none in the financial aspects category. The detailed results per panel can be seen in Figs. S1–S24 in the supplemental file.

The results of the ranking round (round 3) in the Delphi process are shown in Fig. 3. There were some differences in how the three panels ranked the outcomes. In the food/nutrition related and anthropometric measures category, the others panel ranked the outcome *adherence* on rank two, *intake of trigger foods/nutrients* on rank 3, and *practicability of diet* on rank 4. In the category *symptoms & bowel movement*, the bowel movement related outcomes were ranked differently in all panels. In the category QoL & mental health, the others panel ranked the *social functioning related QoL* higher than the *nutrition related QoL*.

4. Discussion

To develop a core outcome set (COS) for nutrition care in adult outpatients with IBS-FI we applied a three round Delphi process. This Delphi process finally resulted in a 14 outcomes COS. Twelve 12 patient-reported outcomes were originally derived from existing COS, guidelines, or quantitative studies. The remaining two outcomes were one patient-reported outcome originally mentioned in a qualitative study and one patient-reported experience measure.

Agreement was high between rounds, with differences between the panels. Most outcomes reaching consensus in round 2 were top-rated in round 1, except social functioning QoL, which gained importance across all panels. Dietitians prioritized symptom and bowel movement outcomes, while health service users and others also emphasized food/nutrition related and QoL outcomes. Some outcomes reached high levels of consensus in specific panels but did not reach consensus across all panels: *heartburn, information received*, *meal composition*, and *control of eating behavior* for dietitians; and *unpredictability of body self* for health service users.

Differences in outcome preferences between panels are common in COS development, with health service users being more likely to include life impact outcomes, such as QoL or well-being [34–37]. In contrast, dietitians often prioritize objective clinical outcomes over subjective ones [38,39]. For example, in a survey for developing a COS for bariatric surgery, health service users prioritized seven QoL items not highlighted by professionals [40]. In our Delphi process, dietitians rated clinical outcomes like symptoms and bowel movement more important than QoL & mental health. Similarly, in a Delphi process developing minimum reporting

Table 1
Characteristics of registered participants in Delphi process.

Characteristics	Panel health service users n (%)	Paneld ietitians n (%)	Panel others – Gastroenter-ologists n (%)	Panel others – Health care decision maker n (%)
Country				
Austria	2 (3.5)	17 (16.3)	2 (11.8)	4 (23.5)
Germany	14 (24.6)	31 (29.8)	0 (0)	4 (23.5)
Switzerland	41 (71.9)	56 (53.8)	15 (88.2)	9 (52.9)
Diagnosis				
IBS	10 (17.6)			
Food intolerance	21 (36.8)			
Both	22 (38.6)			
n.a.	4 (7.0)			
Date of diagnosis				
Up to 2 years ago	13 (22.8)			
3–5 years ago	13 (22.8)			
6–10 years ago	17 (29.8)			
More than 10 years ago	13 (22.8)			
n.a.	1 (1.8)			
Dietitian/gastroenterologist since				
Up to 2 years		9 (8.7)	0 (0)	
3–5 years		17 (16.3)	0 (0)	
6–10 years		15 (14.4)	3 (17.6)	
11–15 years		20 (19.2)	2 (11.8)	
16–20 years		12 (11.5)	4 (23.5)	
More than 20 years		31 (29.8)	8 (47.1)	
Working in IBS-FI since				
Up to 2 years		17 (16.3)		
3–5 years		25 (24.0)		
6–10 years		17 (16.3)		
11–15 years		24 (23.1)		
16–20 years		9 (8.7)		
More than 20 years		11 (10.7)		
n.a.		1 (1.0)		
Referrals to dietitians				
Never			1 (5.9)	
Rarely			5 (29.4)	
Often			9 (52.9)	
Always			2 (11.8)	
Role in health care decision making				
Political				1 (5.9)
Advisory or research activity in health policy				2 (11.8)
Government				2 (11.8)
Health insurance company				2 (11.8)
Health insurance association				3 (17.6)
Quality assurance in a dietetic association				5 (29.4)
Other				2 (11.8)

Table 2
Number of outcomes rated as realistic for routine assessment in nutrition care.

Number of outcomes	Panel health service users n (%)	Paneld ietitians n (%)	Panel others n (%)
1-2 outcomes	8 (17)	9 (9)	2 (6)
3-4 outcomes	18 (38)	38 (38)	12 (36)
5-6 outcomes	7 (15)	24 (24)	11 (33)
7-8 outcomes	3 (6)	15 (15)	2 (6)
9-10 outcomes	1 (2)	6 (6)	1 (3)
Over 10 outcomes	0 (0)	8 (8)	5 (15)
Unable to rate	11 (23)	1 (1)	0 (0)

standards for process and outcomes assessment in Australian private practice dietitians, outcomes reaching consensus were all clinical, anthropometric, biochemical, or dietary, but satisfaction outcomes did not reach consensus [41]. Dietitians may prefer these outcomes due to recommendations emphasizing objective outcomes [42], their perceived clinical relevance, alignment with dietetic practice purpose, and concerns about complexity, time constraints, and subjective data reliability [39,43,44].

The outcomes reaching consensus in the two Delphi rounds encompass a wide range, from those commonly assessed in efficacy and real-world studies [12] such as *digestive symptoms overall, abdominal pain*, and *stool consistency*, to those identified through qualitative literature addressing health service users', such as *perception of symptom triggering foods/nutrients* and *empowerment of self-care*. The same continuum applies to the availability of outcomes measurement instruments: For outcomes already frequently assessed, several validated measurement instruments and recommendations for high-quality instruments exist. However, for other outcomes, such as *adherence,* measurement methods applied are very diverse, or for outcomes based on qualitative literature, they often do not even exist. Further research is warranted to better understand the most appropriate measurement instruments or to develop and validate appropriate measurement instruments, which will be the aim of phase 2 of the project. For early adopters, a pragmatic recommendation is to start with implementing the outcomes already commonly used: *digestive symptoms overall, abdominal pain, stool consistency, stool frequency and physical and social functioning related QoL*. For assessing effectiveness and quality purposes, the outcomes should be assessed at least at baseline and the last encounter, but more frequent assessment (e.g.,

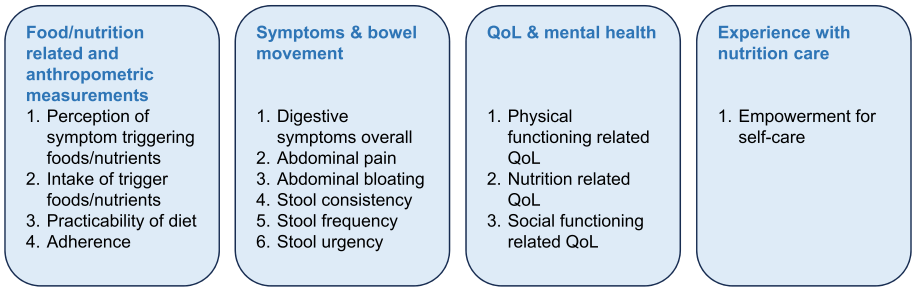

Fig. 3. Outcomes reaching consensus, in the order they were ranked by participants (all panels). QoL: Quality of life.

in each encounter) may facilitate clinical practice. Based on systematic reviews and guidelines evaluating the quality of outcome measurement instruments, we suggest using the adequate symptom relief question [26,45] or IBS symptom severity score (IBS-SSS) [46] for *overall digestive symptoms* in IBS [26]. The IBS-SSS [47] is also recommended for *abdominal pain* [48,49]. For the QoL outcomes, the IBS-QoL questionnaire is considered most suitable [26,50]. *Stool frequency* should be measured as number of bowel movements per week or day, ideally focusing on complete spontaneous bowel movements in IBS with constipation [23]. The Bristol Stool Form Scale is recommended for assessing *stool consistency* [23,51]. Given that nutrition care is applied to all subtypes of IBS, *stool consistency* and *frequency* data should be dichotomized [12]. It is important to note that most studies referenced were conducted over five years ago, primarily focused on clinical trials rather than clinical practice, and were not specific to nutrition care. Furthermore, there is no national or international consensus on the preferred outcome tools for the majority of the proposed outcomes.

Despite the difficulty of recommending measurement instruments for most outcomes, the fact that these outcomes have achieved consensus across all panels emphasizes the importance of incorporating the perspective of health service users as highly recommended by COS guidelines [16,20,52]. This approach enables capturing the needs, preferences, and values of those affected by a health condition and thus enhances patient-centeredness, increases the relevance of research findings, and facilitates the quicker adoption of research results in clinical practice [53–55]. Additionally, the health service user perspective can reveal important outcomes previously overlooked by researchers. For example, during the development process of a COS for inoperable malignant bowel obstruction, abdominal pain was rated as critical outcome by health service users but was rarely assessed in clinical studies before [56].

While the Delphi participants deemed three to four outcomes feasible for everyday practice, fourteen outcomes reached consensus for importance. The number of three to four outcomes needs to be interpreted with caution as it was assessed without context, such as the time required, in the registration phase. Given the lack of literature on feasible outcome numbers in nutrition care, further research is needed to evaluate the practicability of the 14 COS-RD-IBS outcomes, potentially leading to a refined COS and distinguishing the remaining outcomes into core and additional outcomes.

This project aimed to develop the first COS for nutrition care in German-speaking countries, following state-of-the-art guidance [16,18–20] and including four stakeholder groups. However, the study has several limitations. First, we did not meet the a priori defined minimum of 50 participants per panel in the others panel, and only slightly exceeded this number for health service users (n = 54) despite a recruiting time of almost three months. The Outcome Measures in Rheumatology guideline recommends at least 200 participants to have at least 100 participants per panel participating in the entire COS development process [20]. Our attrition rate ranged from 26 % to 48 %, which is consistent with the literature [57,58], but too high to compensate for the low participant numbers. To address this, we implemented several strategies to maintain participant engagement, including clear communication of time commitments, regular reminders, and timely feedback. Furthermore, we analyzed the results per panel to give voice to all participants. Second, the sample was limited to German-speaking participants, with an overrepresentation from Switzerland, likely due to the research group's local network. The focus on German-speaking countries avoided language barriers and the inclusion of health service users with IBS-FI from Germany, Switzerland, and Austria, as shown in a systematic review of international Delphi surveys for COS development where international health service users were underrepresented in the samples [59]. Future studies should aim for a more balanced geographical representation to enhance the robustness of the consensus. Lastly, the outcomes included in the Delphi process were consistently shown to the participants in the same order. Research has shown that the order of items can influence the outcomes rating and, thus, the outcomes included in the final COS [60]. The outcomes reaching consensus after two rounds in the COS-RD-IBS project were from the top half of the outcomes in the symptoms, bowel movement, and QoL & mental health categories, but not in the other categories.

5. Conclusion

The Delphi process applied in the COS-RD-IBS study reached consensus for 14 outcomes, which exceed what is typically considered feasible in routine nutrition care. Further work is needed to refine the COS-RD-IBS and to assess its acceptability and feasibility for routine nutrition care. Significant work remains in developing and validating outcome measurement instruments, particularly for nutrition care in IBS-FI. Currently, some recommended measurement instruments need more validation for this specific context, and others do not exist. Given that COS is a new concept in nutrition care, promoting the uptake of the COS-RD-IBS will require effective communication strategies and implementation science projects to facilitate integration into clinical practice.

Author contribution

SJ: conceptualization, methodology, formal analysis, investigation, writing – original draft, writing – review & editing, visualization, supervision, funding acquisition.

JJKL: investigation, writing – review & editing.

AAM: formal analysis, writing – review & editing.

NB, AB, LV: methodology, writing – review & editing.

GR: conceptualization, methodology, writing – review & editing, supervision.

Data availability statement

The data supporting this study's findings and the questionnaires used are available from the corresponding author upon request.

Declaration of Generative AI and AI-assisted technologies in the writing process

During the preparation of this work the first author used perplexity. ai in order to enhance the language of the manuscript. After using this tool, the author reviewed and edited the content as needed and takes full responsibility for the content of the publication.

Funding information

This work has been financially supported by Bern University of Applied Sciences, Bern, Switzerland.

Conflicts of interest

There are no conflicts of interest.

Acknowledgment

We thank Manuela Zahnd for her contribution to the registration questionnaire and the outcomes list and Michel Kaiser for his work on the recruitment materials. We would also like to thank everyone who contributed to this project by distributing the recruitment email or participating in the Delphi process.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.clnesp.2025.02.017.

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