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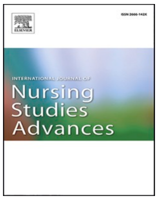

Self-care in children and young people with complex chronic conditions instrument: development and content validation

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ABSTRACT

Introduction: The numbers of children and young people living with chronic conditions are rising, with many experiencing significant functional limitations and complex healthcare needs. As life expectancy improves, there is a growing need to support families in managing care at home and promoting age-appropriate self-care behaviors. Existing frameworks provide evidence that self-care is essential for maintaining health, monitoring and managing changes, as it evolves with the child's development. Few instruments comprehensively assess self-care in pediatric populations or consider the role of parents.

Objective(s): To develop and initially validate an instrument designed to assess self-care behaviors in children and young people with complex chronic conditions, and the contribution of their parents across different developmental stages.

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Methods: This initial validation study, conducted between 2022 and 2023, included four phases: 1) scale development based on theoretical evidence; 2) content and face validation through expert interviews; 3) calculation of Content Validity Indexes; and 4) cognitive interviews for face validity. Eleven variants of the instrument were developed to tailor it to five age groups and addressed three core dimensions of self-care: maintenance, monitoring, and management. Eighty-six expert participants (healthcare providers, parents, and patients) took part in phases 2 and 3, while cognitive interviews were conducted with 5 patients and 13 parents in phase 4. Statistical analyses included Item-Content Validity Indexes and Scale-Content Validity Indexes.

Results: The final instrument, with an average of 37 items per variant, showed strong content validity, with Scale-Content Validity Indexes ranging from 0.91 to 0.98 and Item-Content Validity Indexes between 0.63 and 1. Minimal item revisions were made based on experts' feedback. The instrument demonstrated good face validity and feasibility for online administration, with completion times between 6 and 14 min.

Discussion: A new comprehensive instrument that measures self-care behaviors in children and young people with complex chronic conditions and the contribution of parents was developed, considering the various developmental stages. Initial evidence supports its content and face validity.

Study registration: The study was 'not registered' in any public registry.

What is already known

- There is a growing need for a multidisciplinary approach that ensures continuity of care and enhances quality of life for children and young people with complex chronic conditions.
- Self-care is essential for maintaining well-being, managing health conditions, and promoting positive long-term health outcomes.
- Assessing self-care in children and young people with complex chronic conditions, with valid instruments, is essential for identifying educational needs and care gaps.

What this paper adds

- A new initially validate instrument to assess self-care behaviors in children and young people with complex chronic conditions, incorporating parental contribution and adapted to children's developmental stages.
- Our instrument addresses a significant gap in the literature by providing a theory-based, multidimensional, and developmentally adaptable measure of self-care for children and young people with complex chronic conditions. This was developed through multidisciplinary collaboration and the involvement of children, young people, and their families, ensuring a comprehensive and patient-centered approach to care.

1. Introduction

The number of children and young people living with chronic conditions is steadily increasing. In the United States, nearly 19.4% of children have some form of medical dependency, while in Italy, at least one in every 200 children is affected by a chronic condition (Italian Ministry of Health, 2016; Health Resources and Services Administration, Maternal and Child Health Bureau, 2022). Among them, those with complex chronic conditions are characterized by one or more chronic diseases, severe functional limitations, and high healthcare needs and utilization (Cohen et al., 2011; Feudtner et al., 2014). Examples of the most prevalent pediatric chronic conditions, including those with medical complexity, are severe asthma, cystic fibrosis non-responsiveness to drug therapy, severe dermatological diseases as epidermolysis, chronic lung disease, congenital heart disease, diseases of the digestive system (e.g., short bowel syndrome), chronic renal failure, or liver diseases.

To facilitate their identification and care planning, Cohen et al. recently standardized the definition of medical complexity based on four key domains (Millar et al., 2024). These four domains were identified as (Health Resources and Services Administration, 2022) family-identified healthcare service needs, (Italian Ministry of Health, 2016) one or more chronic clinical condition(s), either diagnosed or unknown, (Feudtner et al., 2014) severe functional limitations, and (Cohen et al., 2011) high projected utilization of health resources (Millar et al., 2024).

As life expectancy among children and young people with complex chronic conditions improves, there is a growing need for a multidisciplinary approach that ensures continuity of care and enhances quality of life. This includes enabling families to manage care at home and supporting children and young people to engage in daily life activities, including but not limited to managing their health conditions (Piva and Fontela, 2020). To meet these challenges, both children and young people and families require targeted education and support that address evolving health needs and developmental changes.

Self-care is a critical component for preserving health, and managing and achieving long-term health outcomes (World Health

Organization, 2022). In pediatrics, self-care begins with parental involvement and gradually shifts toward autonomy as children mature (Shackleford et al., 2019; Dall'Oglio et al., 2021). Healthcare professionals play a key role in fostering this progression, promoting age-appropriate self-care behaviors, and empowering both children and young people and their families.

Riegel's Middle-Range Theory provides a well-established framework for understanding self-care, which includes three dimensions: maintenance (behaviors that maintain clinical stability), monitoring (observing the clinical condition and identifying early signs of deterioration) and management (responding appropriately to changes in health status) (Riegel and Dickson, 2008, De Maria et al., 2021). This model is widely applied in adult populations, and has recently been developed for use in pediatrics as the "Comprehensive Model of Self-Care in Children and Young People with Chronic Conditions" (Dall'Oglio et al., 2021) for children and young people who have the ability to manage aspects of their care based on age, cognitive function, and clinical status.

This model holds a good potential as a self-care framework for those with medical complexity (Dall'Oglio et al., 2021).

In fact, the model emphasizes the multidimensional nature of self-care, integrating physical, emotional, social, and developmental aspects of managing complex chronic conditions. It has several key components: self-care agency (the ability to manage one's condition), health literacy, parental and caregiver involvement, peer and social support, and psychological well-being. As children grow, their capacity for self-care evolves, and caregivers play a crucial role in supporting their autonomy. This model also highlights the important role of environmental factors, such as access to healthcare and socioeconomic status, and the need for collaboration with healthcare professionals. The principal theoretical foundations of this model is Riegel's Middle-Range Theory, providing a comprehensive approach to fostering self-care across developmental stages (Riegel et al., 2012; Vellone et al., 2019).

Overall, this model recognizes that self-care is a dynamic, developmental process, requiring a combination of personal responsibility, social support, and professional guidance. It aims to empower children and young people with chronic conditions to take an active role in their health management while accounting factors that influence their well-being.

Assessing self-care in children and young people with complex chronic conditions is essential for identifying educational needs and care gaps. This includes evaluating the child's ability to maintain health (e.g., treatment adherence, device use), monitor their condition, and respond appropriately to symptoms (Ha Dinh et al., 2016; Dall'Oglio et al., 2021; Spitaletta et al., 2023). It also requires accounting for developmental stages and the evolving role of parents.

Although several instruments exist to assess self-care in adults (De Maria et al., 2025, Riegel et al., 2025), including the Self-Care of Chronic Illness Inventory (Riegel et al., 2018), few instruments are available for children and young people that comprehensively address all three self-care dimensions conceptualized by Riegel (Riegel et al., 2012). A recent literature review identified 11 instruments designed to assess self-care in children and young people. These instruments were developed for children and young people with specific chronic conditions, mostly diabetes and asthma, and across different age groups. Two of them, the University of North Carolina TR(x)ANSITION Scale (Ferris et al., 2012) and Transition Readiness Assessment Questionnaire (Sawicki et al., 2011), were more widely applicable, but focused mainly on care transition. Only one instrument, the Self-Management of Type 1 Diabetes in Adolescence (Schilling et al., 2009), addressed all three dimensions of self-care (Biagioli et al., 2022). Furthermore, most existing instruments are either disease-specific or do not consider the family's role in self-care.

Indeed, while there has been extensive research on self-care in pediatric populations, much of the focus has been on specific conditions, such as asthma or diabetes, with limited emphasis on a broader, more inclusive approach to self-care for children with diverse chronic conditions.

A comprehensive pediatric instrument could help identify common self-care factors across different complex chronic conditions—regardless of underlying etiology—and support clinical decision-making, family education, and the planning of individualized or group-based interventions.

We believe it is crucial to have an instrument that measures self-care behaviours, which can be considered one of the main healthcare outcomes in the context of chronic conditions. The lack of a generalized instrument encompassing all three dimensions of self-care in children and young people with complex chronic conditions is a gap in the literature, which we aim to address.

This study is based on the theories of Riegel (Riegel et al., 2012) and the Comprehensive Model of Self-Care in Children and Young People with Chronic Conditions (Dall'Oglio et al., 2021), which offer valuable frameworks for understanding the unique self-care needs of children and young people with complex chronic conditions. By incorporating these theoretical perspectives, our study focuses on providing a comprehensive instrument to evaluate self-care that is adaptable to the individual needs of children and young people with complex chronic conditions. We believe this will bridge a critical gap in the literature and contribute to improving health outcomes for children managing chronic health issues.

This study is part of a wider program that aims to explore the phenomena of Self-Care in children and young people in chronic conditions and the contribution of their parents. We started from a literature review, developing the above mentioned conceptual model (Dall'Oglio et al., 2021) and we also conducted a systematic review to explore if there were any instruments that measure self-care in this target population (Biagioli et al., 2022). Then, we collected and analyzed the views of different stakeholders beginning from children, young persons and their parents through a qualitative research study, focusing on those with chronic and complex conditions (Dall'Oglio et al., 2021; Spitaletta et al., 2023).

The present study aims to develop and initially validate a new instrument to assess self-care behaviors in children and young people with complex chronic conditions, incorporating parental contribution and adapted to children's developmental stages.

2. Materials and methods

An initial validation study to test the content and face validity of a new instrument was carried out between 2022 and 2023.

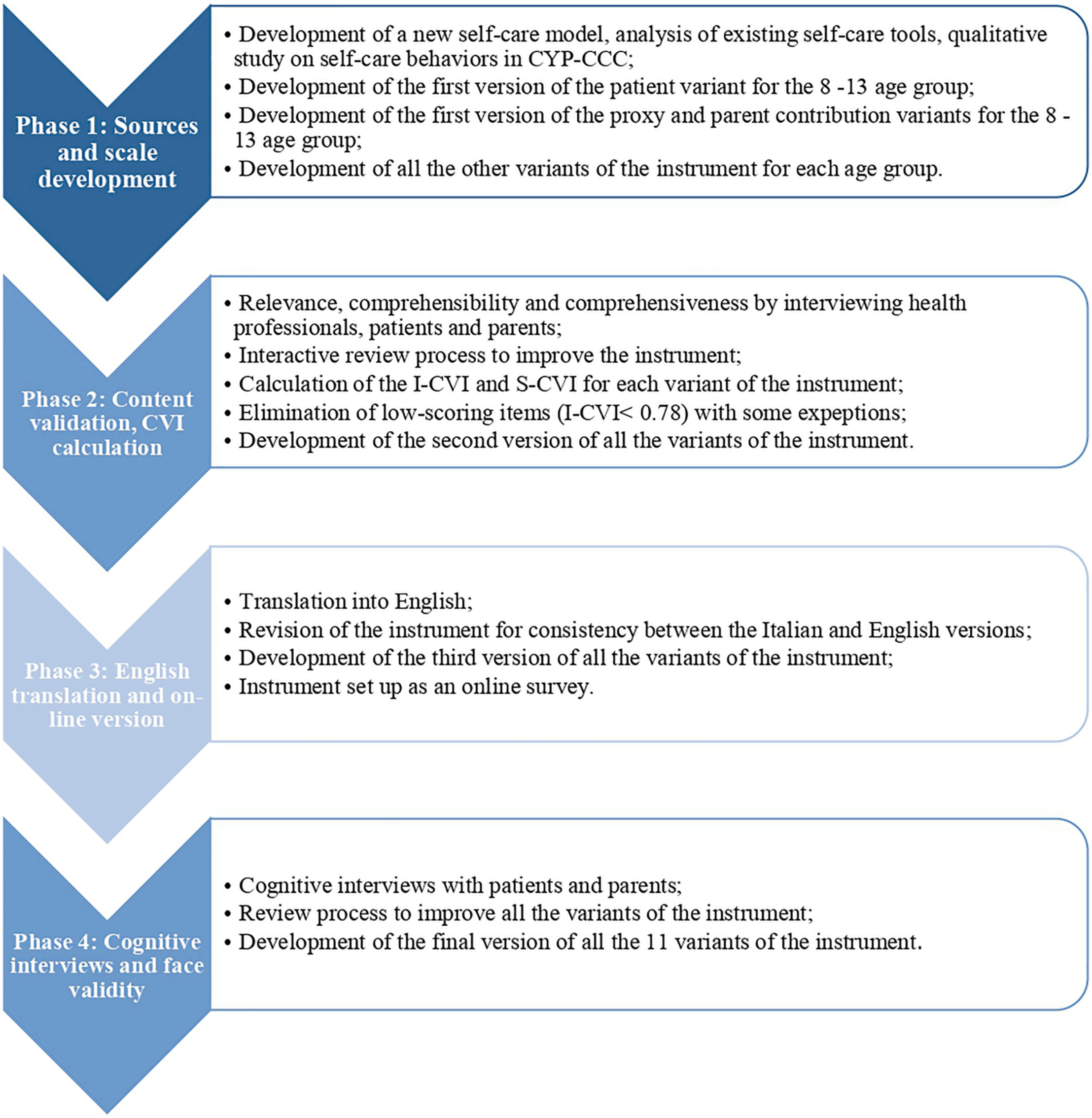
2.1. Ethical considerations

This study was approved by the local Ethics Committee, and informed consent was obtained through an online form from all parents and children and young people, as applicable.

The Ethics Committee of the Bambino Gesù Children's Hospital, Scientific Institute for Research, Hospitalization and Healthcare, approved the study (Prot. N. 2586_OPBG_2021) on 30th November 2021. All participants in the validation process of the Self-Care in Children and Young People with Complex Chronic Conditions Instrument were informed about the study objectives and their roles. In phase four of the study, parents and young people older than 18 years were asked to sign an informed consent form, whereas children and young people between 8 and 17 years of age were asked to compile a dedicated agreement form. Participation was voluntary and anonymous. Data in phase four were collected using pseudonyms.

2.2. Development and initial validation of the self-care in children and young people with complex chronic conditions instrument

The development of the instrument in all its variants and the initial validation of the instrument was performed in four phases, as described in Fig. 1 (Mokkink et al., 2010) (Supplementary Table 1).



Phase 1: Sources and scale development

- Development of a new self-care model, analysis of existing self-care tools, qualitative study on self-care behaviors in CYP-CCC;
- Development of the first version of the patient variant for the 8 -13 age group;
- Development of the first version of the proxy and parent contribution variants for the 8 -13 age group;
- Development of all the other variants of the instrument for each age group.

Phase 2: Content validation, CVI calculation

- Relevance, comprehensibility and comprehensiveness by interviewing health professionals, patients and parents;
- Interactive review process to improve the instrument;
- Calculation of the I-CVI and S-CVI for each variant of the instrument;
- Elimination of low-scoring items (I-CVI< 0.78) with some expeptions;
- Development of the second version of all the variants of the instrument.

Phase 3: English translation and on-line version

- Translation into English;
- Revision of the instrument for consistency between the Italian and English versions;
- Development of the third version of all the variants of the instrument;
- Instrument set up as an online survey.

Phase 4: Cognitive interviews and face validity

- Cognitive interviews with patients and parents;
- Review process to improve all the variants of the instrument;
- Development of the final version of all the 11 variants of the instrument.

Fig. 1. Instrument Development and Initial validation Phases.

2.2.1. Phase 1- Sources and scale development

From a previous study within the wider program of work, a review of the conceptual models of self-care in children and young people with chronic conditions was conducted. This led to the development of a new comprehensive model of self-care specific to this population. "*The comprehensive model of self-care in children and young adults with chronic conditions*" describes self-care as a process driven by health-promoting behaviors carried out by the children and young people themselves, with the contribution of their parents through developmental stages (Dall'Oglio et al., 2021). These behaviors include all three dimensions of Riegel's Middle-Range Theory: condition maintenance (e.g., use devices as prescribed, engaging in safe and appropriate physical activities), symptom monitoring (e.g., tracking the cardiac frequency), and symptom management (e.g., implementing healthcare providers' recommended actions during exacerbations). Moreover, the model emphasized the self-care shift of agency from family to children and young people and provided the conceptual and theoretical foundations for self-care in children and young people with chronic conditions (Dall'Oglio et al., 2021). Lastly, a qualitative study was conducted to explore self-care behaviors in children and young people with complex chronic conditions with their relatives (parents and siblings), the healthcare professionals who usually assist them, and their teachers, and to study factors that may influence their self-care behaviors. This study highlighted five main themes: Self-care management; the 'shift of agency' process of from parents to siblings; the need of Self-care support, also considering the personal development of children and young people; daily self-caremaintenance and monitoring activities; and the importance of treatment adherence. Finally, the theme 'Self-care management' was mostly relevant for parents of children aged between 6 months and 3 years.

Accordingly, item generation was theory-driven and evidence-based: items were developed from a comprehensive literature review, guided by the "The comprehensive model of self-care in children and young adults with chronic conditions" (Dall'Oglio et al., 2021), and informed by results from our qualitative study conducted with children and young people with complex chronic conditions (Spitaletta et al., 2023).

The development of the instrument started with the variant aimed at children 8 to 13 years old, relying on the findings of the literature reviews (Dall'Oglio et al., 2021; Biagioli et al., 2022) and the qualitative study (Spitaletta et al., 2023). Considering the complexity of caring for children or young people with complex chronic conditions, we focused on items regarding pharmacological and non-pharmacological treatments, the use of medical devices and electromedical equipment, and the performance of clinical assessments. Moreover, we developed some items regarding daily life, and behaviors related to emotional and social needs. For each of these domains, the items were aligned with the three dimensions of self-care: maintenance, management and monitoring, in line with Riegel's Middle-Range Theory (Riegel et al., 2012). A 6-point Likert scale was chosen for the maintenance and monitoring dimensions (1=never to 6=always). For the dimension 'Self-care Management' dimension, we choose a 6-point Likert scale from 'not at all possible' (Health Resources and Services Administration, 2022) to 'very possible' (Piva and Fontela, 2020).

The items included in the initial Self-Care in Children and Young People with Complex Chronic Conditions Instrument were 42: 18 on Self-Care Maintenance, 18 on Self-Care Monitoring; and 6 on Self-Care Management). Four age groups were identified for the development of the scale variants: 6 months–7 years, 8–13 years, 14–18 years, and 19–24 years.

Moreover, for each age group, the patient (to measure self-care behaviors in patients), parent (to measure their contribution to self-care activities) and proxy variants (to measure self-care behaviors in children and young people but from the parent's perspective) were developed.

2.2.2. Phase 2 - Content validation and content validity indexes

The relevance, comprehensibility, and comprehensiveness of the instrument were assessed through interviews—conducted both online and in person—with healthcare providers, parents, and children and young people (later referred to as 'experts' in this paper). Four age groups of children and young people and their parents were identified for validity interviews: 6 months–7 years (as in the original plan), 8–13 years, 14–18 years, and 19–24 years. Participants rated each item based on perceived relevance of each item using a 4-point Likert scale (from 1 = 'not relevant' to 4 = 'highly relevant'), to prevent neutral responses and provided suggestions to improve clarity and content coverage. Following each interview, the instrument was revised according to the feedback received. After this initial validation phase, all versions of the instrument were aligned to ensure consistency in item content across age groups, with appropriate linguistic adaptations. As a result, a second version of the instrument was developed (Mokkink et al., 2010).

Based on expert ratings, the Content Validity Index was calculated for each item and the Scale-Content Validity Index for every variant of the instrument. The items that resulted with a score below 0.78 were excluded (Schilling et al., 2009). In line with methodological recommendations suggesting that content validity decisions should not rely exclusively on numerical cut-offs but also on theoretical and clinical relevance, items scoring below 0.78 were reconsidered if deemed conceptually essential (Lynn, 1986; Polit and Beck, 2006). Indeed, some of the proposed items were related to general healthy lifestyle or emotional well-being, which might initially appear not to be directly connected with the self-care of a chronic and complex health condition. The items included in this second version of the Self-Care in Children and Young People with Complex Chronic Conditions Instrument ranged from 37 (parents, or young people [19–24 years old]) to 32 (children [10–13 years old]) and 18 (proxy 6 months-3 years old).

2.2.3. Phase 3- English translation and on-line version

After Phase 2, each version of the instrument was translated by an official native-English translator and from Italian into English. Later, a back translation was provided by a native-Italian translator and from the comparison of the latter with the Italian original version, simpler wording was used some items. Therefore, the translation process provided additional insights that enhanced the comprehensiveness of the original Italian version. Subsequently, the third version of all the variants of the instrument was developed and then implemented as 11 separate online surveys to promote and facilitate the administration, collection, and analysis of data, including when patients were at home.

2.2.4. Phase 4- Cognitive interviews and face validity

This third version of the Self-Care in Children and Young People with Complex Chronic Conditions Instrument developed as an online survey, was administered to children and young people with complex chronic conditions and their parents through cognitive interviews in person, with a minimum of two participants per age group. The objective was to evaluate the online instrument's comprehensibility, completion time, appropriateness, and comprehensiveness. Each participant completed the questionnaire independently using a tablet, under the supervision of a researcher who recorded the time required and conducted a follow-up interview. Participants were asked about the ease of completing the online format, the clarity of the items, the relevance of the questions to their personal experience, and any suggestions for improvement. Based on this feedback, minor revisions were made to enhance all assessed aspects. This process led to the development of the fourth and final version of all instrument variants.

2.3. Participants and setting

A group of healthcare providers, parents, and children and young people was involved in the instrument validation process. The healthcare providers were involved in phase 2 (Content validation). Most professionals were employed at a tertiary academic pediatric hospital where children and young people with complex chronic conditions are treated. Eligible healthcare professionals, including nurses and pediatric nurses, physicians, psychologists, rehabilitation therapists, and dietitians, were required to have at least two years of experience in caring for children and young people with complex chronic conditions. Children and young people were included in phase 2 and 4 of the study. They were children and young people aged 8 to 24, who had complex chronic conditions according to Cohen's criteria (Cohen et al., 2011), with a diagnosis of at least six months, treated in a tertiary, academic children's hospital in Italy and with a good knowledge of the Italian language. Some children and young people were excluded from the validation process: those with oncological pathologies, neurodevelopmental disorders or mental illnesses, based on Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (American Psychiatric Association and Association, 2013); patients in a critical or advanced phase of their clinical condition; children and young people that have been abandoned or included in the foster care system; children and young people that did not meet the inclusion criteria. These exclusion criteria were based on differences in the health-disease trajectory (e.g., children and adolescents with cancer) or limited or absent ability to actively engage and participate in caregiving behaviors considering the developmental age (e.g., children with neurodevelopmental disorders or mental health problems).

Parents of the same population of children and young people, aged 6 months- 24 years old, were also involved in phase 2 and 4 of the study.

The study was 'not registered' in any public registry.

2.4. Data analysis

The responses of the experts' opinion on the relevance of each item of the instrument (Phase 2), were collected, and the scores were grouped into two categories: scores 1 and 2, indicating irrelevant items, were assigned a value of 0, while scores 3 and 4, indicating relevant items, were assigned a value of 1. Next, the Item-Content Validity Index for each item of each variant was determined by adding up all the scores given by experts to each item and dividing the total by the number of experts surveyed. Then, the Scale-Content Validity Index was calculated for each Self-Care in Children and Young People with Complex Chronic Conditions Instrument variant by adding all the Item-Content Validity Index scores and dividing the sum by the number of items. An Item-Content Validity Index above 0.78 was deemed excellent, while a score below 0.78 meant that the item was revised or removed, unless the item was considered essential, based on theoretical and clinical relevance, as described above (2.2 Phase 2). Regarding the Scale-Content Validity Index, a score above 0.90 indicated excellent content validity (Lynn, 1986; Polit and Beck, 2006).

For Phase 4, the time taken by participants to complete the instrument was calculated as a mean with standard deviation, or as a median when appropriate. The main issues that emerged from the interviews conducted after the completion of the instrument were recorded, shared among the researchers, and used to inform improvements to the instrument.

3. Results

3.1. Participants' characteristics

Eighty-six experts were involved, including healthcare providers (n = 63), patients (n = 7), and parents (n = 16) in the content validation of the Self-Care in Children and Young People with Complex Chronic Conditions Instrument (Phase 2). Among the 63 healthcare professionals who participated in the study, the majority were female (n = 52, 82.54%). Regarding professional roles, nurses (n. 16) and pediatric nurses (n.15) represented the largest group (n = 31, 49.21%) of which two were nurse counsellors and one research methodologist. This was followed by physicians (n = 12, 19.05%) and psychologists (n = 10, 15.87%). Dietitians and rehabilitation therapists were equally represented (n = 5, 7.94% for both categories). Of the 63 professionals, 62 were employed in a tertiary, academic children's hospital in Italy, while one worked in an academic setting. They belonged to various medical, surgical, and neuro-rehabilitation clinical areas and related units of the hospital, where children and young people with complex chronic conditions, due to different diseases, are treated and cared and for which they developed clinical expertise, as described in Supplementary file (Table 1.a).

Sixteen parents (all female) of children and young people with complex chronic conditions were involved in the content validation process (Phase 2) of the instrument Self-Care in Children and Young People with Complex Chronic Conditions Instrument, including a patient advocate, as shown in Table 1. The parents represented all the age groups of children and young people. The children and young people represented the related age group (8–13, 14–18 and 19–24 years old).

Additional five children and young people and their 13 parents (10 females and 3 males), were involved in phase four of the instrument development, by participating in the cognitive interviews (Phase 4). Both the children and young people who actively participated in completing the questionnaire and those who participated passively (only the parent completed the instrument) presented with a diverse spectrum of clinical conditions, as reported in Table 1.

3.2. Instrument characteristics

Initially, in phase 1, four age groups were identified. However, during the content validation of the scale variants, it became clear that the first group, ranging from 6 months to 7 years, was too broad due to the diverse behaviors observed within this range. As a result, it was divided into two separate groups: one from 6 months to 3 years, and another from 4 to 7 years, resulting in a total of five age groups.

A total of 11 variants of the instrument were developed based on the five age groups identified (Table 2).

Each variant of the scale included the three dimensions of self-care (self-care maintenance, self-care monitoring, and self-care management) except for the proxy variant for the age group 6 months to 3 years that consisted only of items regarding the self-care maintenance dimension. The items were distributed in each self-care dimension as described in Table 3.

Each subscale had its own introductory question, which was tailored according to the type of respondent, whether it was a parent (for the contribution and proxy variants) or a patient, as well as the patient's age, as shown in Supplementary files 2-4, English version, Supplementary files 5-7, Italian version. The self-care maintenance subscale included items regarding treatment adherence (both pharmacological and non-pharmacological treatments, use of devices and electro-medical devices, clinical examinations or visits), nutrition (e.g., appropriate amount of food and drink, eating healthy and varied foods, and doing enteral/parental nutrition) and lifestyle (e.g. rest and sleep, physical activity, emotional well-being related behaviors). The self-care monitoring subscale included items regarding the monitoring of signs and symptoms, of clinical parameters (also considering pain and the emotional sphere), and checking the functioning of medical and electromedical devices. The self-care management subscale included items regarding behaviors built on the patient's own experience and caregiver or healthcare provider-directed behaviors when the patient is not feeling well or something seems wrong. All these aspects were included in all variants, but items were modified in terms of language based on age groups and type of respondents (patients or parents). In line with Riegel et al. (2018), each of the three scales were scored separately and standardized 0–100 with higher scores indicating better self-care (Riegel et al., 2018). Specifically, we expected a potential improvement in the score due to the child's or young person's age, as well as in relation to their health conditions and the intensity of the associated treatment. We also expected that by improving the self-care level of the child or young person, this should decrease the level of the parents' self-care behaviors.

3.3. Content validity

In the Phase 2, a total of 95 individual semi-structured interviews were conducted with the 86 experts to evaluate content validity

Table 1

Characteristic of parents and patients participating in Content Validation and Cognitive Interviews.

	Phase 2 (content validation)		Phase 4 (cognitive interview)	
	Parents N (%)	Patients N (%)	Parents N (%)	Patients N (%)
Gender				
Female	16 (100)	5 (71.43)	10 (76.92)	3 (60.00)
Male	-	2 (28.57)	3 (23.08)	2 (40.00)
Mean age (mean, SD)	-	-	42.46 (10.56)	16.20 (6.30)
Patients' diagnosis				
Disease of the digestive system [1]	5 (31.25)	2 (28.57)	6 (46.15)	2 (40.00)
Cardiovascular disease [2]	4 (25)	3(42.85)	2 (15.38)	2 (40.00)
Neuro/Neuromuscular disease [3]	2 (12.5)	1 (14.28)	2 (15.38)	0
Nephrological disease [4]	1 (6.25)	-	2 (15.38)	0
Multisystemic disease [5]	4 (25)	1 (14.28)	1 (7.69)	1 (20.00)

[1] Ulcerative colitis and subsequent vertebral collapse; Short bowel syndrome in parenteral nutrition; Microvillus inclusion disease; Post-surgical short bowel syndrome due to intestinal volvulus; Chronic intestinal pseudo-obstruction; Hirschsprung's disease; Post-surgical short bowel syndrome due to hypocomplementemic vasculitis.

[2] Giant cell myocarditis in a patient supported with a left ventricular assist device (LVAD), HeartMate III; Dilated cardiomyopathy with LVAD Heartmate III; Dilated cardiomyopathy secondary to fulminant Parvovirus B19 myocarditis; Status post heart transplantation; Double outlet right ventricle with transposition of the great arteries.

[3] Ondine Syndrome; Duchenne muscular dystrophy with support by a Jarvik 2000 LVAD; Ondine Syndrome; TK2-related mitochondrial DNA depletion syndrome, myopathic form; Leukodystrophy; Calpainopathy (limb-girdle muscular dystrophy); Spinal muscular atrophy type 2a.

[4] Nephrotic Syndrome; Renal transplantation.

[5] Cystic fibrosis; Schimke immuno-osseous dysplasia; Chronic respiratory failure requiring invasive mechanical ventilation.

Table 2
SCYP-CcI variants by age group and respondent.

AGE GROUPS	PATIENT	PROXY PARENT	PARENT CONTRIBUTIONS
6 months - 3 years	NO	YES	YES°
4 years –7 years	NO	YES	YES°
8 - 13 years	YES	YES	YES
14 - 18 years	YES	YES*	YES
19 - 24 years	YES	YES*	YES
Total variants	**3**	**4**	**4**

Table 3
SCYP-CcI items distribution.

	Age group	Self – Care Maintenance (N. items)	Self – Care Monitoring (N. items)	Self – Care Management (N. items)	Total per scale (N. items)
Patients	**8–13 years**	14	12	7	33
	14–18 years	15	13	9	37
	19–24 years	15	13	9	37
Parents	**6 months – 7 years**	15	14	8	37
	8–13 years	15	14	8	37
	14–18 years	15	14	8	37
	19–24 years	15	14	8	37
Proxy	**6 months – 3 years**	15	-	-	15
	4–7 years	15	11	6	32
	8–13 years	14	12	7	33
	14–24 years	15	13	9	37

SCYP-CcI= Self-Care in Children and Young People with Complex Chronic Conditions Instrument.

by investigating the relevance, comprehensibility, and comprehensiveness of the items. In particular, on average 9 experts for each variant (range 6–11) of the scale were asked to rate the relevance of each item. The results showed that Item-Content Validity Index ranged between 0.63 and 1, and Scale-Content Validity Index was 0.96 (range 0.92–0.98) (Table 4).

The Item-Content Validity Index of 9 of 372 overall items scored lower than 0.78, but we decided to remove only two items from all the variants where they were present, for a total of five. The remaining seven items were kept in the scale because they regarded aspects related to physical and emotional well-being, and were considered important, even if less appreciated (Supplementary Table 8).

During the interviews conducted for content validation, it was also found that some items could be too specific for some diseases (e.g., use of device or electromedical device); for this reason, the possible response "not applicable" was included for each item. Finally, in case some participants proposed a new item, as happened for the questions about emotional wellbeing or emotion monitoring, we returned to the previous interviewed experts asking their comments.

3.4. *Cognitive interviews*

In Phase 4, cognitive interviews with children and young people with complex chronic conditions and their parents were conducted to assess face validity, test the feasibility of online administration, and evaluate the time required for the compilation. The mean time for completing the questionnaire was 14 min (SD = 8.9) for the patient variants, 6.2 min (SD = 2.3) for the proxy variants, and 12.4 min (SD = 4.8) for parent variants.

As a result of this process, we decided to make some minimal changes: the variant for children aged 8 to 13 years was administered only to patients aged at least 10, and the response options for the self-care management dimension, only for the patients' variants, were

Table 4
SCYP-CcI Content validity indexes.

AGE GROUPS	PATIENT S-CVI (I-CVI range)	PROXY PARENT S-CVI (I-CVI range)	PARENT CONTRIBUTIONS S-CVI (I-CVI range)
6 months - 3 years	NO	0.92 (0.63–1)	0.98 (0.86–1) °
4 years - 7 years	NO	0.92 (0.63–1)	0.98 (0,86–1) °
8 - 13 years	0.94 (0,90–1)	0.93 (0.80–1)	0.98 (0.75–1)
14 - 18 years	0.97 (0.89–1)	0.97 (0.83–1) *	0.97 (0.78–1)
19 - 24 years	0.97 (0.78–1)	0.97 (0.83–1) *	0.93 (0.55–1)

* ° same variant;

SCYP-CcI= Self-Care in Children and Young People with Complex Chronic Conditions Instrument; S-CVI=Scale Content Validity Index; I-CVI= Item Content Validity Index.

changed from “likely” to “possible”. The final versions of the Self-Care in Children and Young People with Complex Chronic Conditions Instrument variants for the 8–13 age group (patient variant for ages 10–13, and parent and proxy variants for ages 8–13) are provided as examples in the Supplementary Files (2–4).

4. Discussion

We developed a new instrument (Self-Care in Children and Young People with Complex Chronic Conditions Instrument) to assess self-care behaviors in children and young people with complex chronic conditions and the contribution of their parents. To our knowledge, this newly developed instrument—comprising 11 variants—is the first to assess self-care behaviors in this type of population, while accounting for the three dimensions of self-care (maintenance, monitoring, and management), multiple developmental stages from infancy to adolescence, and a range of complex chronic conditions.

A key distinguishing feature of our instrument is that it comprehensively encompasses all dimensions of self-care. Within each of the three dimensions, the tool systematically assesses self-care behaviors related to pharmacological treatment, non-pharmacological treatment, use of medical devices, and use of electromedical equipment. Importantly, the instrument is designed to be applicable across the spectrum of complex chronic conditions rather than being disease specific. Indeed, during the development of the instrument, we were more focused on the patients’ conditions and less on the pathological origin. This choice reflects a nursing approach that places the child and family, their responses, care needs, and daily self-care challenges at the center of their care, rather than focusing exclusively on diagnosis or biomedical categorization (Iovino et al., 2024). Instead, most of the existing instruments are condition-specific, such as Self-Management of Type 1 Diabetes in Adolescence that focuses on diabetes (Schilling et al., 2009).

As shown in Table 1, the population (i.e., parents and children/young people, nurses) involved in our study were representative of a large range of complex chronic conditions (excluding children and young people with neurocognitive disorders and those with onco-hematological conditions). Plus, a second validation step is underway, therefore the number of participants in each age will be expanded and consequently, we believe also the variety of complex chronic conditions will be wider. Therefore, we assume that the Self-Care in Children and Young People with Complex Chronic Conditions Instrument could be generally applied to children and young people with complex chronic conditions.

However, as highlighted by the review conducted by Ke Liu et al., we are conscious that identifying a single generic instrument that is universally applicable across populations remains challenging due to the diversity of chronic conditions and the variability in terms of self-management demands (Liu et al., 2026).

In fact, it should be noted that in the literature, several generic instruments for assessing self-management and self-care in patients with chronic diseases are available but each with its own limitations.

Therefore, the selection of instruments should be guided by the underlying theoretical framework of the study, psychometric validation and reliability, and adapted to the patient’s cultural context (Iovino et al., 2024).

In this context, alignment with self-care theories, such as Riegel’s framework and the Comprehensive Model of Self-Care in Children and Young People, is essential (Riegel et al., 2012; Dall’Oglio et al., 2021).

At the time of the study, no existing instrument was found to include all these characteristics (Biagioli et al., 2022). Specifically, no cross-sectional instrument adaptable across all pediatric age groups was available—one that could accompany individuals through the various developmental stages. Therefore, our instrument addresses a significant gap in the literature by providing a theory-based, multidimensional, and developmentally adaptable measure of self-care for children and young people with complex chronic conditions.

The Self-Care in Children and Young People with Complex Chronic Conditions Instrument, which was content validated by a panel of experts including children and young people and their parents, showed strong Scale-Content Validity Index and Item-Content Validity Index scores across all the 11 variants. This indicates that the items, which were meticulously designed and developed, effectively encapsulated the essential aspects of self-care for this population.

It is significant to note that the items with the lowest scores were primarily associated with aspects of well-being (e.g., resting between one activity and another, or sleeping) or the emotional sphere of the child or young person, which suggests that experts predominantly focused on the management of the pathological condition. This indicates that the general well-being of the children and young people may not have received the same level of consideration as the treatment or management of the illness itself. Furthermore, it is important to emphasize that all the low-scoring items were associated with the self-care maintenance and self-care monitoring subscales, rather than the self-care management subscale, implying that the management aspect was considered of primary importance by the experts. Indeed, self-care management is a critical issue for all stakeholders involved in the care of children and young people with complex chronic conditions (Riegel et al., 2019). The role of parents in contributing to self-management emerged as particularly crucial. In this regard, the instrument recently developed by Genna et al. offers a promising and evidence-informed resource aimed at supporting parents in managing the diverse and demanding aspects of caregiving associated with their child’s deteriorating condition (Genna et al., 2025).

The items of the Self-Care in Children and Young People with Complex Chronic Conditions Instrument reflect the complexity of the self-care process in children and young people with complex chronic conditions, while gathering the features that different chronic conditions may have in common. Moreover, this instrument was created to emphasize the importance of considering not only the aspects related to treatment adherence but also all the aspects of living with a complex chronic condition, including well-being. In particular, the self-care maintenance dimension also covers aspects of nutrition and lifestyle. Nutrition is especially relevant to the pediatric population, since ensuring a healthy and varied diet is intrinsic to the normal parental role, which in this context is supported by the instructions of healthcare providers. Moreover, the lifestyle of children and young people with complex chronic conditions is aimed to preserve their health by adopting behaviors useful for their care (e.g. adequate personal hygiene), to strengthen the body by doing physical activity (e.g. walking), if feasible given the clinical condition, to manage their own energy by resting between one activity and another during their day, and to improve performance by getting enough sleep. Additionally, it is important for children and young people with complex chronic conditions to adopt behaviors that improve their emotional wellbeing while promoting social inclusion (e.g. listening to music or going out with friends).

A similar approach to that used by Riegel et al. in developing the Self-Care of Chronic Illness Inventory (Riegel et al., 2018), will help ensure that the unique needs of children and young people with complex chronic conditions will be addressed holistically, promoting not only medical stability but also emotional well-being, social integration, and an improved quality of life. All these aspects are particularly significant in the field of pediatrics, as they are closely connected to the physiological, emotional, and developmental trajectories of each child and adolescent. Supporting these areas not only contributes to better health outcomes, but also plays a critical role in promoting overall well-being and age-appropriate development throughout childhood and adolescence (Cassidy et al., 2023).

This new instrument supports a holistic approach to the patient, promoting a positive perspective on the condition by viewing it as a health state rather than an illness. Indeed, in collaboration with experts, a decision was made to use only neutral terminology in the monitoring subscale. Terms such as 'the function of the heart' were preferred to minimize language suggesting potential signs of fragility (e.g., bradycardia or tachycardia), except when these terms were included as illustrative examples. This allowed participants to strengthen a positive perception of their health status despite the significant complexity of their condition. This approach was facilitated by the fundamental contribution of nurses trained in counselling, whose expertise in communication and emotional support played a pivotal role in its implementation. Furthermore, the inclusion of specific items related to emotional well-being within the subscales of maintenance, monitoring, and management was strongly encouraged by expert psychologists, who emphasized the importance of addressing psychological health as an integral part of overall patient care. The incorporation of these aspects further enhances the instrument's holistic approach to patient education and care.

Additionally, a proxy variant of the scale for the age group of 6 months to 3 years was added. The original age group, 6 months to 7 years, was deemed too broad by experts due to the significant differences in behavior across this range. This highlights how children's behaviors vary at different developmental stages and how these behaviors may be cooperative. The level of cooperation may depend on two key factors: the age at which the pathological condition is diagnosed, and how the devices and treatments are introduced to children and young people. Specifically, the response could be influenced by their developmental stage at the time of diagnosis, as they have different coping mechanisms consistent with age. Additionally, the way healthcare providers explain and present the use of devices and treatments can impact the child's willingness to engage, with more familiar or age-appropriate approaches potentially leading to greater cooperation (Council on Children with Disabilities and Medical Home Implementation Project Advisory Committee, 2014; Pordes et al., 2018).

Furthermore, the assessment of patients’ self-care behaviors and the parents’ contribution can serve as a significant patient-reported outcome, considering both the management of their health condition and the adherence to the treatment, as well as the healthcare professional interventions aimed at improving self-care and enhancing patients' and families’ empowerment. While some of these interventions are educational, it is also necessary to consider activities or innovations related to medical treatment, the use of devices or electromedical devices, and the monitoring of the patient’s health condition through digital technologies (Casaca et al., 2023; Bonsel et al., 2024).

Finally, it is also important to note that the process of self-care, within the context of complex chronic conditions, is significantly influenced by the developmental stage and cognitive status, where individual capabilities and limits cannot be ignored (Lozano and Houtrow, 2018).

This instrument was built on a conceptual framework supported by various studies conducted in this field, providing a solid theoretical foundation. The contributions of multiple healthcare professions were also crucial to ensure the instrument had a holistic approach by addressing the diverse aspects of care for children and young people with complex chronic conditions. Moreover, the involvement of children and young people and their families was fundamental in enhancing our understanding of the factors related to patient care they considered most important in their daily lives.

However, this study also has some limitations. One key limitation is the non-homogeneity in the selection of experts for each variant of the scale. The number of experts varied across scale variants, ranging from a minimum of 6 to a maximum of 11. This variation is attributable to the necessity required of consulting a larger number of experts in the early stages of the development and validation of the scale, to significantly improve the instrument's structure and content. As the validation process advanced and the core content of the items remained stable, fewer experts were involved, with the focus shifting primarily to refining the language based on the type of respondent and developmental age. Furthermore, although the distribution of the experts’ professional backgrounds was not uniform across all versions of the instrument, all of them had relevant expertise in the management of children and young people with complex chronic conditions.

Furthermore, the present study constituted the initial phase in the validation process of the Self-Care in Children and Young People with Complex Chronic Conditions Instrument. A comprehensive psychometric evaluation is currently underway in various Italian healthcare settings, allowing the exploration of illness, cultural and contextual differences within the same national framework (Biagioli et al., 2023) through the enrolment of one hundred children or young people for the five age groups.

This study rigorously will assess the instrument’s reliability, internal consistency, construct validity, and responsiveness (Mokkink et al., 2010). Subsequently, it will be necessary to assess the instrument’s usability in clinical environments to evaluate its feasibility, acceptability, and its potential to be integrated into routine healthcare practice. Future validation studies in different linguistic and cultural contexts would be highly desirable to have a common instrument to assess self-care in children and young people with complex chronic conditions. Therefore, also the English translation we provided, was only used to optimize the text and evaluate how it could be used from an international perspective, but the current English version still cannot be used.

In conclusion, the Self-Care in Children and Young People with Complex Chronic Conditions Instrument implementation can facilitate a rigorous assessment of patient's self-care behaviors and the contribution of their parents, enhancing the understanding of self-care processes and their influence on health outcomes in children and young people with complex chronic conditions.

While preliminary findings are promising, the Self-Care in Children and Young People with Complex Chronic Conditions Instrument may hold the potential for future integration into clinical practice, pending the completion of a comprehensive validation and the availability of robust psychometric results. Moreover, further statistical analyses will be necessary to define clinically meaningful score ranges or thresholds for each subscale (maintenance, monitoring, and management). These benchmarks could help clinicians to identify specific areas of strength or need in the self-care behaviours of patients and families. Although the instrument is not ready yet for clinical use, its prospective application could contribute to the development of targeted educational, supportive, scientific, and technological interventions aimed at promoting self-care. These tailored interventions might address the specific needs of both children and young people and their families, with the aim of empowering them and potentially improving their quality of life. Moreover, the instrument could serve as a valuable instrument for evaluating the effectiveness of self-care–promoting interventions and advancing research in the management of pediatric complex chronic care.

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Approval of the submitted version of the manuscript

Please check this box to confirm that all co-authors have read and approved the version of the manuscript that is submitted. Signatures are not required.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ijnsa.2026.100597.

Appendix

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