Health and Quality of Life Outcomes

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Development and psychometric validation of a novel health literacy scale for family caregivers of preschool children

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Abstract

Background Health literacy among family caregivers has been found to be strongly correlated with health exposures and outcomes for their children. Accurate assessment of their health literacy contributes to improving child health outcomes. Given the limited evidence on health literacy measures for family caregivers, the study aimed to develop and validate a novel Health Literacy Scale for Family Caregivers of Preschool Children (HLSFC).

Methods The HLSFC was developed in 4 phases: 1) using Nutbeam's conceptual framework of health literacy as a guide to clarify the content to be measured; 2) generating an item pool; 3) providing feedback on the initial items; 4) psychometric analyses. A cross-sectional survey of 443 family caregivers of preschoolers was conducted in Northwest China. Construct validity was assessed using exploratory factor analysis ($n=213$) and confirmatory factor analysis ($n=230$). Reliability was assessed using internal consistency, split-half reliability, and test–retest reliability.

Results Thirty-Three items were included in the final instrument. Principal component analysis yielded a three-factor structure explaining 70.013% of the total variance. All fitting indices met the standard based upon confirmatory factor analysis. The composite reliability values of the factors ranged from 0.928 to 0.944 (> 0.7), and the average variance extracted values ranged from 0.552 to 0.590 (> 0.5), indicating acceptable convergent validity. The Cronbach's alpha value was 0.963. The test–retest reliability was good, with an intraclass correlation coefficient of 0.909. Sociodemographic factors, such as caregiver education, occupation, residence, and monthly household income per person, were significantly associated with health literacy scores.

Conclusion The HLSFC demonstrated adequate reliability and validity, and can measure a wide range of health literacy skills: from functional to interactive and critical health literacy. It could be potentially applied as an effective tool for the health literacy assessment among family caregivers of preschoolers.

Keywords Health literacy, Preschool children, Family caregivers, Reliability, Validity

Introduction

Health literacy (HL), understood as "the skills, knowledge, and motivation to access, understand, and appraise health-related information to make informed health decisions in daily life [1]" has been identified as a key determinant of health and a priority in the public health policy agenda [2]. It plays a crucial role in interpreting differences in health behaviors and outcomes across all populations and age groups [3]. Several recent studies have suggested that limited health literacy may be a substantial contributor to poorer health outcomes, broader inequalities, and higher healthcare costs [4]. Thus, governments around the world have adopted national policies and programs to promote health literacy [5–7].

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These incentives foster the transition of health literacy from the margins to the mainstream. Meanwhile, healthcare stakeholders and professionals are also focusing on the health literacy of key groups such as caregivers of children. The Johnson Health Care Institute (HCI) trains Head Start leadership to support and empower parents to address their children's health care concerns. HCI has implemented a range of initiatives with a focus on the development of parental health literacy and health knowledge [8]. National Health Commission of China has explicitly stated that the health literacy of child caregivers should be improved in the National Action Plan for the Health of Children (2021–2025) [9].

Children's growth and development unfold in a series of distinct, sequential stages, with each stage presenting unique health challenges that require family caregivers to adapt and respond effectively [10]. The preschool years (ages 3–6, typically corresponding to the kindergarten stage) are a crucial period in children's development, marked by rapid growth and significant changes across physical, cognitive, social, and emotional domains [11]. During this period, children are especially vulnerable to preventable health risks, including unintentional injuries (e.g., falls, poisoning, road traffic accidents) [12], infectious diseases (e.g., respiratory infections, gastrointestinal illnesses) [13], and the development of unhealthy habits related to nutrition, physical activity, and oral hygiene [14]. These early health experiences can profoundly and persistently affect lifelong health and well-being, shaping long-term health patterns [11]. Family caregivers play a pivotal role in managing these risks and influencing children's health outcomes, as the healthy development of preschool children relies heavily on the nutrition, education, protection, and support provided by family caregivers [15, 16]. Caregivers' ability to make informed health decisions, correctly administer medications, identify signs and symptoms of illness, and communicate effectively with healthcare providers is essential for preventing and managing health issues [17]. The health literacy of family caregivers directly affects their ability to fulfill these critical roles [18].

Inadequate health literacy among family caregivers is correlated with reduced access to preventive health services and increased exposure to health risks for children. These risks include second-hand tobacco smoke exposure, higher injury rates, obesity, poor oral health, improper medication administration, and unnecessary emergency department visits [19]. In contrast, improving caregiver health literacy leads to better health practices, enhanced disease prevention, and more effective healthcare management, ultimately resulting in improved health outcomes for children [18, 20]. The preschool years provide a critical opportunity to equip caregivers with the knowledge and skills to support their children's well-being, laying the foundation for a healthier future [21]. Interventions designed to improve caregiver health literacy during this stage can help foster healthy habits, prevent chronic conditions, and benefit both children and families in the long term [17]. However, current efforts to improve the health literacy among family caregivers of preschool children remain in the early stages, with interventions such as mobile apps, videos, and web-based programs showing promise but lacking rigorous evaluation [22–24]. To maximize the impact of these interventions, reliable tools for assessing caregiver health literacy are essential. Such tools not only help identify family caregivers in need of support but also enable the evaluation of intervention effectiveness, guiding continuous improvements in health literacy initiatives [25].

Previous studies assessing the health literacy of parents or caregivers have applied instruments that examine general literacy or that predominantly evaluate health literacy in the adult healthcare context [24]. For example, the Test of Functional Health Literacy in Adults (TOFHLA) [26], the Newest Vital Sign (NVS) [27], and the Rapid Estimate of Adult Literacy in Medicine (REALM) [28]. They are often regarded as the "gold standard" for assessing health literacy [29]. However, they evaluate a relatively limited range of health literacy [30, 31] and are therefore less likely to capture changes across the broad range of skills targeted by health literacy interventions. In addition, they are developed for general use and have limited ability to assess the particular effectiveness of health literacy interventions tailored to specific populations [25]. Although validated health literacy tools for parents or caregivers exist, the Parental Health Literacy Activities Test (PHLAT) [32] and the Parenting Plus Skills Index (PPSI) [25], the content of their entries is based on government resources or specific health materials in the United States and Australia, respectively. The generalizability of these tools is limited. In addition, PHLAT can only assess the health literacy of infant caregivers. The Chinese parental health literacy questionnaire was also developed for caregivers of children aged 0–3 years [33]. In summary, current tools used by researchers to assess health literacy in preschooler caregivers have several key limitations. These include a lack of population-specific customization, a narrow focus on certain health literacy skills, regional content biases, and age-specific gaps in assessment [34, 35]. Due to these limitations, comprehensively capturing the diverse skills and knowledge needed by family caregivers of preschool children remained challenging. Such shortcomings may hinder accurate measurement of caregiver health literacy, making it challenging to identify those in need of support and to tailor interventions accordingly [35]. Furthermore,

the absence of a dedicated tool for measuring caregiver health literacy impedes the evaluation of intervention effectiveness and research on the relationship between caregiver health literacy and preschool children's health and well-being [35]. Consequently, inadequate attention to caregiver health literacy may negatively impact children's health outcomes by promoting suboptimal health practices and parenting strategies [36].

Given these gaps, this study aims to develop a novel Health Literacy Scale for Family Caregivers of Preschool Children (HLSFC) and then evaluate its psychometric properties. The HLSFC is designed to assess the health literacy of family caregivers and capture improvements in health literacy skills throughout the specific interventions.

Methods

The development of the HLSFC was guided by a clear guideline for scale development published by Devellis et al. [37]. The development and validation processes were carried out in the following four phases (see Fig. 1). Phase 1, determine the target population and content to be measured, using Nutbeam's (2008) health literacy framework [38] as an aid to clarity. Phase 2, generate an item pool by reviewing the relevant literature and conducting interviews. Phase 3, have the initial scale reviewed by experts, modify the first draft according to the experts' review, and screen items by pilot testing the modified instrument. Phase 4, further validate the scale based on the results of exploratory factor analysis (EFA) and confirmatory factor analysis, and test the reliability of the final version of the scale. As there is no criterion (i.e. "gold standard") validity for health literacy of family caregivers, we hypothesized that higher levels of caregivers' education and income would be associated with improved HLSFC scores according to the established health literacy models [39, 40].

Phase 1: conceptual framework

Nutbeam's conceptual model [38, 41] was employed to guide the scale development. Nutbeam defined health literacy as comprising three dimensions: Functional Health Literacy (FHL), Interactive Health Literacy (IHL), and Critical Health Literacy (CHL). The characteristics of preschoolers and the recommendations from relevant experts were combined in this study to define the dimensions and connotations of health literacy for family caregivers. In the context of childcare, Functional Health Literacy refers to the coverage and mastery of knowledge about health risks and health services for preschoolers, as well as the literacy skills to obtain health information for preschool children. Interactive Health Literacy refers to the literacy and social skills for the acquisition, communication, and application of information related to children's health, and will contribute to the improvement of preschoolers' motivation for health, the shaping of their healthy behavior and the improvement of their health status. Critical Health Literacy refers to the critical analysis of the reliability of child-health-related information and its applicability to exert great control over health-related situations.

Phase 2: Item generation

The item development process began with a comprehensive review of published research on Nutbeam's definition of health literacy [38, 41, 42], its measurement [43–46], and health literacy assessment tools for caregivers of children [25, 32, 33]. The reference resources used for generating the item pool are displayed in Table 1 of the supplementary material. We further interviewed 26 caregivers of preschool children to fully understand their functional, interactive and critical health literacy needs and to propose items related to the three dimensions. Following these stages, an item pool consisting of 44 items and covering three dimensions was generated, including 20 items in FHL dimension, 14 items in IHL dimension, and 10 items in CHL dimension. The item pool addressed several health topics: nutrition/growth, physical activity, health behavior development, immunization, injury/safety, health monitoring, and preventive care. It assesses a range of cognitive, communicative, and social skills that may be necessary for family caregivers in their day-to-day care of children.

Phase 3: Item Modification

Modified expert panel

A multidisciplinary consensus committee, consisting of 15 experts specializing in pediatric health services research and health literacy, was established. Inclusion criteria required at least 10 years of professional experience, familiarity with pediatric healthcare or health literacy, and an intermediate or higher professional title. Expert consultation was conducted using the Delphi method to ensure independent and unbiased feedback. Each expert received a consultation form via email, which included an explanation of the study's objectives, a brief introduction to Nutbeam's health literacy conceptual model, and the preliminary scale items developed in Phase 2. Experts were asked to assess the importance of each item and provide feedback on the appropriateness of the items, clarity of descriptions, and difficulty level. The importance of each item was rated on a 5-point Likert scale (1="not important," 2="slightly important," 3="moderately important," 4="very important," and 5="extremely important"), with a comment section for suggested modifications. To maintain objectivity and

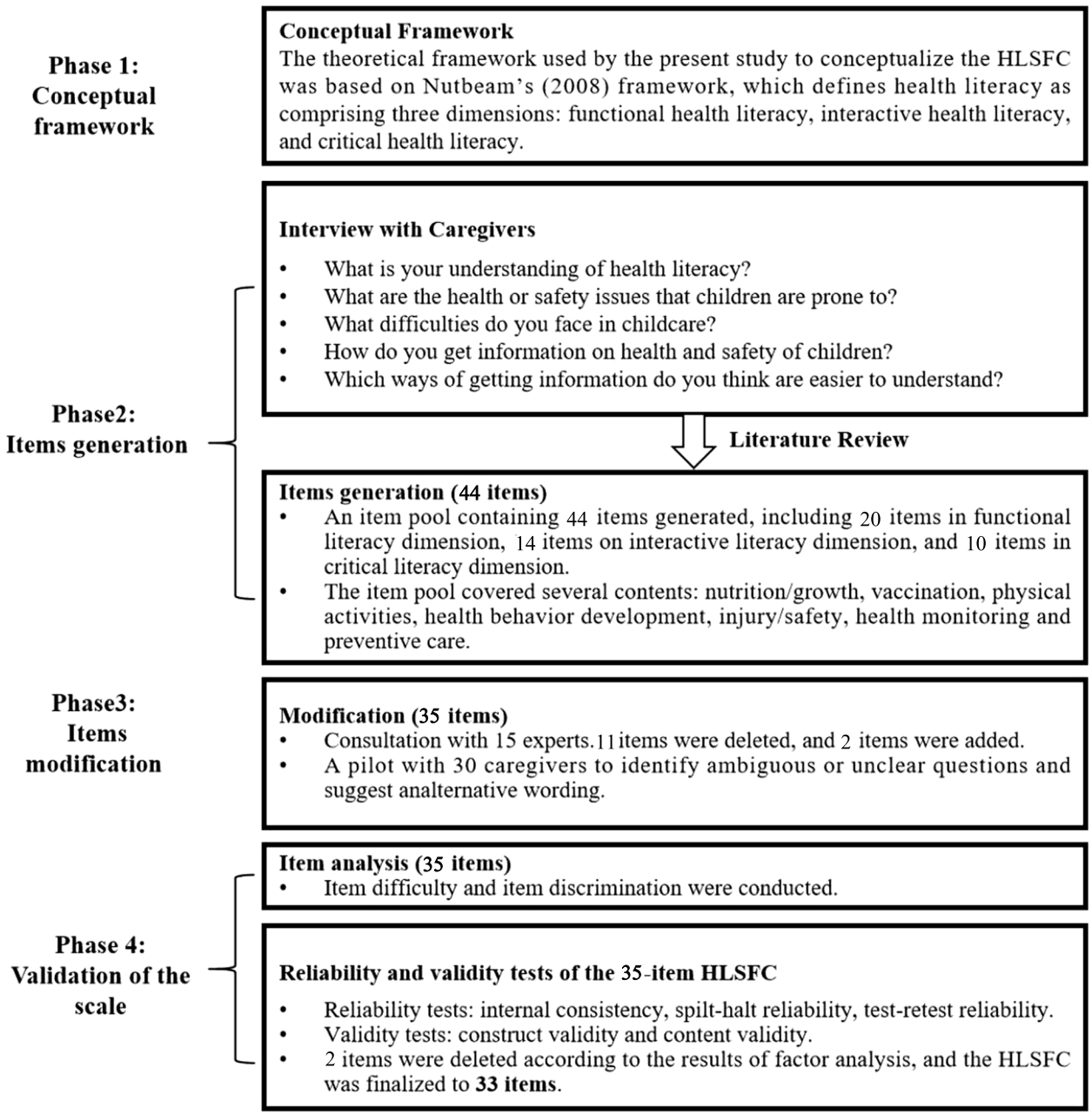

Fig. 1 Diagram for the procedures followed to develop the HLSFC

prevent potential influence among experts, direct communication between panel members was not facilitated. Instead, the research team consolidated the feedback and provided summarized justifications for the changes in the second round of consultation. Following the experts' suggestions, 11 items were deleted and 2 items were added. Finally, the initial version of the HLSFC consisted of 35 items, including 12 items in the FHL dimension, 14 items in the IHL dimension, and 9 items in the CHL dimension.

Pilot test

The research team pilot-tested the initial HLSFC on 30 family caregivers recruited through convenience sampling in Northwest China. All volunteers completed the scale and were interviewed about each item to identify any ambiguous or unclear items and to revise the wording. Minor changes were made for clarity and ease of understanding.

Table 1 Social and demographic characteristics of caregivers and children ($n=443$)

Item		n (%)
Relationship to the child	Mother	308 (69.5)
	Father	112 (25.3)
	Grandparents	14 (3.2)
	Nanny	1 (0.2)
	Others	8 (1.8)
Child's age (5.00 ± 0.87)	3-	54 (12.2)
	4-	159 (35.9)
	5-	181 (40.9)
	6–7	49 (11.0)
Child's gender	Boy	233 (52.6)
	Girl	210 (47.4)
Caregiver's education	Junior school and below	183 (41.3)
	High school/Vocational School	126 (28.4)
	Junior college/undergraduate	134 (30.3)
Caregiver's occupation	Staff of state organs, enterprises and institutions	99 (22.3)
	Worker or Service employee	68 (15.3)
	Self-employed individual	54 (12.2)
	Peasantry	120 (27.1)
	Retired or unemployed	12 (2.7)
	Others	90 (20.4)
Residence	Urban	163 (36.8)
	Rural	280 (63.2)
Monthly household income per person (yuan)	≥ 5000	48 (10.8)
	3000–4999	138 (31.2)
	1000–2999	167 (37.7)
	< 1000	90 (20.3)
Only-child or not	Yes	102 (23.0)
	No	341 (77.0)
Difficulties with childcare	Limited time and energy	291 (65.7)
	Lack of scientific knowledge and experience in childcare	265 (59.8)
	Excessive economic costs	247 (55.8)
	Inadequate social security	102 (23.0)
	Barriers to career development	84 (19.0)
	Insufficient family support	60 (13.5)
	Advanced age or poor physical condition	53 (12.0)
	Others	68 (15.3)
Caregivers' reports of children's health status	Very good	144 (32.5)
	Good	185 (41.8)
	Fair	111 (25.1)
	Poor	3 (0.6)

Phase 4: Validation of the scale

Study setting and participants

A cross-sectional study was conducted at 4 kindergartens using convenience sampling in Northwest China, including both urban and rural districts. Primary family caregivers of preschool children were the target participants. The inclusion criteria comprised: a) capability for literally communication with researchers; b) voluntary willingness to participate in the research. Exclusion criteria were acute or severe illnesses. To validate the initial version of HLSFC, a sample size of 443 family caregivers was recruited and administered the questionnaire, which is sufficient as the sample size for EFA should be at least five times larger than the total number of items, and

the sample size for CFA should be no less than 200 [47]. After a full explanation of the study aims and procedures, informed consent was obtained from all participants. Ethical approval was granted by the Ethics Committees of Xi'an Jiaotong University (No. 2021–1511).

Instruments

The initial version of HLSFC. The initial 35-item HLSFC was scored using a five-point Likert scale. Items 1–12 were scored as 5="fully knowledgeable", 4="mostly knowledgeable", 3="partially knowledgeable", 2="not very knowledgeable", and 1="not at all knowledgeable"; items 13–35 were scored as: 5="almost always", 4="often", 3="sometimes", 2="rarely", 1="never". The scores for each item were summed to obtain the total score. The higher the score, the higher the health literacy level of the respondent.

General Information Questionnaire. Socio-demographic data of children and their family caregivers were obtained with the General Information Questionnaire that we developed. The questionnaire includes the relationship to the child, the child's and caregiver's age, the child's gender, the caregiver's education, occupation, residence, difficulties with childcare, reports of their children's overall health status, monthly household income per person, and only-child or not.

Statistical analysis

Statistical Package for the Social Sciences (SPSS) version 19.0 and Amos version 23.0 were used for data analysis. Frequency tables, means and standard deviations (SD) were employed to statistically describe the demographic variables. The 15 experts were tasked with evaluating the importance of each item utilizing a 5-point Likert scale (as mentioned above). The filter criteria for all items were set at a mean importance score of less than 4 or a coefficient of variation [48] greater than 0.25 [49]. After rating each item, experts could provide recommendations or suggestions in a designated column. Item validity was assessed through item analysis.

The Cronbach alpha coefficient was used to evaluate internal consistency, deeming a value of 0.7 or higher as sufficient [50]. Two weeks after the first survey, 30 participants who had completed the first survey were recruited to fill out the same scale once more to measure the test–retest reliability of the scale. Test–retest reliability was evaluated through the intraclass correlation coefficient (ICC) [51]. ICC values ranging from 0.5 to 0.75 indicated moderate reliability, values between 0.75 and 0.9 indicated good reliability, and values greater than 0.90 indicated excellent reliability [52]. Exploratory factor analysis (EFA) was conducted to ascertain the factor structure of the scale [53]. Confirmatory factor analysis [54] was additionally performed to validate the factor structure. Criteria for the recommended indices included [55]: (a) Chi-squared divided by the degrees of freedom ≤ 3; (b) root mean squared error of approximation (RMSEA) < 0.08; (c) comparative fit index (CFI) and incremental fit index (IFI) > 0.90; (d) parsimony-adjusted comparative fit index (PCFI) > 0.50. Additionally, Composite Reliability (CR) and Average Variance Extracted (AVE) values were computed for each factor to evaluate convergent validity. Discriminant validity was evaluated using the Fornell-Larcker criterion, which involved comparing the square root of the AVE value for each dimension with the corresponding correlations between dimensions. Discriminant validity was achieved when the square root of the AVE of each dimension was greater than its correlations with other dimensions [56]. The significance threshold was set at $P < 0.05$.

Results

Item modification and content validity

The item pool of 44 items was reviewed by experts. A total of 15 experts from various fields participated in this process, including child health and care (6 experts), preschool education (1 expert), health literacy (3 experts), pediatric clinical nursing (3 experts), psychology (1 expert), and nutrition (1 expert). The experts had an average professional experience of 23.07 ± 5.44 years and an average age of 46.25 ± 4.81 years, with all holding at least a Master's degree. The demographic characteristics of the consulted experts are presented in Table 2 of the supplementary material.

In the initial round of consultation, experts independently reviewed all scale items, providing both quantitative ratings and qualitative feedback. The evaluation demonstrated high expert authority, with a judging basis coefficient (Ca) of 0.927, a familiarity coefficient (Cs) of 0.847, and an authority coefficient (Cr) of 0.887. The level of agreement among experts, as measured by Kendall's W, was 0.285 ($P < 0.001$), indicating weak to moderate agreement [57]. This is typical at early stages of scale development due to the diverse perspectives of the panel. The coefficient of variation ranged from 0.00 to 0.272, identifying several items with relatively high variability.

Based on expert feedback, 4 items of the FHL dimension met the predefined cut off value (CV > 0.25), including item 3 (I know that children can supplement with light saline if they sweat more during intense activity), item 18 (I need help from others to read children's health information), item 19 (I need help from others to fill in children's health information) and item 20 (I need help from others to calculate the time and dosage of children's medication). These items were considered to delete. In addition, several experts proposed that item 7 (I know

Table 2 Factor loadings on items of the HLSFC ($n = 213$)

Dimensions	Item No	Items	Factor 1	Factor 2	Factor 3	Communalities
IHL	14	I can guide preschool children to maintain proper standing, sitting, and walking postures	0.907			0.811
IHL	15	I can guide preschool children to develop good sleep habits	0.856			0.782
IHL	16	I can guide preschool children to develop good hygiene habits	0.884			0.755
IHL	17	I can guide preschool children to develop healthy eating behaviors, such as chewing slowly and avoiding picky eating	0.825			0.717
IHL	18	I can guide preschool children to express emotions in an appropriate manner	0.821			0.762
IHL	19	I can guide preschool children to recognize common safety warning signs	0.794			0.725
IHL	20	I can set a good example in terms of behavioral habits for preschool children	0.899			0.746
IHL	21	I can ensure that preschool children receive vaccinations as required	0.845			0.744
IHL	22	I can ensure that preschool children undergo health check-ups on time	0.823			0.754
IHL	23	I can seek assistance from the healthcare or medical assistance system when needed	0.878			0.802
IHL	25	I can communicate accurately with medical personnel regarding preschool children's health information	0.876			0.735
IHL	26	I can discuss with medical professionals when in doubt about medical decisions for preschool children	0.811			0.762
FHL	1	I know the normal temperature range for preschool children		0.843		0.755
FHL	2	I know the meaning of common drug labels, such as "OTC."		0.842		0.751
FHL	3	I know the purpose of vaccinating preschool children		0.800		0.678
FHL	4	I know the nutritional requirements for preschool children		0.872		0.728
FHL	5	I know the activity requirements for preschool children		0.803		0.687
FHL	6	I know the psychological characteristics of preschool children		0.801		0.673
FHL	7	I know the significance of regular health check-ups for preschool children		0.814		0.693
FHL	8	I know the risk factors for cavities in preschool children		0.839		0.680
FHL	9	I know the risk factors for poor eyesight in preschool children		0.836		0.741
FHL	10	I know the dangers of obesity in preschool children		0.779		0.649
FHL	11	I know the symptoms of common diseases in preschool children, such as pneumonia, gastroenteritis and urinary tract infections		0.828		0.671
FHL	12	I know the preventive measures for common infectious diseases in preschool children, such as hand-foot-and-mouth disease, mumps, and chickenpox		0.820		0.679
CHL	27	I can evaluate the reliability of health information for preschool children			0.742	0.662
CHL	28	I can judge the applicability of health information for preschool children			0.813	0.687
CHL	29	I can develop and implement dietary and exercise plans for preschool children			0.732	0.575
CHL	30	I can identify potential physical health issues in preschool children, such as hand-foot-and-mouth disease or anemia			0.794	0.607
CHL	31	I can identify possible psycho-behavioral problems in preschool children			0.758	0.666
CHL	32	I can identify safety hazards in places where preschool children play			0.777	0.582
CHL	33	I can identify and respond urgently to common emergencies in preschool children, such as nosebleeds, choking, febrile seizures, burns, and fractures			0.715	0.610
CHL	34	I can correctly perform cardiopulmonary resuscitation (CPR) for preschool children			0.835	0.645
CHL	35	I can stay informed about health-related policies and social activities related to preschool children			0.708	0.589

FHL, IHL & CHL represent the dimensions of Functional Health Literacy, Interactive Health Literacy and Critical Health Literacy, respectively

that children should cover their mouths and noses with a handkerchief/tissue when coughing) and item 17 (I know that antibiotics for children should be administered under the supervision of a doctor) of the FHL dimension were more relevant to the health of the caregiver than the child. Furthermore, 2 experts noted that the content

of these items was too specific to reflect the connotation of children's health. Feedback also indicated that items 13 (I know the preventive measures for vitamin/trace element deficiencies in children) and 14 (I know the signs of common childhood injuries) of the FHL dimension were overly complicated for family caregivers. In the IHL dimension, items 22 (I can apply the child health information obtained to my daily life) and 34 (I am confident in taking care of children's health and safety) were perceived to be conceptually unrelated to the dimensional connotation. Item 41 (I can respond appropriately to children's loud crying or aggressive behavior) of the CHL dimension was suggested for deletion as it expressed a similar meaning as item 40 (I can identify possible psycho-behavioral problems in children). These 11 items were deleted after discussions among the research team. Following the experts' suggestions, 2 items related to medical insurance and family interactions were added.

In the second round of consultation, the revised 35-item scale, along with detailed explanations of all modifications, was presented to the same expert panel. The response rate remained 100%. This iterative process led to improved agreement among the experts, with Kendall's W increasing to 0.541 ($P<0.001$), reflecting moderate agreement. Additionally, the CV narrowed to a range of 0.00–0.211, indicating reduced variability in expert ratings. This suggested a positive trend toward increasing consensus among the experts regarding the scale. Finally, the initial version of the scale consisted of 35 items, including 12 items in the FHL dimension, 14 items in the IHL dimension, and 9 items in the CHL dimension. A summary of the expert feedback on the scale items is presented in Table 3 of the supplementary material.

Pilot test

The initial 35-item scale was tested on a sample of 30 family caregivers recruited through convenience sampling in Northwest China. The wording of items 1–12 was "I know…". They were scored using a five-point Likert scale (5="strongly agree," 4="agree," 3="uncertain," 2="disagree," 1="totally disagree") in the initial scale. Several participants ($n=3$) proposed to modify the scoring method as 5="Fully knowledgeable," 4="mostly knowledgeable," 3="partially knowledgeable," 2="not very knowledgeable," 1="not at all knowledgeable" for ease of understanding. The order of the individual items was adjusted. The researcher recorded participants' suggestions during the pilot study and made modifications after discussion with experts.

Table 3 The fitting indexes of confirmatory factor analysis of the HLSFC ($n=230$)

Index	χ2/df	RMSEA	CFI	IFI	PCFI
Benchmark	< 3	< 0.05	> 0.9	> 0.9	> 0.5
Model	1.302	0.036	0.970	0.971	0.904

Social and demographic characteristics of participants

Table 1 shows the social and demographic characteristics of caregivers and their children. A total of 443 caregiver-child dyads participated in the study, including 308 mothers (69.5%), 112 fathers (25.3%), and 23 grandparents or other caregivers (5.2%). The average age of caregivers and children was 34.20 ± 6.84 years and 5.00 ± 0.87 years, respectively. 63.2% of participants lived in rural areas. 30.2% of caregivers had a junior college degree or higher. Boys accounted for 52.6% of the participating children, and 77.0% were not the only child.

Item analysis

First, the HLSFC items were categorized into groups of high and low scores based on the participants' total scores. The high sub-group comprises entries from participants with overall scores in the top 27%, while the low sub-group consists of entries in the bottom 27%. Subsequently, an independent sample t-test was utilized to assess the mean scores for each item between the two groups, and the critical ratio (CR) was calculated. The findings indicated that item scores differed significantly between the high and low subgroups ($P<0.001$). The CR exceeded 3 for each item, indicating that each item was sufficiently discriminating without a floor or ceiling effect. None of the items were deleted at this stage.

Construct validity

The total data ($n=443$) were randomly split into two parts. The first 213 samples were utilized for EFA, incorporating oblique rotation to consider the relationship between factors. The CFA was carried out on 230 samples based on the model selected from the EFA.

Exploratory factor analysis

All 35 items were analyzed using principal component analysis with oblique rotation. The correlation matrix indicated a sufficient sample size (Kaiser–Meyer–Olkin measure of 0.961), and the Bartlett test results ($\chi^2=6512.288$, $P<0.001$) refuted the hypothesis of zero correlations. According to Kaiser's criterion to extract factors with eigenvalues greater than 1, a 3-factor structure (Factor 1 = 17.050, Factor 2 = 4.077, Factor 3 = 2.684) was identified by the pattern matrix, explaining 68.031% of the variance in the data. Items 13 (I can proactively seek information about children's health from a range of sources) and 24 (I can take the child to the doctor if he/

she has symptoms such as fever and rash) were subsequently deleted because their factor loadings were below the threshold of 0.40.

After these revisions, the remaining 33 scale items were subjected to EFA. As shown in Table 2, the scale items have factor loadings ranging from 0.708 to 0.907, and each item had a communality value of above 0.575, which was higher than the acceptable value [58]. The principal component analysis with 33 items revealed 3 factors with eigenvalues greater than 1.0 and a total variance of 70.013%. Combined with the scree plot results (see Fig. 2), the Kaiser criterion (eigenvalue) and the significance of the factors, we obtained a 3-factor structure (Factor 1 = 16.371, Factor 2 = 4.076, Factor 3 = 2.657). Factor 1 included 12 items (items 14–23, and 25–26), all taken from the Interactive Health Literacy dimension; Factor 2 included 12 items (items 1–12), all taken from the Function Health Literacy dimension; Factor 3 included 9 items (items 27–35), all taken from the Critical Health Literacy dimension.

Confirmatory factor analysis

CFA was carried out on a total of 230 samples. According to the results of the EFA, a 3-factor structure was constructed (see Table 3 and Fig. 3). All fit indices within the model met the suggested parameters for satisfactory model fit: the RMSEA was 0.036, less than 0.08; χ^2/df was 1.302, less than 3; the PCFI was 0.904, above 0.50; the CFI was 0.970 and the IFI was 0.971, exceeding the benchmark of 0.90. Ultimately, the 3-factor structure fitted the survey data well and was considered to be appropriate for the population studied.

Convergent and discriminant validity analysis

As shown in Table 4, the standardized regression weight of the standardized factor loading values ranged from 0.691 to 0.897. The composite reliability (CR) values ranged from 0.928 to 0.944 and the average variance extracted (AVE) values ranged from 0.552 to 0.590, meeting the standard value (CR > 0.7, AVE > 0.5) [59].

The square root of the AVE values for dimensions of FHL, IHL and CHL were 0.765, 0.743 and 0.768, respectively, which were greater than all correlations between the factors of the HLSFC (see Table 5). This result confirms the discriminant validity of the scale.

Known-group validity analysis

The study found that caregivers with higher education and income, living in urban areas, and reporting their children in very good health scored higher on the HLSFC (see Table 6).

Reliability

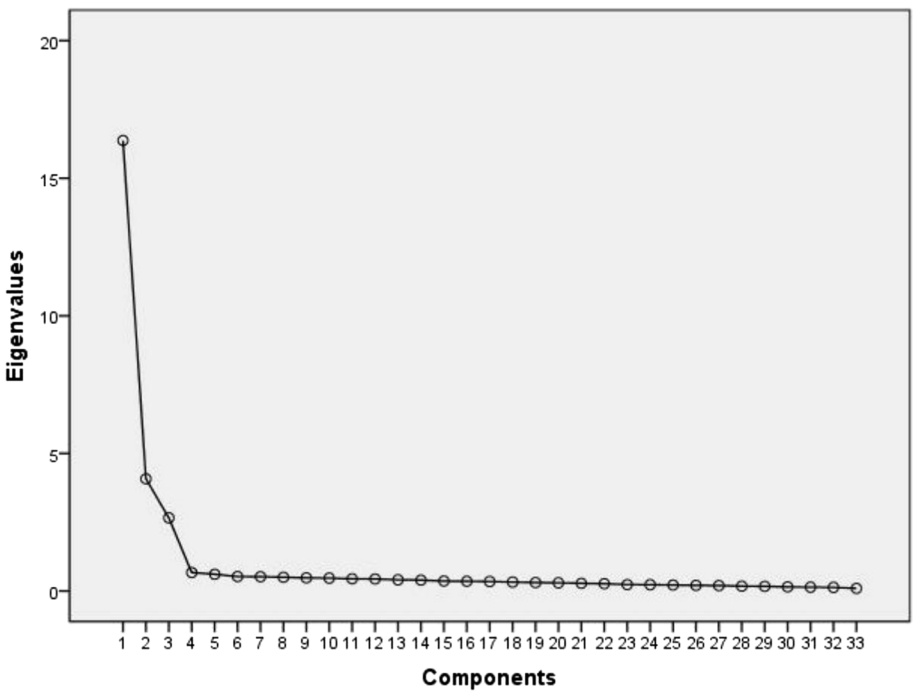

Fig. 2 Scree plot of the HLSFC ($n = 213$)

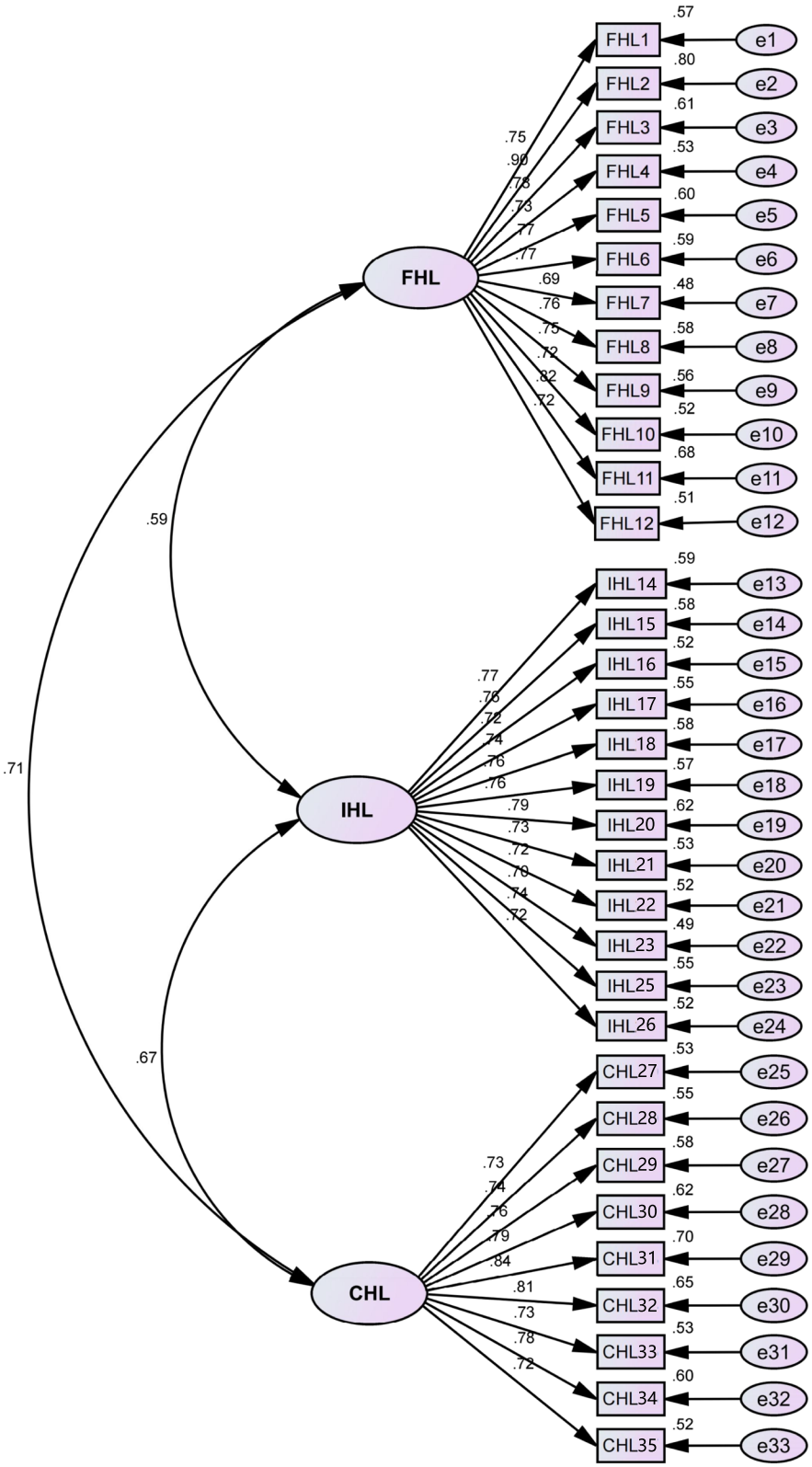

Fig. 3 A schematic diagram of standardized model fitting of the HLSFC ($n = 230$)

Table 4 Convergent validity of the HLSFC ($n=230$)

Paths			Estimate	CR[a]	AVE[b]
Item 1	<--	FHL	0.754	0.944	0.586
Item 2	<--	FHL	0.897		
Item 3	<--	FHL	0.781		
Item 4	<--	FHL	0.731		
Item 5	<--	FHL	0.772		
Item 6	<--	FHL	0.767		
Item 7	<--	FHL	0.691		
Item 8	<--	FHL	0.764		
Item 9	<--	FHL	0.747		
Item 10	<--	FHL	0.721		
Item 11	<--	FHL	0.823		
Item 12	<--	FHL	0.716		
Item 14	<--	IHL	0.767	0.937	0.552
Item 15	<--	IHL	0.762		
Item 16	<--	IHL	0.720		
Item 17	<--	IHL	0.740		
Item 18	<--	IHL	0.765		
Item 19	<--	IHL	0.755		
Item 20	<--	IHL	0.787		
Item 21	<--	IHL	0.727		
Item 22	<--	IHL	0.724		
Item 23	<--	IHL	0.701		
Item 25	<--	IHL	0.741		
Item 26	<--	IHL	0.724		
Item 27	<--	CHL	0.730	0.928	0.589
Item 28	<--	CHL	0.744		
Item 29	<--	CHL	0.761		
Item 30	<--	CHL	0.789		
Item 31	<--	CHL	0.837		
Item 32	<--	CHL	0.807		
Item 33	<--	CHL	0.731		
Item 34	<--	CHL	0.777		
Item 35	<--	CHL	0.724		

FHL, IHL & CHL represent the dimensions of Functional Health Literacy, Interactive Health Literacy and Critical Health Literacy, respectively

[a] CR represents composite reliability

[b] AVE represents average variance extracted values

Table 5 Discriminant validity of the HLSFC ($n=230$)

	Functional Health Literacy	Interactive Health Literacy	Critical Health Literacy
Functional Health Literacy	0.765[a]		
Interactive Health Literacy	0.557	0.743[a]	
Critical Health Literacy	0.669	0.628	0.768[a]

[a] represents the square root of the average variance extracted values of each dimension

The overall 33-item HLSFC had high internal consistency (Cronbach's $\alpha=0.963$), high split-half reliability (Spearman-Brown coefficient = 0.877) and high test–retest reliability (ICC = 0.909). Regarding the three dimensions, the Cronbach's α coefficient was 0.951 (FHL), 0.954 (IHL) and 0.925 (CHL), respectively; the Spearman-Brown coefficient was 0.929, 0.952 and 0.954; and the test–retest reliability coefficient was 0.743, 0.747 and 0.752.

Discussion

In the present study, we developed and validated a novel health literacy assessment tool for family caregivers of preschool children. The research team developed and psychometrically validated the scale following established guidelines [37], which ensured the scientific rigor of the study. The validation study was carried out among 443 family caregivers recruited from both urban and rural areas. Psychometric analyses indicate that the HLSFC has good reliability and validity. The final 33-item HLSFC covers a variety of content areas (such as nutrition/growth, physical activity, health behavior development, immunization, injury/safety, health monitoring, and preventive care) and can be applied to measure a wide range of health literacy, from Functional Health Literacy to Interactive and Critical Health Literacy.

Compared to existing parental health literacy scales, such as the Chinese Parental Health Literacy Questionnaire (CPHLQ) [33], Parenting Plus Skills Index (PPSI) [25], and Parental Health Literacy Activities Test (PHLAT) [32], the HLSFC differed in several key aspects. The CPHLQ focused on caregivers of children aged 0–3 and primarily assessed health literacy in the areas of healthcare, disease prevention, and health promotion, it did not specifically address interactive or critical health literacy, which were included in the HLSFC. The PPSI and PHLAT, targeting Australian and infant caregivers, respectively, primarily assessed functional health literacy, emphasizing practical skills like interpreting health instructions. These scales tended to be more concise but less comprehensive. In contrast, the HLSFC appeared to offer a broader and more detailed evaluation, incorporating not only functional literacy but also interactive and critical literacy. This makes the HLSFC potentially well-suited for addressing the diverse challenges faced by family caregivers of preschool children, who must navigate a wide range of health issues.

The first three phases of this study aimed to develop and revise scale items. The application of Nutbeam's [38] conceptual model of health literacy provided improved clarity regarding the connotation of health literacy and the three dimensions to be measured. An item pool consisting of 44 items was generated following the literature review and interview. Based on the recommendations of

Table 6 Differences in HLSFC by participants' characteristics ($n=443$)

Item		Total score of HLSFC	F/t	P
Caregiver's education	Junior school and below	131.38 ± 19.04	9.127	< 0.001
	High school/Vocational School	134.04 ± 18.38		
	Junior college/undergraduate	140.37 ± 18.44		
Caregiver's occupation	Staff of state organs, enterprises and institutions	143.91 ± 16.44	12.453	< 0.001
	Worker or Service employee	129.37 ± 18.63		
	Self-employed individual	139.91 ± 16.90		
	Peasantry	128.25 ± 18.19		
	Retired or unemployed	119.58 ± 21.76		
	Others	136.84 ± 18.50		
Residence	Urban	138.37 ± 19.64	8.970	0.003
	Rural	132.81 ± 18.37		
Monthly household income per person (yuan)	≥ 5000	146.10 ± 14.12	7.062	< 0.001
	3000–4999	134.86 ± 18.92		
	1000–2999	133.29 ± 19.30		
	< 1000	131.73 ± 19.02		
Caregivers' reports of children's health status	Very good	138.92 ± 17.92	6.177	< 0.001
	Good	135.08 ± 18.81		
	Fair	129.74 ± 18.96		
	Poor	115.00 ± 37.32		

15 experts, 4 items were deleted due to a coefficient of variation greater than 0.25 [48]. 6 items were deleted as they were too complicated for family caregivers, or less related to the child's health and the dimensional connotation. 1 item was proposed for deletion as it had a similar meaning to another item. 2 items related to medical insurance, together with family interactions were added. The parenting plus skills index (PPSI), designed to assess the health literacy skills of Australian parents was also based on Nutbeam's conceptual model of health literacy. Similarly, items that were more related to the parental health, as well as writing and calculation skills in the PPSI were deleted during the expert review stage [25]. After these modifications, the initial HLSFC contained 35 items.

Phase 4 assessed the construct validity and reliability of the initial 35-item HLSFC. The results of EFA indicated that items 13 and 24 should be removed as their factor loadings were less than 0.40 [59]. The EFA performed on the remaining 33 items yielded a KMO value of > 0.8 and a cumulative variance contribution rate of 70.013%. The three common factors extracted from the EFA fitted well with the previously adapted and defined dimensions for family caregivers of preschool children in phase 1 of the study. Functional Health Literacy is reflected in items 1–12, focusing on the caregivers' knowledge about health risks and health services for preschool children. Interactive Health Literacy is reflected in items 14–23 and 25–26, measuring the family interactions to shape children's healthy behavior and caregivers' social skills. Critical Health Literacy is reflected in items 27–35. The definition of CHL is reflected in items 27–28, as caregivers' critical analysis of the reliability and appropriateness of child-health-related information. Items 29–35 reflect the applicability of health information to exert great control over health-related situations. CFA results further indicated the three-factor structure accounted for an optimal model fit. Several other health literacy scales have also been developed based on Nutbeam's conceptual model of health literacy, including the Chronic Pain Health Literacy Assessment (HLCP) [46], Cancer Health Literacy Scale (C-HLS) [60], and the Iranian Nutbeam Health Literacy Scale [44]. The Iranian Nutbeam Health Literacy Scale for the general population also supported a three-factor structure, demonstrating the broad applicability of Nutbeam's model. However, EFA results on the HLCP and C-HLS revealed a four-factor structure. The additional factors identified in these scales were related to self-care practices and more specific aspects of critical health literacy. These factors were particularly relevant for populations managing chronic conditions or cancer, suggesting that disease-specific populations may require more detailed factors to capture the complex health literacy skills needed in their contexts.

The study found that caregivers with higher education and income, living in urban areas, and reporting

their children in very good health scored higher on the HLSFC. This is consistent with previous studies that have reported demographic factors such as education level, residence and income are antecedents of health literacy [40, 61]. The HLSFC scores of caregivers living in urban districts were significantly higher than those living in rural districts, which may be related to the relatively concentrated distribution of urban health resources and the abundance of health education activities. Similarly, caregivers with lower levels of education and family income may have limited access to health knowledge and their children may have more unmet health care needs [62].

This 4-phase study resulted in a validated 33-item health literacy assessment tool. The HLSFC is designed based on the Nutbeam's Conceptual Model of Health Literacy and measures a range of cognitive, communicative, and social skills that may be necessary for family caregivers in their day-to-day care of children. This tool has multifaceted implications. Firstly, it may facilitate more accurate identification of caregivers with limited health literacy, potentially guiding the development of targeted, timely interventions to reduce negative impacts on children's health and well-being. Secondly, when used as a pre- and post-intervention assessment, the tool might offer evidence on the effectiveness of various strategies, supporting the design of more impactful programs. Thirdly, the data generated from the HLSFC could provide insights for healthcare policy decisions and resource allocation related to child health. A shared understanding of caregivers' health literacy levels could possibly foster the creation of more cohesive and comprehensive support systems for families, ultimately contributing to improved health outcomes for both caregivers and children.

Despite the satisfactory results of the HLSFC, the study has several limitations. First, family caregivers in this study were recruited in Northwest China, which may lead to selection bias and have influenced the generalization and application of the scale to some extent. However, the sample in this study included a wide range of locations, educational backgrounds and occupations, suggesting that the HLSFC is generally understood and accepted by family caregivers of preschool children. Secondly, criterion validity remains undetermined due to the lack of a definitive gold standard. Future research should focus on further developing, validating, and applying the HLSFC to enhance its utility and impact. Firstly, researchers will conduct expanded validation across diverse populations through large-scale, multi-center studies. Secondly, the development of normative data will be prioritized to facilitate the interpretation of HLSFC scores. Statistical methods will be used to establish age- and demographic-adjusted norms, enabling the classification of caregivers into distinct health literacy levels. Finally, large-scale surveys will be undertaken to assess the prevalence of health literacy among family caregivers, identifying high-risk groups in need of targeted interventions. The effectiveness of these interventions in improving both parental health literacy and child health outcomes will be evaluated, alongside an examination of the predictive validity and clinical relevance of the HLSFC.

Conclusion

The HLSFC appears to be a sensitive measure of health literacy in family child care settings. The HLSFC assesses multiple dimensions of health literacy among family caregivers, reflecting the specific characteristics of preschool children. It has the potential to be used in various settings (e.g., research, clinical practice, and public health) to assess caregiver health literacy, evaluate the effectiveness of interventions, and inform policy decisions related to child health and well-being.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12955-025-02349-z.

Supplementary Material 1.

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Authors' contributions
Yin-Ping Zhang: Conceptualization, Supervision. Yitong Jia: Formal analysis, Writing-original draft, Writing-review & editing. Xinqi Zhuang: Investigation, Methodology. Yanzi Zhao: Formal analysis, Writing-original draft. Ge Meng: Writing-review & editing. Jianzhong Zhang: Methodology, Resources. Yueying Cao: Writing-review & editing. All authors approved the final manuscript.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committees of Xi'an Jiaotong University (approval number: 2021–1511). Informed consent was obtained from all individual participants included in the study.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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