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Cross-cultural validation of a conceptual model of Crohn's disease in Chinese patients: A qualitative focus group study

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Research Article

Keywords: Crohn's disease, Disease conceptual model, Chinese patients, Qualitative study

Posted Date: May 27th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-9483208/v1

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Additional Declarations: Competing interest reported. LL and SC are employees of Sanofi and may hold stocks or stock options in the company. EBH is an external contractor working for Sanofi as a COA Lead. YZ is an employee working for Sanofi as a Patient Engagement Lead. YL is the leader of healthcare service line for Ipsos China, working on the study with sponsorship from Sanofi. XA is a researcher in Ipsos healthcare team. YC and DX is working for The Second Affiliated Hospital, Zhejiang University School of Medicine. JZ is an employee working for the China Crohn's and Colitis Foundation (CCCF) as a Senior Project Manager and have no conflicts of interest to disclose.

Abstract

Background: Crohn's Disease (CD) is a chronic inflammatory disorder of the gastrointestinal tract, which can lead to progressive bowel damage and disability. The incidence of CD in China has increased steadily over recent decades; however, most of the patient-reported outcome (PRO) instruments were developed based on the experiences of patients with CD from the United States. Their cultural relevance to Chinese patients with CD has not been systematically evaluated. Therefore, this study aimed to access and validate the original conceptual model of CD to reflect the experiences of Chinese patients with CD.

Methods: A qualitative study was conducted using four focus group discussions, including three patient groups (n = 18) and one healthcare professional (HCP) group (n = 6) from China. Insights from Chinese patients with CD and relevant HCPs was collected through these focus group discussions. The study explored participants' perceptions of CD-related symptoms, impacts, and coping strategies to validate the relevance and cultural applicability of the original conceptual model of CD to Chinese patients.

Results: Among 107 concepts in the original conceptual model, 100 concepts (93.5%) were validated by Chinese participants. All 27 high-frequency concepts were confirmed by at least two focus groups, indicating strong cross-cultural consistency. The discussions also identified high-frequency, most bothersome, and salient concepts in Chinese patients' experiences. Furthermore, 17 new concepts were incorporated, leading to the creation of a new conceptual model of CD tailored to the Chinese context.

Conclusion: This study validated the cross-cultural relevance of the original CD conceptual model through focus groups in China and confirmed its applicability to Chinese patients with CD. These findings provide a theoretical foundation for applying established PRO and clinical outcome assessment instruments in the Chinese context and support development of a culturally adapted disease conceptual model tailored to Chinese patients with CD. Furthermore, it provides a basis for an in-depth understanding of the experiences of Chinese patients with CD.

Introduction

Crohn's disease (CD) is an inflammatory bowel disease that causes complex, chronic inflammation of the gastrointestinal (GI) tract with unknown aetiology, predominantly affecting the terminal ileum and colon. It follows a protracted, relapsing course and presents with diverse clinical manifestations. The symptoms of CD fluctuate between active and remission phases and often worsen progressively over time. This causes persistent damage to patients' intestinal structure and function, leading to complications [1]. Approximately 58% of patients require surgical intervention within 10 years of CD diagnosis [2]. While surgery can alleviate symptoms, it cannot cure the disease. Besides impairing patients' physical function, CD restricts their social interactions, academic performance, professional careers, and other aspects related to quality of life (QoL) [3].

The global incidence of CD is increasing, with a trend towards younger age at onset [4, 5]. The median global incidence has reached up to 3.5 cases per 100,000 person-years [6]. The growing incidence has made CD one of the major chronic diseases threatening public health [7]. As the incidence and prevalence rates increase across all ethnic groups, CD will progressively affect a broader and more diverse population.

However, the clinical manifestations and impacts of CD vary across different populations because of genetic, environmental, and cultural factors [8]. Despite the increasing disease burden, data on the disease-specific experiences and burden among Chinese patients remain limited [9]. In 2022, Chinese authorities issued the draft guidelines for the Application of Patient-Reported Outcomes (PROs) in Drug Clinical Research, which emphasise the importance of using scientifically rigorous PRO measures in clinical trials conducted in China [10–12]. These draft guidelines are in line with similar initiatives from the Food and Drug Administration (FDA) [13] and the European Medicines Agency (EMA) [14], reflecting a global movement towards incorporating patient perspectives into drug development. However, many PRO instruments currently in use were developed within Western cultural settings and therefore reflect Western perspectives of health and disease [15, 16]. Although an original conceptual model of CD has been developed based on collected perspectives from patients with CD from the United States (US), its applicability to Chinese patients is currently unclear [17]. A culturally relevant conceptual model is crucial for accurately capturing the unique disease burden in the Chinese population. Therefore, it is necessary to assess the original CD conceptual model within the demographic characteristics of the Chinese CD population. This conceptual model provides a scientific basis for the formulation of public health strategies supporting improved patient QoL through targeted pharmacotherapeutic and healthcare interventions.

Methods

Study Design

This study adopted a qualitative approach, collecting insights from Chinese patients with CD and relevant healthcare professionals (HCPs) through focus group discussions. Focus groups create an environment for interactive group discussions, allowing participants to fully express their real experiences and emotions. This method also enabled researchers to collect in-depth and rich data [18, 19], which could be used to verify the relevance and cultural applicability of the original conceptual model for CD to Chinese patients.

Initially, a conceptual model was developed through an extensive literature review, which was subsequently enriched by conducting in-depth interviews with 12 patients with CD from the Unites States. Employing content and framework analysis, novel concepts identified from the patient interviews were integrated into the initial model. The original conceptual model of CD was formally established by synthesizing key concepts from both the literature review and interview phases.

Based on this original model, two structured discussion guides were developed, one for patients (Supplementary file 1) and another other for HCPs (Supplementary file 2) to facilitate focus group discussions aimed at validating the original conceptual constructs. A total of four focus group discussions were conducted, comprising three patient groups and one HCP group, with six participants per group.

All focus group sessions were held online, each lasting approximately 1 hour. An experienced moderator guided participants through discussions on CD-related symptoms, impacts of the disease, and coping strategies in alignment with the predeveloped guides. The concepts articulated by participants were systematically collated and compared with the original conceptual model. Additionally, researchers explored participants' perspectives on differences in CD management and experience, while investigating how Chinese patients with CD perceive and interpret the concepts derived from the original model.

Participants and Focus Group

Purposive sampling was adopted to include diverse groups of participants with varying ages, geographical locations, and city tiers. In line with the focus group design, a total of 18 Chinese patients and six HCPs from China were recruited.

The 18 patients with CD were required to have a confirmed CD diagnosis for at least 12 months. They were divided into three focus groups based on different age ranges, as discussions among peers would facilitate communication among patients.

The six HCPs included five gastroenterologists and one specialized nurse from an inflammatory bowel disease (IBD) centre. All HCPs were required to have extensive experience in treating/managing CD in China (with at least 10 years of relevant experience for clinicians and at least 3 years for nurses) and to have treated/managed at least 20 patients with CD per month.

Qualitative Data Analysis

During the focus group discussions, concepts reported by participants were collected and simultaneously compared with the original conceptual model of CD, with a focus on identifying the salient symptoms and the most frequent and most bothersome concepts within the model. After the interviews, two professional qualitative researchers coded the transcribed interview texts to further organize the relevant concepts. Concepts related to the experiences of patients with CD were further identified and were organised and summarised in accordance with the framework of the original conceptual model. When the coding indicated results that differed from the original conceptual model, the conceptual model for Chinese patients was appropriately adjusted.

Concept frequency

During the focus group discussions, the CD-related symptoms, impacts, and coping strategies reported by each patient were recorded. For each concept, the frequency of being reported by a single respondent was counted as one only. Among all participants (n = 24), core concepts were defined as those reported by both patients and HCPs and mentioned by at least 25% of participants (n = 6).

Most bothersome concepts

The most bothersome symptoms and impacts on Chinese patients with CD were identified based on participants' ranking of bothersome concepts. All participants selected and ranked the concepts they perceived as the most bothersome for CD. Each participant could choose up to three symptoms and three impact domains and were requested to score their bothersome levels. The final ranking of bothersome levels was determined by the score of each bothersome concept mentioned by all participants. If two concepts had the same total frequency, the one with higher counts of being ranked first was considered more bothersome.

Salient symptoms

A salient concept was defined as one mentioned by more than 50% of participants and more than 75% of focus groups, with an average bothersome score exceeding five points. The concepts mentioned by more than 75% of participants with an average bothersome score of > 5 were designated as the most salient concepts of special concern. These concepts not only had high reporting frequencies but also caused severe bother, indicating that they were common among patients with CD and had a significant negative impact on patients' QoL.

Ethics

The study was conducted in accordance with the principles of the Declaration of Helsinki [20] and was approved by the Ethics Committee of the Second Affiliated Hospital Zhejiang University School of Medicine on 10 June, 2025 (Ethic review No. (2025) 0861).

All individuals were informed that they could withdraw their consent or assent at any time before, during, or after the interview without prejudice or the need to provide a reason. Participants who withdrew consent to participate in the study were excluded.

Results

Participant Demographics

A total of 18 patients and six HCPs from China were recruited to participate in this study. The 18 patients were divided into three patient (PT) focus groups based on age (PT1: 16–25 years, PT2: 26–45 years, PT3: 46–75 years), whereas the six HCPs formed one HCP focus group.

The demographic characteristics of the 18 patients are presented in Table 1. The average age (range) of the patients was 36.11 (16–72) years. The average duration since diagnosis was 6 years and 11 months, with the shortest durations being 1 year and 9 months, and the longest durations being 19 years and 4 months. The number of patients in eastern China (n = 6) and southern China (n = 6) were higher than that in northern China (n = 3) and western China (n = 3). The city tiers (representing the level of regional development) and the gender ratio were balanced, and patients with different marital status and work or study status were included. These met the requirement for sample diversity and enabled the collection of diverse information on the experiences of patients with CD.

Table 1
Demographics of Chinese patient with CD (N = 18)

Demographic characteristics		**Participants, n (%)**
Age (years)	Mean (median) [range]	36.11 (33) [16 – 72]
Region	East	6 (33)
	South	6 (33)
	North	3 (17)
	West	3 (17)
City	Tier 1	7 (39)
	Tier 2	5 (28)
	Tier 3	6 (33)
Gender	Male	10 (56)
	Female	8 (44)
Marital status	Married	9 (50)
	Unmarried	9 (50)
Work/study status	Student - continue	4 (22)
	Student - medical leave due to CD	1 (6)
	Working full-time in paid job	7 (39)
	Working part-time in paid job	2 (11)
	Retired	4 (22)
CD, Crohn’s disease		

A total of six HCPs from China participated in the study. Their demographic details are summarised in Table 2. The HCP focus group included five gastroenterologists and one specialized nurse from an IBD centre. The geographical distribution revealed that the largest proportion of HCPs were from eastern and

southern China (n = 2 each region), followed by western China (n = 1) and northern China (n = 1). All HCPs were affiliated with tertiary hospitals located in first- or second-tier cities, which are characterized by concentrated medical resources and up-to-date clinical practices in China. This ensured the HCPs possessed specialized expertise in CD and extensive experience in managing CD cases in China. The clinicians had an average of 12.4 years of CD-specific work experience, whereas the nurse had 4 years of experience in CD care.

Table 2
Demographics of Chinese HCPs (N = 6)

Demographic characteristics		**Participants, n (%)**
Region	East	2 (33)
	South	2 (33)
	North	1 (17)
	West	1 (17)
City	Tier 1	3 (50)
	Tier 2	3 (50)
Hospital level	Level 3/ Tertiary hospitals	6 (100)
Position in hospital	Chief physician	2 (33)
	Vice chief physician	3 (50)
	Specialised nurse at an IBD centre	1 (17)
Member of the IBD centre	Yes	5 (83)
CD-related experience (years)	Physician: mean (median) [range]	12.4 (12) [10–15]
	Nurse	4

CD, Crohn's disease; HCP, healthcare professional; IBD, inflammatory bowel disease.

Patients' Perspectives

This study gained in-depth insights into first-hand disease experiences of Chinese patients with CD through patient focus group discussions. An analysis was conducted based on the original conceptual model of CD, leading to the identification of 113 concepts from the patient data. These concepts were categorised into 43 symptoms, 55 impacts, and 15 coping strategies.

All four symptom subdomains (GI, extraintestinal, nutrition-related, and pain-associated) were validated in all three patient focus groups, with at least one concept identified under each subdomain. Abdominal

pain (n = 17/18) was the most prevalent among the Chinese CD patient population, with the highest reporting frequency, followed by diarrhoea (n = 14/18) and weight loss (n = 13/18).

In addition to symptoms, the impacts of CD affected multiple aspects of patients' lives. The impact-related concepts included a total of 10 subdomains, all of which were validated by the 3 patient focus groups. Changed/restricted diet (n = 13/18) was the most frequently reported impact, highlighting the influence of Chinese dietary culture on patients' QoL. This was followed by increased planning (when going out) (n = 11/18) and disrupted sleep (n = 8/18).

Patients adopted diverse approaches in terms of coping strategies, including symptom-specific strategies and general coping strategies. Notable strategies included maintaining a positive outlook (n = 7/18), strengthening bonds with friends/family (n = 5/18), and engaging in exercise (n = 5/18).

The three most bothersome symptoms reported by patients were abdominal pain (pain-associated symptoms), diarrhoea (GI symptoms), and bowel obstruction (GI symptoms) (Fig. 1). The most bothersome impacts were associated with three subdomains: diet, work and education, and emotional wellbeing.

Among the salient symptoms identified from the patient focus groups, diarrhoea, abdominal pain, weight loss, and fatigue met the following criteria: >50% of patients, > 75% of focus groups, and the average distress score exceeded 5 points. Diarrhoea and abdominal pain were analysed as the most salient symptoms requiring special attention, as they were mentioned by > 75% of patients and had an average bothersome score > 5.

Healthcare Professional's Perspectives

The HCP focus group discussions provided professional clinical insights, with the collected information derived from their years of professional experience in clinical practice. A total of 82 concepts were identified, including 37 symptoms, 35 impacts, and 10 coping strategy-related concepts.

All four subdomains of symptoms were validated by the HCP focus group. Diarrhoea (n = 6/6), abdominal pain (n = 6/6), and weight loss (n = 6/6) were the most frequently reported symptoms by HCPs, all of which were confirmed by each HCP as part of the experience of Chinese patients with CD.

In terms of impacts, all 10 subdomains were confirmed by HCPs. Emotional wellbeing issues received the most attention from HCPs: the most frequently reported impacts were anxiety/worry (n = 5/6), low mood/depression (n = 4/6), and reduced intimate relationships (n = 4/6).

The HCPs not only recommended coping strategies for patients to improve their QoL but also collected some proactive strategies adopted by patients to manage their CD. These strategies also covered the two subdomains included in the original conceptual model. Among them, the most frequently reported strategies by HCPs were self-training/self-limiting behaviour (n = 4/6), strengthened bonds with other

patients (n = 4/6), maintaining a positive outlook (n = 3/6), and proactive arrangement for medical visits (n = 3/6).

As shown in Fig. 2, HCPs identified abdominal pain (pain-associated symptoms), diarrhoea (GI symptoms), and bloating (GI symptoms) as the three most bothersome symptoms for patients. The three most bothersome impacts were associated with three subdomains: emotional well-being, social life, and family and relationships.

For the HCP focus group, diarrhoea, abdominal pain, weight loss, difficulty absorbing nutrients, and fatigue were the salient symptoms. Among these, diarrhoea, abdominal pain, weight loss, and difficulty in absorbing nutrients were analysed as the most salient symptoms requiring special attention. HCPs indicated that in clinical practice Chinese patients, including those with or without CD, rarely perceive difficulty absorbing nutrients or malnutrition as bothersome. However, for HCPs, difficulty in absorbing nutrients, is a symptom that requires attention; thus, this salient symptom is limited to the perspective of HCPs.

"From the patients' perspective, they may rank malnutrition relatively low. For example, some patients, even when very thin, do not consider themselves malnourished. We have encountered extremely thin adolescents, with a BMI of only 14 or 15, yet they still find this acceptable. In fact, malnutrition may not be very bothersome for them, but the situation is different from a doctor's viewpoint." (HCP-2)

Final Conceptual Model of Crohn's Disease in China

Building on the original conceptual model of CD, this study integrated the findings from patient and HCP focus groups to develop a Chinese conceptual model of CD (Fig. 3). A total of 117 concepts were identified, including 46 symptom-related concepts, 56 impact-related concepts, and 15 coping strategy-related concepts. These concepts enhanced the understanding of disease experiences among Chinese patients with CD.

- Symptom-related concepts (46 concepts): These concepts include four subdomains: GI symptoms, extraintestinal symptoms, nutritional symptoms, and pain-associated symptoms.
- Impact-related concepts (56 concepts): These concepts included 10 subdomains: Diet, emotional wellbeing, sleep, activities of daily living, social life, family and relationships, work and education, physical functioning, hobbies and leisure, treatment and healthcare.
- Coping strategy-related concepts (15 concepts): These concepts include two subdomains: symptom-specific coping strategies and general coping strategies.

Integrating the discussion results from Chinese patients and HCP focus groups (Fig. 3), the symptoms rated as the most bothersome were abdominal pain, diarrhoea, and bowel obstruction, whereas the most bothersome impacts fell into three subdomains: diet, emotional well-being, and work and education.

Additionally, compared with the original conceptual model, 17 new concepts were added (Fig. 3), including six symptom-related concepts, six impact-related concepts, and five coping strategy-related concepts. These newly added concepts collectively served as a supplement to the CD conceptual model based on this study on Chinese patients' experiences.

As shown in Fig. 4, the Chinese conceptual model contained 41 core concepts, defined as those reported by both patient and HCP focus groups and mentioned by at least 25% of participants (n = 6). These core concepts included three domains and 13 subdomains. There were 41 core concepts in the conceptual model, defined as those reported by both patient and HCP focus groups, as well as by ≥ 25% of respondents (n = 6). The core concepts mainly comprised of signs and symptoms, among which GI symptoms account for the largest number of core concepts, totalling 12 core concepts. These findings indicate that GI symptoms play an important role in the disease experiences of both Chinese patients with CD and HCPs, and most of these symptoms are recurrent and prevalent.

Validation and Identification of Concepts

This study systematically validated the applicability of the original conceptual model of CD, which was developed based on US patient experiences, in the Chinese CD patient population through three patient focus groups and one HCP focus group. Among the four focus groups in this study, 100 (93.5%) out of 107 concepts from the original conceptual model of CD were confirmed (Fig. 5). Notably, all 40 symptom-related concepts and 27 high-frequency concepts from the original conceptual model of CD were validated by two or more focus groups in China, demonstrating a high degree of consistency in the core dimensions of symptoms and impacts across cultural contexts.

In the original model, the most bothersome symptoms reported by the US patients were fatigue, frequent bowel movements, and diarrhoea (Fig. 6). In contrast, the most bothersome symptoms among Chinese patients were abdominal pain, diarrhoea, and bowel obstruction; fatigue and frequent bowel movements were not among the most bothersome symptoms for Chinese patients. Although fatigue was not among the top three most bothersome symptoms, three Chinese patients reported it as bothersome, and other Chinese patients acknowledged that fatigue lasted for extended periods. However, when selecting bothersome symptoms, they were more likely to choose 'visible' symptoms. Regarding the concept of 'frequent bowel movements', the concept 'diarrhoea' in the Chinese context typically included both frequent bowel movements and watery stools. Thus, when patients selected diarrhoea as a bothersome symptom, the concept of frequent bowel movements was not excluded. Therefore, frequent bowel movement would no longer be repeatedly and additionally selected as a bothersome symptom. On the other hand, abdominal pain and bowel obstruction were the most bothersome symptoms only for Chinese patients. For most of the Chinese patients, bowel obstruction was a major cause of abdominal pain.

"I have small bowel obstruction, which sometimes causes abdominal pain." (PT3-6)

"When complicated with acute intestinal obstruction, the pain is relatively severe." (HCP-4)

Abdominal pain was also reported as bothersome by 4/12 the US patients. Therefore, there was a little difference in the experience and perception of bothersome symptoms between Chinese and the US patients, as there were potential correlations among these differences.

The most bothersome impacts reported by the US patients (based on the original conceptual model of CD) were in three subdomains: activities of daily living, social life, and work and education (Fig. 7). In this study, work and education also ranked third among the most bothersome impacts. This highlights that, as a chronic disease, CD is characterised by persistent symptoms and frequent treatment requirements, which directly disrupt work and education among both Chinese and the US patients, making it one of the most bothersome cross-cultural impacts of CD. For activities of daily living and social life, which are impacts that are most bothersome to US patients, Chinese patients reported that such bother could be alleviated through treatment and friends' support. Therefore, these impacts were not reported as excessively troublesome for Chinese CD patients. The most bothersome impacts only reported for Chinese patients were diet and emotional wellbeing. Among these, dietary bother was reported by the largest number of Chinese CD patients. Of note, dietary impacts, to some extent, reflected the impacts on Chinese patients' activities of daily living and social life. Due to the unique dietary culture in China, changes in eating habits are linked to various aspects of life:

"It (diet) affects (going out). For example, I want to visit a place to try the local delicacies, but I can't eat them and have to just watch others enjoy the meal." (PT1-2)

"I can't eat spicy food; all the food at school is spicy. So I have to commute from home… All the other girls are resident students, and the number of girls is odd. Everyone else pairs up…so I feel a bit lonely." (PT1-6)

"Once you can't drink alcohol or attend social gatherings, whether during the stable phase or relapse phase of the disease, it actually has a certain impact on work." (PT2-6)

Although emotional wellbeing was not among the top three most bothersome impacts, 5/12 of the US patients reported it as bothersome. Despite differences in the ranking of the most bothersome impacts compared to the original conceptual model of CD, there was a consensus between the groups that emotional wellbeing was impacted for both Chinese and US CD patients. Overall, there were minor differences in the most bothersome impacts of CD between Chinese and the US CD patients relative to the original model; however, consensus could be reached regarding the underlying reasons for these minor differences.

Based on patient-reported data from both groups, fatigue was a common salient symptom among Chinese and the US CD patients. Although abdominal pain, diarrhoea, and weight loss did not meet the criteria for being 'salient symptoms' in the original conceptual model of CD, they were reported as bothersome symptoms by the US patients, with bother frequencies of n = 4/12, n = 4/12, and n = 1/12, respectively, and all bother scores exceeded 5 points. Therefore, these symptoms require attention in both Chinese and the US patient populations with CD, consistent with the focus of the original conceptual model of CD on symptom management.

Discussion

This study systematically validated the applicability of the original conceptual model of CD in the Chinese cultural context through focus groups involving Chinese patients with CD and HCPs from China. Despite minor cultural differences in the frequency of concept reporting and the level of bothersome symptoms and impacts, the Chinese and the US patients exhibited high commonality in the core disease experiences of CD. This finding is consistent with the results of an epidemiological study conducted by Ng et al.[21], which was based on a multi-country Asian cohort and revealed high consistency in disease progression, complications, and treatment pathways between Asian and US patients with CD.

In addition, the methodological approach was primarily confirmatory rather than fully exploratory. Guided by an existing conceptual framework, the study was designed to assess the relevance and applicability of predefined domains within the Chinese context, rather than to generate an entirely new model inductively. While this theory-informed approach enhances conceptual focus, it may have constrained the identification of novel or unanticipated themes. Future exploratory research in more diverse patient populations may further expand the model. The Chinese conceptual model developed in this study comprises 117 concepts, which comprehensively represent the diverse situations that may be experienced by Chinese patients with CD, including symptoms, impacts, and coping strategies. The results showed that the concepts covered in the original conceptual model could generally capture the experiences of Chinese patients with CD. Although 17 new concepts were identified and added in this study based on focus group discussions, none of these new concepts were categorised as key (high-frequency, bothersome, or salient) concepts in the Chinese conceptual model of CD. This study demonstrated that all key concepts in the Chinese model were already included in the original conceptual model for CD[22].

Despite minor differences in the specific manifestations of symptom reporting and disease impacts, these variations appeared to reflect cross-cultural cognitive and linguistic nuances observed during the interviews. Importantly, they did not suggest substantive divergence from the core constructs underlying the patient-reported outcome (PRO) and clinical outcome assessment (COA) instruments derived from the original conceptual model. For example, ‘frequent bowel movements’ is a symptom reported as bothersome by the US patients and was not among the most bothersome symptoms of Chinese patients. However, ‘diarrhoea’ listed as one of the most bothersome symptoms by Chinese patients already encompasses the meaning of frequent bowel movements. Another example pertains to the dietary impact, which was reported as the most bothersome by Chinese patients but was not among the most bothersome impacts in the original conceptual model. However, the study found that in the context of traditional Chinese dietary culture, dietary impacts reflected the impacts on patients’ daily life, social life, work and education [23]. Therefore, the focus on daily life, social life, work and education in the original conceptual model for CD is appropriate to capture the emphasis on the quality of life of Chinese CD patients. The difference in these studies primarily reflects the influence of different cultural backgrounds on the perception of QoL, rather than posing substantive challenges to the core structure or application of CD COA tools. The original core dimensions used to assess the impacts of CD, including

physical function, psychological state, and social life are common to both Chinese and US patients. This consistency ensures the applicability and validity of existing CD COA tools in Chinese clinical practice and clinical trials [24, 25].

The strengths of this study lie in its adoption of focus group discussions, which integrated dual perspectives from patients and HCPs. This study design enabled patients with CD and HCPs treating CD patients to fully express their views and experiences in an interactive and relaxed setting, thereby facilitating in-depth exploration of CD-related information. Furthermore, conducting separate focus group discussions with patients and HCPs helped to examine and refine the original conceptual model from multiple perspectives. In addition, analysis of the underlying causes of differences between China and the US, through group discussions, allowed for more comprehensive and objective study results as they incorporated both patients' actual perceptions and professional medical judgements, thereby enhancing the credibility of the study [26].

However, this study also has some limitations. First, the sample does not encompass all subgroups of patients with CD in China, may limit the transferability of the findings[27]. Although qualitative research does not seek statistical representativeness, the absence of certain populations may still constrain the breadth of perspectives captured. In particular, patients from remote or rural regions, those with very early or very late disease onset, and individuals with limited access to specialist care were underrepresented. These groups may have distinct disease-management experiences or healthcare-seeking behaviours that were not fully reflected in the data. Nevertheless, the core symptom and impact domains identified were broadly consistent with existing clinical and qualitative literature, suggesting conceptual relevance across patient populations. Second, group interaction in focus group discussions may lead to individual viewpoints being influenced by group thinking, and some voices may potentially get overshadowed [28]. To mitigate this risk, experienced moderators employed structured facilitation strategies to promote balanced contribution across participants. Although no clear dominance patterns emerged during the discussions, the possibility of subtle group influence cannot be entirely excluded. Finally, this study primarily focused on concept validation and has not yet conducted empirical testing on the operability of the model in Chinese patients with CD using quantitative tools such as scales [29].Despite potential limitations, this study validated the relevance and applicability of Sanofi's original conceptual model for CD in the Chinese cultural context.

Conclusion

The Chinese conceptual model of CD, developed from the original framework, provides a structured representation of the disease experiences of Chinese patients with CD. The concepts within the model were highly aligned with patients' reported experiences and HCPs' clinical observations, supporting its cultural relevance and contextual applicability within the Chinese setting. This study not only provides empirical evidence for the application of the conceptual model of CD in China but also further enriches the academic community's understanding of Chinese patients with CD, contributing to the advancement of research and practice related to the COA of CD[30].

Abbreviations

CD
Crohn’s disease
PRO
Patient-reported outcome
HCP
Healthcare professional
GI
Gastrointestinal
COA
Clinical outcome assessment
IBD
Inflammatory bowel disease
QoL
Quality of life

Declarations

Ethics approval and consent to participate

The study was conducted in accordance with the principles of the Declaration of Helsinki[13] and was approved by the Ethics Committee of the Second Affiliated Hospital Zhejiang University School of Medicine on 10 June, 2025 (Ethic review No. (2025) 0861).

Informed consent to participate was obtained from all the participants in the study.

All individuals were informed that they could withdraw their consent or assent at any time before, during, or after the interview without prejudice or the need to provide a reason. Participants who withdrew consent to participate in the study were excluded.

Consent for publication

The written informed consent for publication from the participants was obtained for the manuscript.

Availability of data and materials

All data generated or analysed during this study are included in this article.

Funding

This study was funded by Sanofi. No additional financial support was provided for the development of the manuscript.

Conflict of interest

LL and SC are employees of Sanofi and may hold stocks or stock options in the company. EBH is an external contractor working for Sanofi as a COA Lead. YZ is an employee working for Sanofi as a Patient Engagement Lead. YL is the leader of healthcare service line for Ipsos China, working on the study with sponsorship from Sanofi. XA is a researcher in Ipsos healthcare team. YC and DX is working for The Second Affiliated Hospital, Zhejiang University School of Medicine. JZ is an employee working for the China Crohn’s and Colitis Foundation (CCCF) as a Senior Project Manager and have no conflicts of interest to disclose.

Authors' contributions

YL contributed to the conceptualization, methodology, study design, data curation, formal analysis, visualization, validation, and preparation of the original draft. EBH, YC, DX, LL and JZ contributed to the conceptualization, methodology, and study design. SC and YZ contributed to the methodology and study design development. XA contributed to the review and editing of the manuscript. All authors critically reviewed and edited the manuscript and approved the final version for submission.

Acknowledgements

The editorial support was provided by Ravina Darekar from Sanofi.

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Figures

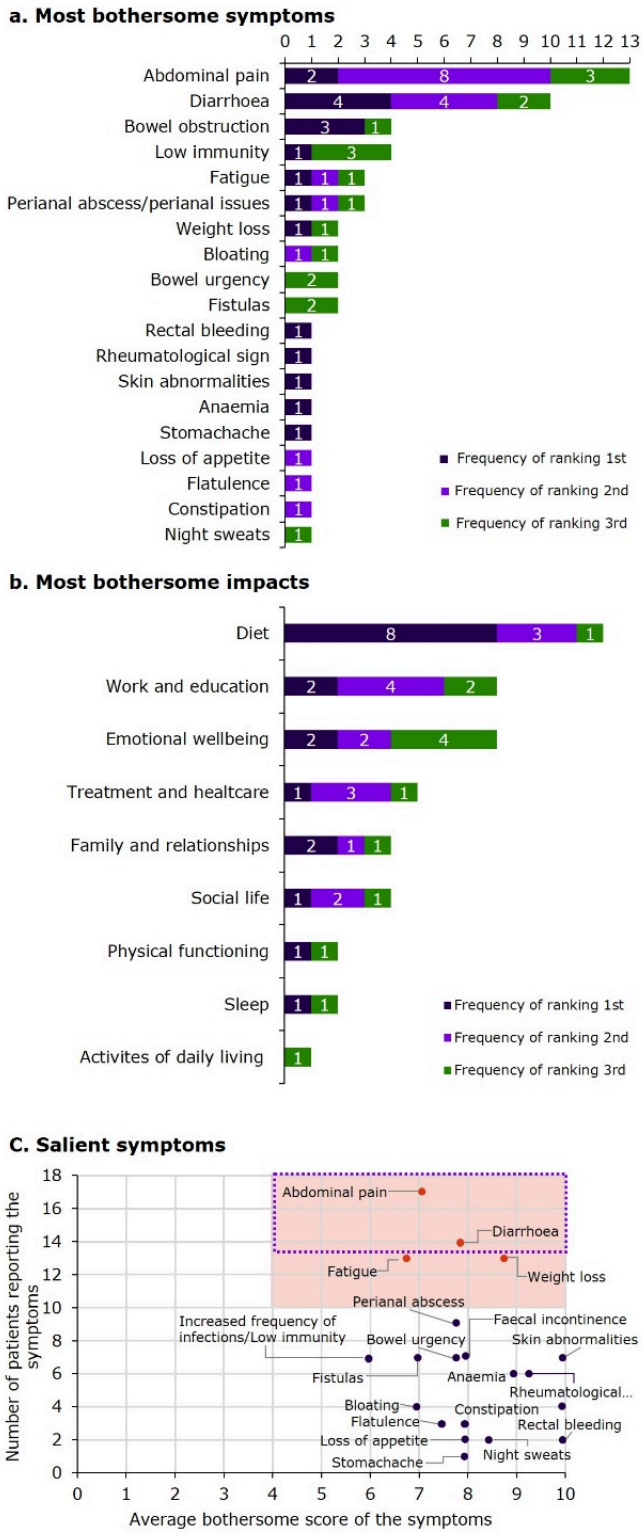

Figure 1

Key concepts related to CD perceived by Chinese patients (n = 18). (a) Most bothersome symptoms: the bothersome symptoms reported by patients. (b) Most bothersome impacts: the bothersome impact subdomains reported by patients. (c) Salient symptoms: the ‘number of patients reported the symptoms’, and ‘average bothersome score’ are used as dimensions to visually show the salience of symptoms

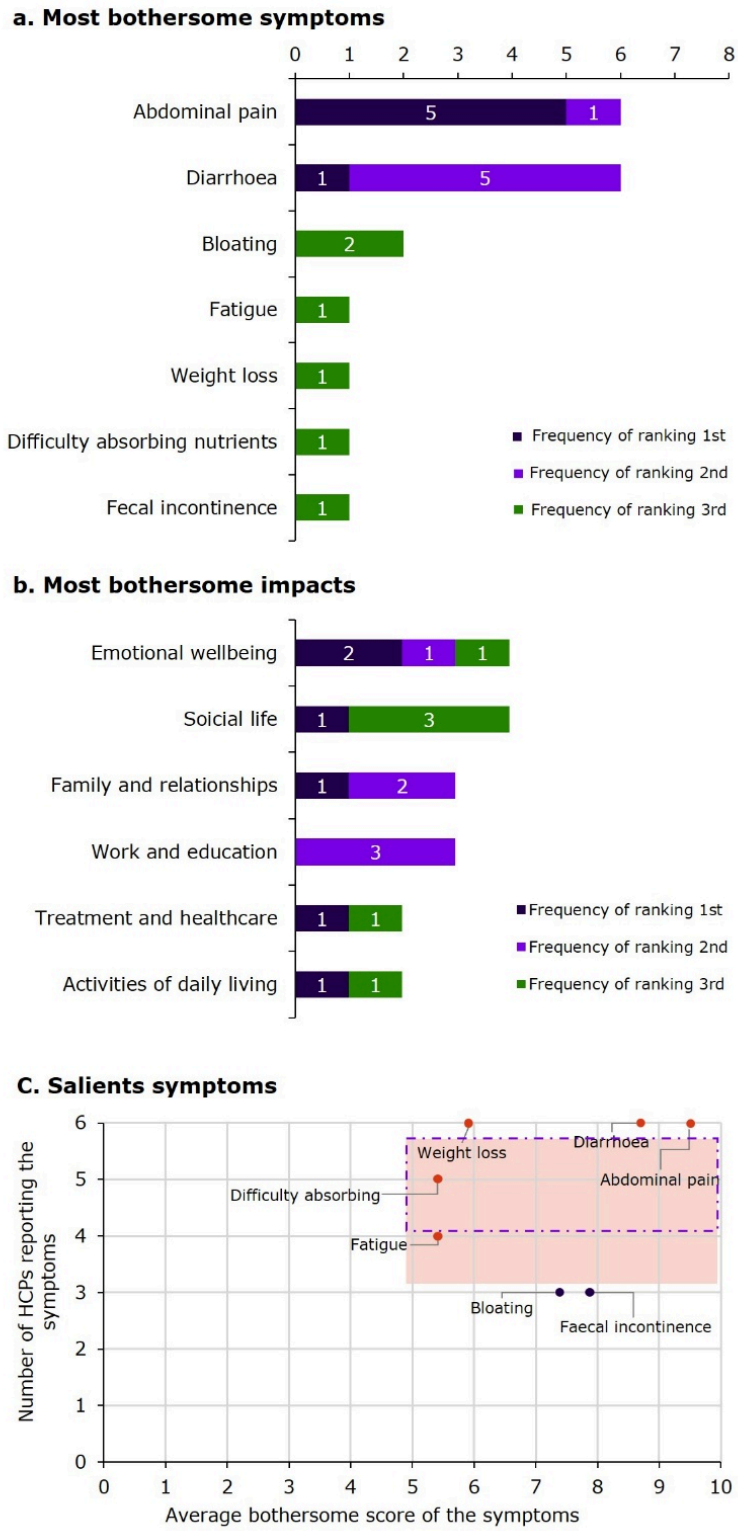

Figure 2

Key concepts related to CD perceived by Chinese HCPs (n = 6). (a) Most bothersome symptoms: the bothersome symptoms for patients as perceived by HCPs. (b) Most bothersome impacts: the bothersome impact subdomains for patients as perceived by HCPs. (c) Salient symptoms: the ‘number of HCPs reported the symptoms’, and ‘average bothersome score’ are used as dimensions to present the salience of symptoms

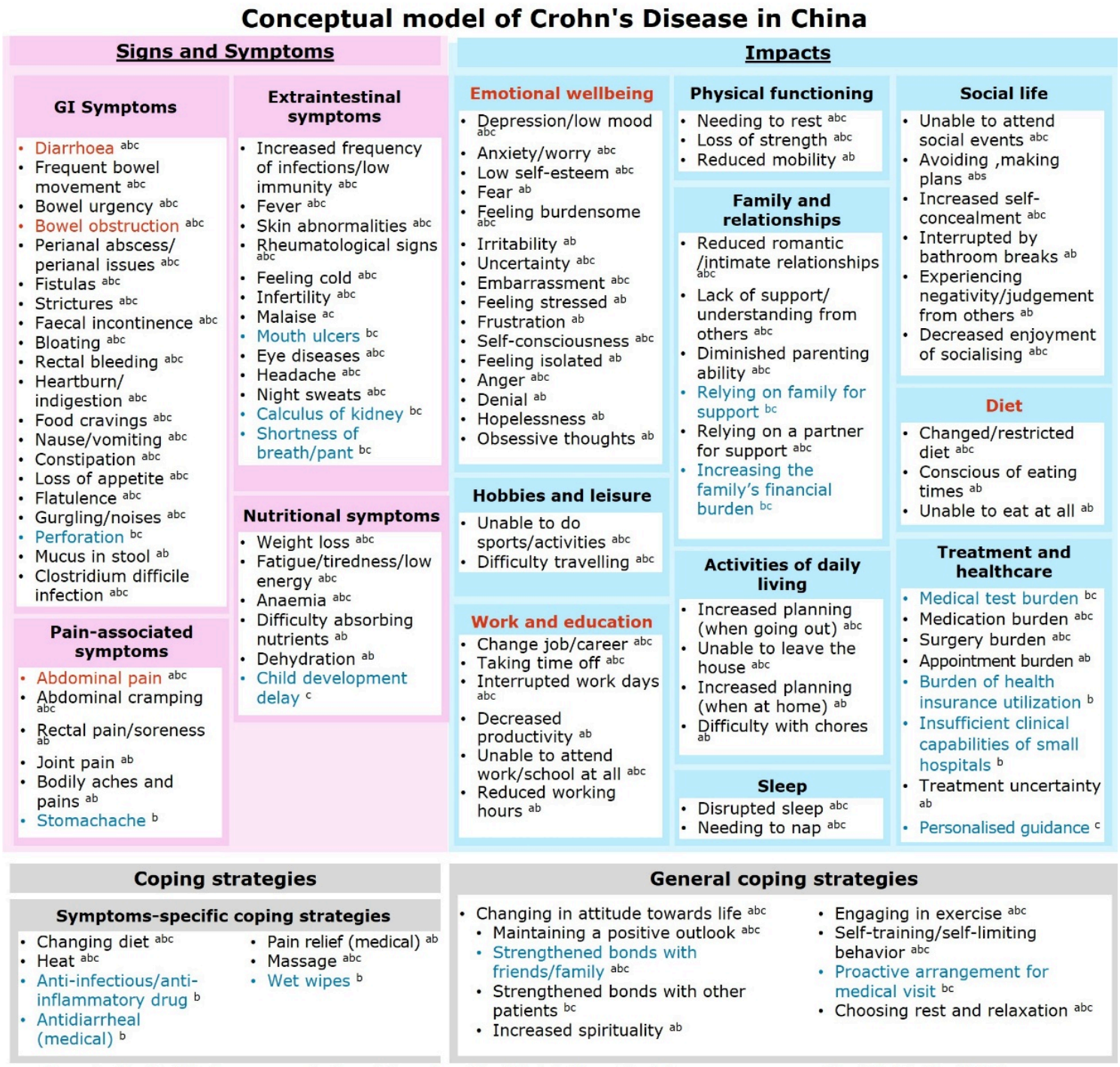

Figure 3

The conceptual model of Crohn's disease in China

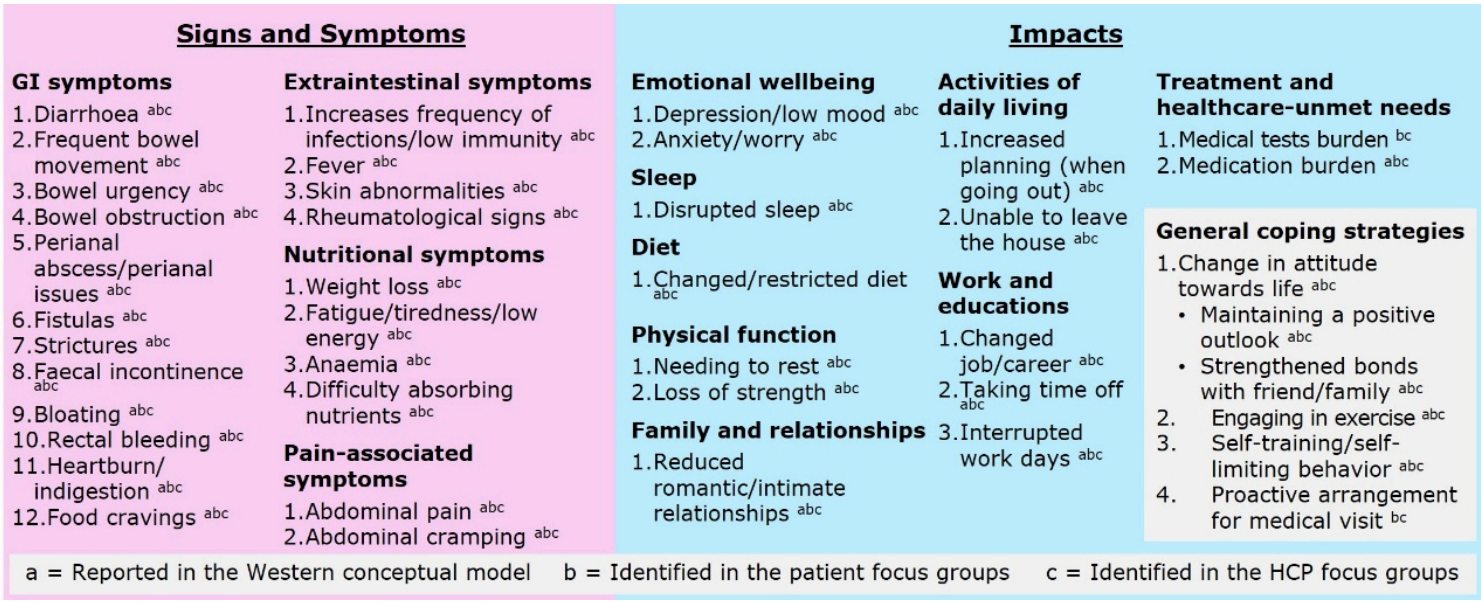

Figure 4

The core concepts in Chinese conceptual model of CD

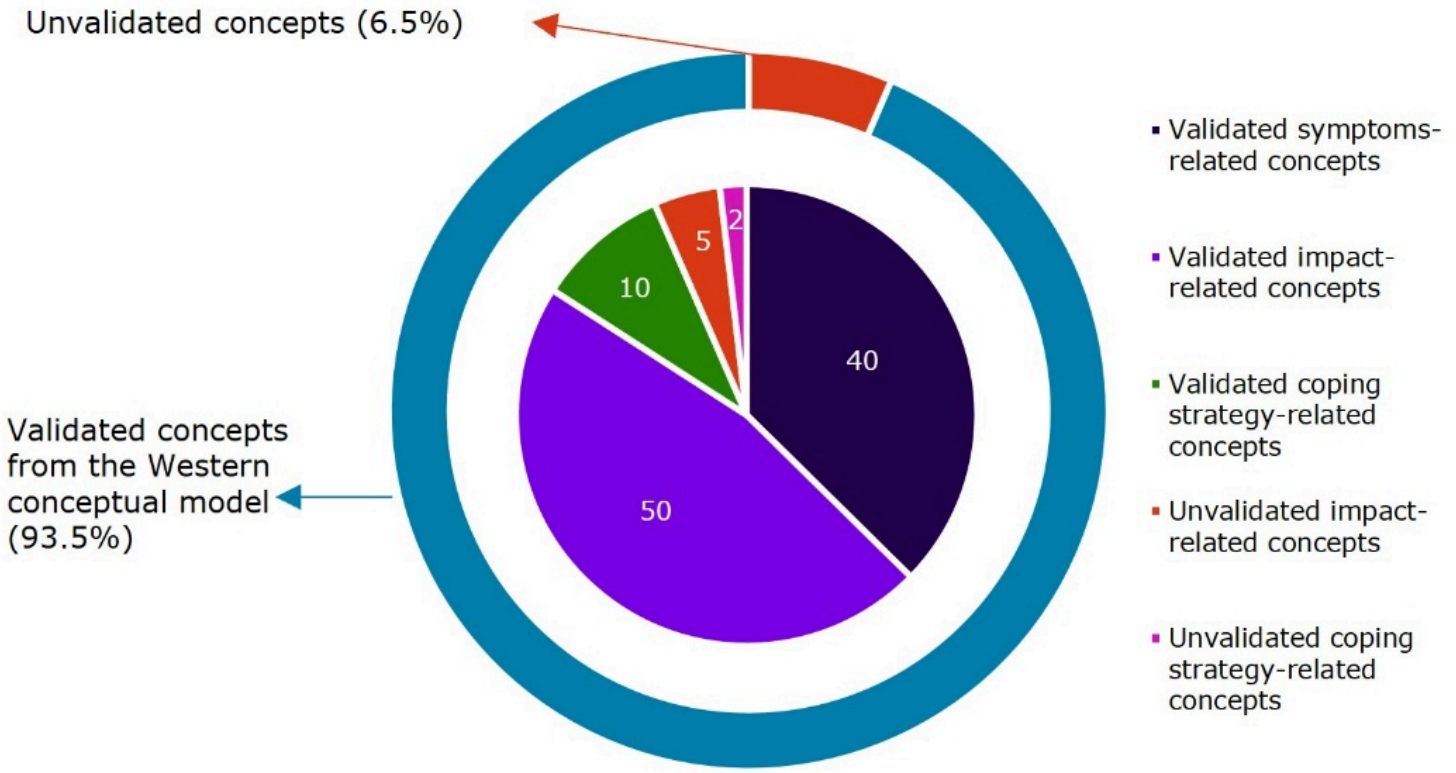

Figure 5

Composition of the original conceptual model of CD: 40 symptoms, 55 impacts, and 12 coping strategies (40 symptoms, 50 impacts, and 10 coping strategies have been validated in China)

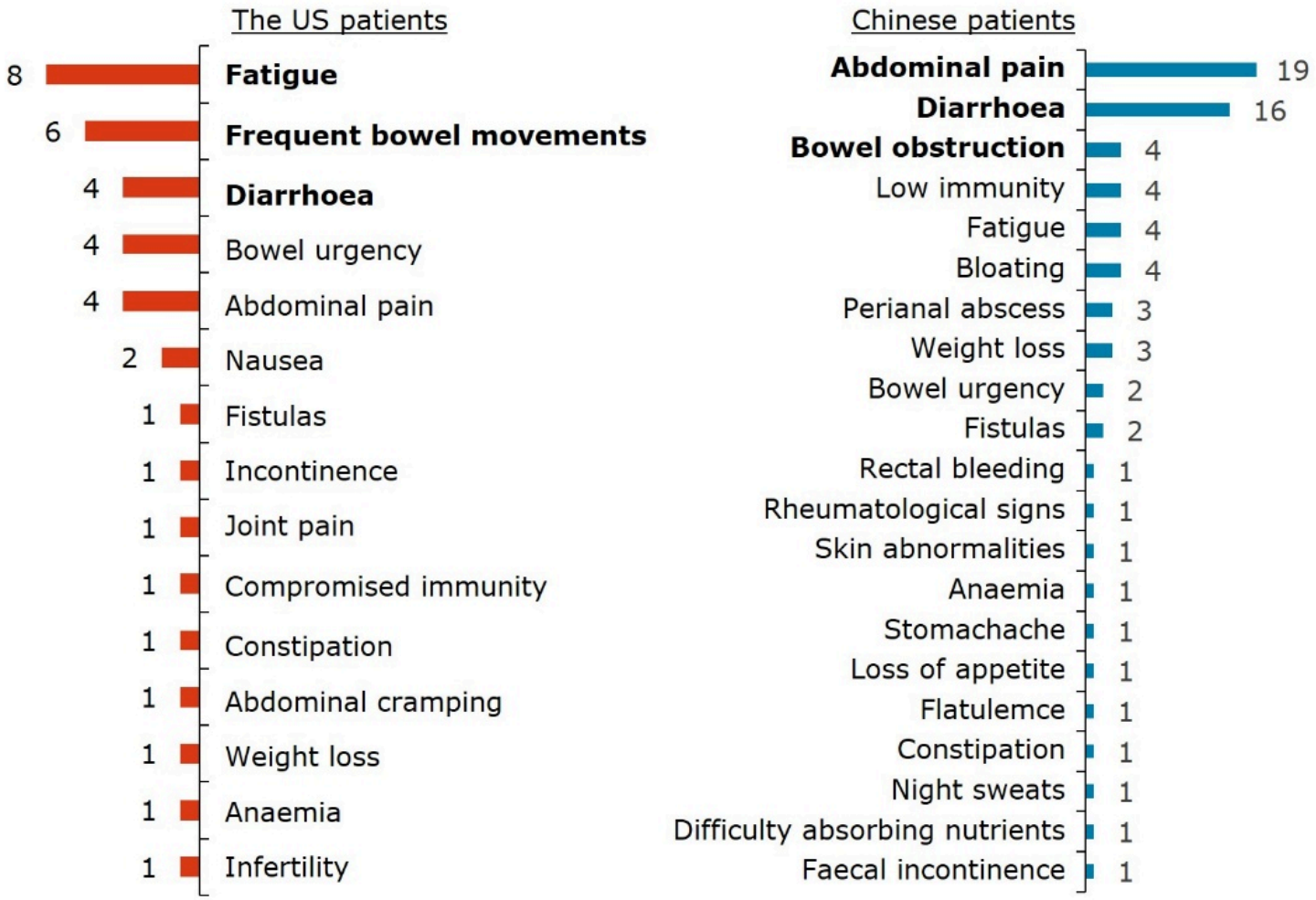

Figure 6

Comparison of the most bothersome symptoms between Chinese and the US patients

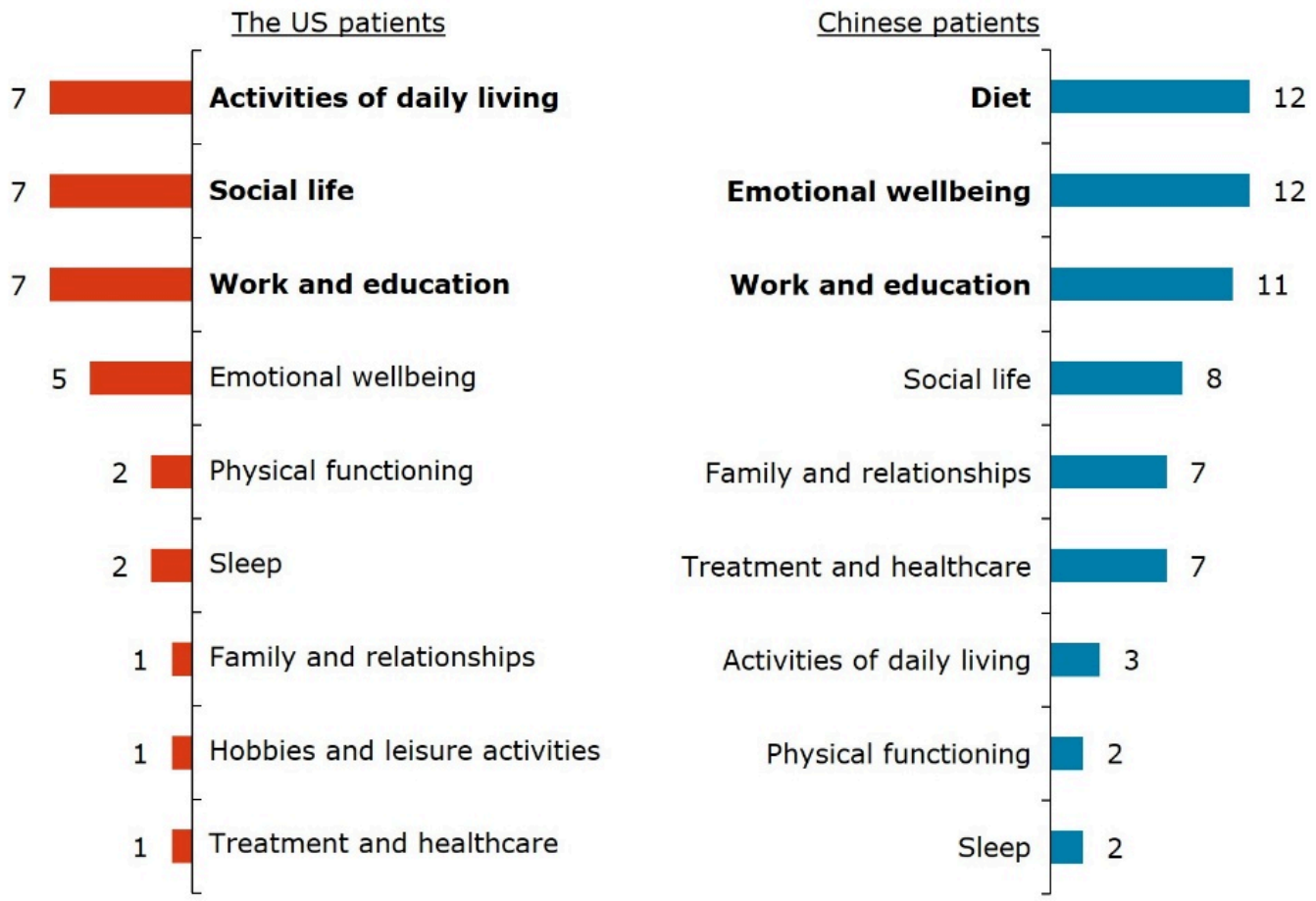

Figure 7

Comparison of the most bothersome impacts between Chinese and the US patients

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