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Development and validation of the parents' healthcare needs scale for adolescents with congenital heart disease

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ABSTRACT

Purpose: The healthcare needs of parents of adolescents with congenital heart disease (CHD) have been under-investigated as no valid and reliable tools have been developed for assessing their needs. Therefore, this study aims to develop and validate the Parents' Healthcare Needs Scale for adolescents with CHD (PHNS-CHD).
Design and methods: A multi-method approach and multi-phase design were employed. Phase one referred to generating scale items based on emerging themes in the literature, and phase two showed the validation process, divided into three steps. Step one tested the content and face validity of the first version of the PHNS-CHD. After that, step two described the initial psychometric validation process of scale using an exploratory factorial analysis (EFA). Then, step three confirmed the PHNS-CHD factorial structure and assessed its internal consistency.
Results: The PHNS-CHD showed evidence of face and content validity, adequate construct, and internal consistency and stability. Specifically, it had 22 items grouped into five domains, labeled as follows: Healthcare education to the child; to be supported as a parent, clinical support to the child, the continuum of care to the child; emotional support to the child.
Conclusions: The PHNS-CHD is a psychometrically robust measure for assessing the healthcare needs of parents of adolescents with CHD.
Practice implications: The PHNS-CHD might help clinicians, especially pediatric nurses, assess the healthcare needs of parents of adolescents with CHD and design adequate care plans for the whole family.

Introduction

Congenital heart disease (CHD) is one of the major global health problems (Pei, Kang, Zhao, & Yan, 2017), acknowledging the prevalence of birth defects (Chen, Su, Chiang, Shu, & Moons, 2017). To date, having a CHD does not preclude becoming an adult due to different medical and surgical treatments (van der Bom et al., 2011). So far, the transition from childhood to adulthood is a whole period of challenges and changes in the lives of patients with CHD: adolescence is a complex process for every young person and is particularly important for CHD adolescents (Flocco et al., 2018, 2019). Adolescence is a crucial phase for forming the personality (Moceri et al., 2015), during which adolescents with CHD have to face the consequences of their disease and the need to be adherent to their follow-up indications (Chiang et al., 2015). During the transition into adulthood, CHD adolescents could be exposed to many psychological issues related to their development of self-identity, self-esteem, and self-image.

Adolescents with CHD should learn about their disease, overcome frustration and anxiety, and develop self-care strategies (Chiang et al., 2015). Parents play a key role in this process, being a landmark for CHD adolescents (Chen et al., 2018). The CHD adolescents' parents perform an essential supportive role during the transition from childhood to adulthood. They are extensively involved in care activities, such as accompanying their child to visits, always staying with them for the entire time, and administering their daily medications (Clarizia et al., 2009).

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Parental involvement in adolescent care is challenging (Bratt et al., 2018): the recent literature shows that CHD adolescents' parents experience anxiety, stress, and depression (Wei, Roscigno, Hanson, & Swanson, 2015), often feeling uncertain about their roles during the transition (Burström, Öjmyr-Joelsson, Bratt, Lundell, & Nisell, 2016). Accordingly, parents needed support to facilitate their adolescent children becoming independent and autonomous (Burström et al., 2016). There is currently available measurement of CHD youth's healthcare needs (Dellafiore et al., 2020); however, parents' healthcare needs have been under-investigated as no valid and reliable tools have been developed to assess their needs during the transition process. Therefore, this study aimed at developing and validating the healthcare needs measuring scale for parents of adolescents with CHD – i.e., the Parents' Healthcare Needs Scale for adolescents with CHD (PHNS-CHD).

Methods

Study design

According to the recommendations for scale design and development (Rattray & Jones, 2007), this study was developed with a multimethod and multi-phase design. Specifically, the 'STrengthening the Reporting of OBservational studies in Epidemiology' (STROBE) checklist as well as Enhancing the QUAlity and Transparency of Health Research' (EQUATOR) guidelines led the study development (see Supplementary File 1).

The conceptualization of the PHNS-CHD was the initial phase of the process (phase one), and it involved three steps. The literature review (step 1) aimed to identify the main challenges related to the healthcare needs of parents of adolescents with CHD. During Step 2, a group discussion was performed between the authors for a wide-ranging examination of the literature review results and a shared consensus. The last step (i.e., step 3) of this phase involved evaluating the initial pool of items from team discussion and drafting a priori dimension of the PHNS-CHD.

The validation phase (phase two) came after the conceptualization and was based on three different steps. Firstly, the face and content validity of the initial pool of items coming from phase 1 was performed, with the implication of an independent panel of experts (i.e., step 1). A preliminary cross-sectional data collection was then encompassed to highlight the psychometric characteristics of the PHNS-CHD by using an exploratory factorial analysis (EFA) (i.e., step 2). Lastly, the second round of data collection was carried out using the version of the tool generated from the previous step to confirm its factorial structure and assess its reliability (i.e., internal consistency) (step 3).

Phase 1: conceptualization and the initial pool of items

Ahead of this process, there was a need to determine the main healthcare needs and challenges for parents of adolescents affected by CHD. This need provided the reason for an independent literature review that occurred between June and August 2019 by two researchers (FD and SF). Once the principal features were revealed, the authors involved a team group in sharing, comparing, and discussing the summarized results through a narrative approach (Hsieh & Shannon, 2005) (September 2019). In consequence, five main interpretative themes were identified: a) physical health needs, b) family health needs, c) personal health needs, d) needs for interpersonal relationships, and e) policy needs. Each theme was member-checked and peer-debriefed for further evaluations (Lincoln & Guba, 1986); later, the interpretative themes were operationalized in 25 statements to represent the initial pool of items. This part of the process occurred in October 2019, following the wording error avoidance recommendations (Dillman, Smyth, & Christian, 2014). Resulted items were applied to measure real-world situations with questions like: 'How important is it for you and your child to receive the following actions from your healthcare providers to meet your child's *healthcare needs*?' Each item answered was designed to be rated by a five-point Likert scale, ranging from 'absolutely not important' (=1) to absolutely important or essential (=5).

Phase 2: validation process

Face and content validity (step 1)

For this processing part, twelve independent expert nurses in CHD nursing and research methodology were selected to establish and assess the face and content validity of the preliminary version of the PHNS-CHD produced by the conceptualization phase (Polit & Beck, 2014). It was performed in November 2019 and aimed at improving and deleting redundant, unclear, or useless items. Experts were chosen using a purposeful sampling strategy in a cardiology research hospital in northern Italy. Open-ended questions were used to study face validity, referring to the panelists' understanding of the items and their view on the global measured concepts. Questions inquired about nurses' perception of every item's wording and content to highlight any possible ambiguity. Panelists' answers were reported *Verbatim* for textual analysis (Lincoln & Guba, 1986).

Likewise, panelists' perception of every item considered appropriate for outlining its measurement object indicated the 'quantitative' agreement, namely, content validity. This one was determined by computing the content validity ratio (CVR) and content validity index for items-level and scale-level (I-CVIs and S-CVI) (Lawshe, 1975). Broadly, CVR consisted of a three-point scale (1 = not essential; almost essential; 3 = essential) and ranged from −1 (total disagreement among experts) to +1 (total agreement among experts). According to current recommendations, a level of agreement superior to 50% is identified as the lowest CVR level, thus, the critical CVR threshold (Wilson, Pan, & Schumsky, 2012). Considering the type I error equal to 0.05 (using a one-tailed test) (Wilson et al., 2012) and the answers from 12 panelists, the cut-off of 0.60 indicates a minimum consensus among raters of 50%. I-CVIs and S-CVI were based on a four-point scale used for rating how each item was relevant to nutrition care (1 = completely not relevant; 4 = completely relevant) (Polit & Beck, 2014). To obtain I-CVIs, we calculated the number of panelists who rated each item as completely relevant divided by the number of panelists. S-CVI was calculated as the mean of I-CVIs. I-CVIs and S-CVI were equal to or higher than 0.70 and were considered adequate (Polit & Beck, 2014).

Explorative appraisal of psychometric characteristics (step 2)

Parents of adolescents with CHD in the abovementioned cardiology research hospital were enrolled for cross-sectional data collection (sample A) between December 2019 and February 2020, using consecutive and convenience sampling. Data collection encompassed (a) parents' socio-demographic characteristics, (b) socio-demographics and clinic characteristics of their sons with CHD, and (c) the version of the PHNS-CHD coming from the face and content validity step (step 1).

Eligible parents have been assessed for the following inclusion criteria, aimed to define the characteristics of the enrolled sample: (a) parents of adolescents with CHD, according to the 2018 AHA/ACC Guideline for the Management of Adults With Congenital Heart Disease (Stout et al., 2018); (b) to express the willingness to participate to the study through the signature of the informed consent form. The exclusion criteria used to select the sampling were the presence of cognitive impairment, assessed using Six Item Screener (SIS: if SIS ≤4), and not understanding of the Italian language.

Confirmatory factorial analysis and reliability (step 3)

The second round of cross-sectional data collection (sample B) was performed in this stage of the process using the refined version of the PHNS-CHD according to the analysis performed on previous sample A. The same inclusion criteria and data collection procedure of sample A were applied to sample B between March and May 2020. Specifically, this step aimed to corroborate the most plausible factorial structure

derived from the EFA analysis on sample A (step 2) using a Confirmatory Factorial Analysis (CFA). The socio-demographic characteristics of sample B are described in Table 2, and Table 3 shows the CFA. Additionally, the internal consistency of the overall scale and five domains have been tested (See Fig. 1).

Data analysis

According to Watkins's recommendations (Watkins, 2018), at least five participants per item were needed for an acceptable size for both sample sizes. Considering 25 items in the face and content validity phase of the scale version, at least 500 parents were required to be divided for EFA performance in sample A. Parents' socio-demographic characteristics were summarized by descriptive statistics. Additionally, the researchers collected socio-demographic and clinical data of the offspring of parents who were recruited in this study that were summarized using descriptive statistics.

Before performing EFA, Bartlett's test and Kaiser-Mayer-Olkin (KMO) index were used to evaluate the factorability of the correlation matrix and the sample adequacy to EFA; EFA was performed by employing a robust maximum likelihood estimator (MLR) and following the criteria (analysis of the eigenvalues, the scree test, and the framework given by phase one) for choosing the numbers of factor to extract (Reise, Waller, & Comrey, 2000). A Geomin rotation was used for simplifying the interpretation model and factor loadings. Items showing cross-loadings were removed as considered ambiguous, and the ones with loading values higher than 0.30 were considered valuable for further validation steps (Reise et al., 2000). Similarly, a chi-square (χ^2) difference test on the Satorra–Bentler scaled χ^2 statistic for nested models was applied to compare this three-dimensional model to other plausible EFA alternatives. Additionally, for a plausible explanation of the inter-correlations between the first-order factors and an accurate evaluation of the general factor of parents' healthcare needs, the presence of a second-order factor was tested when analyzing sample B (in which a confirmatory factor analysis (CFA) was performed to assert EFA derived factor-structure). The observed covariance matrixes derived from sample A and B were estimated with the fitness of each EFA and CFA models (related, namely, to sample A and sample B) by using:: χ^2/degree of freedom (between 1.5 and 5 is acceptable), Satorra–Bentler χ^2, the comparative fit index (CFI; values >0.90 proved acceptable fit); the root mean square error of approximation (RMSEA; values <0.06 proved an acceptable fit); and the weighted root mean square residual (values close to 1.0 showed an optimal fit). Cronbach's α coefficient was applied to evaluate the reliability (internal consistency). Statistics were determined with $\alpha = 0.05$, using the software MPlus version 7.1.

Ethical considerations

The study promoter's ethical committee (Protocol n. 136/int/2017 of 12th December 2017) and review boards promoted this research. The study was conducted accordingly to the international ethical principles (Good Clinical Practice, GCP) and the European requirements for non-interventional studies. The study's aim and methodology were clearly explained to enrolled participants, who also had to sign a written consent form. Participants of each phase were also informed about the confidentiality of their responses.

Results

Face and content validity (step 1)

Twelve nurses with expertise in CHD and research methodology were included as panelists for the face and content validity were mainly female ($N = 8$; 81.25%), with an average age of 33.73 years (SD = 9.74). Four experts worked in a CHD ward, three developed high competencies in the research field, and the last five were experts in both CHD and research settings. Considering their work experience, they reported having 9.7 years (SD = 7.8) of average experience. Three worked in post-operative units (25%), one in intensive care units (8.4%), four in CHD units (33.2%), and one in ambulatory units (8.4%). Finally, three

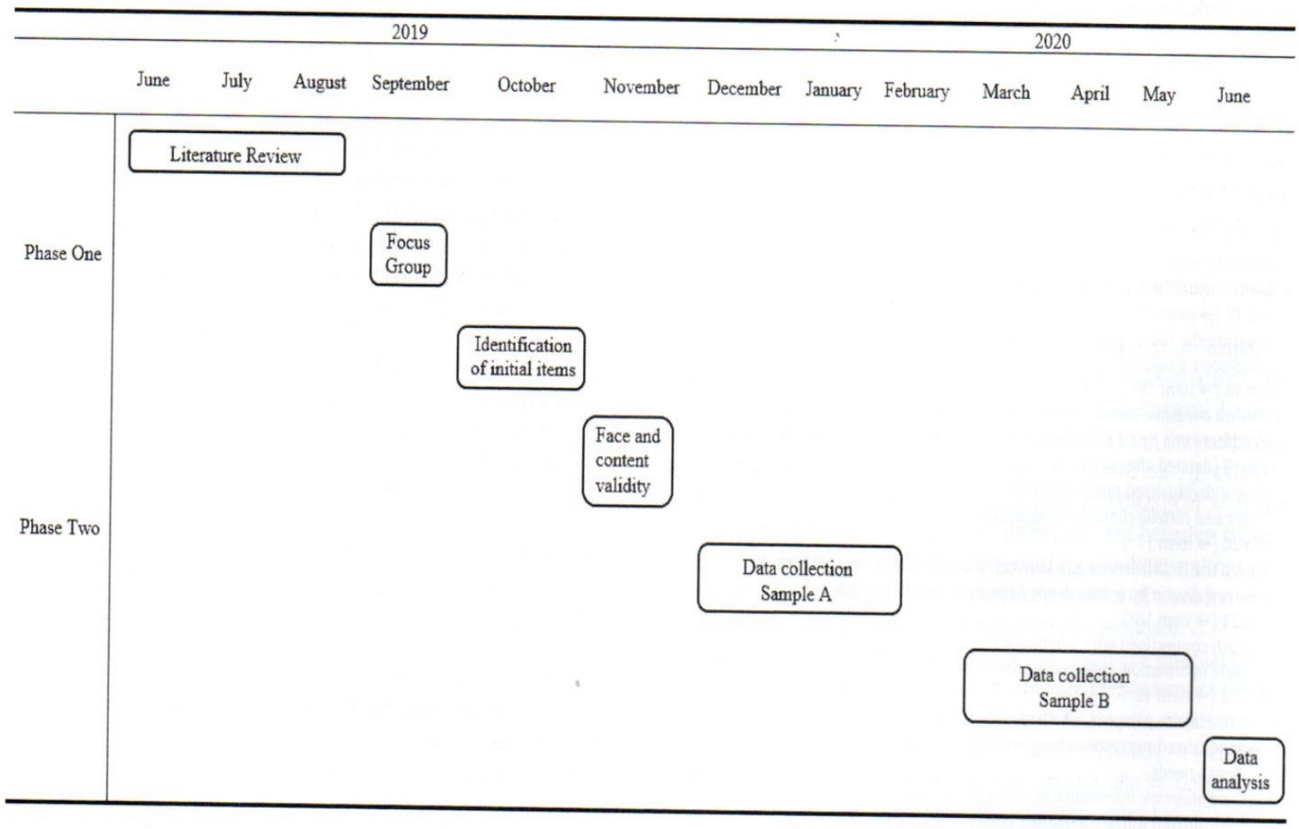

Fig. 1. Gantt chart to illustrate the study process.

Table 1
CVR, I-CVI and S-CVI of the PHNS-CHD.

	CVR	Interpretation	I-CVI	Interpretation	S-CVI
Item 1 (➔ item 1*)					0.86
Provide more information about my child's illness and clarify doubts promptly. *(Ricevere informazioni esaustive riguardo la condizione di mio figlio/a e aver chiarimenti tempestivi in merito ad ogni dubbio)*	0.63	Essential	0.88	Relevant	
Item 2 (delated after phase 2 - EFA)					
Simultaneously explain the condition of my child to the patient and family caregiver *(Ricevere spiegazioni riguardo la condizione di mio figlio/a in presenza del paziente e della famiglia)*	0.47	Not Essential	0.53	Not Relevant	
Item 3 (➔ Item 2*)					
Encourage my child to learn health self-management. *Incoraggiare mio figlio/a ad imparare ad autogestire la sua salute)*	0.88	Essential	0.75	Relevant	
Item 4 (➔ Item 3*)					
Discuss the importance and methods of weight control for my child *(Discutere sull'importanza e sui metodi per il controllo del peso corporeo di mio figlio/a)*	0.92	Essential	0.92	Relevant	
Item 5 (➔ Item 4*)					
Increase my child's knowledge about the course of his/her disease *(Incrementare le conoscenze di mio figlio/a in merito al decorso della sua condizione)*	1.00	Essential	0.81	Relevant	
Item 6 (➔ Item 5*)					
Discuss the progression, prevention, and management of symptoms with my child *(Discutere sull'evoluzione, sulla prevenzione e sulla gestione dei sintomi della condizione di mio figlio/a)*	0.88	Essential	1.00	Relevant	
Item 7 (➔ Item 6*)					
Teach my child how to recognize symptoms *(Educare mio figlio/a su come riconoscere i sintomi della sua condizione)*	0.63	Essential	0.81	Relevant	
Item 8 (➔ Item 7*)					
Discuss the significance and importance of regular follow-up with my child *(Discutere sul significato e sull'importanza dei controlli medici regolari per mio figlio/a)*	0.88	Essential	1.00	Relevant	
Item 9 (➔ Item 8*)					
Make an effort to facilitate parent-child interaction, such as communicating worries *(Ricevere supporto per facilitare la relazione con mio figlio/a, come nella condivisione delle nostre preoccupazioni)*	1.00	Essential	0.88	Relevant	
Item 10 (➔ Item 9*)					
Encourage parents to assist their children in learning about self-care. *(Ricevere incoraggiamento per assistere mio figlio/a nell'apprendimento della cura di sé)*	0.38	Essential	0.92	Relevant	
Item 11 (➔ Item 10*)					
To be sustained in cultivating a positive attitude towards the illness of my child *(Ricevere sostegno nel coltivare un atteggiamento positivo verso la condizione di mio figlio/a)*	1.00	Essential	1.00	Relevant	
Item 12 (➔ Item 11*)					
Improve self-assessment and self-control abilities of my child and engage him in a physical activity that enhances health *(Incoraggiare mio figlio/a migliorare la capacità di autogestione della sua condizione, come intraprendere un'attività fisica per migliorare la sua salute)*	0.88	Essential	1.00	Relevant	
Item 13 (➔ Item 12*)					
Encourage timely communication with teachers and provide them with information about the disease, such as medications, exercise, and work. *(Incoraggiare mio figlio/a nella corretta comunicazione con insegnanti, come nel fornire loro informazioni sulla condizione di mio figlio/a, sua terapia farmacologica e sua tolleranza allo sforzo fisico)*	0.92	Essential	1.00	Relevant	
Item 14 (—- > Item 13*)					
Encourage timely communication with employers and provide them with information about the disease, such as instructions about medications, exercise, and work. *(Incoraggiare mio figlio/a nella corretta comunicazione con i datori di lavoro, come nel fornire loro informazioni sulla condizione di mio figlio/a, sua terapia farmacologica e tolleranza allo sforzo fisico)*	0.92	Essential	0.75	Relevant	
Item 15 (delated after phase 2)					
Maintain a sense of privacy for my child *(Tutelare la privacy di mio figlio/a)*	0.53	Not Essential	0.33	Not Relevant	
Item 16 (➔ Item 14*)					
Appreciate empathy for my child. *(Essere empatici nei confronti di mio figlio/a)*	1.00	Essential	0.81	Relevant	
Item 17 (➔ Item 15*)					
Recognize the value of taking care of my child. *(Riconoscere il valore di chi si prende cura di mio figlio/a)*	0.63	Essential	1.00	Relevant	
Item 18 (➔ Item 16*)					
Establish a feasible medical referral system and follow-up care system for my child. *(Identificare una figura professionale di riferimento per i controlli di mio figlio/a)*	0.63	Essential	0.81	Relevant	
Item 19 (delated after phase 2)					
Set up individualized medical records *(Creare una cartella clinica personalizzata)*	0.33	Not Essential	0.47	Not Relevant	
Item 20 (➔ Item 17*)					
Shorten the health service gap between urban and rural areas for my child. *(Ridurre il divario fra le cure di mio figlio/a in ospedale e a casa)*	0.88	Essential	1.00	Relevant	
Item 21 (➔ Item 18*)					
Establish connections with a network resource or with associations of people with the same condition as my child *(Ricevere informazioni sulle associazioni disponibili di persone con la stessa condizione di mio figlio/a)*	0.63	Essential	1.00	Relevant	
Item 22 (➔ Item 19*)					
Provide a health passport, which records physiological data and the status of medications for cardiac care and includes individualized suggestions for suitable sports, follow-up times, and counsel regarding pregnancy, depending on the patient's needs. *(Ricevere materiale informativo in merito all'educazione sanitaria di mio figlio/a, come ad esempio indicazioni sulla sua terapia medica, attività fisiche compatibili, controlli futuri, o possibilità di gravidanza)*	0.88	Essential	1.00	Relevant	

Table 1 (*continued*)

	CVR	Interpretation	I-CVI	Interpretation	S-CVI
Item 23 (→ Item 20*) Promptly notify regarding the results of applying for catastrophic illness cards of my child *(Ricevere informazioni sullo stato di eventuale invalidità di mio figlio/a)*	0.63	Essential	0.63	Relevant	
Item 24 (→Item 21*) Simplify the administrative procedures for obtaining a catastrophic illness card for my child. *(Ricevere supporto nella richiesta di eventuale stato di invalidità di mio figlio/a)*	0.63	Essential	0.88	Relevant	
Item 25 (→ Item 22*) Provide individualized health information on my child's illness. *(Ricevere informazioni personalizzate riguardo alla condizione di mio figlio/a)*	1.00	Essential	0.63	Relevant	

EFA = Exploratory Factor Analysis.
CVR = Content Validity Ratio.
I-CVI = Item-level content validity index.
S-CVI = Scale-level content validity index.
PHNS-CHD = Parents' Healthcare Needs Scale for adolescents with Congenital Heart Disease.
* Items at the end of the validation process.

worked at Health Professions Research and Development Unit (25%) (Table 1).

After two rounds of panel discussions needed, satisfactory CVRs, I-CVIs, and S-CVI indexes were obtained. No item was removed, having CVRs higher than 0.30 and I-CVIs higher than 0.60, and is described by experts as not redundant in the thematic analysis for face validity. Accordingly, the PHNS-CHD encompassed 25 items and the three a priori domains derived from the conceptualization phase (i.e., physical health needs, family health needs, personal health needs, needs interpersonal relationships, and policy needs).

Explorative appraisal of psychometric characteristics (step 2)

A sample of 209 parents of CHD adolescents was enrolled in the explorative appraisal of the psychometric characteristics of the PHNS-CHD through EFA (sample A). Table 2 shows the socio-demographic profile of Sample A, underlining that most parents were mothers (64.1%), married (90.4%), and Italian (92.4%). Half of the included parents (49.8%) reported having a secondary school education. The mean age of the included sample A was 45.15 years (SD = 7.83), and their age at becoming a parent was 31.01 (SD = 5.19).

As per the factorability assessment, Bartlett's test of sphericity was significant ($p < 0.0001$), and the KMO was 0.961. Accordingly, the correlation matrix was considered suitable for the factor analysis. The study of the eigenvalues, the scree test, and the semantic interpretation of the items in the frame of their underlying domain suggested that the five-factor model was adequate. Overall, the five-domain model showed adequate fit to the data: $\chi^2_{(131)} = 270.334$; $p < 0.001$; RMSEA = 0.051; 90% CI (0.043–0.060); CFI = 0.957; TLI = 0.924; SRMR = 0.027 (total explained variance = 57.89%). Factor loadings for each item revealed that the items were kept by their domains slightly different from the hypothesized structure in phase one.

Table 2
Socio-demographic of parents in sample A and sample B.

		EFA		CFA	
		Sample A ($n = 209$)		Sample B ($n = 191$)	
		N	%	N	%
Parents	Mother	134	64.1	131	68.6
	Father	75	35.9	60	31.4
Marital status	Single	20	9.6	21	11.0
	Married	184	90.4	168	89.0
Education	Primary school	39	18.7	40	24.8
	Secondary school	104	49.8	97	50.8
	High school	52	31.5	42	24.4
Nationality	Italian	194	92.9	180	94.3
	other	15	7.1	11	5.8
Age	years (M; SD)	43.15	7.83	43.96	6.89
Age becoming parent	years (M; SD)	31.01	5.19	31.06	4.81

Legend: EFA = Exploratory Factor Analysis; CFA = Confirmatory Factor Analysis; M = mean; SD = standard deviation.

For this reason, the labels of the theoretical domains were changed compared to the previous phase to capture the real meaning of the items kept for each underlying factor. The new labels were: (a) Healthcare education to the child; (b) To be supported as a parent; (c) Clinical support to the child; (d) Continuum of care of the child; (e) Emotional support to the child. The factor loadings are presented in Table 2. In this step, Item 2, item 15, and item 19 showed important cross-loadings; thus, they were removed before the subsequent data collection for the next validation step (Table 2 and Table 3).

Confirmatory factorial analysis and reliability (step 3)

A sample of 191 parents of CHD adolescents took part in the confirmative analysis of the PHNS-CHD (sample B). As in sample A, most enrolled parents were mothers (68.6.1%), married (89.0%), and Italian (94.3%). The mean age of the included sample B was 43.96 years (SD 6.89), and their age at becoming a parent was 31.06 (SD 4.81) (Table 2).

The confirmatory model ($\chi^2_{(204)} = 575.192$, $p < 0.0001$; $\chi^2/df = 2.82$; RMSEA = 0.098; 90% CI [0.089–0.108]; CFI = 0.864; TLI = 0.846; SRMR = 0.055) showed sufficient evidence of the adequacy of the five-factor model (total explained variance = 57.89%), with all items significantly retained on the respective domain (Table 3). Considering the semantics of similar items and exploring residual correlations, we specified the model by correlating residuals of items 6 and 7, items 23 and 24. The model showed a good fit to the data: ($\chi^2_{(200)} = 438.665$, $p < 0.0001$; $\chi^2/df = 2.19$; RMSEA = 0.069; 90% CI [0.059–0.079]; CFI = 0.914 TLI = 0.901; SRMR = 0.057). Exploring the theoretical presence of a second-order factor predicting the variances of the first-order factors, the model explained data as well: ($\chi^2_{(202)} = 407.337$, $p < 0.0001$; $\chi^2/df = 2.01$; RMSEA = 0.068; 90% CI [0.057–0.082]; CFI = 0.921; TLI = 0.901; SRMR = 0.055). The χ^2 difference test between the two models showed no significant difference, thus indicating that both models explained data as well. Given the presence of a second-order factor, a total score of healthcare needs was also proposed.

Finally, Cronbach's alfa was performed to assess the internal consistency of the overall scale and its five domains, showing adequate indexes. Specifically, the PHNS-CHD reported a Cronbach's alfa = 0.948 and a $\text{mean}_{(\text{standardized domain})}$ (SD) = 67.01 (10.95). 'Healthcare education to the child' reported the Cronbach's alfa = 0.883 [$\text{mean (SD)}_{(\text{standardized domain})} = 69.29$ (10.91); 'To be supported as a parent' reported the Cronbach's alfa = 0.910 [$\text{mean(SD)}_{(\text{standardized domain})} =$ 62.37 (17.44); 'Clinical support to child' reported the Cronbach'

Table 3
Psychometric evaluation: item selection and exploratory phase and construct validity.

	EFA Factor Loadings (Sample A; n = 209)						CFA Factor Loadings (Sample B: n = 191)					
	Mean ± SD	Healthcare education to the child	To be supported as a parent	Clinical support to the child	Continuum of care to the child	Emotional support to the child	Mean ± SD	Healthcare education to the child	To be supported as a parent	Clinical support to the child	Continuum of care to the child	Emotional support to the child
Explained variance (%); total = 57.89%		14.18	11.33	9.90	9.70	12.78	Explained variance (%); total = 61.98%		16.23	11.33	11.25	10.39	12.78
Item 1	4.79 ± 0.47	**0.403**	0.074	−0.072	0.017	0.212	Item 1*	4.75 ± 0.59	**0.482**				
Item 2	4.16 ± 0.99	0.248	0.094	0.045	0.082	0.102	/	/					
Item 3	4.56 ± 0.68	**0.614**	0.000	0.106	0.055	−0.046	Item 2*	4.57 ± 0.73	**0.755**				
Item 4	3.94 ± 0.96	**0.409**	−0.002	0.298	0.052	0.050	Item 3*	3.99 ± 0.95	**0.651**				
Item 5	4.30 ± 0.85	**0.613**	−0.026	0.322	−0.036	−0.101	Item 4*	4.31 ± 0.81	**0.771**				
Item 6	4.52 ± 0.66	**0.807**	0.009	0.037	0.023	−0.027	Item 5*	4.46 ± 0.73	**0.835**				
Item 7	4.60 ± 064	**0.840**	0.017	−0.041	−0.016	0.041	Item 6*	4.57 ± 0.72	**0.833**				
Item 8	4.60 ± 0.63	**0.554**	0.039	0.217	−0.024	0.102	Item 7*	4.52 ± 0.69	**0.738**				
Item 9	4.18 ± 0.93	0.023	**0.966**	−0.012	−0.018	−0.015	Item 8*	4.08 ± 0.98		**0.947**			
Item 10	4.15 ± 0.98	0.044	**0.884**	0.020	−0.003	−0.001	Item 9*	4.08 ± 0.99		**0.938**			
Item 11	4.12 ± 0.93	−0.056	**0.465**	0.238	0.089	0.203	Item 10*	4.09 ± 0.95		**0.763**			
Item 12	4.34 ± 0.78	0.260	0.029	**0.403**	0.083	0.174	Item 11*	4.34 ± 0.74			**0.715**		
Item 13	4.33 ± 0.87	0.009	−0.003	**0.846**	−0.017	0.107	Item12*	4.28 ± 0.85			**0.846**		
Item 14	4.22 ± 0.91	0.042	0.073	**0.778**	0.044	−0.031	Item 13*	4.21 ± 0.93			**0.836**		
Item 15	4.33 ± 0.93	0.064	0.072	0.187	0.085	0.240	/	/					
Item 16	4.42 ± 0.81	−0.060	0.103	0.128	−0.005	**0.721**	Item 14*	4.34 ± 0.78					**0.856**
Item 17	4.51 ± 0.71	0.099	−0.041	0.019	−0.023	**0.835**	Item 15*	4.43 ± 0.72					**0.807**
Item 18	4.59 ± 0.63	0.245	0.034	0.002	0.080	**0.408**	Item 16*	4.49 ± 0.85					**0.606**
Item 19	4.39 ± 0.77	0.257	−0.028	−0.026	0.258	0.298	/	/					
Item 20	4.15 ± 0.85	0.050	0.166	0.011	**0.488**	0.086	Item 17*	4.22 ± 0.94				**0.637**	
Item 21	3.74 ± 1.01	0.151	0.134	0.046	**0.436**	−0.005	Item 18*	3.80 ± 1.02				**0.630**	
Item 22	4.29 ± 0.82	0.211	0.080	0.000	**0.504**	0.061	Item 19*	4.23 ± 0.92				**0.639**	
Item 23	4.30 ± 0.82	−0.021	−0.014	−0.035	**0.959**	−0.021	Item 20*	4.29 ± 0.87				**0.852**	
Item 24	4.22 ± 0.96	−0.114	0.007	0.110	**0.837**	−0.049	Item 21*	4.27 ± 0.88				**0.847**	
Item 25	4.50 ± 0.76	0.144	−0.039	0.016	**0.599**	0.116	Item 22*	4.52 ± 0.71				**0.742**	

Legend: EFA = Exploratory Factor Analysis; CFA = Confirmatory Factor Analysis; SD = standard deviation.
Estimates indicated in bold are > 0.32; items with an * are those renumbered after item selection performed after EFA.

alfa = 0.832 [mean(SD)$_{(standardized\ domain)}$ = 65.91 (14.87); 'Continuum of care to child' reported the Cronbach's alfa = 0.873 [mean (SD)$_{(standardized\ domain)}$ = 64.45 (13.71); and 'Emotional support to child' reported the Cronbach's alfa = 0.792 [mean(SD)$_{(standardized\ domain)}$ = 69.35 (12.71).

Discussion

This study provided the first instrument to assess parents' healthcare needs, testing its validity and reliability, and its scoring procedure is presented in Supplementary File 1. The PHNS-CHD encompassed 22 items and five domains - namely, 'Healthcare education to the child'; 'To be supported as a parent'; 'Clinical support to the child'; 'Continuum of care to the child'; 'Emotional support to the child'. The developed tool showed a robust factorial structure and adequate reliability coefficients. The psychometric structure that emerged from the data analysis is consistent with a recent publication (Dellafiore et al., 2020) describing healthcare needs for youth with congenital heart disease, which are namely 'Healthcare education', 'Clinical support', 'Emotional support', 'Continuum of care'. Parents recognized the same four domains of CHD adolescents' healthcare needs, adding a fifth domain highlighting their need to be supported by healthcare providers to face the challenges of their offspring's transition phase (Bratt et al., 2018).

Although the PHNS-CHD is specific for the parents of adolescents with CHD, its domains are comparable with other genetic tools for assessing the parental needs for rare diseases (Khair & Pelentsov, 2019). For instance, the Parental Needs Scale for Rare Diseases encompasses domains focused on investigating the general understanding of the disease, the need for partnering with healthcare providers, the burden of emotional issues, and financial needs (Khair & Pelentsov, 2019). The advantage of the PHNS-CHD compared to generic tools is mainly given by the contents of each item for capturing the scores for each domain, which are focused on the specific situation of living with a CHD.

The PHNS-CHD has the potential to assess and, subsequently, address the healthcare needs in a tailored way, as it allows clinicians to detect the priority needs that CHD adolescents' parents perceive. Parents feel responsible, experiencing the burden of guiding their children in the correct health management (Landolt, Ystrom, Stene-Larsen, Holmstrøm, & Vollrath, 2014). While adolescents with CHD become independent and autonomous, realizing the parents' role as essential becomes more challenging, even if the concerns about effective autonomy will accompany the parent for all their lives (Bratt et al., 2018; Lawoko & Soares, 2002).

Practice implications

The developed scale encompassed evidence-grounded domains in measuring parents' needs. Parents are often aware that adhering to follow-up and lifestyle indications is essential for maintaining their offspring's stable health over time (Bratt et al., 2018; Lawoko & Soares, 2002). However, adherence to indications is not easily achieved: health problems have been previously linked to poor educational outcomes with possible disadvantages throughout the life of patients with chronic conditions (Brekke, 2015). Because of these worries related to the need for adherence, parents feel obligated and under pressure to teach their children how to maintain their health (Landolt et al., 2014). While adolescents with CHD become independent and autonomous, the realization of the parents' role as essential becomes more challenging (9), even if the concerns about effective autonomy accompany the parent for all their lives (Bratt et al., 2018; Lawoko & Soares, 2002). Even if parents felt trust and confidence in the pediatric healthcare providers (Wei et al., 2015), leaving pediatric care was more difficult for parents than for their children (Chiang et al., 2015). In the developed scale, these

elements have been included to address the most common challenges experienced by adolescents with CHD.

Limitations

This study has some limitations. Firstly, no parents were involved as panelists during the face and content validity. Although the literature review provided insightful viewpoints from parents, the involvement of parents in the content validity would have played a pivotal role in corroborating or adjusting some statements. Therefore, future testing of this new scale should enrich the evidence of content validity by involving parents of adolescents with CHD. Secondly, the parents enrolled came from Italian settings; thus, we can expect possible influences from the cultural context on the dimensionality of the scale. Thirdly, the optimal sample size for performing the cross-validation of the PHNS-CHD was equal to 500 participants, and this study enrolled only 400 parents (80% of the optimal sample size). Although the analyses have shown a good fit to sample statistics, the limited sample size for the validation approach (EFA and CFA in two different sub-samples) suggests caution in generalizing the study results. In addition, future testing of the invariance of the scale in culturally different settings and languages would clarify whether the adopted psychometric structure of the PHNS-CHD could be confirmed internationally. Moreover, convenience sampling and cross-sectional data collection oblige prudence in generalizing the study's results. Finally, longitudinal data to detect the scale's stability over time could help assess its reliability.

Conclusion

The PHNS-CHD encompasses 22 items, which were explained by five domains: 'Healthcare education to the child'; 'To be supported as a parent'; 'Clinical support to the child'; 'Continuum of care to the child'; 'Emotional support to the child'. Overall, the developed scale showed adequate evidence of validity and reliability. The PHNS-CHD could be used by clinicians, especially pediatric nurses, to assess the healthcare and psychosocial needs of parents of adolescents with CHD. Each domain represents a cluster of healthcare and psychosocial needs perceived by parents of adolescents with CHD. Future research could be useful to test the described factor structure for its measurement equivalence at an international level.

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CRediT authorship contribution statement

Federica Dellafiore: Conceptualization, Methodology, Writing – original draft. **Cristina Arrigoni:** Methodology, Validation, Writing – original draft. **Serena Francesca Flocco:** Visualization, Investigation, Project administration. **Serena Barello:** Methodology, Data curation, Writing – review & editing. **Federica Pagliara:** Methodology, Investigation, Validation. **Barbara Bascape:** Methodology, Investigation, Validation. **Tiziana Nania:** Methodology, Data curation, Writing – review & editing. **Irene Baroni:** Methodology, Investigation, Validation, Software. **Sara Russo:** Methodology, Investigation, Validation. **Ida Vangone:** Methodology, Investigation, Validation. **Gianluca Conte:** Methodology, Investigation, Validation, Software. **Arianna Magon:** Methodology, Investigation, Validation, Software. **Massimo Chessa:** Methodology, Investigation, Validation, Software. **Rosario Caruso:** Conceptualization, Methodology, Data curation, Formal analysis, Supervision, Writing – review & editing.

Declaration of Competing Interest

The authors declare no conflicts of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pedn.2022.12.006.

References

van der Bom, T., Zomer, A. C., Zwinderman, A. H., Meijboom, F. J., Bouma, B. J., & Mulder, B. J. M. (2011). The changing epidemiology of congenital heart disease. *Nature Reviews Cardiology*, *8*(1), 50–60. https://doi.org/10.1038/nrcardio.2010.166.

Bratt, E. L., Burström, Å., Hanseus, K., Rydberg, A., Berghammer, M., & On Behalf on the STEPSTONES-CHD Consortium (2018). Do not forget the parents-Parents' concerns during transition to adult care for adolescents with congenital heart disease. *Child: Care, Health and Development*, *44*(2), 278–284. https://doi.org/10.1111/cch.12529.

Brekke, I. (2015). Health and educational success in adolescents: A longitudinal study. *BMC Public Health*, *15*(1). https://doi.org/10.1186/s12889-015-1966-0.

Burström, Å., Öjmyr-Joelsson, M., Bratt, E. -L., Lundell, B., & Nisell, M. (2016). Adolescents with congenital heart disease and their parents. *The Journal of Cardiovascular Nursing*, *31*(5), 399–404. https://doi.org/10.1097/JCN.0000000000000288.

Chen, C. W., Ho, C. L., Su, W. J., Wang, J. K., Chung, H. T., Lee, P. C., ... Hwang, B. T. (2018). Initial validation of a healthcare needs scale for young people with congenital heart disease. *Journal of Advanced Nursing*, *74*(1), 223–231. https://doi.org/10.1111/jan.13390.

Chen, C. -W., Su, W. -J., Chiang, Y. -T., Shu, Y. -M., & Moons, P. (2017). Healthcare needs of adolescents with congenital heart disease transitioning into adulthood: A Delphi survey of patients, parents, and healthcare providers. *European Journal of Cardiovascular Nursing: Journal of the Working Group on Cardiovascular Nursing of the European Society of Cardiology*, *16*(2), 125–135. https://doi.org/10.1177/1474515116643622.

Chiang, Y. -T., Chen, C. -W., Su, W. -J., Wang, J. -K., Lu, C. -W., Li, Y. -F., & Moons, P. (2015). Between invisible defects and visible impact: The life experiences of adolescents and young adults with congenital heart disease. *Journal of Advanced Nursing*, *71*(3), 599–608. https://doi.org/10.1111/jan.12546.

Clarizia, N. A., Chahal, N., Manlhiot, C., Kilburn, J., Redington, A. N., & McCrindle, B. W. (2009). Transition to adult health care for adolescents and young adults with congenital heart disease: Perspectives of the patient, parent and health care provider. *The Canadian Journal of Cardiology*, *25*(9), e317–e322. https://doi.org/PMC2780894.

Dellafiore, F., Flocco, S. F., Arrigoni, C., Barello, S., Nania, T., Russo, M. G., ... Caruso, R. (2020). Italian validation of the healthcare needs scale for youth with congenital heart disease and its short-form development. *Congenital Heart Disease*, *15*(3), 167–180. https://doi.org/10.32604/CHD.2020.012438.

Dillman, D. A., Smyth, J. D., & Christian, L. M. (2014). *Internet, phone, mail, and mixed-mode surveys: the tailored design method (fourth)*. Wiley.

Flocco, S. F., Caruso, R., Dellafiore, F., Pittella, F., Giamberti, A., Micheletti, A., ... Chessa, M. (2018). The effects of a standardized set of educational interventions on the health perception of adolescents with congenital heart disease (transition model): Preliminary results of a quasi-experimental study. *Giornale Italiano di Cardiologia*, *19*(6), 386–393. https://doi.org/10.1714/2922.29372.

Flocco, S. F., Dellafiore, F., Caruso, R., Giamberti, A., Micheletti, A., Negura, D. G., ... Chessa, M. (2019). Improving health perception through a transition care model for adolescents with congenital heart disease. *Journal of Cardiovascular Medicine*, *20*(4), 253–260. https://doi.org/10.2459/JCM.0000000000000770.

Hsieh, H., & Shannon, S. (2005). Three approaches to qualitative content analysis. *Qualitative Health Research*, *15*(9), 1277–1288.

Khair, K., & Pelentsov, L. (2019). Assessing the supportive care needs of parents with a child with a bleeding disorder using the parental needs scale for rare diseases (PNS-RD): A single-Centre pilot study. *Haemophilia: the Official Journal of the World Federation of Hemophilia*, *25*(5), 831–837. https://doi.org/10.1111/hae.13826.

Landolt, M. A., Ystrom, E., Stene-Larsen, K., Holmstrøm, H., & Vollrath, M. E. (2014). Exploring causal pathways of child behavior and maternal mental health in families with a child with congenital heart disease: A longitudinal study. *Psychological Medicine*, *44*(16), 3421–3433. https://doi.org/10.1017/S0033291713002894.

Lawoko, S., & Soares, J. J. F. (2002). Distress and hopelessness among parents of children with congenital heart disease, parents of children with other diseases, and parents of healthy children. *Journal of Psychosomatic Research*, *52*(4), 193–208.

Lawshe, C. (1975). A quantitative approach to content validity. *Personnel Psychology*, *28*, 563–575.

Lincoln, Y., & Guba, E. (1986). But is it rigorous? Trustworthiness and authenticity in naturalistic evaluation. *New Directions for Evaluation*, *30*, 73–84.

Moceri, P., Goossens, E., Hascoet, S., Checler, C., Bonello, B., Ferrari, E., Acar, P., & Fraisse, A. (2015). From adolescents to adults with congenital heart disease: The role of transition. *European Journal of Pediatrics*, *174*(7), 847–854. https://doi.org/10.1007/s00431-015-2557-x.