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Questionnaire on the Care Needs of Primary Caregivers of Premature Infants at Home: A Tool Development and Validation Study Based on the KANO Model

Fenfen Lan
Department of Neonatology, Yichang Central People's Hospital (The First College of Clinical Medical Science, China Three Gorges University)
Jiaohua Yu
yujiaohua2008@126.com

Nursing Department, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology
Hong Qu
Patient Services Office, Yichang Central People's Hospital (The First College of Clinical Medical Science, China Three Gorges University)
Feifan Wang
Outpatient Department, Yichang Central People's Hospital (The First College of Clinical Medical Science, China Three Gorges University)
Zhaohua Huo
Department of Neonatology, Yichang Central People's Hospital (The First College of Clinical Medical Science, China Three Gorges University)
Yuanyuan Wang
Department of Neonatology, Yichang Central People's Hospital (The First College of Clinical Medical Science, China Three Gorges University)
Huiqin Liu
Department of Neonatology, Yichang Central People's Hospital (The First College of Clinical Medical Science, China Three Gorges University)
Yuanyu Liao
Department of Emergency Medicine, Shenzhen Hospital of Southern Medical University

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Abstract

Background

Systematically assessing the nursing needs of primary caregivers of premature infants in the home environment can provide targeted support for primary caregivers of premature infants. The aim of this study is to develop and validate a questionnaire on the care needs of primary caregivers of premature infants at home

Methods

The initial questionnaire was formed through a literature review, semistructured interviews, and Delphi expert consultation. On the basis of the KANO model questionnaire design principles, each need item was phrased as paired positive and negative questions and pretested. A cross-sectional survey was subsequently conducted among primary caregivers of premature infants discharged within the past 6 months. The sample was randomly split into two parts for item analysis, validity, and reliability evaluation.

Results

A preliminary questionnaire containing 49 items was constructed and transformed into a format with paired positive and negative questions according to the KANO model. After exploratory factor analysis (EFA), the final questionnaire retained 27 items covering three dimensions: existence needs, relatedness needs, and growth needs. Confirmatory factor analysis (CFA) showed good fit for both the positive and negative questionnaires: positive questionnaire: $\chi^2/df = 2.857$, RMR = 0.012, SRMR = 0.049, RMSEA = 0.077, IFI = 0.914, TLI = 0.906, CFI = 0.914; negative questionnaire: $\chi^2/df = 2.785$, RMR = 0.016, SRMR = 0.045, RMSEA = 0.075, IFI = 0.930, TLI = 0.923, CFI = 0.930. The questionnaire demonstrated good convergent and discriminant validity. The item-level content validity index (I-CVI) ranged from 0.71-1.00, and the scale-level average content validity index (S-CVI/Ave) was 0.93. The internal consistency reliability (Cronbach's α) was 0.932 for the positive questionnaire and 0.940 for the negative questionnaire.

Conclusion

The caregiver care needs questionnaire for premature infants at home, which was developed on the basis of the KANO model in this study, has good reliability and validity. It is suitable for assessing the care needs of this population and shows good potential for clinical application.

Introduction

The global incidence of premature birth has shown a continuous increasing trend, with approximately 13 million premature infants born annually, representing an incidence rate of approximately 10% [1]. Preterm birth-related complications are a significant cause of neonatal mortality, accounting for 36% of neonatal deaths worldwide, and are also a leading cause of death in children under 5 years of age [2]. In China, the premature birth rate is approximately 6%, ranking fourth in the world. The increase is most significant among very premature infants (28–31 weeks gestation), followed by late premature infants (34–36 weeks gestation). This trend may be associated with factors such as advanced maternal age, increased pregnancy complications, higher rates of multiple pregnancies, the implementation of the universal two-child policy, and lower socioeconomic status [3].

Preterm infants often experience various clinical problems after birth, including respiratory diseases, hyperbilirubinemia, feeding difficulties, and hypoglycemia, leading to prolonged hospital stays, increased risk of readmission, and further increasing the public health burden [4]. Readmission rates for premature infants are generally high, reaching 56% within 2 years after discharge, which is particularly significant for those with a gestational age less than 32 weeks or birth weight less than 1500 g (readmission rate up to 41.5% within 2 years, averaging 1.7 readmissions per infant), with the first 6 months post-discharge being the peak period for readmission [5–6]. Even late premature infants (34–36 weeks) are at risk of readmission within 30 days after discharge, which is twice that of term infants [7].

However, primary caregivers have limited participation during premature infant hospitalization, receive incomplete care information at discharge, encounter inconsistent nursing guidance after discharge, and commonly exhibit insufficient care confidence due to a lack of peer and professional support [8–10]. When undertaking the demanding task of home care, they often face a lack of coping ability [11], psychological adaptation difficulties, delayed role transition [12], and significant care pressure [13], thus urgently requiring systematic support and presenting clear and multifaceted care needs.

Notably, specialized tools capable of directly and systematically assessing the specific care needs of primary caregivers of premature infants at home are currently lacking. Existing relevant assessment tools are mostly comprehensive scales or can only indirectly reflect needs. For example, the Kenner Transition Questionnaire (developed in 1994) comprehensively evaluates a family's transition quality from hospital to home across five dimensions: information needs, stress and coping, grief, social interaction support, and parent–infant role development [14]. Its core lies in assessing overall adaptation levels through the interaction of dimensions rather than directly quantifying specific need gaps. Others, such as the Post-Discharge Coping Difficulty Scale for Parents developed by Weiss et al. (2008) [15], assess the degree of care difficulty, including for parents of NICU infants; the Parental Version Readiness for Hospital Discharge Scale for Preterm Infants developed by Tiryaki et al. (2021) [16], covering feeding care, health maintenance, and nursing practices, aims to identify weaknesses in predischarge preparation; and the Preterm Infant Mother's Care Ability Scale developed by Tajalli et al. (2024) [17], which assesses maternal nursing ability from cognitive, skill, and psychological dimensions. These tools collectively outline the overall profile of care challenges for premature infant families but indirectly reveal needs by assessing factors such as care ability and psychological preparedness, failing to achieve direct measurement of care needs.

To accurately and directly identify the actual needs of primary caregivers during home care, this study developed an assessment questionnaire specifically targeting the care needs of primary caregivers of premature infants at home on the basis of the KANO model. The KANO model, as a classical needs analysis tool, has been introduced into pediatric nursing in recent years and has shown good effectiveness in identifying unmet family needs and optimizing service strategies [18–19].

This paper systematically describes the development process of this questionnaire and reports its reliability and validity verification results among primary caregivers of premature infants at home in China. This tool aims to provide a theoretical basis for formulating targeted nursing service plans to meet the actual needs of caregivers, ultimately improving the quality of home care for premature infants.

Aim of the study

To develop and validate a questionnaire based on the KANO model for assessing the care needs of primary caregivers of premature infants at home, its validity and feasibility in Chinese families with premature infants were tested, thereby providing a reliable tool for the systematic assessment of care needs in this population.

Methods

Study Design

This study developed an initial questionnaire through group discussions based on literature analysis, semistructured interviews with primary caregivers of premature infants at home, and expert consultation opinions. The initial questionnaire was subsequently converted into a format complying with the Kano model's questioning method. Its feasibility was assessed through a pilot test, leading to further revision and refinement of the questionnaire. Finally, reliability and validity testing of the questionnaire was conducted through a cross-sectional survey. The final version of the questionnaire is provided in Supplementary Material 1. The study was done in two phases.

Phase 1:Questionnaire development

Item Generation

This study used the ERG needs theory as a framework, combined with literature analysis and qualitative research methods, to systematically review the care needs of primary caregivers of discharged premature infants, forming an initial item pool. This theory has been widely used in population need research and need assessment tool construction [20–21]. During the literature review stage, Chinese and English databases such as PubMed, Web of Science, Embase, Cochrane, CINAHL, CNKI, Wanfang, VIP, and SinoMed were systematically searched. On the basis of the ERG theoretical framework and research objectives, the initial item pool was constructed through the following steps. First, the practical application of ERG theory in the nursing field was analyzed to clarify the specific manifestations of existence, relatedness, and growth needs in the context of premature infant care. Second, high-frequency themes of home care needs for primary caregivers of premature infants were extracted from domestic and international literature. Through research group discussions and consultations with premature infant nursing experts and qualitative research methodology experts, a preinterview outline was subsequently drafted. Finally, preinterviews were conducted with 2 primary caregivers of premature infants, and after revision, a formal interview guide was formed, along with inclusion and exclusion criteria. The inclusion criteria for premature infants were as follows: (1) gestational age at birth < 37 weeks and (2) age within 6 months after discharge. The exclusion criteria were as follows: (1) severe

complications, such as moderate-to-severe or worse anemia or retinopathy; (2) genetic diseases or congenital malformations; (3) transfer to another hospital because of a condition; and (4) family members who abandoned treatment and signed out against medical advice. The inclusion criteria for primary caregivers were as follows: (1) were female aged ≥ 20 years and male aged ≥ 22 years [22]; (2) were family members undertaking primary care tasks for premature infants, including parents and grandparents, providing care for no less than 6 hours per day; (3) had normal cognition and no communication barriers; and (4) provided informed consent and voluntary participation. The exclusion criteria were as follows: (1) severe heart, brain, lung, kidney, or other organ diseases; and (2) withdrawal from the study midway. From October to November 2023, purposive sampling was used to select primary caregivers of premature infants at home as research subjects on the basis of factors such as the premature infant's gestational age, time since discharge, singleton/multiple status, and relationship to the infant, following the maximum variation principle. Face-to-face semi-structured interviews were conducted. The sample size was determined by information saturation, i.e., until no new themes emerged, ultimately including 25 interviewees. The interview guide included the following: (1) What are your care experiences and feelings during daily baby care? (2) From which channels did you acquire existing knowledge and skills related to premature infant care? (3) What difficulties have you encountered during daily baby care? How did you resolve these difficulties? (4) What support and help have you received during home care (from family, hospital, society)? Through what channels? (5) What changes have caring for the baby at home brought to your life (role changes, life values)? (6) Are you willing to participate in premature infant care skill training and share care experiences? How would you prefer to participate? (7) What unmet care needs do you have at this stage? What do you think are the reasons? (8) Do you have any additions regarding the discussed questions? The semi-structured interview guide used to collect qualitative data for the initial item pool was derived from our previously published study [23]. This guide has been published in Chinese and was specifically developed for investigating the lived experiences and unmet needs of primary caregivers of premature infants during the post-discharge period. To ensure clarity, an English translation of the full interview guide is provided as a supplementary file (Supplementary Material 2)

Expert Consultation

From January to March 2024, 21 experts from 17 tertiary Grade A hospitals in 9 regions of China (Beijing, Hubei, Guangdong, Fujian, Jiangsu, Zhejiang, Guangxi, Sichuan, and Chongqing) were selected for two rounds of correspondence consultation. A total of 52.38% of the experts held a master's degree or higher, 76.19% held senior professional titles or above, and 61.9% had over 20 years of work experience. Their research fields included premature infant clinical nursing, nursing management, child healthcare, and nursing education. Standardized electronic consultation materials were sent to the expert panel via email and WeChat, inviting them to evaluate the questionnaire items and provide guidance suggestions, with a requested response within 2 weeks. To ensure the scientific validity of the consultation process and the credibility of the results, expert selection strictly followed questionnaire development principles, comprehensively considering their familiarity with the research problem and professional depth in the field. The inclusion criteria for the experts were as follows: (1) were familiar with the research topic; (2) held a bachelor's degree or higher; (3) had an intermediate or higher professional technical title; (4) worked in premature infant clinical nursing or nursing management for 10 years or more; and (5) voluntarily participated. The exclusion criteria were as follows: (1) did not provide feedback within the specified time ;(2) withdrew from the study midway.

The expert consultation form consisted of three parts: (1) Expert invitation letter and project introduction: briefly explaining the research background, purpose, significance, and contact information; (2) Expert basic information questionnaire: including general demographic data, self-assessment of judgment basis, and self-assessment of familiarity with the consultation content; (3) Consultation rating form: using a Likert 5-point scoring method (1="very unimportant", 5="very important") for experts to evaluate the importance of each indicator, with "modification suggestions and "supplementary indicators" columns for further recommendations. Instructions were provided before the form, and thanks were given at the end. The research team revised the questionnaire items on the basis of expert feedback to enhance their scientificity, reliability, and validity. The item screening criteria were as follows: importance score ≤ 3.5, full score rate ≤ 20%, and coefficient of variation (CV) ≥ 0.25 [24].

Kano Questionnaire Transformation

The initial 49-item questionnaire was transformed into the Kano model questionnaire format. This model uses a paired-question design, where each service item has a positive question (e.g., "How would you feel if this service were provided?") and a negative question (e.g., "How would you feel if this service were NOT provided? "), ensuring consistency in wording between the positive and negative questions. Each question has five standardized options: "Satisfied (5 points)", "It should be that way (4 points)", "Neutral (3 points)", "Acceptable (2 points)", and "Dissatisfied (1 point)".

Pilot Test

A pilot test was conducted before the formal survey, recruiting no fewer than 30 subjects for a small-sample test [25]. Feedback on item wording was collected from participants, and items with ambiguity or comprehension difficulties were linguistically optimized until all items were unambiguous.

Phase 2:Questionnaire Reliability and Validity Testing

Participants and Data Collection

From May to November 2024, a cross-sectional survey was conducted among primary caregivers of discharged premature infants at two campuses of a tertiary Grade A hospital in Yichang city, Hubei Province, China. The sample size estimation was based on 5–10 times the number of scale items [26]. Considering the need to perform both exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) separately, the total sample size was expanded to 10–20 times the number of items, with the CFA subsample needing to be greater than 200 and larger than the EFA subsample. This questionnaire has 49 items, with a minimum requirement of 490 samples. Furthermore, considering a 10% attrition rate, the final determined sample size was at least 539. In accordance with the inclusion and exclusion criteria (consistent with the earlier semistructured interview criteria), 625 participants were recruited. The sample was randomly divided into two parts via a random grouping method: Subsample 1 (N1 = 310) for item analysis and EFA and Subsample 2 (N2 = 315) for reliability testing, CFA, convergent validity, and discriminant validity analysis.

The research tool was a structured questionnaire based on the Kano model and included three parts: (1) an informed consent form; (2) a general information questionnaire for premature infants and primary caregivers; and (3) the Preterm Infant Primary Caregiver Home Care Needs Questionnaire, which contains 49 paired positive and negative items. Both positive and negative questions used the standard Kano 5-point Likert scale, with options ranging from "dissatisfied" to "satisfied" scored from 1–5.(Supplementary Material 3)

The survey was conducted after ethical approval was obtained. Paper questionnaires were primarily administered through the premature infant follow-up clinic. For special circumstances where caregivers interrupted the questionnaire due to infant care or missed follow-up visits, home visits were arranged after providing informed consent to ensure data quality. The questionnaires were collected onsite by researchers and checked for completeness. Items with missing data or logical contradictions were filled or corrected after onsite verification. The principles of voluntary participation, anonymity, confidentiality, and the right to withdraw at any time were clearly explained before the survey, and written consent was obtained before starting.

The items were screened according to the following criteria: (1) Critical ratio method: Items were ranked by total score, with the top 27% as the high-score group and the bottom 27% as the low-score group. Independent samples t tests were performed, deleting items with a critical ratio value < 3 or $P > 0.05$. (2) Correlation coefficient method: The correlation coefficient between each item and the total score is calculated, and items with r < 0.4 are deleted. (3) Internal consistency method: Assess item homogeneity. The item deletion criterion was as follows: Cronbach's alpha if item deleted (CAID) increased or the corrected item-total correlation (CITC) < 0.4 [24].

On the basis of the item analysis, EFA was conducted to optimize the questionnaire structure. First, the KMO test and Bartlett's test of sphericity were performed [27]. If KMO > 0.8 and Bartlett's test was significant ($P < 0.05$), the data were suitable for factor analysis. Principal component analysis was used to extract factors with eigenvalues > 1. Items were deleted according to the following criteria: (1) Loaded solely on one factor; (2) maximum factor loading < 0.5; and (3) exhibited significant cross-loading (high loadings on two or more factors) [24].

To verify the construct validity of the questionnaire, CFA was performed on the basis of the factor structure obtained from EFA, and model fit was assessed. The good fit standards were as follows: $\chi^2/df < 3$, SRMR < 0.05, RMSEA < 0.08, CFI, IFI, and TLI ≥ 0.90 [28]. Convergent validity was considered ideal if the average variance extracted (AVE) > 0.5 and composite reliability (CR) > 0.7; discriminant validity was considered ideal if the square root of the AVE for each dimension was greater than the correlation coefficient between that dimension and other dimensions [29–30].

On the basis of expert ratings of item relevance, content validity indices were calculated. The questionnaire was considered to have good content validity if I-CVI) > 0.70 and the S-CVI/AVE ≥ 0.80 [31].

Cronbach's α coefficient was used to evaluate the internal consistency reliability of the questionnaire. A Cronbach's α > 0.8 was considered indicative of good reliability [32].

Ethical Statement

This study followed the principles of the Declaration of Helsinki and was approved by the Medical Ethics Committee of Tongji Medical College, Huazhong University of Science and Technology (Approval Number: [2023] Ethics Review S134). The survey process strictly adhered to the principles of anonymity and confidentiality. All participants provided informed consent and signed written agreements.

Data Analysis

IBM SPSS Statistics 26.0 and IBM SPSS Amos 27.0 were used for data analysis. Descriptive statistics were used to analyze the general characteristics of premature infants and their primary caregivers. Categorical data are presented as frequencies and composition ratios (%).

Results

Phase 1

Item Generation

Synthesizing the results of the literature review and qualitative interviews, the care needs of primary caregivers of discharged premature infants were summarized and analyzed through group discussions, categorized according to ERG needs theory, and a 42-item care needs questionnaire for primary caregivers of premature infants at home was constructed, which served as the basis for the first round of expert consultation.

Expert Consultation

After the first round of consultation, all the revisions (including item addition/deletion, semantic adjustments, and dimension restructuring) were fed back to the original expert panel in the form of annotations for their reference during the second round of evaluation; the consultation was terminated when expert opinions tended to converge. Finally, through two rounds of expert consultation and revision of questionnaire items, an initial care needs questionnaire for primary caregivers of premature infants at home was constructed, containing 3 dimensions and 49 items.Supplementary Material 4

Pilot Test

The first survey involved 16 participants to collect opinions on the wording of the questionnaire items. On the basis of the feedback, the wording of the items that were questionable or difficult to understand was modified. A subsequent survey of 26 primary caregivers of discharged premature infants revealed that they could understand the questionnaire content, that the time to complete the questionnaire was approximately 10–15 minutes, and that the questionnaire was feasible.

Phase 2: psychometric analysis

Participant characteristics

This study recruited 625 participants, who were randomly divided into two groups: Subsample 1 (N1=310) and Subsample 2 (N2=315), which were used for different analyses. Among the premature infants, singletons constituted the majority (66.31%), and at the time of the survey, most were 4–5 months post-discharge (21.51%). The primary caregivers were predominantly female (69.6%), with mothers of premature infants accounting for 32.96%. The detailed data are shown in Table 1.

Table 1 Characteristics of the participants (N1=625)

Premature infants				Primary caregivers			
Iten	Group	Number	composition ratio(%）	Item	Group	Number	Composition ratio（%）
Gender	Female	169	60.57	Gender	Female	435	69.60
	Males	110	39.43		Males	190	30.40
				Age	<35	323	51.68
					35~	116	18.56
single fetus	Yes	185	66.31		≥60	186	29.76
	No	94	33.69	Relationship	Mother	206	32.96
					Father	170	27.20
Gestational age at birth (weeks)	<28	2	0.72		grandmother	124	19.84
	28~	26	9.32		grandfather	20	3.20
	32~	92	32.97		maternal grandmother	105	16.80
	34~37	159	56.99	Highest education level	Primary school and below	37	5.92
					Junior	161	25.76
					Senior	79	12.64
Birth weight (kg)	1~	6	2.15		Junior college	169	27.04
	1.5~	261	93.55		bachelor degree and above	179	28.64
	≥2.5	12	4.30	parenting experience	Yes	316	50.56
					None	309	49.44
				Occupation	State organs/institutions	95	15.20
Time since discharge (months)	<1	58	20.79		Enterprise	194	31.04
	1~	32	11.47		Freelance work	132	21.12
	2~	36	12.90		Farming/working	11	1.76
	3~	50	17.92		None	193	30.88
	4~	60	21.51	Residence	City	575	92.00
	5~6	43	15.41		Nonurban areas	50	8.00

Item Analysis

The results of the critical ratio method revealed that all the items in the positive questionnaire had critical ratio values greater than 3, and the differences were statistically significant ($P < 0.05$); in the negative questionnaire, 2 items had critical ratio values less than 3. The correlation coefficient method revealed that 5 items each in the positive and negative questionnaires had correlation coefficients, with total scores less than 0.4. Internal consistency analysis revealed that the overall Cronbach's α coefficient for positive items was 0.952, with 10 items having CITC values less than 0.4, among which the Cronbach's α increased after 5 items were deleted; the overall Cronbach's α coefficient for negative items was 0.968, with 6 items having CITC values less than 0.4, among which the Cronbach's α increased after 3 items were deleted.

According to the above criteria, 10 items were ultimately deleted from the positive items, resulting in 39; 6 items were deleted from the negative items, resulting in 43.

Validity Analysis

Construct validity

Exploratory Factor Analysis (EFA)

EFA was performed on Subsample 1 (N1=310) for the positive and negative items separately. For the positive items, the retained 39 items had a KMO value of 0.935, Bartlett's test of sphericity $\chi^2 = 12678.472$ ($P < 0.001$), which was suitable for factor analysis. After multiple exploratory analyses, 9 items were deleted, resulting in the retention of 30 items. Three common factors with eigenvalues greater than 1 were extracted. The factor loadings ranged from 0.675 to 0.912, and the cumulative variance explained was 73.174%. The specific results are shown in Table 2 and Table 3.

Table 2 Interpretation of the total variance of each factor in the forward question questionnaire (N1=310)

Factor	Initial eigenvalue			sum of squared loads			Sum of squared rotational loads		
	Total	Percentage of variance	Accumulate □%□	Total	Percentage of variance	Accumulate □%□	Total	Percentage of variance	Accumulate □%□
1	13.918	46.394	46.394	13.918	46.394	46.394	12.263	40.876	40.876
2	6.449	21.496	67.889	6.449	21.496	67.889	6.331	21.104	61.98
3	1.585	5.284	73.174	1.585	5.284	73.174	3.358	11.194	73.174

Table 3 Forward question exploring the rotated component matrix after factor analysis (N1=310)

Items	Component of factor		
	existence needs	relatedness needs	growth needs
3.6 Guidance on the identification of pathological jaundice	**0.874**	0.101	0.048
1.9 Education on normal urination and defecation patterns	**0.870**	0.056	0.085
5.2 Instruction on tactile stimulation techniques	**0.862**	0.169	0.147
3.7 Guidance on the management of vomiting and aspiration during feeding	**0.856**	0.091	0.008
4.1 Instruction on emergency management of burns	**0.854**	0.186	0.073
4.2 Instruction on emergency response to accidental falls from bed	**0.842**	0.165	0.085
3.8 Guidance on recognition and management of feeding-related hypoxemia (oxygen desaturation during feeding)	**0.842**	0.217	0.042
5.6 Instruction on visual engagement and vocal interaction strategies	**0.834**	0.148	0.157
1.7 Education on principles of growth and development	**0.833**	-0.012	0.035
3.5 Guidance on identification of respiratory abnormalities (e.g., apnea)	**0.827**	0.117	0.036
3.3 Guidance on recognition and management of abnormal defecation (diarrhea and constipation)	**0.825**	0.091	-0.040
1.5 Education on medication administration methods and precautions	**0.749**	-0.03	0.059
2.1 Guidance on assessing feeding timing and volume	**0.747**	0.11	0.156
2.2 Instruction on home care for premature infants requiring oxygen therapy or tube feeding postdischarge	**0.741**	0.053	0.047
2.3 Guidance on sensory integration training for premature infants (multisensory stimulation, passive exercise)	**0.739**	0.114	0.103
3.2 Guidance on identification of abdominal distension	**0.735**	0.124	-0.028
4.3 Instruction on emergency management of choking	**0.699**	0.148	0.131
2.9 Guidance on techniques to promote intestinal gas expulsion	**0.693**	0.063	0.147
1.2 Education on timing and methods for transitioning between feeding types (specialized formula, standard formula, and breast milk)	**0.675**	0.094	0.040
6.2 Provision of premature infant disease-related information via scientific lectures, official social media, and internet-based platforms	0.127	**0.912**	0.167
6.3 Implementation of multidisciplinary follow-up strategies including outpatient, home, and telephone visits for premature infants	0.115	**0.908**	0.192
8.2 Engagement in shared decision-making with family members regarding premature infant care	0.119	**0.879**	0.275
7.2 Access to peer support from other caregivers of premature infants	0.143	**0.873**	0.233
7.1 Availability of financial assistance resources and acquisition pathways from relevant institutions	0.166	**0.860**	0.153
8.1 Access to support from family members	0.098	**0.859**	0.336
6.1 Provision of diversified healthcare services (online consultations, in-person accompaniment, special appointments, etc.)	0.147	**0.823**	0.181
10.1 Participation in training workshops for continuous enhancement of premature infant care skills	0.108	0.434	**0.858**
10.2 Sharing of effective care experiences with other caregivers	0.119	0.414	**0.853**
9.2 Capacity for independent care of premature infants	0.114	0.358	**0.838**
9.1 Ability to maintain emotional stability during caregiving	0.158	0.462	**0.819**

Insert Table 3 here

For the negative items, the remaining 43 items had a KMO value of 0.951, Bartlett's test $\chi^2 = 16749.100$ ($P < 0.001$), which was suitable for factor analysis. After multiple exploratory analyses, 7 items were deleted, and 36 items were retained. Three common factors with eigenvalues greater than 1 were extracted. The factor loadings ranged from 0.637 to 0.937, and the cumulative variance explained was 72.661%. The specific results are shown in Table 4 and Table 5.

Table 4 Interpretation of the total variance of each factor in the reverse question questionnaire(N1=310)

Factor	Initial eigenvalue			sum of squared loads			Sum of squared rotational loads		
	Total	Percentage of variance	Accumulate □%□	Total	Percentage of variance	Accumulate □%□	Total	Percentage of variance	Accumulate □%□
1	17.266	47.961	47.961	17.266	47.961	47.961	16.326	45.351	45.351
2	7.022	19.506	67.468	7.022	19.506	67.468	6.410	17.805	63.156
3	1.870	5.193	72.661	1.870	5.193	72.661	3.422	9.505	72.661

Table 5 Reverse question exploring the rotated component matrix after factor analysis (N1=310)

	Component of factor		
Items	existence needs	relatedness needs	growth needs
3.7 Lack of guidance on the management of vomiting and aspiration during feeding	**0.866**	0.015	0.005
1.9 Absence of education regarding normal urination and defecation patterns	**0.858**	0.029	0.099
3.4 Failure to provide information on the timing and methods of nutritional supplementation (e.g., vitamin AD and vitamin D3)	**0.855**	0.108	-0.003
3.6 Lack of instruction on the identification of pathological jaundice	**0.851**	0.064	0.042
1.8 Absence of education on immunization knowledge	**0.846**	0.044	0.057
3.3 Lack of guidance on recognition and management of abnormal defecation (diarrhea and constipation)	**0.844**	0.098	-0.005
1.7 Failure to provide information on growth and development principles	**0.839**	0.054	0.068
5.6 Absence of instruction on visual engagement and vocal interaction techniques	**0.838**	0.083	0.035
3.2 Lack of guidance on identification of abdominal distension	**0.835**	0.089	-0.020
5.2 Failure to provide instruction on tactile stimulation techniques	**0.816**	0.126	0.156
2.7 Absence of guidance on appropriate adjustment of daily clothing for premature infants	**0.810**	0.069	0.002
4.3 Lack of instruction on emergency management of choking	**0.807**	0.077	0.105
2.1 Failure to provide guidance on assessing feeding timing and volume (including transition between specialized formula, standard formula, and breast milk)	**0.801**	0.047	0.111
5.5 Absence of instruction on interpreting premature infant cries and body language	**0.799**	0.147	0.122
2.8 Lack of guidance on monitoring vital signs (body temperature, respiration)	**0.798**	0.115	0.021
4.2 Failure to provide instruction on emergency response to accidental falls from bed	**0.791**	0.130	0.131
2.11 Absence of guidance on home care for premature infants requiring oxygen therapy or tube feeding postdischarge	**0.789**	0.094	0.073
1.5 Lack of education on medication administration methods and precautions	**0.785**	0.039	0.007
2.6 Absence of instruction on proper measurement of height, weight, and head circumference	**0.783**	0.054	0.059
1.2 Failure to provide information on the timing and methods of transitioning between milk types	**0.779**	0.086	-0.042
2.3 Lack of guidance on sensory integration training for premature infants (multisensory stimulation, passive exercise)	**0.777**	0.129	0.152
3.1 Absence of instruction on identification and management of skin abnormalities (e.g., rash, diaper dermatitis)	**0.770**	0.079	0.078
1.10 Failure to provide information on outpatient follow-up schedules	**0.767**	0.090	0.035
2.9 Lack of guidance on techniques to promote intestinal gas expulsion	**0.752**	0.049	0.100
2.5 Absence of instruction on basic care practices (bathing, oral, perineal, ocular, umbilical, and skin care)	**0.637**	0.064	0.185
6.2 Failure of the hospital to disseminate disease-related information for premature infants through scientific lectures, official social media, and internet-based platforms	0.119	**0.937**	0.199
8.1 Inability to obtain support from family members	0.089	**0.905**	0.230
8.2 Failure to engage in shared decision-making with family members regarding premature infant care	0.086	**0.900**	0.231
7.2 Inability to access peer support (assistance from other caregivers of premature infants)	0.088	**0.898**	0.174

6.3 Lack of multidisciplinary follow-up strategies (e.g., outpatient, home, and telephone visits) for premature infants by the hospital	0.091	**0.897**	0.173
6.1 Absence of diversified healthcare services (e.g., online consultations, in-person accompaniment, special appointments)	0.103	**0.887**	0.201
7.1 Failure of relevant institutions to provide financial assistance resources and acquisition pathways	0.133	**0.868**	0.146
10.2 Inability to share effective care experiences with other caregivers	0.124	0.353	**0.868**
9.1 Failure to maintain emotional stability during caregiving	0.118	0.372	**0.865**
10.1 Inability to participate in training workshops for continuous enhancement of premature infant care skills	0.113	0.354	**0.861**
9.2 Capacity for independent care of premature infants	0.095	0.422	**0.851**

□Insert Table 5 here□

After optimization through item analysis and EFA, the positive and negative questionnaires retained 27 common items. Because the items were optimized in both positive and negative directions, exploratory factor analysis was performed again on the 27 retained items to examine the correlation between each item and its assigned dimension. Analysis of the positive items revealed a KMO value of 0.922, Bartlett's test $\chi^2 = 9327.608$ ($P < 0.001$), 3 common factors with loadings of 0.672--0.914, and a cumulative variance of 73.338%. The specific results are shown in Table 6 and Table 7. Analysis of the negative items revealed a KMO value of 0.927, Bartlett's test $\chi^2 = 10126.964$ ($P < 0.001$), 3 common factors with loadings of 0.751--0.934, and a cumulative variance of 76.273%. The specific results are shown in Table 8 and Table 9.

Table 6 Interpretation of the total variance of each factor in the 27-item positive question questionnaire (N1=310)

Factor	Initial eigenvalue			sum of squared loads			Sum of squared rotational loads		
	Total	Percentage of variance	Accumulate □%□	Total	Percentage of variance	Accumulate □%□	Total	Percentage of variance	Accumulate □%□
1	11.998	44.436	44.436	11.998	44.436	44.436	10.186	37.727	37.727
2	6.226	23.059	67.495	6.226	23.059	67.495	6.213	23.010	60.737
3	1.578	5.8430	73.338	1.578	5.843	73.338	3.402	12.601	73.338

Table 7 The 27-item forward question questionnaire explored the component matrix after factor analysis rotation (N1=310)

Items	Component of factor		
	existence needs	relatedness needs	growth needs
1.9 Education on normal urination and defecation patterns	**0.872**	0.063	0.081
3.6 Guidance on the identification of pathological jaundice	**0.869**	0.106	0.051
5.2 Instruction on tactile stimulation techniques	**0.865**	0.176	0.143
3.7 Guidance on the management of vomiting and aspiration during feeding	**0.851**	0.096	0.011
1.7 Education on principles of growth and development	**0.842**	-0.004	0.028
3.3 Guidance on recognition and management of abnormal defecation (diarrhea and constipation)	**0.834**	0.103	-0.049
5.6 Instruction on visual engagement and vocal interaction strategies	**0.832**	0.154	0.157
4.2 Instruction on emergency response to accidental falls from bed	**0.812**	0.162	0.103
1.5 Education on medication administration methods and precautions	**0.764**	-0.018	0.045
2.1 Guidance on assessing feeding timing and volume	**0.763**	0.119	0.144
2.3 Guidance on sensory integration training for premature infants (multisensory stimulation, passive exercise)	**0.754**	0.125	0.09
2.11 Instruction on home care for premature infants requiring oxygen therapy or tube feeding postdischarge	**0.751**	0.062	0.037
3.2 Guidance on identification of abdominal distension	**0.739**	0.133	-0.033
2.9 Guidance on techniques to promote intestinal gas expulsion	**0.709**	0.073	0.133
4.3 Instruction on emergency management of choking	**0.683**	0.145	0.145
1.2 Education on timing and methods for transitioning between feeding types (specialized formula, standard formula, and breast milk)	**0.672**	0.098	0.042
6.2 Provision of premature infant disease-related information via scientific lectures, official social media, and internet-based platforms	0.128	**0.914**	0.171
6.3 Implementation of multidisciplinary follow-up strategies including outpatient, home, and telephone visits for premature infants	0.111	**0.908**	0.200
8.2 Engagement in shared decision-making with family members regarding premature infant care	0.115	**0.877**	0.282
7.2 Access to peer support from other caregivers of premature infants	0.130	**0.869**	0.247
7.1 Availability of financial assistance resources and acquisition pathways from relevant institutions	0.157	**0.859**	0.165
8.1 Access to support from family members	0.094	**0.856**	0.345
6.1 Provision of diversified healthcare services (online consultations, in-person accompaniment, special appointments, etc.)	0.145	**0.825**	0.187
10.1 Participation in training workshops for continuous enhancement of premature infant care skills	0.106	0.424	**0.864**
10.2 Sharing of effective care experiences with other caregivers	0.114	0.405	**0.860**
9.2 Capacity for independent care of premature infants	0.118	0.351	**0.839**
9.1 Ability to maintain emotional stability during caregiving	0.155	0.454	**0.824**

Insert Table 7 here

Table 8 Interpretation of the total variance of each factor in the 27-item reverse question questionnaire (N1=310)

Factor	Initial eigenvalue			sum of squared loads			Sum of squared rotational loads		
	Total	Percentage of variance	Accumulate □%□	Total	Percentage of variance	Accumulate □%□	Total	Percentage of variance	Accumulate □%□
1	12.065	44.687	44.687	12.065	44.687	44.687	10.876	40.28	40.28
2	6.678	24.735	69.421	6.678	24.735	69.421	6.253	23.16	63.44
3	1.850	6.852	76.273	1.850	6.852	76.273	3.465	12.833	76.273

Table 9 The 27-item reverse question questionnaire explored the component matrix after factor analysis rotation (N1=310)

Items	Component of factor		
	existence needs	relatedness needs	growth needs
3.7 Lack of guidance on the management of vomiting and aspiration during feeding	**0.878**	0.019	0.004
1.9 Absence of education on normal urination and defecation patterns	**0.870**	0.034	0.093
3.6 Lack of instruction on the identification of pathological jaundice	**0.862**	0.067	0.041
1.7 Failure to provide information on principles of growth and development	**0.852**	0.058	0.067
3.3 Absence of guidance on recognition and management of abnormal defecation (diarrhea and constipation)	**0.842**	0.096	0.009
5.6 Lack of instruction on visual engagement and vocal interaction techniques	**0.838**	0.081	0.045
3.2 Failure to provide guidance on identification of abdominal distension	**0.826**	0.092	-0.013
4.3 Absence of instruction on emergency management of choking	**0.826**	0.080	0.100
2.1 Lack of guidance on assessing feeding timing and volume	**0.804**	0.052	0.106
4.2 Failure to provide instruction on emergency response to accidental falls from bed	**0.802**	0.134	0.126
5.2 Absence of guidance on tactile stimulation techniques	**0.800**	0.127	0.159
1.5 Lack of education on medication administration methods and precautions	**0.799**	0.039	0.014
2.11 Failure to provide instruction on home care for premature infants requiring oxygen therapy or tube feeding postdischarge	**0.793**	0.099	0.072
1.2 Absence of education on timing and methods for transitioning between feeding types (specialized formula, standard formula, and breast milk)	**0.784**	0.088	-0.035
2.3 Lack of guidance on sensory integration training for premature infants (multisensory stimulation, passive exercise)	**0.780**	0.129	0.151
2.9 Failure to provide guidance on techniques to promote intestinal gas expulsion	**0.751**	0.051	0.099
6.2 Absence of provision of premature infant disease-related information via scientific lectures, official social media, and internet-based platforms by the hospital	0.114	**0.934**	0.216
8.1 Inability to obtain support from family members	0.084	**0.901**	0.247
8.2 Failure to engage in shared decision-making with family members regarding premature infant care	0.081	**0.896**	0.248
7.2 Inability to access peer support (assistance from other caregivers of premature infants)	0.08	**0.895**	0.19
6.3 Lack of implementation of multidisciplinary follow-up strategies (e.g., outpatient, home, and telephone visits) for premature infants by the hospital	0.085	**0.894**	0.192
6.1 Absence of provision of diversified healthcare services (online consultations, in-person accompaniment, special appointments, etc.) by the hospital	0.101	**0.883**	0.219
7.1 Failure of relevant institutions to provide financial assistance resources and acquisition pathways	0.136	**0.867**	0.158
10.2 Inability to share effective care experiences with other caregivers	0.117	0.337	**0.875**
9.1 Failure to maintain emotional stability during caregiving	0.116	0.355	**0.874**
10.1 Inability to participate in training workshops for continuous enhancement of premature infant care skills (Note: This item was evaluated under the condition that such service was available.)	0.117	0.336	**0.872**
9.2 Ability to maintain emotional stability during caregiving	0.094	0.405	**0.861**

Insert Table 9 here

On the basis of the ERG needs theory framework, the three common factors extracted from both the positive and negative items were named: existence needs, relatedness needs, and growth needs.

Confirmatory Factor Analysis

CFA was performed on Sample 2 (N2=315) to verify the three-factor structure identified through EFA. The fit indices for the positive questionnaire were as follows: χ^2/df = 2.857, RMR=0.012, SRMR=0.049, RMSEA=0.077, IFI=0.914, TLI=0.906, CFI=0.914. The fit indices for the negative questionnaire were χ^2/df =2.785, RMR=0.016, SRMR=0.045, RMSEA=0.075, IFI=0.930, TLI=0.923, and CFI=0.930. The model fit was good.

Convergent validity and discriminant validity

Convergent Validity

The composite reliability (CR) for each dimension of the questionnaire was greater than 0.7, and the average variance extracted (AVE) was greater than 0.5, indicating good convergent validity for the questionnaire, as shown in Table 10 and Table 11.

Table 10 Convergent validity of the forward question questionnaire (N2=315)

Dimension	Items	Normalized factor loading	S.E	*P*	AVE	CR
existence needs	1.2	0.788			0.517	0.944
	1.5	0.782	0.063	<0.001		
	1.7	0.793	0.064	<0.001		
	1.9	0.740	0.067	<0.001		
	2.1	0.701	0.064	<0.001		
	2.3	0.586	0.060	<0.001		
	2.9	0.597	0.070	<0.001		
	2.11	0.596	0.076	<0.001		
	3.2	0.646	0.06	<0.001		
	3.3	0.724	0.067	<0.001		
	3.6	0.861	0.068	<0.001		
	3.7	0.711	0.063	<0.001		
	4.2	0.698	0.065	<0.001		
	4.3	0.718	0.064	<0.001		
	5.2	0.764	0.068	<0.001		
	5.6	0.736	0.062	<0.001		
relatedness needs	6.1	0.889			0.724	0.948
	6.2	0.908	0.039	<0.001		
	6.3	0.813	0.054	<0.001		
	7.1	0.821	0.054	<0.001		
	7.2	0.839	0.048	<0.001		
	8.1	0.847	0.046	<0.001		
	8.2	0.834	0.046	<0.001		
growth needs	9.1	0.841			0.849	0.957
	9.2	0.922	0.046	<0.001		
	10.1	0.972	0.042	<0.001		
	10.2	0.944	0.044	<0.001		

Table 11 Convergent validity of the reverse question questionnaire (N2=315)

Dimension	Items	Normalized factor loading	S.E	*P*	AVE	CR
existence needs	1.2	0.716			0.552	0.951
	1.5	0.758	0.081	<0.001		
	1.7	0.864	0.078	<0.001		
	1.9	0.767	0.077	<0.001		
	2.1	0.724	0.085	<0.001		
	2.3	0.658	0.079	<0.001		
	2.9	0.549	0.076	<0.001		
	2.11	0.597	0.082	<0.001		
	3.2	0.528	0.074	<0.001		
	3.3	0.784	0.082	<0.001		
	3.6	0.839	0.083	<0.001		
	3.7	0.851	0.081	<0.001		
	4.2	0.797	0.082	<0.001		
	4.3	0.826	0.08	<0.001		
	5.2	0.711	0.08	<0.001		
	5.6	0.81	0.08	<0.001		
relatedness needs	6.1	0.954			0.804	0.966
	6.2	0.956	0.025	<0.001		
	6.3	0.891	0.034	<0.001		
	7.1	0.87	0.036	<0.001		
	7.2	0.829	0.038	<0.001		
	8.1	0.871	0.034	<0.001		
	8.2	0.899	0.032	<0.001		
	9.1	0.885			0.863	0.962
growth needs	9.2	0.938	0.04	<0.001		
	10.1	0.962	0.037	<0.001		
	10.2	0.930	0.04	<0.001		

Discriminant validity

The correlation coefficients between the dimensions of the questionnaire were all less than the square root of the corresponding AVE, indicating good discriminant validity, as shown in Table 12 and Table 13.

Table 12 Discriminant validity of the positive questions questionnaire (N2=315)

	existence needs	relatedness needs	growth needs
existence needs	**0.719**		
relatedness needs	0.225***	**0.851**	
growth needs	0.246***	0.388***	**0.921**

Note: *** represents *p* < 0.001.

Table 13 Discriminant validity of the reverse question questionnaire (N2=315)

	existence needs	relatedness needs	growth needs
existence needs	**0.743**		
relatedness needs	0.219***	**0.897**	
growth needs	0.335***	0.469***	**0.929**

Note: *** represents *p* < 0.001.

Content validity analysis

In terms of the expert ratings, the questionnaire's I-CVI ranged from 0.71--1, and the S-CVI/AVE was 0.93, suggesting good content validity.

Reliability Analysis

The Cronbach's α coefficient for the positive questionnaire was 0.932, and the Cronbach's α coefficients for its dimensions ranged from 0.939--0.957. The Cronbach's α coefficient for the negative questionnaire was 0.940, and the Cronbach's α coefficients for its dimensions ranged from 0.950--0.966. This indicates good internal consistency for the questionnaire, as shown in Table 14.

Table 14 Reliability test results for the questionnaire (N2=315)

Way of asking questions		Dimensions of questionnaire		
	Total	existence needs	relatedness needs	growth needs
Forward direction	0.932	0.939	0.947	0.957
Reverse direction	0.940	0.950	0.966	0.961

Discussion

An Assessment Framework for Primary Caregivers of Preterm Infants at Home Based on ERG Theory

This study developed an assessment questionnaire based on the ERG needs theory, integrating expert opinions and empirical data. The instrument covers multidimensional physiological, psychological, and social needs and demonstrated acceptable psychometric properties within the study sample, indicating that the ERG theory provides a relevant theoretical framework for understanding the needs of primary caregivers of discharged premature infants. The ERG theory, a humanistic needs theory derived from Maslow's hierarchy of needs [33], comprises three core dimensions: existence needs, relatedness needs, and growth needs. This framework posits that needs at different levels can coexist and interact dynamically. After lower-level needs are met, individuals continue to pursue higher-level needs without diminishing the importance of basic needs. When higher-level needs are unattainable, individuals may experience "frustration-regression," shifting their focus back to lower-level needs. This flexible hierarchical structure aligns well with real-world contexts, providing a useful perspective for understanding the multidimensional and dynamic nature of caregivers' needs following a premature infant's discharge: (1) the three dimensions of existence, relatedness, and growth collectively capture key aspects of caregivers' physiological, psychological, and social support needs; (2) the interaction among different needs reflects the complex reality of caregivers managing multiple pressures; and (3) the non-sequential nature of need satisfaction and the potential for regression offer a theoretical lens for interpreting changes in caregivers' needs over time. Based on these findings, this study proposes a structured and operable framework for assessing care needs.

Practical Significance of the Questionnaire

Accurately identifying the needs of primary caregivers after a premature infant's discharge is a crucial step towards providing effective support. Many existing assessment tools capture needs indirectly, which may limit the ability to identify specific gaps in the home care process. Therefore, a tool designed to explicitly evaluate care needs holds practical value.

In this study, an initial item pool was established based on ERG theory and refined through two rounds of Delphi expert consultation. Following the Kano model requirements, each item was transformed into paired positive and negative questions. After reliability and validity testing, a final 27-item care needs questionnaire for primary caregivers of discharged premature infants was developed, comprising 16 items on existence needs, 7 on relatedness needs, and 4 on growth needs. During the survey, participants were required to answer both the positive and negative forms of each item. Applying Kano analysis to the response data can help clarify the nature and priority of caregivers' needs, thereby supporting healthcare professionals in planning targeted interventions.

Furthermore, while previous research has predominantly focused on parents, this study also included grandparent caregivers. As an important caregiving group [34], the needs of grandparents are often overlooked in research, and support strategies rarely consider their specific requirements. Expanding the research scope to include different types of primary caregivers may enhance the alignment between support services and actual needs.

Rigor of Questionnaire Construction

The initial items were developed through qualitative interviews and literature analysis, and subsequently refined via two rounds of expert consultation. The high levels of expert engagement and authority ensured the reliability of this process. The questionnaire was strictly designed according to the Kano model, with each item presented as paired positive and negative questions. A pilot test confirmed the questionnaire's feasibility before the formal survey was conducted. Reliability and validity analyses indicated that both the positive and negative question sets exhibited acceptable psychometric properties. The development process was theoretically guided and employed standardized methods, thereby enhancing the methodological rigor of the questionnaire. This instrument can serve as a useful tool for assessing the care needs of caregivers of premature infants at home and provides a reference for developing targeted support interventions.

Limitations

This study has several limitations. The development and validation of the questionnaire were primarily based on data from late preterm infants and their parental populations. The representation of very/extremely preterm infants and other types of caregivers (such as grandparents and other core family members) remains insufficient, which may affect the tool’s applicability to broader populations. Additionally, all data were collected from a single center, and the sample source was relatively homogeneous, limiting the generalizability of the findings across different regions, levels of healthcare institutions, and cultural contexts. Methodologically, although the study assessed reliability and validity through multiple indicators—including internal consistency reliability, content validity, and construct validity—test–retest reliability was not evaluated due to constraints in the research timeline and design. This methodological gap should be addressed in future research.

Suggestions for Future Research

Future research could expand the sample scope and diversity by including more infants of different gestational ages (especially very premature and extremely premature infants) and different types of caregivers (such as grandparents) and conducting multicenter, cross-regional collaborations to increase the representativeness and generalizability of the questionnaire. Second, test—retest reliability testing should be supplemented in subsequent studies to comprehensively verify the questionnaire's reliability. Furthermore, personalized intervention plans based on the assessment results can be further developed, such as skill training programs tailored to different family structures and caregiver types, and the construction of a continuous nursing support system linking hospitals, communities, and families can be explored. Finally, cross-cultural adaptation and validation are encouraged to examine the applicability of this questionnaire in different healthcare systems and sociocultural contexts.

Conclusion

Based on the ERG theory of needs, this study developed a questionnaire consisting of three dimensions: existence needs, relatedness needs, and growth needs. According to the Kano model, each item was transformed into paired positive and negative questions. A cross-sectional survey verified the reliability and validity of the questionnaire in assessing the care needs of primary caregivers of premature infants at home. Both the positive and negative versions demonstrated good measurement properties. This tool shows potential for

systematically assessing care needs, providing a basis for developing personalized care plans, and thereby contributing to the overall improvement of care quality for premature infants.

Abbreviations

I- CVI
item-level content validity index
S- CVI/Ave
scale-level average content validity index
EFA
exploratory factor analysis
CFA
confirmatory factor analysis
CAID
cronbach's alpha if item deleted
CITC
corrected item-total correlation
AVE
average variance extracted
CR
composite reliability

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the principles of the Declaration of Helsinki. The study protocol was approved by the Medical Ethics Committee of Tongji Medical College, Huazhong University of Science and Technology (Approval Number: [2023] Ethics Review S134). Informed consent was obtained from all participants prior to their inclusion in the study. Clinical trial number: not applicable.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing Interests

The authors declare that they have no competing interests

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Authors' contributions

FF.L：Thesis writing, data collection and analysis;**JH.Y**:Theoretical guidance, data review, and paper revision;**FF.W** and **H.Q:** paper revision;**ZH.H** and **YY.W**:data collection;**HQ.L**:data collection and paper revision;**YY.L**:data review and analysis.All authors read and approved the final manuscript.

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