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Development and assessment of the health-related quality of life scale for children with hearing loss in China

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Abstract

Background Hearing loss significantly affects children's lives; however, the health-related quality of life (QoL) of children with this disability is not well measured. We sought to develop a reliable and valid measure of health-related QoL in children with hearing loss.

Methods We constructed a conceptual framework to assess the QoL of children with hearing loss based on the Pediatric Quality of Life Inventory™ Version 4.0 child quality of life scale and World Health Organization Quality of Life Brief Version disability general version. The item pool was generated through two rounds of the Delphi method and subsequent group discussions. Subsequently, both a pre-survey and a formal survey were administered across eight hospitals and nine special education schools located in Shanxi and Hebei Province, China. The process of selecting items was grounded in classical test theory and item response theory. Ultimately, we assessed the reliability and validity of the QoL Scale designed for children with hearing loss in China.x`

Results The final health-related QoL scale for children with hearing loss (HRQOL-CHL) included 37 items, 6 domains, and 8 subdomains. Reliability assessment encompassed Cronbach's alpha coefficient, split-half reliability, and retest reliability measures. Specifically, for the entire scale, Cronbach's alpha yielded a coefficient of 0.755, binary reliability of 0.796, and retest reliability of 0. 931. The validity findings indicated that the scale performed as anticipated. Both exploratory factor analysis and confirmatory factor analysis demonstrated that this multidimensional scale was well-suited for assessing children with hearing loss, demonstrating a superior fit.

Conclusions The HRQOL-CHL exhibits positive reliability, validity, and feasibility, which makes it an efficient QoL assessment tool for children with hearing loss in China.

Keywords Quality of life, Children, Hearing loss, Reliability, Validity

Background

Hearing is one of the main ways humans obtain external information. Therefore, hearing loss significantly affects patients' lives [1]. Hearing loss is defined as having a hearing threshold > 20 dB in both ears. Hearing loss can be mild, moderate, severe, or profound. It can affect one or both ears, leading to difficulties in hearing conversations or loud sounds [2].

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One study found that, in contrast to normal hearing children, children with hearing loss showed a lag in their social adaptation ability, with more severe hearing loss leading to lower social adaptation ability [3]. In these children, challenges in communication can result in instances of teasing, social isolation, and maltreatment [4], ultimately impacting their ability to form and sustain relationships [5]. Hearing loss has profound effects on children. Early hearing loss leads to delayed language acquisition and speech development, hindering the development of interpersonal communication and social communication skills. Thus, it easily induces psychological problems, which negatively impact the cognition, emotion, and personality of children with hearing loss [6]. This indicates that a notable difference in quality of life (QoL), regarding social and emotional functioning as measured by relevant scales, may exist between children with hearing loss and their peers without. This is particularly evident in school and social settings where the impact of hearing loss on children is pronounced [7]. Hence, focusing on assessing the QoL of children with hearing loss is crucial, enabling timely interventions aimed at enhancing their QoL.

In China, the QoL of children with hearing loss is typically assessed using general scales, rather than scales specifically designed for hearing loss, such as the Nottingham Health Profile [8], the 36-Item Short Form Health Survey [9], the World Health Organization Quality of Life-100 [10], the Symptom Checklist-90 [11], the KIDSCREEN-52 [12], and the Pediatric Quality of Life Inventory [13]. Currently, several professional hearing scales, or those tailored for assessing the rehabilitation effects of hearing aids are utilised in clinical practice; this includes the Speech, Spatial, and Qualities of Hearing Scale (SSQ) [14], the 5-item version of the SSQ [15], the Communication Profile for the Hearing Impaired [16], the Communication Strategies Scale [17], the Hearing Implant Sound Quality Index [18], and the International Classification of Functioning, Disability and Health [19]. However, these professional hearing scales focus on the function of hearing itself or the assessment of the rehabilitation effect of hearing AIDS and lack the dimensional assessment of the quality of life and insufficient consideration of social psychological aspects. To evaluate QoL in children and teenagers who have experienced hearing impairment, only the Youth Quality of Life–Deaf and Hard of Hearing (YQOL-DHH) [20] and Hearing Environments and Reflection on Quality of Life (HEAR-QL) exist. The YQOL-DHH scale was developed specifically for youth aged 11–19 years who are unable to hear or hard of hearing, and examines three domains: self-acceptance/advocacy, perceived stigma, and participation. The HEAR-QL applying to 7–12 [7] and 13–18-year-olds [5], respectively comprises four subscales: social interactions, school difficulties, feelings, and hearing situations. Although these two scales reflect the QoL in children with hearing loss to some extent, they are based on Western cultural values and medical systems, making them unsuitable for direct use in China. For example, HEAR-QL participants were mostly white, from middle-to-high-income families, and had highly educated parents [5]. This contrasts with the economic background in China, where many children with disabilities come from low-income families [21]. Additionally, these scales do not address physical health, a key concern for Chinese parents regarding children's body structures and functions [22].

Cultural factors, such as the importance of family support and traditional educational values, play a significant role in the well-being of children [23] but are not considered in HEAR-QL and YQOL-DHH, which were developed in different cultural contexts. Chinese children, including those with hearing impairments, grow up in an environment that emphasises physical health, academic achievement, and social conformity [24].

The Chinese version of the Pediatric QoL Inventory™ Version 4.0 (PedsQL™4.0) [21] and the World Health Organisation QoL Brief Version (WHOQOL-BREF) disability general version [22] are better adapted to these cultural factors. PedsQL™ 4.0, with 23 items across 4 domains—physical, emotional, social, and role (school)—is flexible and can be modified to meet the specific needs of Chinese children.WHOQOL-BREF provides a broad framework that can be adapted to reflect China's unique cultural and social context. While these established scales provide a solid framework, they require modifications for cultural adaptation to ensure their applicability and accuracy in China. Given that QoL is influenced by cultural factors, direct translation is not feasible; therefore, developing a QoL scale specifically for Chinese children and adolescents with hearing loss is crucial.

This study developed a health-related QoL scale for children with hearing loss (HRQOL-CHL) (see Supplementary Information) to assess the QoL of Chinese children with hearing loss and examine the reliability and validity of the scale, which combines the advantages of two internationally recognised QoL scales, providing an intercultural comparative perspective for international readers. Moreover, as a country with a large population of children with hearing loss, the development of life-quality assessment tools in China has important implications for global health research on children with hearing loss.

Methods

The development of the HRQOL-CHL was divided into three phases [25].

Phase 1: formulation of the scale's theoretical framework (domain system) and the selection of items

(1) Construction of a conceptual framework: Through literature analysis, core group discussions, and considerations that the scale serves special groups, we constructed the conceptual framework of the hearing-loss children's QoL evaluation scale based on the Chinese version of the Pediatric Quality of Life Inventory™ Version 4.0 (PedsQL™4.0) child quality of life scale [26] developed and translated by Sun Yat-sen University and the World Health Organization Quality of Life Brief Version (WHOQOL-BREF) disability general version [27]. The PedsQL™4.0 and WHOQOL-BREF scales were chosen because they better address the cultural context of Chinese children's physical health, school learning, and emotional/social development. While these two scales have high authority, reliability, and validity in assessing the QoL of children and children with disabilities, they are still translation scales. Owing to the differences in social, economic, cultural, and religious contexts between China and the West, these scales require adjustment. We have modified the language of certain items and removed those that are not suitable for domestic conditions. To address the weak specificity for children with disabilities, we have added a specific module to the scale.

(2) Creation of the item pool: A pool of 44 items was formed by consulting relevant literature in various fields, core group discussions, and expert opinions in the field of comprehensive rehabilitation (see Supplementary Material 1).

(3) Item screening: The scale items were screened through two rounds of expert consultation involving 26 experts specializing in hearing impairment recovery, hearing speech training, social medicine, medical statistics, paediatrics, rehabilitation medicine and medical psychology, among others, in Beijing, Taiyuan and other cities. The selection criteria included (1) an intermediate title or above, and (2) worked for no < 10 years. The data showed that the areas and items designed in the expert consultation questionnaire received good rating scores consistently recognised by experts. Ultimately, the item pool of the HRQOL-CHL consisted of 38 items and six domains.

(4) Score of the scale: According to the Likert scoring method, items were given 1('never') to 5 ('almost') points. Negative items were recoded as five minus the original score [28]. Higher scores indicate a worse QoL.

Phase 2: formation of final scales

Five methods were used to screen the items in the HRQOL-CHL formation process. The five methods encompassed four classical test theory (CTT) and item response theory (IRT) approaches for screening items. Recognised as potential trait theory, IRT is the favoured statistical methodology for analysing patients' latent traits [29]. An item was considered for selection if it was retained by three or more methods. Before deleting an item, we first considered its practical significance. Items deemed meaningful were retained kept and subjected to screening in the formal survey. If subsequent testing suggested that an item should be removed, it was then deleted.

Statistical methods

Five methods were used to evaluate the items:

(1) The standard deviation of each item was used to evaluate the degree of dispersion. The standard deviation of an item reflects its sensitivity in assessing QoL differences between individuals: a larger standard deviation indicates greater variation in scores, while a smaller one suggests less variation. Conversely, a small standard deviation indicates minimal variation in scores among individuals, making it less effective in distinguishing QoL differences. Therefore, items with a standard deviation < 1 were deleted [30].

(2) For each item, we computed the corrected item-total correlation (CITC), representing the correlation between the item and the scale when excluding that specific item. In scale development, a CITC value below 0.20 indicates a weak relationship between the item and the overall construct, which may affect the internal consistency and validity of the scale. Therefore, items with CITCs < 0.20 were deleted or adjusted [31].

(3) If the Cronbach's alpha for a deleted item exceeded the total scale's value, it suggested the item may not be contributing positively to the scale's reliability. Therefore, the item was reviewed and adjusted, possibly through revision, rephrasing, or removal. A Cronbach's alpha value after item removal indicates improved internal consistency [32].

(4) Factor loadings represent the correlation between an item and the underlying factor it measures. A factor loading < 0.4 indicates a relatively weak relationship, suggesting that the item may not effectively measure the construct. Items with factor loadings < 0.4 or those related to other factors in the exploratory factor analysis were either removed or adjusted. Items with factor loadings below 0.4 or

those exhibiting proximity to other factors in the exploratory factor analysis were either removed or adjusted [33].

(5) We employed IRT to inform test preparation and item selection [34]. In Samejima's graded response model [35], the difficulty and discrimination parameters are taken as two reference indexes for item screening. Generally, if the item discrimination parameter a) < 0.4, it should be considered for deletion. If the difficulty parameter (b)'s range is generally between −3 and 3, the excess part is considered for deletion.

Phase 3: evaluation of the HRQOL-CHL

The characteristics of the ultimate version of HRQOL-CHL were evaluated utilising data gathered from a comprehensive formal investigation.

Evaluation of reliability

The split-half reliability was employed to assess the consistency of the scale across its items [36].

Test-retest reliability, which reflects the stability and consistency of a scale across time, was then assessed. A re-test sample size of at least 25 participants was deemed applicable [37]. A correlation coefficient exceeding 0.75 indicates robust test-retest reliability.

To evaluate the internal consistency of the HRQOL-CHL, the Cronbach's alpha coefficient of the six subdomains was employed. A Cronbach's alpha coefficient of over 0.8 generally signifies excellence, whereas a range between 0.6 and 0.8 indicates good internal consistency [38].

Evaluation of validity

Content validity

Content validity, reflecting how well the items captured the concept of interest, was established through a thorough review of relevant literature, a caucus discussion, and a two-round expert consultation [39].

Construct validity

A factor analysis was used to test the structural validity of the scale. Absolute fit indices, namely Chi-square value/freedom degree (χ^2/df), the goodness-of-fit (GFI), absolute goodness-of-fit (AGFI), root-mean-square error of approximation (RMSEA), and standardised root mean square residual (SRMR), were calculated. Additionally, incremental fit indices (IFI), a comparative fit index (CFI), and parsimony fit indices, including the parsimony normed fit index (PNFI) and the parsimony goodness-of-fit index (PGFI), were considered.

If these indices reached the following values, the model fit was highlighted [40]. GFI, AGFI, CFI, NFI, NNFI, and IFI were all > 0.90, indicating a good model fit [41]. In the case of RMSEA, a value between 0.05 and 0.08 suggests an acceptable model fit, while a value less than 0.05 indicates a great model fit. Generally, RMSEA, SRMR, and RMR values < 0.08 indicate an acceptable model fit [42]. A parsimony fit index (PNFI, PGFI) exceeding 0.5 was considered satisfactory [43]. χ^2/df serves as an absolute fit index, with a smaller value indicating a better model fit. A χ^2/df less than 3 is indicative of a good model fit [44].

Convergent validity

We evaluated the convergent validity using factor loadings. The scale's convergent validity was met when the standardised factor loadings exceeded 0.5, as indicated by previous research [45].

Discriminant validity

Discriminant validity assesses the ability to distinguish between two groups. In this study, a t-test was employed to compare children with hearing loss and their healthy counterparts, with a statistical significance level defined as $\alpha = 0.05$.

Participants

We conducted a cross-sectional study using cluster sampling for data collection. Both the pre-survey and the formal survey were administered across eight hospitals, six special education schools in Shanxi Province, and three special education schools in Hebei Province, China. The development of the HRQOL-CHL scale was undertaken with eligible children with hearing loss aged 8 to 18 years. A total of 766 children and adolescents with hearing loss were included in the pre-survey and 1055 were included in the formal investigation; healthy children in local schools were selected as the control group, and a total of 850 questionnaires were collected for analysis.

Before collecting samples, the investigators contacted the target hospitals and schools' relevant departments and obtained the support of hospital and community leaders, as well as the parents of the children. The study was approved by the Ethics Review Committee of the Shanxi Medical University and was carried out in accordance with the Declaration of Helsinki.

The inclusion criteria included permanent sensorineural, mixed, or conductive hearing loss with a pure tone average of ≥ 30 dB hearing level for any three adjacent test frequencies in at least one ear [5], and informed consent given voluntarily by participants and their parents.

The exclusion criteria included the following: (1) persistent temporary or wave-conductive deafness, such as otitis media; (2) medical problems related to cognitive impairment (e.g. Down syndrome, congenital cytomegalovirus infection, and chemotherapy history); (3) known

cognitive impairments or mental illness; (4) did not speak Chinese; (5) participants were unable to provide informed consent.

Research procedures

Ten trained investigators conducted individual face-to-face interviews with participants who had a hearing disability, assisting in comprehending the questions and selecting appropriate responses. Meanwhile, teachers at the special training school handled supplementary surveys, distributing, completing, and collecting questionnaires through face-to-face interviews. The investigators only focused on reading questions without further explanation to prevent leading answers. After the questionnaires were collected, a strict audit was conducted, erroneous questionnaires were eliminated, valid questionnaires were numbered, and a two-person dual-machine input was carried out using EpiData version 3.1 software system (Odense, Denmark). The input data were checked individually to ensure data quality.

Results

Participant characteristics

The preliminary survey incorporated 766 children with hearing loss; Supplementary Table 1 displays the survey findings. In the formal survey, 1,905 questionnaires were analysed, comprising 1,055 children with hearing loss and 850 healthy children. Baseline data for both groups were compared using the t-test for continuous variables and the chi-square test for categorical variables. Results indicated comparable baseline data for both groups of children with hearing loss and healthy children when the significance level was set at $\alpha = 0.05$ (Table 1).

The conceptual framework of the HRQOL-CHL

The conceptual framework comprises six domains. Through literature review and interviews with children with hearing loss and their parents, we established an initial library comprising 44 items. Based on two rounds of expert consultation, we deleted six items and amended five. The conceptual framework consisted of 38 items in six domains (physiological, emotional, social, role, general, and special modules). The conceptual framework is illustrated in Fig. 1.

Final scale formed by selecting items

Five methods were used to select the items: Cronbach's alpha coefficient, standard deviation, exploratory factor analysis, CITCs, and IRT (Fig. 2).

The discrimination parameters a and difficulty parameters b for scale items were estimated using MULTILOG 7.03 software from Scientific Software International Inc. (Skokie, USA). We created an item characteristic curve (ICC) matrix for the HRQOL-CHL

Table 1 Comparison of demographic characteristics of children with hearing-loss children and healthy children

Variables	Group	Children with hearing-loss, *n* (%)	Healthy children *n*(%)	t/χ^2	*P*
Age		13.85 ± 2.656	13.91 ± 2.771	0.523	0.061
Gender	Male	472(44.74)	400(47.06)	1.02	0.312
	Female	583(55.26)	450(52.94)		
Place of residence	Urban	269(25.50)	206(24.23)	2.868	0.238
	Rural	786(74.50)	644(75.77)		
Type of medical insurance	Self-paying	101(9.57)	66(7.76)	4.522	0.21
	Urban residents' Basic medical Insurance	351(33.27)	280(32.94)		
	New rural cooperative medical insurance	450(42.65)	396(46.59)		
	Others	153(14.51)	108(12.71)		
Grade of disability	Level 1	675(63.98)			
	Level 2	183(17.34)			
	Level 3	121(11.47)			
	Level 4	76(7.21)			
Whether to wear hearing aids or cochlear implants	Yes	568(53.84)			
	No	487(46.16)			
Per capita household income	< 1000元	413(39.15)	346(40.71)	4.333	0.228
	1000–3000元	456(43.22)	338(39.77)		
	3000–5000元	114(10.81)	113(13.29)		
	> 5000元	72(6.82)	53(6.23)		

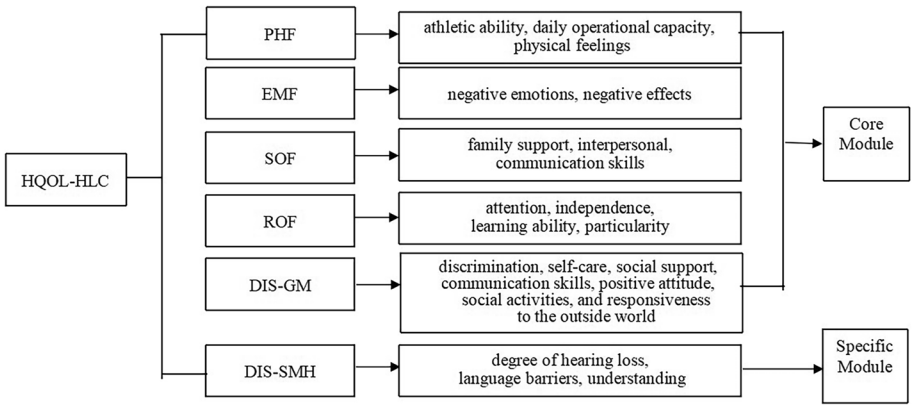

Fig. 1 Scale envisioned framework of HRQOL-CHL

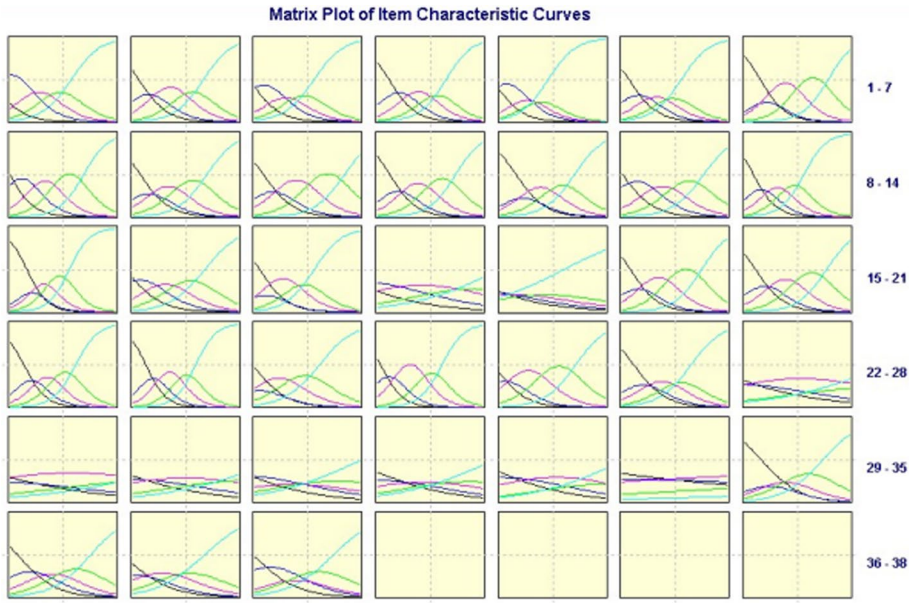

Fig. 2 Item characteristic curve matrix diagram

project (Fig. 2). Ideally, ICC should be monotonic with black and cyan curves, while the blue, magenta, and green curves should follow a normal distribution. The five curves represent options for each item, with 1–5 for 'never,' 'occasionally,' 'sometimes,' 'often,' and 'almost always.' If the characteristic curve is on the left of the X-axis, the test difficulty is low; if on the right, it is high. A sharper curve indicates better differentiation. The intersection with the Y-axis reflects the probability of answering correctly, with higher intersections indicating greater chances of success for low-ability individuals. As per the ICC matrix, the ICCs for item 34 (DIS-GM10) did not meet the desired criteria. We evaluated the items using the aforementioned five methods, considering their practical implications. Based on the results in Table 2, item 34 (DIS-GM10) was deleted, resulting in 37 scale items in six domains (see Supplementary Material 2).

Evaluating the properties of the HRQOL-CHL

The validity, reliability, and feasibility of the final HRQOL-CHL were evaluated using data from 1055 hearing-impaired children and 850 healthy children.

Reliability

The HRQOL-CHL demonstrated a split-half reliability of 0.796. A retest conducted two weeks later on 30 hearing-impaired children at a specialised school in Taiyuan, showed a test-retest reliability of 0.931 for the overall scale. The Cronbach's alpha coefficient for the total scale was 0.755. Detailed domain-specific results are outlined in Table 3.

Table 2 Screening results of the items using classical test theory (CTT) and item response theory (IRT)

Item	Content	CTT				IRT					Retained
						Discrimination	Difficulties				
		CITC	Alpha if items deleted	EFA	SD	α	b_1	b_2	b_3	b_4	
PHF1	Walking	0.333	0.722	0.712	0.938	1.22	−4.06	−1.99	−0.77	0.43	√
PHF2	Running	0.403	0.72	0.690	1.095	1.26	−2.64	−1.56	−0.18	1	√
PHF3	Playing	0.415	0.72	0.566	1.019	1.2	−3.3	−1.75	−0.76	0.32	√
PHF4	Lighting	0.424	0.719	0.564	1.153	1.33	−2.34	−1.25	−0.12	0.87	√
PHF5	Showering	0.382	0.721	0.685	0.933	1.27	−3.39	−1.86	−1.04	−0.28	√
PHF6	Housework	0.426	0.719	0.755	1.089	1.26	−2.61	−1.57	0.59	0.32	√
PHF7	Pain	0.427	0.719	0.531	1.112	1.38	−2.11	−1.42	0.02	1.71	√
PHF8	Fatigue	0.467	0.719	0.449	1.055	1.45	−3.02	−1.67	−0.41	1.14	√
EMF1	Fear	0.424	0.719	0.598	1.086	1.21	−2.56	−1.62	−0.36	1.19	√
EMF2	Depressed	0.508	0.718	0.702	1.076	1.18	−2.51	−1.47	0.13	2.05	√
EMF3	Angry	0.419	0.719	0.522	1.055	1.33	−2.29	−1.34	−0.06	1.41	√
EMF4	Sleep	0.403	0.719	0.563	1.193	1.21	−2.07	−1.32	−0.09	1.21	√
EMF5	Worry	0.468	0.718	0.714	1.122	1.13	−2.97	−1.38	−0.03	1.6	√
SOF1	Other children	0.445	0.719	0.525	1.082	1.55	−2.49	−1.62	−0.68	0.33	√
SOF2	Keep up with peers	0.524	0.717	0.701	1.131	1.74	−2.04	−1.51	−0.72	0.33	√
SOF3	Make fun	0.45	0.718	0.570	1.162	1.02	−3.38	−1.82	−0.48	1.05	√
SOF4	Complete work	0.511	0.717	0.537	1.192	1.26	−2.73	−2.09	−0.75	0.32	√
SOF5	Others' help	0.269	0.721	0.729	1.307	0.41	−5.71	−2.1	1.12	3.86	√
SOF6	Parents' care	0.242	0.722	0.674	1.361	0.43	−5.66	−3.28	−1.33	0.58	√
ROF1	Attention	0.438	0.719	0.607	1.136	1.29	−2.52	−1.64	−0.28	1.47	√
ROF2	Miss things	0.472	0.718	0.451	1.125	1.24	−2.37	−1.35	−0.02	1.61	√
ROF3	Study	0.47	0.717	0.687	1.215	1.58	−2.22	−1.39	−0.44	0.69	√
ROF4	No end	0.435	0.719	0.416	1.077	1.73	−2.24	−1.42	−0.39	0.55	√
ROF5	Absent	0.34	0.721	0.333	1.085	1.03	−3.15	−2.36	−0.94	0.61	√
DIS-GM1	Dysfunction affect	0.385	0.72	0.570	1.149	1.59	−2.82	−1.86	−0.45	0.63	√
DIS-GM2	Self feeling	0.471	0.718	0.609	1.087	1.16	−3.31	−2.2	−0.58	1.27	√
DIS-GM3	Friends' understanding	0.462	0.718	0.637	1.246	1.11	−2.33	−1.36	−0.21	0.87	√
DIS-GM4	Communication	0.278	0.721	0.720	1.277	0.33	−5.34	−1.96	2.31	5.02	√
DIS-GM5	People like	0.285	0.721	0.708	1.306	0.26	−6.43	−2.41	3.32	7.52	√
DIS-GM6	Care or help	0.319	0.72	0.700	1.32	0.32	−5.47	−1.85	1.87	5.22	√
DIS-GM7	Washing clothes	0.264	0.721	0.572	1.435	0.39	−5.26	−1.94	0.31	2.97	√
DIS-GM8	Social activity	0.289	0.721	0.646	1.318	0.38	−4.55	−1.68	0.9	3.57	√
DIS-GM9	Wish or dream	0.294	0.721	0.646	1.307	0.39	−4.46	−1.36	1.76	4	√
DIS-GM10	Outside situation	−0.059	0.729	0.406	1.246	0.12	−8.58	1.14	12.74	24.71	×
DIS-SMH1	Hearing severity	0.296	0.721	0.763	1.409	0.92	−2.04	−1.21	−0.14	1.4	√
DIS-SMH2	Interact	0.292	0.721	0.780	1.421	0.93	−2.56	−1.21	0.02	1.52	√
DIS-SMH3	Hearing loss/affect study	0.234	0.722	0.790	1.379	0.75	−3.55	−2.13	−0.54	1.03	√
DIS-SMH4	Spoken English	0.259	0.721	0.781	1.373	0.8	−3.1	−1.21	−0.17	1.41	√

PHF physiological function, *ROF* role function, *SOF* social function, *EMF* emotional function, *DIS-SMH* disability general module, *DIS-SMH* Hearing-loss disabilities specific module

Table 3 Reliability of the HRQOL-CHL

Domain	Split-half reliability	Test-retest reliability	Cronbach's alpha coefficient
PHF	0.792	0.962	0.841
EMF	0.709	0.721	0.77
SOF	0.562	0.699	0.62
ROF	0.615	0.712	0.707
DIS-GM	0.646	0.906	0.748
DIS-SMH	0.792	0.783	0.833
TOTEL	0.796	0.931	0.755

PHF physiological function, *ROF* role function, *SOF* social function, *EMF* emotional function, *DIS-SMH* disability general module, *DIS-SMH* Hearing-loss disabilities specific module

Validity

Content validity

The formation and implementation of the Quality of Life Measurement Scale item pool for children with hearing was based on the PedsQL™4.0 Chinese version and the WHOQOL-BREF disability general version, two mature scales in China. The supplementary items also refer to the literature of domestic scale experts. The quantitative DELPHI expert consultation method was adopted in the item selection process. By engaging in discussions within the core group and consulting experts in various fields, the final scale group should have a good domain system and item content validity.

Construct validity

The average Kaiser–Meyer–Olkin index was 0.884 in the EFA. Bartlett's sphericity test demonstrated that the samples were factorable ($P<0.001$), affirming the appropriateness of the correlation matrix for factor analysis.

Eight subdomains were selected using maximum variance rotation. The cumulative contribution was 57.008%. The final scale's structural framework is outlined in Table 4.

Utilising the findings from the EFA, we conducted a confirmatory factor analysis(CFA) of the HRQOL-CHL with the assistance of R software (Auckland, New Zealand). The outcomes satisfied the fitting criteria, indicating that the eight-domain model exhibited satisfactory factorial validity in the present sample (Table 5). $\chi^2=1631.515$, df$=601$, $\chi^2/df=2.715$, and root mean square error of approximation$=0.040$.

RMSEA, root-mean-square error of approximation; SRMR, standardized root mean square residual; RMR, root mean square residual; PGFI, parsimony goodness-fit-index; PNFI, parsimony normed fit index; IFI, incremental fit indices; NNFI, non-normed fit index; RFI, relative fit index; GFI, goodness-of-fit; AGFI, absolute goodness of fit; CFI, comparative fit index; NFI, normed-fit index.

Table 6 displays the CFA outcomes. The standardized factor loadings of the eight subdomains exceeded 0.5, indicating satisfactory construct validity, as illustrated in Fig. 3.

Table 4 Structural framework of the HRQOL-CHL

Domains	Subdomains	Item
Physiological function	physiological function	1,2,3,4,5,6,7,8
Emotional function	Emotional function	9,10,11,12,13
Social function	communication skills	14,15,16,17
	family support	18,19
Role function	role function	20,21,22,23,24
Disability general module	positive attitude	25,26,27
	social support	28,29,30,31,32,33
Hearing-loss children-specific module	specific module	34,35,36,37

Table 5 Fitting indices of confirmatory factor analysis of the HRQOL-CHL

Fitting index	RMSEA	SRMR	RMR	PGFI	PNFI	χ^2/df	IFI
Fit the index results	0.040	0.051	0.072	0.828	0.848	2.715	0.961
Standard	<0.08	<0.08	<0.08	>0.5	>0.5	<3	>0.9
Fitting index	NNFI	RFI	GFI	AGFI	CFI	NFI	p
Fit the index results	0.957	0.933	0.969	0.964	0.961	0.94	<0.001
Standard	>0.9	>0.9	>0.9	>0.9	>0.9	>0.9	<0.05

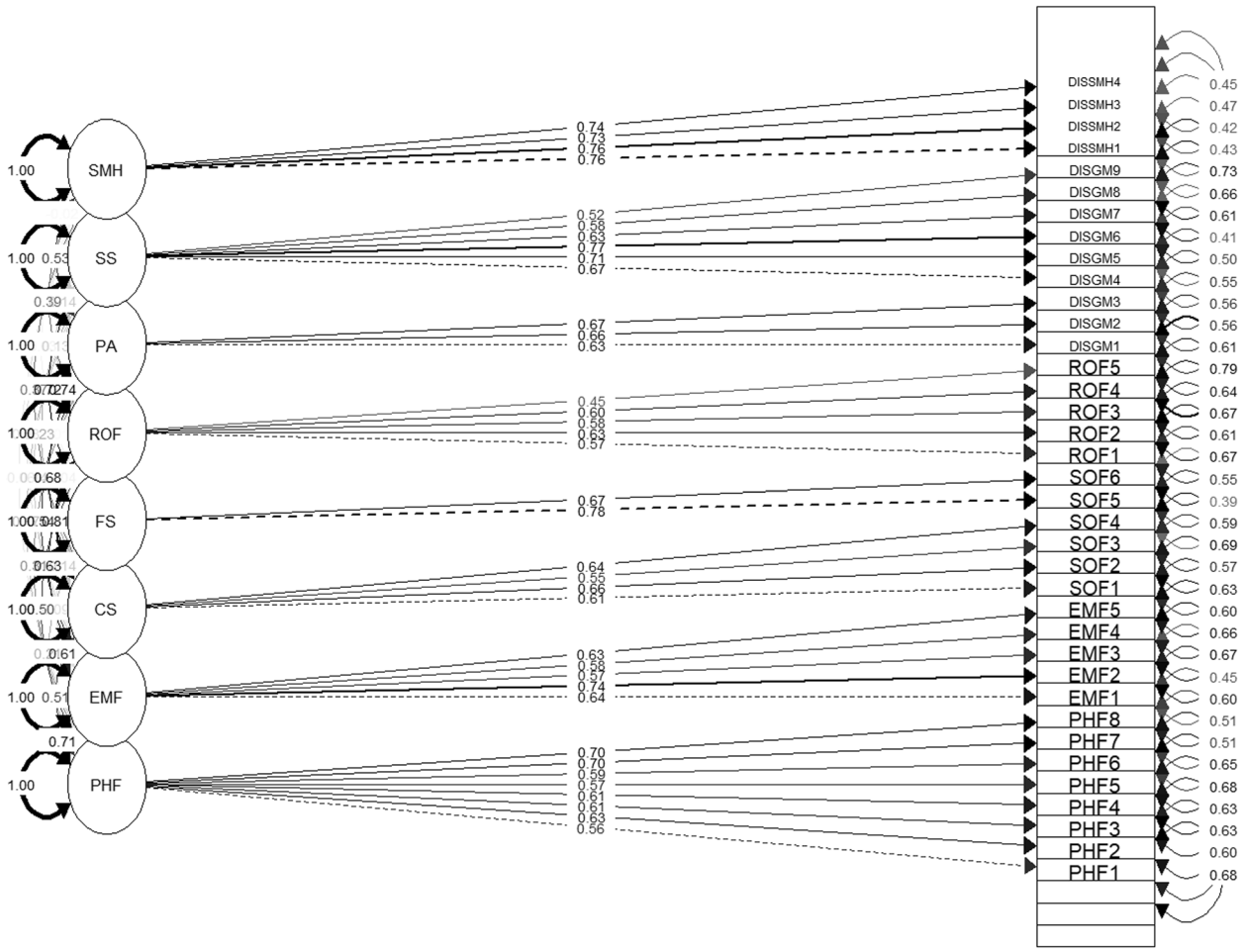

Fig. 3 Confirmatory factor analysis of the health-related quality of life scale for hearing-loss children

Discriminant validity

Discriminant validity results are presented in Table 7. Discriminant validity ($P < 0.05$) indicated that the HRQOL-CHL was a suitable instrument for distinguishing children with hearing loss from healthy children.

Feasibility

During the pre-investigation, the HRQOL-CHL exhibited a recovery rate of 95.75%. In the formal investigation, the recovery rates were 89.47% for healthy children and 91.97% for children with hearing loss. The completion time of the survey was controlled to about 15 min, indicating that the HRQOL-CHL has good feasibility.

Discussion

The HRQOL-CHL consists of 37 items, six domains, and eight subdomains. This was the first specific QOL scale developed for children aged 8–18 years old in China. This study confirmed the scale's psychological properties including reliability, validity, and discrimination. Based on CTT, the HRQOL-CHL was developed strictly following the module and methodology provided by the WHO [46], using a scientifically rigorous methodology that applied recent advanced conceptual and practical measurements and drawing on strong theoretical foundations of the IRT's Rasch model. The accuracy and validity of the HRQOL-CHL were confirmed from the perspective of children with hearing loss themselves. The findings of this study indicate that the HRQOL-CHL serves as an effective instrument for evaluating the QoL of children with hearing loss in China.

The HRQOL-CHL analysed the QoL of children with hearing loss in China from multiple perspectives. Compared with existing hearing loss scales, the HRQOL-CHL provides a more comprehensive assessment of QoL. Children with hearing loss cannot express and meet some of their needs owing to hearing loss and speech disorders. They may experience physiological and psychological

Table 6 Results of the confirmatory factor analysis

Subdomains	Item	Nonstandard factor loading	Standard factor loading	Standard error	z	*P*
PHF = physiological function	PHF1	1.000	0.562			<0.001
	PHF2	1.258	0.632	0.050	25.866	<0.001
	PHF3	1.136	0.607	0.044	25.597	<0.001
	PHF4	1.298	0.610	0.050	25.730	<0.001
	PHF5	1.015	0.570	0.042	24.226	<0.001
	PHF6	1.182	0.592	0.047	25.212	<0.001
	PHF7	1.422	0.702	0.054	26.149	<0.001
	PHF8	1.337	0.697	0.051	26.228	<0.001
EMF = emotional function	EMF1	1.000	0.635			
	EMF2	1.159	0.774	0.042	27.772	<0.001
	EMF3	0.863	0.572	0.034	25.216	<0.001
	EMF4	0.989	0.580	0.039	25.324	<0.001
	EMF5	1.001	0.630	0.038	26.306	<0.001
CS = communication skills	SOF1	1.000	0.611			
	SOF2	1.113	0.659	0.042	26.395	<0.001
	SOF3	0.967	0.553	0.039	24.682	<0.001
	SOF4	1.117	0.641	0.042	26.349	<0.001
FS = family surpport	SOF5	1.000	0.780			
	SOF6	0.884	0.670	0.047	18.861	<0.001
ROF = role function	ROF1	1.000	0.575			
	ROF2	1.063	0.628	0.041	25.783	<0.001
	ROF3	1.067	0.577	0.042	25.134	<0.001
	ROF4	1.003	0.601	0.040	25.275	<0.001
	ROF5	0.754	0.453	0.034	21.987	<0.001
PA = positive attitude	DISGM1	1.000	0.626			
	DISGM2	1.053	0.663	0.039	25.074	<0.001
	DISGM3	1.160	0.667	0.046	24.990	<0.001
SS = social surpport	DISGM4	1.000	0.669			
	DISGM5	1.053	0.705	0.045	23.162	<0.001
	DISGM6	1.160	0.765	0.049	23.632	<0.001
	DISGM7	1.004	0.628	0.045	22.201	<0.001
	DISGM8	0.882	0.584	0.041	21.774	<0.001
SMH = specific module	DISGM9	0.795	0.522	0.038	20.767	<0.001
	DISSMH1	1.000	0.755			
	DISSMH2	1.009	0.763	0.042	23.738	<0.001
	DISSMH3	0.935	0.727	0.040	23.490	<0.001
	DISSMH4	0.960	0.739	0.041	23.581	<0.001

problems owing to strong conflicts between needing to express their needs and their actual ability to do so [47]. Therefore, the first two parts of the scale were divided into physiological and emotional function domains. The results demonstrated that both the physiological and emotional functions of children with hearing loss were inferior to those of their normal-hearing counterparts, which is consistent with prior studies [7] and highlights the significance of improving the physiological and emotional functions of children with hearing loss.

Simultaneously, hearing loss may also affect their language and communication skills, resulting in difficulties communicating with others and understanding others' language and emotional expressions [48], thus affecting their social skills. Therefore, we designed the social function domain to assess the social situation of children with hearing loss. We found that the social situation of children with hearing loss is poor, which is consistent with previous findings [5]. Attention should be given to all these aspects to help children with hearing loss build

Table 7 Comparisons between healthy children and hearing loss children (x ± s)

Subdomains	hearing loss children	healthy children	Cohen's d	t/t'	*P*
physiological function	33.42 ± 5.825	14.40 ± 4.926	3.53	75.836	<0.001
emotional function	19.11 ± 3.996	10.71 ± 3.882	2.13	46.201	<0.001
communication skills	16.15 ± 3.292	7.90 ± 3.253	2.52	54.662	<0.001
family support	7.46 ± 2.266	2.308 ± 2.266	1.15	25.050	<0.001
role function	18.99 ± 3.805	10.95 ± 3.724	2.14	46.284	<0.001
positive attitude	11.33 ± 2.685	6.63 ± 2.704	1.74	37.851	<0.001
social support	19.97 ± 5.578	16.50 ± 5.045	0.65	14.072	<0.001
specific module	12.53 ± 4.479	9.589 ± 3.476	0.74	15.746	<0.001

confidence in their interpersonal communication. Notably, the reliability indices in the social domain are lower. This may be because the social function domain is inherently complex. It encompasses a wide range of aspects such as social interaction skills, relationships with peers and family, and participation in social activities. For children with hearing-loss, these aspects may be influenced by multiple factors, including the degree of hearing loss, the effectiveness of assistive devices, and the environment in which they grow up [49]. The heterogeneity of these influencing factors may lead to inconsistent responses among children with impairment, resulting in a relatively low split-half reliability. Moreover, the sample of children with hearing may have a certain degree of variability in terms of their social function. This variability could stem from age differences, the type of hearing loss (congenital vs. acquired), and the length of time since diagnosis. Such differences within the sample can make it more difficult to achieve high reliability in the social function domain. To address the issue of lower reliability in the social function domain, future research could consider the following: Rephrasing ambiguous items and adding new items that better capture the unique social function characteristics of hearing - loss children. Despite the low reliability in the social functional domain, the scale still showed good reliability in other domains, which helped maintain its overall reliability.

For education, children with hearing loss may have difficulties learning, including understanding teacher explanations, listening to recorded materials, and participating in class activities [50]. Therefore, we designed a role function domain to assess the adaptability of children with hearing loss as students. The results suggest that hearing-impaired children need additional support and guidance in education to compensate for the impact of hearing loss, which is consistent with Worsfold's view [51]. Further, research has shown that when the difficulty level is low and the text is accompanied by illustrations, reading comprehension indicators such as achievement, time, and speed are optimal [52]. Therefore, we designed a scale with illustrations to facilitate children's reading comprehension.

The family support and social support items about adapting to daily life and the social environment prompt multi-faceted collaboration and support to promote the psychological health and social adaptation abilities of children with hearing loss. Overall, children with hearing loss face various difficulties and challenges. Our scale involves family, school, society, physiology, emotion, and other fields to wholistically assess their QoL.

The HRQOL-CHL design fully considers the cultural background and living environment of Chinese children. The items in the scale are based on the international scale framework and incorporate elements that reflect the characteristics of Chinese children's life, such as learning pressure, family relations, and social interactions. These culture-specific entries aim to more accurately assess the quality of life of children in China and ensure the cultural sensitivity and validity of the assessment results. For example, in Chinese culture, education is regarded as the cornerstone of personal and social development [53], so learning pressure has become an important factor affecting children's quality of life. There are items in the scale designed to measure the impact of learning stress on children's mental and physical health. The family occupies a core position in Chinese culture, and the harmony of family relationship is very important to the growth of children [54]. The scale reflects the satisfaction of children's family relationship by assessing how they get al.ong with their families.When Chinese children grow up, their social activities are often influenced by a collectivist culture that emphasizes teamwork and a sense of belonging to a group [55]. The relevant items in the scale were designed to assess children's engagement and satisfaction with social activities. Although the HRQOL-CHL design fully considers the characteristics of Chinese culture, its core framework is still based on the internationally common PedsQL™ 4.0 and WHOQOL-BREF theory,

which has a certain universality. This makes it possible for us to adapt the scale to other cultural environments.

We used diverse methods to screen items to ensure that the scale has good representativeness, independence, and sensitivity. IRT is a new measurement theory that emerged in the 1950s following CTT. Generalisability theory has further been widely recognised in all research fields owing to its parameter invariance [56]. IRT has been widely used because it is a mature method; moreover, it is an easy-to-understand mathematical model, and it provides an independent estimation of recognition and difficulty on tested samples. The matrix diagram of the ICC shows that most items have a large amount of information; further, the error curve is below the mean, indicating that the measurement error of the items is relatively small and ideal.

Our assessment of the scale's internal consistency revealed high reliability over an extended duration. Our sample size in both the pre-survey and formal survey meets the requirement of 5–10 times the observed variable [57]. Construct, content, and discriminant validity tests were also conducted, and the expert consultation method guaranteed good content validity. To assess discriminative validity, healthy children were used as the control group, and the outcomes demonstrated the scale's capability to effectively differentiate between healthy children and those with hearing loss, affirming its strong discriminative validity [58]. The results signify the scale's effectiveness and importance in accurately evaluating the quality of life of children with hearing loss, providing a reliable and valid tool for further research and clinical applications in this area.

Limitation

Although the study included many children with hearing loss and healthy controls, limitations exist. Children under 8 years were excluded, and future research could incorporate age-specific sub-scales for preschoolers, school-age children, and adolescents. The study was also limited to Shanxi and Hebei Provinces, with samples from hospitals and special education schools, which may introduce selection bias, as it might not fully capture the diversity of the entire population of children with hearing loss in terms of geographical location, socioeconomic status, and cultural backgrounds. Future studies should use a multi-centre approach, including diverse locations and populations, and stratify by urban and rural areas to better understand QoL differences.

Self-reported data may be affected by recall bias, social desirability bias, and limited self-awareness, particularly in children. Future strategies could include proxy reports from parents or caregivers, especially for younger children or those with severe hearing loss who may struggle with self-expression. Structured interview protocols could also be developed to guide self-reporting and enhance response reliability.

Conclusions

In summary, the HRQOL-CHL exhibits strong reliability, validity, and feasibility. It is well-suited for examining the QoL of children with hearing loss and can serve as an evaluation tool to investigate strategies aimed at improving their QoL and social participation capabilities.

Abbreviations

AGFI	absolute goodness-of-fit
CFI	comparative fit index
CITC	corrected item-total correlation
CTT	classical test theory
GFI	goodness-of-fit
HEAR-QL	Hearing Environments and Reflection on Quality of Life
HRQOL-CHL	health-related quality of life scale for children with hearing loss
CC	item characteristic curve
IFI	incremental fit indices
IRT	item response theory
PNFI	parsimony normed fit index
PGFI	parsimony goodness-of-fit index
PedsQL™4.0	Paediatric Quality of Life Inventory™ Version 4.0
QoL	quality of life
RMSEA	root-mean-square error of approximation
SRMR	standardised root mean square residual
SSQ	speech, spatial, and qualities of hearing scale
WHOQOL-BREF	World Health Organization Quality of Life Brief Version
YQOL-DHH	Youth Quality of Life–Deaf and Hard of Hearing

Supplementary Information

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Supplementary Material 1.

Supplementary Material 2.

Supplementary Material 3.

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Authors' contributions

JLiu wrote the original draft, handled data curation, performed formal analysis, and wrote the methodology section. YW, GZ, JC was responsible for the overall data collection, investigation, and methodology. JLi, JW handled data curation, utilised the software, and wrote the methodology section. DW served as a resource project administrator. JZ supervised and validated the information in our study. Finally, LH was responsible for writing (reviewing and editing) and the study's overall conceptualisation. All the authors have read and approved the manuscript.

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Data availability
Please contact the corresponding author for the study data, which we will provide upon reasonable request.

Declarations

Ethics approval and consent to participate
This study was approved by the Institutional Review Board of Shanxi Medical University (approval number: 2018LL294). We received written informed consent from all individual(s) and minor(s) legal guardians/next of kin.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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