

Psychometric Properties of the Persian Version of the Pediatric Quality of Life Inventory 3.0 (PedsQL™) Cancer Module

Afsoon Hassani Mehraban PhD¹, Fatemeh Mahdizadeh Karizaki PhD Student^{*2}, Hossein Alibakhshi PhD³, Armin Hajizadeh MD⁴, Farbod Matin Sadr BSC⁵, Maryam Mehdizadeh PhD⁶

1. Professor, Department of Occupational Therapy, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran.

2. PhD student, Faculty of Health, Dalhousie University, Nova Scotia, Canada.

3. Assistant professor, Department of Occupational Therapy, School of Rehabilitation, Semnan University of Medical Sciences, Semnan, Iran.

4. Associate physician, Thoracic Surgery Division, Queen Elizabeth II Health Sciences Centre, Nova Scotia Health Authority, Nova Scotia, Canada.

5. Department of Practical Informatics, Deggendorf Institute of Technology, Deggendorf, Germany.

6. Department of Neurosciences, Faculty of Advanced Technologies in Medicine, Iran University of Medical Sciences, Tehran, Iran.

*Corresponding author: Fatemeh Mahdizadeh Karizaki, PhD student in Health, Faculty of Health, Dalhousie University, 1094 Wellington Street, Nova Scotia, Canada/ Postal Code: B3H 2Z9. Email: f.mahdizadehkarizaki@dal.ca. ORCID ID: 0000-0003-2052-9385.

Received: 26 August 2024

Accepted: 26 February 2025

Abstract

Background: Pediatric cancer significantly impacts children's physical, emotional, and social well-being, making quality of life (QoL) assessment essential. The Pediatric Quality of Life Inventory 3.0 (PedsQL™ 3.0) includes both child self-report and parent proxy versions, which are widely used to evaluate QoL in children with chronic conditions, including cancer. However, validating its psychometric properties across different cultural contexts is necessary.

Materials and Methods: A methodological research design was employed for a sample of 200 participants including 100 inpatient children with cancer (mean age \pm SD: 9.30 ± 1.85 years) and their mothers (mean age \pm SD: 33.61 ± 6.03 years). The content, face, and structural validities of the study were assessed using exploratory factor analyses. The test reliability was also measured through internal consistency calculated with Cronbach's alpha. Moreover, the intra-class correlation coefficient (ICC) was used to evaluate the test-retest reliability.

Results: The results of the study demonstrated acceptable content and face validity for both the child and mother versions of the instrument. The structural validity analysis revealed a five-factor structure for the child version and a six-factor structure for the mother version. The reliability of the instrument was confirmed with satisfactory Cronbach's alpha values ($\alpha = 0.85$) for both versions, indicating strong internal consistency. Additionally, the inter-rater reliability was assessed with ICC. The assessments yielded the values of 0.87 for the child version and 0.88 for the mother version, suggesting excellent agreement.

Conclusion: The Persian version of the PedsQL™ 3.0 is a valid and reliable tool for assessing the quality of life in children with cancer and their mothers.

Keywords: Cancer, Pediatric, Psychometrics, Quality of life, Reliability, Validity

Introduction

Childhood cancer imposes profound challenges not only on the affected children but also on their families, particularly parents (1). It affects various aspects of a child's life, ranging from daily activities and social interactions to emotional well-being and, thus, the overall quality of life (QOL) (2). This impact highlights the necessity of effective tools

to accurately assess and monitor QOL in this vulnerable population (3, 4). Fortunately, in recent decades, advancements in treatment have greatly improved survival rates for pediatric cancer patients in developed countries, with many of those patients achieving long-term remission (5). Despite these improvements, a significant percentage of patients with advanced neuroblastoma, soft

tissue sarcomas, and brain tumors may still face poor prognoses (6, 7). Thus, healthcare professionals must balance minimizing treatment side effects with optimizing the quality of life for those who survive (8). Accurate assessment tools are also essential for capturing the multifaceted nature of QOL. One such tool is the Pediatric Quality of Life Inventory™ (PedsQL™) 3.0, which is designed to measure the health-related QOL of children with chronic conditions, including cancer (9). This tool provides valuable insights into the physical, emotional, and social dimensions of a child's experience (9). Yet, assessing QOL in children can be complex due to developmental differences; children's cognitive abilities and perspectives often differ significantly from those of adults, which can complicate both self-reporting and proxy reporting (10, 11). Differences in how children and parents understand and report symptoms can be significant (12). Parents may experience fear, distress, and anxiety, influencing their perception of their child's quality of life, while children might assess their QOL based on their personal experiences, which can be influenced by their cognitive and emotional development (12, 13). This divergence underscores the importance of capturing both child self-reports and parent proxy-reports to obtain a comprehensive understanding of the child's conditions (14-16). Effective assessment requires evaluating the same symptoms from different perspectives to provide a holistic view of the child's well-being (17). Although the PedsQL™ 3.0 has been validated in various cultural contexts (18-24), there is a notable gap in the psychometric evaluation of its Persian version. Limited research on QOL assessment tools for pediatric cancer patients in Iran and the absence of culturally and linguistically appropriate instruments hinder comprehensive evaluations (18). Developing a Persian

version of the PedsQL™ 3.0 is critical to ensure its relevance and effectiveness for Persian-speaking children and their families, thereby enhancing the accuracy and utility of QOL assessments in this population. To address this gap, the present study aims to evaluate the psychometric properties of the Persian version of the PedsQL™ 3.0 Cancer Module from the perspectives of children with cancer (self-report) and their mothers (parent proxy-report). By assessing the validity and reliability of this instrument for Iranian children with cancer and their mothers, this research contributes to more effective and culturally sensitive healthcare practices, ultimately improving the quality of life for pediatric cancer patients in Iran.

Materials and Methods

General setup

This research involved 100 inpatient children with cancer (mean age \pm SD: 9.30 \pm 1.85 years) and their mothers (mean age \pm SD: 33.61 \pm 6.03 years). Initially, the participants completed a demographic questionnaire collecting information on age, sex, education level, disease stage, medication use, and comorbidities. The Pediatric Quality of Life Inventory 3.0 (PedsQL™ 3.0) Cancer Module (9) was administered on the second day of hospital admission, following a chemotherapy session. To assess the test-retest reliability, 30% of the participants were asked to complete the questionnaire again three days later (on day 5). This three-day interval was chosen due to the hospital setting, where the children could have varying lengths of stay, and some were likely to leave the hospital sooner than anticipated. By scheduling the follow-up after three days, we aimed to balance the need for sufficient time to measure stability in the responses with the practical constraints of the hospital environment. The administration was repeated under the

same conditions as the initial assessment, and the mothers completed the questionnaire in a separate room to ensure privacy.

Participant's selection

The participants (children with cancer and their mothers) were recruited from MAHAK Specialized Pediatric Cancer Hospital & Research Center and Hazrat-e Ali Asghar Pediatrics Hospital in Tehran, Iran. They were selected through a convenience sampling method because of the practical constraints in the clinical setting, such as patient availability and ethical considerations when working with children with cancer (25). The inclusion criteria for the children were a confirmed diagnosis of cancer, an age range of 8 to 12 years, and the ability to communicate effectively. For the mothers, the inclusion criteria required literacy, fluency in Persian, no apparent cognitive impairments (Mini Mental Status Examination ≥ 24) (26), and minimal levels of anxiety and depression (Hospital Anxiety and Depression Scale [HADS] score < 11) (27). The exclusion criteria for both children and mothers were any serious concurrent health conditions that could impact the responses, significant mood disorders as indicated by a HADS score of 11 or higher to prevent potential biases in the assessment due to psychological distress, cognitive disorders, non-fluency in Persian, and any serious family or personal issues that might interfere with their ability to participate in the study reliably.

Preparation and translation

This process began with the consent of the original designer of the PedsQL™ 3.0 Cancer Module and adhered to the guidelines outlined by the International Quality of Life Assessment (IQOLA) project (28). Initially, two experienced native Persian translators independently translated the English version of the

module into Persian. Following this, two additional experienced translators conducted a back-translation into English to ensure accuracy and conceptual equivalence. The final Persian version was developed after a thorough review and discussion with all the translators. This version underwent further revisions to resolve any issues identified during the review. To ensure that the translation maintained the integrity of the original instrument, the re-translated English version was sent back to the original designer for a review and final approval. With their consent and endorsement, the Persian version was confirmed for its accurate reflection of the original content and the intent of the tool.

Scale validation methods

To validate the scales, we assessed their content validity, face validity, and structural validity. Their reliability was also examined through measures of internal consistency and test-retest stability, ensuring that the results were consistent both within the study and across repeated assessments.

1. Content validity

The content validity was rigorously assessed through a combination of expert review and quantitative measures. The Persian version of the PedsQL™ 3.0 Cancer Module was evaluated by two oncologists and thirteen occupational therapists to ensure that the translation accurately captured the intended constructs and was relevant for the target population. The Content Validity Index (CVI) was calculated based on the proportion of the experts who rated each item as "Relevant but Needs a Review" or "Completely Related". Additionally, the Content Validity Ratio (CVR) was determined by the experts' rating of each item as 1) Necessary, 2) Necessary but not important, or 3) Unnecessary. Thus, only the "Necessary" items were retained. The

experts involved in the content validity assessment also participated in the formal validation process, ensuring consistency (29). The qualitative feedback from these experts was used to refine and finalize the questionnaire, ensuring comprehensive coverage and relevance for assessing the quality of life in children with cancer.

2. Face validity

The face validity of the scales was assessed separately for the children and the mothers. For the child version, a group of children aged 8 to 12 reviewed the questionnaire to ensure that the items were relevant, clear, and understandable for their age group. Similarly, for the parent proxy version, the mothers evaluated the questionnaire to determine its relevance and clarity from their perspective. Each group rated the items on a 4-point scale concerning relevance, clarity, and simplicity. The items with scores above 0.79 were considered suitable for further analysis (29).

3. Structural validity

The structural validity of the Persian version of the PedsQL™ 3.0 Cancer Module was evaluated through Exploratory Factor Analysis (EFA) (30). To ensure the data were suitable for factor analysis, the Kaiser-Meyer-Olkin (KMO) Index and Bartlett's Test of Sphericity were used. A KMO value of 0.6 or higher was considered acceptable for proceeding with factor analysis. Bartlett's Test of Sphericity confirmed the adequacy of the correlation matrix for factor analysis, with a significant χ^2 value ($p < 0.0001$) (30, 31). These indices served to validate the appropriateness of the data for exploring the factor structure of the instrument

4. Internal consistency

The internal consistency of the measuring tools was assessed through Cronbach's alpha coefficients with certain interpretations; values from 0.6 to 0.7 indicated acceptable reliability, values above 0.8 signified good reliability, and

0.95 or higher values reflected excellent reliability (32).

5. Test-retest reliability

Test-retest reliability was evaluated by administering the PedsQL™ 3.0 questionnaire twice to 30 children with cancer and their parents, with a three-day interval between the two administrations. The three-day interval was selected to balance the need for response stability with the practical challenges of the hospital environment, such as patient discharges or variable treatment schedules. This approach aligned with similar studies that utilized short intervals to minimize the changes in participants' conditions while accommodating the clinical constraints (33-35). Intraclass Correlation Coefficient (ICC) values were interpreted as follows: values of 0.7 and above were deemed highly satisfactory, values from 0.4 to 0.7 indicated moderate reliability, and values below 0.4 were considered poor (25).

Instruments

The Pediatric PedsQL™ 3.0 is a standardized instrument designed to measure the quality of life in children with chronic health conditions, including cancer. It comprises a Child Version and a Parent Proxy Version, each containing 27 items distributed across eight subcategories including Pain and Injury (2 items), Nausea (5 items), Procedural Anxiety (3 items), Treatment Anxiety (3 items), Concern (3 items), Cognitive Problems (5 items), Understanding Physical Appearance (3 items), and Communication (3 items) (9). Both versions used a 5-point Likert scale, with responses ranging from 0 (Never) to 4 (Almost Always). The total scores were calculated by summing the item responses and converting them to a scale from 0 to 100, where higher scores indicated a better quality of life. The minimum possible score was 0, while the maximum was 100 (9). Originally developed by James W. Varni and colleagues, the PedsQL™ 3.0

has been widely validated, demonstrating strong psychometric properties. These include high internal consistency, robust test-retest reliability, and strong construct and content validity across diverse studies and populations (9).

Statistical analysis

The statistical analysis was conducted using SPSS version 16.0, with a significance level set at $p < 0.05$ for all the tests. Descriptive statistics, such as mean and standard deviation (SD), were employed to summarize the demographic characteristics of the participants, as presented in Table I.

Ethical considerations

This study did not involve any interventions. Ethical approval was granted by the Ethics Committee of Iran University of Medical Sciences in Tehran, Iran (Ethical Code: IR.IUMS.REC1395.9411355008). Prior to participation, informed consent was obtained from all the participants or their legal guardians.

The participants were ensured about the confidentiality of their responses and the anonymity of their data. All the data were securely stored and used exclusively for the purposes of this study. Participation was voluntary, and the individuals had the freedom to withdraw at any time without facing any negative consequences. The study strictly followed the ethical guidelines for research involving human subjects, ensuring that all the procedures would adhere to the established ethical standards.

Results

Table I reports the demographic characteristics and medical data of the participants. In this study, out of the 100 enrolled children, 66% were male and 34% were female, all within the age range of 8

to 12 years. Most of these children had left school during the study. Leukemia, affecting 44% of the children, was the most frequent malignancy. The PedsQL™ 3.0 Cancer Module was translated into Persian following the guidelines of the International Quality of Life Assessment (IQOLA) project. After the initial translation and back-translation by experienced translators, the Persian version was reviewed and revised by experts, including oncologists and occupational therapists, to ensure accuracy and relevance. Regarding the content validity, the Content Validity Index (CVI) was 0.97 for the child self-report scale and 0.98 for the parent proxy-report scale, indicating excellent content relevance. The face validity scores were 0.95 for the child self-report and 0.92 for the parent proxy-report, reflecting the high clarity and appropriateness of the scales. An exploratory factor analysis (EFA) was performed to assess the structural validity of the Persian version of the PedsQL™ 3.0 Cancer Module. The suitability of the sample size for the factor analysis was confirmed by Kaiser-Meyer-Olkin (KMO) Index scores of 0.70 for the child version and 0.72 for the parent version, which are considered adequate. Bartlett's Test of Sphericity supported the appropriateness of the data for the factor analysis with a significant result ($p < 0.0001$). Although the original English version of the PedsQL™ 3.0 Cancer Module features an 8-factor structure (9), our analysis identified fewer factors in the Persian version. For the child scale, the factor analysis identified several key factors. Factor 1 aggregated items from various subscales, including items 4 to 7 from the Nausea subscale, item 8 from the Procedural Anxiety subscale, items 11 to 13 from the Treatment Anxiety subscale, item 17 from the Cognitive Problems subscale, items 22, 23 and 24 from the

Physical Appearance subscale, and items 25 and 26 from the Communication subscale. This indicates a factor that combines different aspects of physical discomfort and emotional challenges. Factor 2 included the items related to Nausea (items 3 and 6), Procedural Anxiety (items 9 and 10), and Worry (items 14, 15 and 16), reflecting a dimension of procedural-related distress and worry. Factor 3 was characterized by the items from the Cognitive Problems subscale (items 18, 19, 20 and 21) and Nausea (item 5), showing a combined factor of cognitive impact and associated nausea. Factor 4 included items 1 and 2 from the Pain and Injury subscale, focusing specifically on pain and injury, while Factor 5 consisted of item 27 from the Communication subscale, indicating a separate factor for communication issues (Table II).

For the parent scale, Factor 1 included items from the Procedural Anxiety (items 8, 9 and 10), Treatment Anxiety (items 11, 12 and 13), Anxiety (items 14, 15 and 16), Cognitive Problems (item 17), and Communication (items 25 and 26) subscales. This factor combines multiple dimensions of anxiety and communication from the parent's perspective. Factor 2 aggregated items from the Nausea subscale (items 5 and 6) and Cognitive Problems (items 19 and 20), reflecting a factor related to cognitive issues and nausea. Factor 3 included items from the Nausea subscale (items 3, 4 and 7) and Cognitive Problems (items 18 and 21), representing a combined factor of nausea and cognitive impact. Factor 4 consisted of item 24 from the Physical Appearance subscale and item 27 from the Communication subscale, highlighting concerns about physical appearance and communication. Factor 5 included items 22 and 23 from the Physical Appearance subscale, focusing specifically on physical appearance, while Factor 6 was represented by items 1 and 2

from the Pain and Injury subscale, emphasizing pain and injury (Table III). The differences observed in the factor structures between the original English version and the Persian adaptation can be attributed to several factors. Cultural and linguistic variations may influence how respondents interpret items, and the translation process might alter item comprehension (36, 37). Additionally, psychometric variations and sample-specific factors, such as socio-demographic differences, can impact factor loadings (38). These differences underscore the need for cultural adaptation and validation of assessment tools to ensure their relevance and accuracy in different contexts (36-38). The internal consistency of the child self-report scales was evaluated using Cronbach's alpha coefficients (25), which were all found to be acceptable, with values equal to or greater than 0.7 across all the subscales. The total internal consistency for the child self-report version was 0.85, indicating a high level of reliability. Similarly, the total internal consistency for the parent proxy-report version was also 0.85, demonstrating equivalent reliability from the parents' perspective (Table IV). These findings suggest that both versions of the PedsQL™ 3.0 Cancer Module exhibit robust internal consistency and are reliable for measuring the quality of life in children with cancer and their parents. The test-retest reliability of the scales was assessed using the Intraclass Correlation Coefficient (ICC) (34). For the child self-report scale, all the subscales achieved an ICC score greater than 0.7, with the overall score of the scale reaching 0.88. This indicates strong reliability for the child self-report version over time. In contrast, for the parent proxy-report scale, the subscale measuring pain and injury had a notably lower ICC of 0.24, reflecting weaker reliability in this specific area. The other subscales of the parent proxy-report scale

had ICC scores above 0.7, and the total ICC for the parent proxy-report scale was

0.87, demonstrating overall strong test-retest reliability (Table V).

Table I: Demographical characteristics of the participants

Participant	Mean age (year) (SD)	9.30 (1.85)	
Children	Variable	Frequency (%)	
	Sex	Male	66 (%66)
		Female	34 (%34)
	Diagnosis	Leukemia	44 (%44)
		Sarcoma	20 (%20)
		Other diagnosis	36 (%36)
	The duration after the diagnosis	< year	58 (%58)
		13 month 19	19 (%19)
		20 month 24	9 (%9)
		> 2 year	14 (%14)
	Admission day	Second	40 (%40)
		Third	34 (%34)
		Fourth	19 (%19)
		Fifth	5 (%5)
		Sixth	2 (%2)
Treatment received	Chemotherapy	62 (%62)	
	Radiotherapy	18 (%18)	
	Surgery	11 (%11)	
	Bone marrow transplant (BMT)	9 (%9)	
History of cancer in the family	Yes	42 (%42)	
	No	58 (%58)	
Mothers	Mean age (year) (SD)	33.61 (6.03)	
	Variable	Frequency (%)	
	Education	< Diploma	34 (%34)
		Diploma	42 (%42)
		> Diploma	24 (%24)

Table II: Exploratory factor analysis of the PedsQL™ 3.0 Cancer Module in children self-reports

Items	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
A24: Embarrassing others to see the body	.716	-.066	-.132	-.444	-.226
A23: Don't like other people to see scars	.653	-.036	-.038	-.382	-.250
CP17: It is hard to figure out what to do when something bothers you	.585	.342	.393	-.030	.302
A22: Don't feel good-looking	.573	.046	-.100	-.445	-.205
TA13: Getting scared when going to the hospital	.568	-.344	-.060	-.011	.364
C25: It is hard to tell the doctors how to feel	.565	-.293	.196	.215	-.476
PA8: Needle sticks hurt	.564	-.423	.027	.109	.174
N4: Food does not taste good	.537	.335	-.380	.048	.206
C26: It is hard to ask the doctors questions	.532	-.321	.032	.289	-.414
TA12: Getting scared when going to the doctor	.531	-.342	-.293	-.138	.324
TA11: Getting scared when seeing the doctor	.452	-.351	-.299	.144	.277
N7: Some foods and smells make sick	.409	.293	-.237	.242	.213
PA9: Getting scared when having a blood test	.488	-.666	-.011	.050	.131
PA10: Getting scared when having needle sticks	.544	-.638	.007	.026	.109
W15: To worry about whether medical treatments are working	.488	.594	-.012	-.320	-.124
W16: To worry about whether the cancer will be back or relapse	.423	.577	-.061	-.294	-.166
W14: To worry about side effects	.524	.537	.171	-.224	.045
N3: Stomach sickness during the medical treatment	.338	.430	-.231	.298	.106
N6: Feeling sick in stomach to eat	.313	.344	-.309	.137	.279
CP21: It is hard to remember what to read	.278	.098	.676	.033	.181
CP19: To have trouble writing school papers	.430	.109	.599	.190	.149
CP20: It is hard to pay attention to things	.255	-.009	.454	.089	.119
CP18: To have trouble solving math problems	.193	.158	.399	.113	.219
N5: Stomach sickness during thinking about medical treatment	.052	.247	-.310	.225	.223
P1: Ache or hurt in joints and/or muscles	.294	.338	-.053	.609	-.314
P2: Hurt a lot	.412	.306	-.121	.586	-.265
C27: It is hard to explain illness to other people	.363	-.226	-.023	.116	-.496
P: Pain and hurt					
N: Nausea					
PA: Procedural anxiety					
TA: Treatment anxiety					
W: Worry					
CP: Cognitive problems					
A: Perceived physical appearance					
C: Communications					

Table III: Exploratory factor analysis of the PedsQL™ 3.0 Cancer Module in mother's self-report

Items	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6
PA8: Needle sticks hurt	.704	-.410	.021	-.295	.090	-.211
PA9: Getting scared when having a blood test	.696	-.371	.139	-.337	.075	-.179
TA11: Getting scared when seeing the doctor	.695	-.467	-.026	-.037	.036	-.089
TA12: Getting scared when going to the doctor	.687	-.523	-.016	-.049	-.146	-.111
TA13: Getting scared when going to the hospital	.687	-.387	.016	-.253	-.252	-.042
PA10: Getting scared when having needle sticks	.683	-.325	.128	-.387	.092	-.281
C25: It is hard to tell the doctors how to feel	.609	-.197	-.010	.294	-.114	.409
W14: To worry about side effects	.588	.021	.207	.232	-.310	.176
CP17: It is hard to figure out what to do when something bothers you	.541	.314	.062	-.270	.154	.105
W16: To worry about whether the cancer will be back or relapse	.532	.160	.103	.212	-.427	.118
W15: To worry about whether medical treatments are working	.500	-.019	.147	.373	-.060	.027
C26: It is hard to ask the doctors questions	.490	-.263	.031	.356	-.134	.375
N6: Feeling sick in stomach to eat	.379	.549	-.476	.006	-.205	-.176
CP20: It is hard to pay attention to things	.226	.521	.469	-.286	-.082	.013
CP19: To have trouble writing school papers	.334	.489	.453	-.312	.000	.214
N5: Stomach sickness during thinking about medical treatment	.398	.437	-.338	-.008	.037	.036
CP18: To have trouble solving math problems	.322	.478	.587	-.274	.008	.169
N7: Some foods and smells make sick	.429	.420	-.577	-.044	-.067	-.278
CP21: It is hard to remember what to read	.195	.472	.514	-.130	-.127	.021
N4: Food does not taste good	.506	.348	-.508	-.050	-.019	-.131
N3: Stomach sickness during having medical treatment	.479	.477	-.499	.007	-.219	-.045
C27: It is hard to explain illness to other people	.409	-.014	-.004	.675	-.067	.279
A24: Embarrassing others to see the body	.454	.050	.200	.483	.416	-.373
A23: Don't like other people to see scars	.332	.180	.262	.482	.537	-.275
A22: Don't feel good-looking	.424	.362	.137	.284	.466	-.144
P2: Hurt a lot	.219	-.100	-.328	-.203	.554	.575
P1: Ache or hurt in joints and/or muscles	.338	.018	-.362	-.329	.445	.506
P: Pain and hurt N: Nausea PA: Procedural anxiety TA: Treatment anxiety W: Worry CP: Cognitive problems A: Perceived physical appearance C: Communications						

Table IV. Internal consistency of the Iranian version of the PedsQLTM 3.0 Cancer Module

Subscale	Child self-report (8-12 years)		
	Mean	SD	Cronbach's Alpha
Total	1.15	1.29	0.85
Pain and hurt	1.34	1.10	0.86
Nausea	1.54	1.22	0.70
Procedural anxiety	1.43	1.51	0.88
Treatment anxiety	0.85	1.24	0.76
Worry	0.98	1.43	0.91
Cognitive problems	0.71	1.05	0.71
Perceived physical appearance	1.10	1.38	0.89
Communication	1.26	1.45	0.79
Mother's self-report			
Total	1.55	1.45	0.85
Pain and hurt	1.42	1.13	0.88
Nausea	1.78	1.25	0.86
Procedural anxiety	2.09	1.41	0.94
Treatment anxiety	1.61	1.46	0.91
Worry	1.60	1.69	0.70
Cognitive problems	0.89	1.60	0.81
Perceived physical appearance	1.55	1.35	0.81
Communication	1.47	1.73	0.83

Table V. Intraclass correlation of the Iranian version of the PedsQLTM 3.0 Cancer Module

Subscale	ICC (Child's self-report)	ICC (Mother's self-report)
Total	0.87	0.88
Pain and hurt	0.86	0.24
Nausea	0.70	0.85
Procedural anxiety	0.88	0.80
Treatment anxiety	0.76	0.72
Worry	0.91	0.97
Cognitive problems	0.71	0.88
Perceived physical appearance	0.89	0.70
Communication	0.79	0.89

ICC: intra-class correlation coefficient

Discussion

The present study was conducted to validate the Persian version of the PedsQL™ 3.0 Cancer Module, focusing on its psychometric properties. Our findings confirm the validity and reliability of the tool in the Iranian context, reflecting its suitability for assessing the quality of life in children with cancer and their parents. The face and content validities were robust, with both children and parents rating the items favorably. This suggests that the translated version of the

questionnaire is perceived as relevant and clear by the target population. For the structural validity, our Exploratory Factor Analysis (EFA) revealed a modified factor structure compared to the original English version. Specifically, five factors were identified for the child self-report scale and six for the parent proxy-report scale. These variations may be attributed to cultural differences in how cancer-related issues are perceived and reported, highlighting the importance of contextual factors in psychometric assessments. The discrepancies observed between the

Persian version and the original English version of the PedsQL™ 3.0 Cancer Module underscore the need for cultural adaptations in psychometric tools (36-38). These variations could reflect differences in cultural attitudes towards cancer, the emotional impact of the disease, and the subjective nature of quality-of-life assessments (39, 40). For instance, perceptions of pain and injury might vary significantly across cultures, influencing how parents and children report these experiences (41, 42). Similar differences were reported in the Japanese version of the PedsQL™ 3.0, where the number of the factors differed from that in the original version, with a higher number of factors in the children's version compared to the parents' (21). These findings emphasize the importance of adapting psychometric tools to account for cultural variations in the experience and reporting of health-related quality of life. Cronbach's alpha coefficients for internal consistency in our study were above 0.7 for all the subscales, aligning with the results from the original English version (9). This indicates that the Persian version maintains good reliability in measuring quality of life across both children and parents, similar to other validated versions. The choice of a 3-day interval for the test-retest reliability in our study was guided by the need to capture short-term variations in quality of life perceptions due to pediatric chemotherapy protocols and their impact on treatment-related judgments. This interval helps mitigate interference from changing conditions, aligning with practices in other studies that assess quality of life over short periods. While Shun et al. (43) have not used test-retest reliability in their study of psychological features in children with cancer, they, along with Nunnally and Bernstein (33), argued that longer intervals may not be suitable for dynamic conditions like

cancer-related symptoms due to their fluctuating nature over time. They suggest that shorter intervals are more effective in reflecting true variations in these symptoms. Our findings support this approach, as the 3-day interval allowed us to better capture short-term changes, though the low ICC score for the pain and injury subscale in the parent proxy-report suggests potential differences in pain perception and reporting, possibly influenced by subjective and cultural factors. The other subscales showed satisfactory ICC levels, consistent with the psychometric findings from the Brazilian and German versions of the scale (19, 23). Overall, this study highlights the critical need for integrating both child self-reports and parent proxy-reports when assessing the quality of life in pediatric oncology. After a cancer diagnosis, parents often experience significant fear, distress, and anxiety, which can influence their perception of their child's quality of life (14, 15). Conversely, children with chronic illnesses, including cancer, may evaluate their quality of life differently based on their personal mental, emotional, and physical experiences of the disease. Younger children, in particular, may have more limited cognitive capacity, which can affect how they report their quality of life (16, 17). The observed discrepancies between child and parent reports may reflect these differences in understanding and interpreting quality of life. Recognizing these differences is crucial, as a parent's perception of his or her child's quality of life can directly impact caregiving and, consequently, the child's overall well-being (14-17). Utilizing patient-based assessment tools such as questionnaires can complement the existing evaluations and help identify individual treatment priorities and personalized care strategies (14-17). By capturing both child and parent's

perspectives, these tools provide a more comprehensive view of the impact of cancer and its treatment, ultimately supporting more effective and personalized interventions.

Conclusion

The Persian version of the PedsQL™ 3.0 is a valid and reliable tool for assessing the quality of life in children with cancer and their mothers.

Limitations

This study had several limitations, including challenges in recruiting both children and parents due to the sensitive nature of cancer-related symptoms, which may have affected participant engagement, response rates, and data quality. The psychological impact of cancer could have influenced responses, complicating the reliability and validity of the tool. Variability in hospital settings, with differences in treatment environments, may have affected quality of life perceptions. Additionally, the use of convenience sampling and the sample's demographic characteristics limit the generalizability of the findings. The low reliability of parent-proxy reports and differences in factor structures between versions suggest the need for refinement and cultural adaptation. Lastly, the lack of external validation calls for future comparisons to assess external validity.

Implications and further studies

This study emphasizes the importance of cultural adaptation in psychometric tools, highlighting differences between the Persian and English versions of the PedsQL™ 3.0 Cancer Module. It stresses the need for tools to reflect cultural contexts to accurately assess quality of life and the value of integrating both child self-reports and parent proxy-reports for a comprehensive understanding of well-being. A 3-day test-retest interval was

useful in capturing short-term quality of life variations, suggesting its potential in dynamic contexts. Future research should focus on longitudinal studies, broader cultural inclusion, and psychometric analyses, along with exploring child-parent report discrepancies. Addressing sample diversity, parent-proxy reliability, and external validation will enhance the tool's utility and its ability to improve personalized care for children with cancer.

Ethical Considerations

This study did not involve any interventions. Ethical approval was granted by the Ethics Committee of Iran University of Medical Sciences in Tehran, Iran (Ethical Code: IR.IUMS.REC1395.9411355008). Prior to participation, informed consent was obtained from all the participants or their legal guardians.

The participants were ensured about the confidentiality of their responses and the anonymity of their data. All the data were securely stored and used exclusively for the purposes of this study. Participation was voluntary, and the individuals had the freedom to withdraw at any time without facing any negative consequences. The study strictly followed the ethical guidelines for research involving human subjects, ensuring that all the procedures would adhere to the established ethical standards.

Acknowledgments

We sincerely appreciate all the children with cancer and their families who participated in this study. We also extend our gratitude to the Iran University of Medical Sciences for their support in conducting this research. This work was conducted without the use of AI.

Authors' Contributions

Fatemeh Mahdizadeh Karizaki led the study design, data collection, analysis, and manuscript drafting. Afsoon Hassani Mehraban supervised the study and revised the manuscript. Hossein Alibakhshi contributed to data analysis, while Armin Hajizadeh assisted with literature review and editing. Farbod Matin Sadr supported data collection, and Maryam Mehdizadeh contributed to methodology and review. All authors approved the final manuscript

Funding

This study was funded by Iran University of Medical Sciences, Tehran, Iran

Conflict of Interest

The authors declare that there is no conflict of interests regarding the publication of this paper. All the authors have contributed to the work in a manner that justifies authorship, and there are no financial, personal, or professional interests that could have influenced the outcomes of this research.

References

1. Hashemi A, Kokab M, Kamalian M, Zarezadeh M, Sheikhpour E, Azod L, et al. The effect of Aloe vera syrup on prevention of fever and neutropenia in children with acute lymphoid leukemia. *Iran J Ped Hematol Oncol* 2020; 10(3): 144-149.
2. Eilertsen ME, Jozefiak T, Rannestad T, Indredavik MS, Vik T. Quality of life in children and adolescents surviving cancer. *EJON* 2012; 16(2): 185-193.
3. Wallander JL, Koot HM. Quality of life in children: a critical examination of concepts, approaches, issues, and future directions. *Clin Psychol Rev* 2016; 45: 131-143.

4. Rezaei Z, Sani MS, Ostadhashemi L, Harouni GG. Quality of life of mothers of children with cancer in Iran. *Koomesh* 2024; 20(3): 425-431.
5. Pizzo PA, Poplack DG. Principles and practice of pediatric oncology. *J Am Coll Surg* 1997; 2(185):203-204.
6. Pui CH, Gajjar AJ, Kane JR, Qaddoumi IA, Pappo AS. Challenging issues in pediatric oncology. *Nat Rev Clin Oncol* 2011; 8(9): 540-549.
7. Mulhern RK, Horowitz ME, Ochs J, Friedman AG, Armstrong FD, Copeland D, et al. Assessment of quality of life among pediatric patients with cancer. *Psychol Assess* 1989; 1(2): 130-138.
8. Varni JW, Katz ER, Colegrove R Jr, Dolgin MJ. Adjustment of children with newly diagnosed cancer: cross-informant variance. *J Psychosoc Oncol* 1995; 13(4): 23-38.
9. Varni JW, Burwinkle TM, Katz ER, Meeske K, Dickinson P. The PedsQL™ in pediatric cancer: reliability and validity of the pediatric quality of life inventory™ generic core scales, multidimensional fatigue scale, and cancer module. *Cancer* 2002; 94(7): 2090-2106.
10. Bruil J, Detmar SB. Measuring health-related quality of life in children: difficulties and challenges. *Expert Rev Pharmacoecon Outcomes Res* 2005; 5(5): 511-514.
11. Arbuckle R, Abetz-Webb L. "Not just little adults": qualitative methods to support the development of pediatric patient-reported outcomes. *The Patient* 2013; 6(3): 143-159.
12. Eiser C, Varni JW. Health-related quality of life and symptom reporting: similarities and differences between children and their parents. *Eur J Pediatr* 2013; 172: 1299-1304.
13. Montgomery KE, Vos K, Raybin JL, Ward J, Balian C, Gilger EA, et al. Comparison of child self-report and parent proxy-report of symptoms: results from a

longitudinal symptom assessment study of children with advanced cancer. *J Pediatr Nurs* 2021; 26(3): 1-10.

14. Upton P, Lawford J, Eiser C. Parent-child agreement across child health-related quality of life instruments: a review of the literature. *Qual Life Res* 2008; 17(6): 895-913.

15. Davis E, Davies B, Waters E, Priest N. The relationship between proxy-reported health-related quality of life and parental distress: gender differences. *Child Care Health Dev* 2008; 34(6): 70-83.

16. Eiser C, Morse R. Can parents rate their child's health-related quality of life? Results of a systematic review. *Qual Life Res* 2001; 10(4): 347-357.

17. Weaver MS, Wang J, Reeve BB, Porter AS, Baker JN, Mack JW, et al. Agreement and disagreement between child-caregiver symptom and function reports in pediatric oncology. *Pediatr Blood Cancer* 2024; 71(1): 1-9.

18. Gheissari A, Farajzadegan Z, Heidary M, Salehi F, Masaeli A, Mazrooei A, et al. Validation of Persian version of PedsQL™ 4.0™ generic core scales in toddlers and children. *Int J Prev Med* 2012; 3(5): 341-350.

19. Scarpelli AC, Paiva SM, Pordeus IA, Ramos-Jorge ML, Varni JW, Allison PJ. Measurement properties of the Brazilian version of the Pediatric Quality of Life Inventory (PedsQL™) cancer module scale. *Health Qual Life Outcomes* 2008; 6(1): 1-8.

20. Kabak VY, Yakut Y, Çetin M, Düger T. Reliability and validity of the Turkish version of the PedsQL 3.0 Cancer Module for 2-to 7-year-old and the PedsQL 4.0 Generic Core Scales for 5-to 7-year-old: the Hacettepe University experience. *Turk J Hematol* 2016; 33(3): 236-243.

21. Tsuji N, Kakee N, Ishida Y, Asami K, Tabuchi K, Nakadate H, et al. Validation of the Japanese version of the Pediatric Quality of Life Inventory

(PedsQL) cancer module. *Health Qual Life Outcomes* 2011; 9(1): 1-16.

22. Robert RS, Paxton RJ, Palla SL, Yang G, Askins MA, Joy SE, et al. Feasibility, reliability, and validity of the Pediatric Quality of Life Inventory™ generic core scales, cancer module, and multidimensional fatigue scale in long-term adult survivors of pediatric cancer. *Pediatr Blood Cancer* 2012; 59(4): 703-707.

23. Felder-Puig R, Frey E, Proksch K, Varni J, Gadner H, Topf R. Validation of the German version of the Pediatric Quality of Life Inventory™ (PedsQL™) in childhood cancer patients off treatment and children with epilepsy. *Qual Life Res* 2004; 13(1): 223-234.

24. Lau JT, Yu XN, Chu Y, Shing MM, Wong EM, Leung TF, et al. Validation of the Chinese version of the Pediatric Quality of Life Inventory™ (PedsQL™) cancer module. *J Pediatr Psychol* 2009; 35(1): 99-109.

25. de Rojas T, Neven A, Towbin AJ, Carceller F, Bautista F, Riedl D, et al. Clinical research tools in pediatric oncology: challenges and opportunities. *Cancer Metastasis Rev* 2020; 39: 149-160.

26. Mystakidou K, Tsilika E, Parpa E, Galanos A, Vlahos L. Brief cognitive assessment of cancer patients: evaluation of the mini-mental state examination (MMSE) psychometric properties. *Psycho-Oncology* 2007; 16(4): 352-357.

27. Sharma BP, Haque MI, Hossain MB, Sarker RJ, Abedin ES, Shahinuzzaman M, et al. Depression and anxiety status among informal caregivers of patients with cancer treated at selected tertiary hospitals in Nepal. *J Taibah Univ Med Sci* 2024; 19(3): 482-491.

28. Aaronson NK, Acquadro C, Alonso J, Apolone G, Bucquet D, Bullinger M, et al. International Quality of Life Assessment (IQOLA) Project. *Qual Life Res* 1992; 1(5): 349-351.

29. Mahdizadeh F, Mehraban AH, Faranoush M, Mohammadi A. Assessing the content and face validity of Persian version of fatigue scale in children with cancer, from the perspective of parents and hospital staffs. *J Clin Physiother Res* 2017; 2(4): 177-181.
30. Mitchell KA, Brassil KJ, Fujimoto K, Fellman BM, Shay LA, Springer AE. Exploratory factor analysis of a patient-centered cancer care measure to support improved assessment of patients' experiences. *Value Health* 2020; 23(3): 351-361.
31. Mahdizadeh F, Mehraban AH, Faranoush M, Amini M, Mehdizadeh M. Fatigue in children with cancer: Reliability and validity of the Persian version of child, parent, and staff fatigue scale. *Asia Pac J Oncol Nurs* 2020; 7(2): 174-179.
32. Hajjar ST. Statistical analysis: internal-consistency reliability and construct validity. *Int J Quant Qual Res Methods* 2018; 6(1): 27-38.
33. Nunnally JC, Bernstein IH. *Psychometric Theory*. 3rd Ed. New York: McGraw-Hill; 1995; 60(2):313-315.
34. Marx RG, Menezes A, Horovitz L, Jones EC, Warren RF. A comparison of two time intervals for test-retest reliability of health status instruments. *J Clin Epidemiol* 2003; 56(8): 730-735.
35. Weertman A, Arntz A, Dreesen L, van Velzen C, Vertommen S. Short-interval test-retest interrater reliability of the Dutch version of the Structured Clinical Interview for DSM-IV personality disorders (SCID-II). *J Pers Disord* 2003; 17(6):562-567.
36. Rahnemoon SN, Ahangar AA, Nourmohammadi E. Thematic structure and translation: A case study of the translation of English news into Persian. *Lingua* 2017; 194: 26-50.
37. Hatami G, Motamed N, Ashrafzadeh M. Confirmatory factor analysis of Persian adaptation of multidimensional students' life satisfaction scale (MSLSS). *Soc Indic Res* 2010; 98: 265-271.
38. Please NW. Comparison of factor loadings in different populations. *Br J Math Stat Psychol* 1973; 26(1): 61-89.
39. Olschewski M, Schulgen G, Schumacher M, Altman DG. Quality of life assessment in clinical cancer research. *Br J Cancer* 1994; 70(1): 1-5.
40. Rojas M. Quality of life, conceptualization. In: *Encyclopedia of Quality of Life and Well-Being Research*. Cham: Springer International Publishing; 2024; 5747-5751.
41. Hadjistavropoulos T, Craig KD. A theoretical framework for understanding self-report and observational measures of pain: a communications model. *Behav Res Ther* 2002; 40(5): 551-570.
42. Zborowski M. Cultural components in responses to pain. *J Soc Issues* 1952; 8(4):1-9.
43. Shun SC, Beck SL, Pett MA, Berry PH. Psychometric testing of three Chinese fatigue instruments in Taiwan. *J Pain Symptom Manag* 2006; 32: 155-167.