Journal of Health Literacy

Breast Cancer Literacy Assessment Tool (B-CLAT): Psychometric Properties of the Persian Version

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Background and Objective: Assessing women's literacy about breast cancer is essential to identify existing knowledge gaps and design effective interventions. To translate, culturally adapt, and psychometrically evaluate the Breast Cancer Literacy Assessment Tool (B-CLAT) for use among Iranian women.

Materials and Methods: This methodological study was conducted in 2024–2025 among 400 women attending comprehensive health service centers in Tehran, Iran, selected through multistage sampling, to translate and validate the B-CLAT, originally developed in the U.S. The translation process followed the standard forward–backward method by two independent translators in each phase. Face validity was assessed by 10 women, and content validity by 10 experts, according to standard methodological practice. content validity ratio and content validity index were calculated. Construct validity was examined using confirmatory factor analysis and the known-groups method, comparing literacy scores by age and education. Reliability was determined through internal consistency (Cronbach's alpha) and stability (Intra-class Correlation Coefficient) in a sample of 30 participants. Data were analyzed using SPSS 16 and EQS 6.4 software.

Results: Most participants were aged 30–39 years (46%), married (82.5%), and had a university degree (69.3%). The cultural adaptation of the Persian version showed satisfactory equivalence. The overall CVI was 0.942, indicating strong content validity. CFA confirmed acceptable model fit indices (RMSEA=0.063, IFI=0.913, CFI=0.903, GFI=0.919, CMIN/DF=2.956, MFI=0.933, AGFI=0.900). Known-groups comparison showed no significant relationship between literacy scores and age ($P>0.05$), but a significant association with education level ($P<0.05$), confirming construct validity. Reliability analysis indicated acceptable stability (ICC=0.868) and internal consistency ($\alpha=0.722$).

Journal of Health Literacy

Conclusion: The Persian version of the Breast Cancer Literacy Assessment Tool (IB-CLAT) demonstrated good validity and reliability. It can effectively assess breast cancer literacy among Iranian women, guide educational interventions, and promote screening and prevention behaviors.

Keywords: Breast Cancer, Health Literacy, Psychometrics

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Introduction

Breast cancer is the most common malignancy among women worldwide and was the leading cause of cancer-related death in women in 2020 (1). According to the World Health Organization (WHO), approximately 2.3 million women were diagnosed with breast cancer in 2022, and an estimated 670,000 lost their lives to the disease (2). In Iran, breast cancer is also the most frequently diagnosed cancer and the primary cause of cancer-related mortality among women (3). A 2022 report by the International Agency for Research on Cancer (IARC, GLOBOCAN 2022), recorded 15,492 new breast cancer cases in Iran, ranking it as the second most common cancer after stomach cancer. These cases represented 11.3% of all newly diagnosed cancers in the country, with a cumulative risk of 1.3%—meaning that nearly 3 out of every 100 Iranian women are expected to develop breast cancer during their lifetime (4). Research in Iran has shown that the onset of breast cancer occurs nearly a decade earlier than in many other countries, and approximately 71% of cases are diagnosed at advanced stages (5). These findings emphasize the need to implement effective strategies in breast cancer prevention, early detection, and management at all levels of prevention (6).

Environmental and lifestyle modifications, vaccination, and early detection through screening programs can prevent nearly half of all breast cancer cases and related deaths (7, 8). In Iran, five-

and ten-year survival rates among breast cancer patients have been reported at 80% and 69%, respectively (3). Survival outcomes are strongly linked to individuals' levels of education and awareness. Therefore, enhancing individuals' understanding of breast cancer risks and management—commonly referred to as health literacy—is essential for effective prevention, timely diagnosis, and improved treatment outcomes at every stage of breast cancer care (9). This highlights the critical need to examine health literacy in the context of breast cancer, as it directly influences patients' engagement with preventive measures, screening programs, and treatment adherence (10).

Health literacy in the context of cancer refers to "all the knowledge a layperson needs to possess to understand the information and advice the health system has to offer with regard to preventing, diagnosing, and treating cancer" (7, 11). It encompasses three core dimensions: functional, interactive, and critical. Functional health literacy refers to a woman's ability to comprehend her own and her family's risk for developing cancer, understand preventive strategies such as early screening and lifestyle modifications, and access healthcare services and professional support (12). Interactive health literacy involves the ability to actively engage in health-related situations, extract and comprehend information, and apply it effectively to changing circumstances. Critical health literacy encompasses the cognitive and social skills required to critically evaluate the relevance and reliability of health information for personal decision-making, such as assessing the performance of healthcare providers (13). Individuals with low health literacy often lack a clear understanding of their health conditions and may be unaware of the importance of routine screenings and self-examinations in cancer prevention and early detection (14). Following diagnosis, awareness of the disease, its risk factors, and available treatment options becomes essential for controlling disease progression. Health literacy also plays a key role in reducing fear and anxiety, increasing patient satisfaction with the recovery process, and enabling informed decision-making during treatment (15). Studies have shown that individuals with low health literacy are at a higher risk of developing cancer (7) and, among breast cancer patients, have greater fear of recurrence, poorer quality of life, weaker social support,

and more unmet needs in accessing primary care services (16). Therefore, enhancing public knowledge and health literacy is crucial for promoting healthy lifestyles and supporting cancer prevention and control efforts (7).

Improving health literacy has become one of the most important global public health priorities (17). Various tools have been developed to measure this concept, each based on different perspectives and often serving diverse measurement purposes. For instance, the Health Literacy Scale (HLS) was developed and psychometrically validated in 2022 to assess health literacy among literate Turkish-speaking adults (17). Similarly, in 2023, Tian et al. developed and validated the Hong Kong Health Literacy Scale (HLS-HK), a 31-item instrument grounded in Nutbeam's framework, which measures three domains of health literacy: functional, interactive, and critical health literacy (18). The large number and diversity of health literacy assessment tools have encouraged researchers to examine and compare them. For example, a study conducted by Jessup et al. in 2023 compared four widely used instruments, namely the Test of Functional Health Literacy in Adults (TOFHLA), the Newest Vital Sign (NVS), the European Health Literacy Survey Questionnaire (HLS-EU-Q47), and the Health Literacy Questionnaire (HLQ). The findings revealed that although all these instruments assess the overarching concept of health literacy, the correlations among them were low to moderate (19). This discrepancy is attributed to the fact that each instrument targets different constructs of health literacy. Therefore, understanding the differences between these tools is essential, enabling researchers to select the most appropriate instrument according to their specific research objectives.

Assessing breast cancer health literacy is essential, as it helps identify high-risk populations and supports behavior change by promoting preventive measures such as cancer screening and the adoption of healthy lifestyles. It also guides the development and evaluation of targeted educational interventions (7, 20). Such assessments enable health educators to determine the effectiveness of their programs and ensure that core concepts are clearly communicated to the intended audience. However, collecting this critical information requires the use of a valid and

reliable tool specifically designed for research purposes. Thus, the first step is to ensure access to an appropriate tool tailored to these needs.

Breast Cancer Literacy Assessment Tool: Original version of the B-CLAT

The B-CLAT is a well-known tool developed by Williams et al. (21) in 2013 and psychometrically validated in three versions of English, Arabic, and Spanish. This tool consists of 34 items that assess breast cancer literacy in non-specialist individuals across three dimensions including 1) awareness, 2) knowledge and screening, and 3) prevention and control. The B-CLAT was developed to assess women's health literacy regarding breast cancer and was implemented as part of a community-based intervention called Kin KeeperSM. In this study, 21 Community Health Workers (CHWs) from three ethnic groups (Arab, Latina, and African American) participated. Each CHW identified women from their active caseload who belonged to the same ethnic group and administered the tool during home visits. The assessment was conducted orally, in the participant's preferred language (English, Spanish, or Arabic), to ensure accurate evaluation of functional health literacy regardless of reading ability. For the psychometric evaluation, confirmatory factor analysis and calculation of Cronbach's alpha were employed. The reported results indicated acceptable validity and reliability of the tool among women from three different ethnic groups. Most existing instruments are limited to assessing general health literacy, and to date, no disease-specific tool for evaluating breast cancer–related health literacy has been identified in Iran. The only available instrument is the HELBA questionnaire, which was designed for use among patients with breast cancer and primarily focuses on secondary and tertiary levels of prevention. Although multidimensional health literacy instruments such as All Aspects of Health Literacy Scale (AAHLS) and Cancer Health Literacy Scale (C-HLS) exist, they are not fully aligned with the objectives of this study. AAHLS assesses general health literacy and is not cancer-specific, while C-HLS was developed for individuals with newly diagnosed cancer and focuses on early treatment-related needs. Given that the aim of the present study is to assess functional health literacy related to breast cancer among healthy women at the level of primary prevention, the B-CLAT was selected as the most appropriate instrument. This choice ensures a focus on preventive education and aligns with the study's objective of identifying gaps in breast cancer

literacy within the Iranian population. In contrast, the B-CLAT instrument is applicable at the level of primary prevention among healthy women and can serve as an appropriate tool for identifying and assessing educational needs related to the prevention of breast cancer. Its design is aligned with Iran's healthcare priorities, supporting the development of targeted educational interventions, informed policy planning, and national health literacy initiatives, including screening promotion and community-based programs. Nonetheless, a key limitation should be acknowledged: relying on self-reported responses may introduce reporting bias, highlighting the need for careful interpretation and, where possible, supplementation with complementary assessment methods.

Several tools have been developed and utilized in Iran to assess awareness and literacy related to breast cancer; however, none have specifically addressed functional health literacy in this context. For instance, The Health literacy for women with breast cancer (HELBA) tool was designed and psychometrically evaluated by Khalili et al. in 2017 to assess breast cancer literacy in Iran. This tool specifically focuses on measuring breast cancer literacy among women diagnosed with breast cancer and is not applicable for preventive purposes in healthy women (22). Another study conducted by Rakhshkhorshid et al. in 2018 aimed to investigate the relationship between health literacy and awareness, perception, and breast cancer screening. In this study, two tools were used for data collection: the Iranian Health Literacy Questionnaire (IHLQ) and the Champion's Health Belief Model Scale (23). However, neither of these tools assesses specifically functional breast cancer literacy. Functional health literacy represents the most fundamental level of health literacy and plays a critical role in empowering individuals to make informed decisions regarding prevention, screening, and treatment. Possessing this type of literacy can effectively contribute to reducing the disparities of disease (24). The B-CLAT has been specifically designed to measure functional health literacy related to breast cancer and thus fills a significant gap in the existing assessment tools. It effectively addresses all aspects of breast cancer literacy, and since its design incorporates cultural and social diversity, it enhances its adaptability to Iranian culture and society. This study aims to translate and psychometrically validate the Persian version of this tool.

Iranian researchers will utilize it to assess breast cancer health literacy, identify existing gaps in this crucial aspect and high-priority population, and ultimately design and implement appropriate policies and educational interventions for the prevention of this disease.

Materials and Methods

Study Design & Population

This methodological study was conducted in 2024–2025 among women covered by the comprehensive health service centers affiliated with Shahid Beheshti University of Medical Sciences in Tehran, Iran.

The minimum recommended number for forming an expert panel is 5 to 7 members. Also, for face validity assessment, it is generally recommended to use the feedback of 5 to 10 members of the target population (25). Therefore, content validity was evaluated by a panel of 10 experts, while face validity was assessed by 10 women attending the centers who were not part of the main study. According to existing guidelines, the appropriate sample size for construct validity analysis ranges from 50 to over 1000 participants (26).

Sampling was performed using a multistage method. Shahid Beheshti University of Medical Sciences, which covers a large and diverse population, was selected as the study setting. Due to the lack of access to a complete list of eligible individuals, a multistage approach was adopted to ensure feasibility and representativeness. Based on the recommended number of 5 to 10 participants per item (27), the minimum required sample size was calculated to be 310. Considering that a sample size of 300 to 400 is recommended for confirmatory factor analysis (28), and to enhance statistical power and obtain stable parameter estimates, a total of 400 participants were included in the study. First, three university headquarters (Shemiranat, North, and East) were considered as strata. In the second stage, the comprehensive health service centers affiliated with each selected headquarters were considered as clusters. A complete list of centers under each headquarters was prepared, and each center was assigned a unique identification number. Using a lottery-based random selection method, a total of eight centers were selected as clusters, including one center from Shemiranat, four centers from the East, and

three centers from the North. In the final stage, 50 eligible women from each selected center were recruited using convenience sampling. Inclusion criteria included providing informed consent and having no history of breast cancer. Exclusion criteria were incomplete questionnaire responses, immigrant status, inadequate literacy, and inability to read, write, or understand Persian **(Figure 1).**

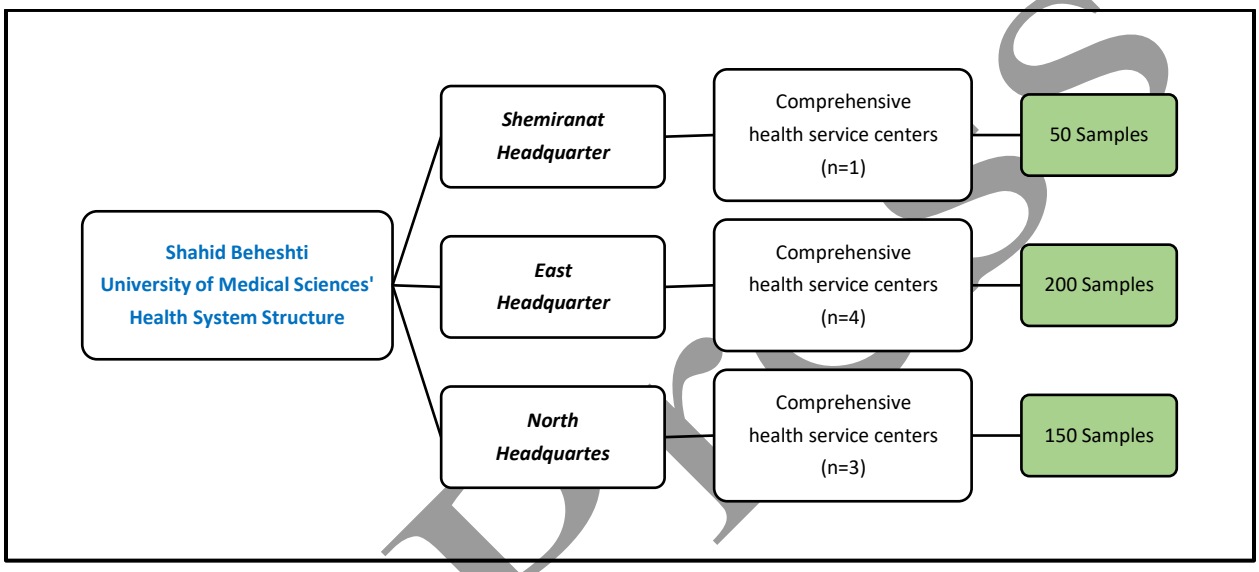

Figure 1. Sampling method process

Original Tool

The tool used in this study was a questionnaire comprising two sections. The first section included questions related to participants' demographic characteristics such as; age, marital status, employment status, educational level, economic status, number of pregnancies, health insurance coverage, frequency of internet use for searching health-related information, and membership in virtual health-related groups. The Breast Cancer Literacy Assessment Tool, or briefly B-CLAT, was the second section of the questionnaire, which was designed and psychometrically evaluated in 2013 by Williams et al. to assess breast cancer literacy. The tool demonstrated varying levels of reliability (Cronbach's alpha), ranging from 0.81 among African American participants to 0.73 in the overall culturally diverse sample, with the lowest alpha (0.61) observed among Latino participants (21). The B-CLAT is available in English, Spanish, and Arabic and consists of 34 items

across three dimensions: awareness, knowledge and screening, and control and prevention. The awareness dimension includes 6 items, the knowledge and screening dimension comprises 13 items, and the control and prevention dimension contains 15 items. Here, we aimed to culturally adapt and validate the B-CLAT for use among Iranian women. Psychometric evaluation is a critical step in the development of valid measurement tools, with validity and reliability being two key indicators of tool quality (29). In present study, the tool's validity was assessed through translation procedures, as well as evaluations of face, content, and construct validity. Its reliability was examined using methods assessing internal consistency and stability.

Validity

A. Translation & Cross-cultural Validity

The translation process followed the WHO's standardized protocol (30). First, two experts fluent in English independently translated the original tool into Persian. Their translations were then reviewed and synthesized into a single version. Next, two additional bilingual experts—unfamiliar with the original tool —independently performed back-translations of the Persian version into English. The research team compared these back-translated versions with the original to ensure conceptual and linguistic equivalence. Due to the high level of agreement between the original and back-translated versions, the Persian version was approved for further validation. Cultural adaptation was integrated throughout the translation process, with adjustments made to ensure the tool's relevance and clarity within the Iranian context. Several challenges emerged during translation, including the identification of accurate Persian equivalents for specialized terms, aligning certain concepts with local cultural norms, and maintaining both scientific rigor and linguistic simplicity. These issues were addressed through iterative discussions in consensus meetings among all translators and researchers, followed by multiple rounds of revision to ensure semantic accuracy, cultural adaptation and clarity of language in the finalized tool.

B. Content Validity

Content validity was evaluated using both qualitative and quantitative methods. For the qualitative assessment, a panel of 10 experts—comprising six specialists in health education and promotion with expertise in measurement tools development and psychometrics in the field of

women's health, as well as experience in planning interventions related to cancer, particularly breast cancer. along with four professionals in women's health (including one midwife, two gynecologists, and one radiologist)—reviewed the tool. They assessed each item based on criteria such as grammatical correctness, appropriateness of wording, clarity of phrasing, and the relevance and comprehensibility of response scales. Revisions were made accordingly to improve clarity, linguistic precision, and cultural appropriateness. In the quantitative phase, content validity was assessed using Content Validity Ratio (CVR) and Content Validity Index (CVI). Experts rated each item on a three-point scale: "essential," "useful but not essential," and "not essential." CVR values were calculated using the following formula (31), and based on Lawshe's critical value table (32), items with a CVR above 0.62 were retained. This process ensured that only items deemed necessary by the majority of experts were included in the final version of the tool.

$$CVR = \frac{n_E - \frac{N}{2}}{\frac{N}{2}}$$

n_E = the number of experts who answered the necessary option / N = the total number of experts

To assess CVI, each item was independently evaluated by the expert panel based on three criteria: simplicity, relevance, and clarity. A 4-point Likert scale was used for scoring (1 = not relevant, 2 = somewhat relevant, 3 = relevant, and 4 = highly relevant). CVI for each item was calculated by dividing the number of experts who assigned a score of 3 or 4 by the total number of experts (33). Items with a CVI greater than 0.79 were considered acceptable and retained in the tool.

C. Face Validity

Face validity, which examines whether the tool appears appropriate and understandable to the target population (31), was assessed qualitatively through feedback from the target population. The B-CLAT is a breast cancer literacy assessment tool designed to identify educational needs for preventive purposes. Thus, for the assessment of face validity, the Persian version of the B-CLAT was administered to 10 women recruited from comprehensive health service centers affiliated with Shahid Beheshti University of Medical Sciences. Participants were selected based on the

study's inclusion criteria, with efforts made to ensure maximum demographic diversity. Participants were asked to provide feedback on aspects such as the fluency, clarity, transparency, and relevance of the items. Based on their input, necessary revisions were made to improve the tool's readability and comprehensibility. Notably, these women did not take part in the subsequent phases of the psychometric evaluation.

D. Construct Validity

Construct validity assesses the extent to which an tool accurately measures the intended construct (31). In this study, construct validity was evaluated using two approaches: Confirmatory Factor Analysis (CFA) and known-groups comparison, based on a sample of 400 participants. Since the B-CLAT has a previously established factor structure, CFA was employed rather than Exploratory Factor Analysis (EFA), which is typically applied when the factor structure is unknown. CFA was used to determine how well the observed items represent the underlying factors and to examine the suitability of each item in measuring its respective domain (28). The theoretical framework and factor structure established by Williams et al. (2013) during the original development of the B-CLAT were adopted to guide the analysis (21). This approach ensured alignment with the original validation process and allowed us to assess whether the Persian version retained the same factor structure. Model fit was evaluated using standard goodness-of-fit indices. In the known-groups comparison, two hypotheses were formulated:

(1) There is no significant difference in mean breast cancer literacy scores across different age groups, and

(2) Individuals with higher educational attainment are expected to have higher levels of breast cancer literacy.

Reliability (Stability & Internal Consistency)

To evaluate the reliability of the tool, it was administered to a group of 30 women attending comprehensive health service centers on two separate occasions, with a two-week interval between the administrations to minimize recall bias. Test-retest reliability was assessed by

calculating Intra-class Correlation Coefficient (ICC). Additionally, internal consistency was evaluated using Cronbach's alpha coefficient.

Data Analysis

Following data collection via the questionnaire, responses were compiled and entered into the system using appropriate software. Data analysis was conducted using SPSS version 16 (34) for descriptive statistics and reliability analyses, while CFA was performed using EQS version 6.4. Content validity was examined through the calculation of CVR and CVI. Construct validity was assessed using CFA and known-groups comparison. Reliability was evaluated in two ways: stability was measured through the test-retest method and ICC, while internal consistency was assessed using Cronbach's alpha coefficient.

Results

In total, data from 400 women were analyzed. Of these participants, 184 (46%) were aged between 30 and 39 years. The majority were married (n=330; 82.5%), and nearly half (n = 197; 49.3%) held a diploma or bachelor's degree. Most participants were unemployed (n=242; 60.5%) and reported having an average economic status (n = 256; 64.8%). The most frequently reported number of pregnancies was one (n=135; 33.8%). Additionally, 233 women (58.3%) had health insurance coverage, 146 (36.5%) used the internet to some extent for searching health-related information, and 207 (51.7%) were members of virtual health-related groups **(Table 1).**

Table 1. Demographic characteristics, Internet usage to search for health-related content, and Membership-SNG

Variables / Groups		N (%)
Age	20-29	115 (28.7)
	30-39	184 (46.0)
	40 & more	101 (25.3)
Marital Status	Single	70 (17.5)
	Married	330 (82.5)
Education level	Diploma & below	123 (30.8)
	Associate's & Bachelor's degrees	197 (49.3)
	MSc & PhD	80 (20.0)
Employment status	Non-Employed	242 (60.5)
	Employed	158 (39.5)

Journal of Health Literacy

Economic status	Week	45 (11.3)
	Middle	256 (64.8)
	Good	96 (24.0)
Pregnancy Frequency	No pregnancy	105 (26.3)
	One pregnancy	135 (33.8)
	Two pregnancies	93 (23.3)
	Three pregnancies & more	67 (16.8)
Insurance	Has	233 (58.3)
	Not has	167 (41.8)
Internet usage to search for health-related content	Very much	135 (33.8)
	Much	119 (29.8)
	Some	146 (36.5)
Membership-SNG	Yes	193 (48.3)
	No	207 (51.7)

The translation of the tool followed a standard forward–backward translation procedure to ensure the preservation of the original meaning. Initially, the tool was translated from English to Persian and then back-translated from Persian to English by independent bilingual experts. Following a thorough comparison and alignment of the original and back-translated versions, necessary cultural adaptations were made to enhance contextual relevance. The final Persian version was thus developed, preserving the intended meanings of the items while ensuring cultural appropriateness.

Content validity was evaluated by an expert panel with a mean age of 42 ± 9.8 years **(Table 2 for demographic characteristics).** During the qualitative assessment, panel members reviewed the tool and provided detailed feedback. Based on their recommendations, the response option “I don’t know” or “I have no opinion” was added to all items to better capture knowledge gaps and facilitate more accurate responses. Furthermore, to eliminate ambiguity, the term “radiologist” was added in parentheses next to “X-ray technician” wherever it appeared. In addition, item 31 was revised based on expert input: the word “program,” which did not clearly convey the intended meaning in the Iranian context, was replaced with “centers” to enhance clarity and cultural relevance.

Table 2. Demographic Characteristics of Expert Panel Members

Journal of Health Literacy

Variable	Group	N (%)
Gender	Male	2 (20.0)
	Female	8 (80.0)
Educational level	Bachelor Degree	1 (10.0)
	Ph.D.	6 (60.0)
	Professional Doctorate	3 (30.0)
Area of Expertise	Health education & health promotion	6 (60.0)
	Midwifery	1 (10.0)
	Gynecology	2 (20.0)
	Radiology	1 (10.0)
Years of Experience	< 5	2 (20.0)
	5-10	3 (30.0)
	10-15	2 (20.0)
	> 15	3 (30.0)
Job Position	Faculty Member	3 (30.0)
	Health Education and Promotion Consultant	2 (20.0)
	Public Health Researcher	1 (10.0)
	Clinical Midwifery Instructor	1 (10.0)
	Radiology Specialist	1 (10.0)
	Gynecologist	2 (20.0)

The quantitative assessment of content validity was performed by calculating CVI and CVR. The CVI scores for relevance, clarity, and simplicity were 0.967, 0.929, and 0.932, respectively, resulting in an overall mean CVI of 0.942. In the CVR evaluation, three items (numbers 1, 15, and 18) received values of 0.40, 0.40, and 0.20, respectively, which fell below the acceptable threshold of 0.62. Following consultation and approval by the research team, these items were excluded from the final tool **(Table 3).**

Table 3. Content Validity Ratio and Content Validity Index of IB-CLAT

Item	CVR	CVI			Final status
		Relevance	Clarity	Simplicity	
1. Although there are many different names for types of cancers you can get them the same way.	0.4	0.7	0.8	0.7	excluded
2. Breast Cancer is	1	1	1	0.8	retained
3. If someone hits my breast, I will get breast cancer.	0.2	0.8	0.9	0.8	retained
4. Which of the following can lead to breast cancer?	0.8	1	1	1	retained
5. Women with large breasts are more likely to get breast cancer compared to women with small breasts	0.4	1	0.9	0.9	retained
6. Breastfeeding a baby can protect you from getting breast cancer.	1	1	1	1	retained
7. Who does breast self-examination, and how often?	1	1	0.8	0.9	retained

Journal of Health Literacy

8. Breast self-examination should be done	1	1	1	1	retained
9. To perform breast self-examination, I should use	1	1	0.9	0.9	retained
10. Swelling of the all or part a breast (even if no lump is felt) is a possible sign of breast cancer.	1	1	1	1	retained
11. Who does a clinical breast examination, and how often?	1	0.9	0.8	0.8	retained
12. A clinical breast examination should be done	1	1	1	1	retained
13. Who does a mammography, and how often?	1	1	1	1	retained
14. Mammography should be done	1	1	0.9	0.8	retained
15. Which of these commonly used screening practices are the same?	0.4	1	0.8	0.7	excluded
16. Which of the following statements are correct?	0.8	0.8	0.9	0.9	retained
17. Mammography can cause breast cancer to spread.	0.6	0.9	0.9	0.9	retained
18. You only need to get a mammogram if you have been diagnosed with breast cancer	0.2	0.9	0.6	0.7	excluded
19. Getting a yearly mammogram beginning at age 40 decreases my probability of dying from breast cancer.	1	1	1	1	retained
20. Annual screenings increase a woman's chance of surviving breast cancer.	1	1	1	1	retained
21. Having breast cancer screening does not mean that I will never get breast cancer.	1	1	1	1	retained
22. If I find a lump under my arm, I should	1	1	0.9	1	retained
23. My family history of breast cancer or prostate cancer may mean I should start mammography earlier than age 40.	0.8	0.9	0.9	1	retained
24. If a family member has had breast cancer, I am at higher risk of developing it.	1	1	0.9	1	retained
25. I may also be at risk of developing breast cancer.	1	1	1	1	retained
26. Women who are overweight have an increased risk of developing breast cancer.	1	1	1	1	retained
27. Women who eat a lot of high-fat foods increase risk of breast cancer.	0.8	1	1	1	retained
28. I am confident that I know how to perform breast self-examination correctly.	1	1	1	1	retained
29. I can reduce my risk of breast cancer by	1	1	1	1	retained
30. I can prevent breast cancer by taking vitamins.	1	1	0.8	1	retained
31. Breast cancer screening is available for women without health insurance at health centers (such as hospitals, clinics, laboratories, etc.).	1	1	1	1	retained
32. Do you know centers that provide breast cancer screening covered by insurance?	1	1	1	1	retained

Journal of Health Literacy

33. There are centers that offer breast cancer screening (such as clinical breast examinations) at low cost or free of charge.	1	1	1	1	retained
34. I know how to guide my family members to receive breast cancer screening services at a low cost.	0.8	1	0.9	0.9	retained
Average		0.942			

In the next phase, the tool was administered to 10 individuals from the target population who were not involved in the main study to evaluate qualitative face validity (See supplementary file 1 for participants' demographic characteristics). Based on their feedback, several modifications were made to enhance the clarity and transparency of the items. For instance, most participants recommended adding the response options "I don't know" and "I have no opinion" to the items. These revisions were also aligned with the suggestions provided by the expert panel.

In the original tool, items 7, 11, and 13 addressed both who conducted the screening and how often it occurred. Based on participant feedback, the phrase "How often?" was added to these items to better align the questions with their response options. Additionally, the phrase "my chance of death" in item 19 was found to evoke negative emotions, so it was replaced with the more neutral term "my probability of death." Furthermore, the term "sources" in item 31 was unclear and confusing for respondents. To improve clarity, it was replaced with "healthcare center," along with examples such as hospitals, clinics, and laboratories in parentheses that were added to the item **(Table 4).**

Table 4. Changes made based on women's opinions in the face validity

Original item	Persian version
Who does a breast self-examination?	Who does breast self-examination and how often?
Who does a clinical breast examination?	Who does a clinical breast examination and how often?
Who does a mammogram?	Who does a mammogram and how often?
Getting a yearly mammogram beginning at age 40 decreases my chances of dying from breast cancer.	Getting a yearly mammogram beginning at age 40 decreases my probability of dying from breast cancer.
Resources for breast cancer screening are available for women without health insurance.	Breast cancer screening is available for women without health insurance at health centers (such as; hospitals, clinics, laboratories, etc.).

CFA was conducted on data from 400 women to evaluate the tool's factor structure. The model fit was assessed using several indices. The Goodness of Fit Index (GFI) indicates how well the sample data fit the proposed model, with values above 0.9 reflecting a good fit. The Adjusted Goodness of Fit Index (AGFI) is a modified version of GFI that also accounts for model complexity, with values above 0.9 considered desirable. The Comparative Fit Index (CFI) and Incremental Fit Index (IFI) compare the performance of the proposed model with a baseline model, and values above 0.9 indicate an acceptable fit; these indices are particularly important in psychometrics as they confirm the alignment of the factor structure with the observed data. The McDonald's Fit Index (MFI) similarly measures the correlation between the observed and modeled matrices. Finally, the Root Mean Square Error of Approximation (RMSEA) reflects the approximate error of the model in the population, with values below 0.08 indicating an acceptable fit and values below 0.05 indicating a very good fit. Using these indices is crucial in psychometrics because they allow researchers to assess the structural validity of measurement tools and ensure that the factors and items accurately measure the intended psychological constructs (35). The results indicate that the three-factor model of the tool fits the data well. Specifically, the RMSEA value of 0.063 reflects a low approximation error. The GFI (0.919) and AGFI (0.90) indices suggest a good fit, while the MFI (0.933), CFI (0.903) and IFI (0.913) also confirm an acceptable model fit. Additionally, the CMIN/DF value of 2.956 lies within the desirable range, further supporting the model's structural validity. Overall, these fit indices confirm the appropriateness of the tool's factorial structure. Diagram 1, generated using EQS version 6.4, illustrates the CFA results. The 31 items are grouped into three factors: 1) Awareness (items 1–5), 2) Knowledge and Screening (items 6–16), and 3) Prevention and Control (items 17–31). Factor loadings for each item are presented on the arrows pointing to the corresponding factors. This diagram provides a visual representation of the tool's factorial structure and supports the CFA results reported in the manuscript. Significant positive correlations were observed between the factors: the correlation (r) between Awareness and Knowledge and Screening, as well as Awareness and Prevention and Control, was 0.44, while the correlation between Knowledge and Screening and Prevention and

Journal of Health Literacy

Control was stronger at 0.85 (P < 0.001). More details about the items, factor loadings, and associated dimensions are provided in Supplementary File 2 **(Table 5, Diagram 1).**

Table 5. Model Fit Indices of IB-CLAT

FIT INDICES	CMIN	DF	CMIN/DF	AGFI[1]	GFI[2]	IFI[3]	CFI[4]	MFI[5]	RMR[6]	RMSEA[7]
Results	1265.462	428	2.956	0.900	0.919	0.913	0.903	0.933	0.044	0.063
Acceptable Domain	-	-	1-3	≥ 0.90	≥ 0.90	≥ 0.90	≥ 0.90	≥ 0.90	≤ 0.08	≤ 0.08

[1] *Adjusted Goodness of Fit Index*
[2] *Goodness of Fit Index*
[3] *Incremental Fit Index*
[4] *Comparative Fit Index*
[5] *Mcdonald's Fit Index*
[6] *Root Mean-square Residual*
[7] *Root Mean Square Error of Approximation*

To further assess construct validity through known-groups comparison, the mean breast cancer literacy scores were analyzed across different age groups and educational levels. Results from the ANOVA test revealed no significant differences in literacy scores among the various age groups (P-value=0.691). However, a statistically significant difference was found based on educational level (P-value=0.001), with individuals holding higher levels of education demonstrating significantly greater breast cancer literacy. These findings support the study's hypotheses and confirm that the tool effectively differentiates between known groups. Therefore, the construct validity of the tool is supported **(Table 6).**

Table 6. Results of Known Groups Method for IB-CLAT Construct Validity

Group		N	IB-CLAT Mean (SD)	ANOVA	
				F	Sig.
All		400	53.45 (7.83)	-[a]	-
Age	20-29	115	53.16 (8.85)	0.369	0.691
	30-39	184	53.32 (7.49)		
	40 & more	101	54.03 (7.23)		
Education level	Diploma & below	123	50.49 (7.18)	16.775	0.001
	Associate's & Bachelor's degrees	197	54.02 (7.78)		
	MSc & PhD	80	56.62 (7.47)		

[a] Not applicable.

Journal of Health Literacy

To assess the reliability of the tool, both internal consistency and stability were evaluated. The calculated Cronbach's alpha coefficients for the three subscales—Awareness, Screening, and Prevention—were 0.720, 0.687, and 0.744, respectively. The overall Cronbach's alpha for the entire tool was 0.722, indicating acceptable internal consistency. In terms of stability, the ICC was found to be 0.868 (P-value = 0.001), demonstrating a high level of agreement between the scores from the first and second administrations. This result confirms the reproducibility of the subscales and the tool as a whole, indicating strong stability and reliability of the IB-CLAT **(Table 7).**

Table 7. The Stability and Internal Consistency Reliability of IB-CLAT

Dimensions (Name)	Number of items	Cronbach's α Coefficient	ICC*
F1 (Awareness)	5	0.720	0.964
F2 (Screening & Knowledge)	11	0.687	0.824
F3 (Prevention & Control)	15	0.744	0.948
IB-CLAT	31	0.722	0.868
*ICC=Intra-class Correlation Coefficient - Confidence Interval 95%			

Finally, following the psychometric evaluation process, the Iranian version of the B-CLAT (IB-CLAT)—comprising 31 items across three subscales—was developed for use in Persian-speaking populations.

Journal of Health Literacy

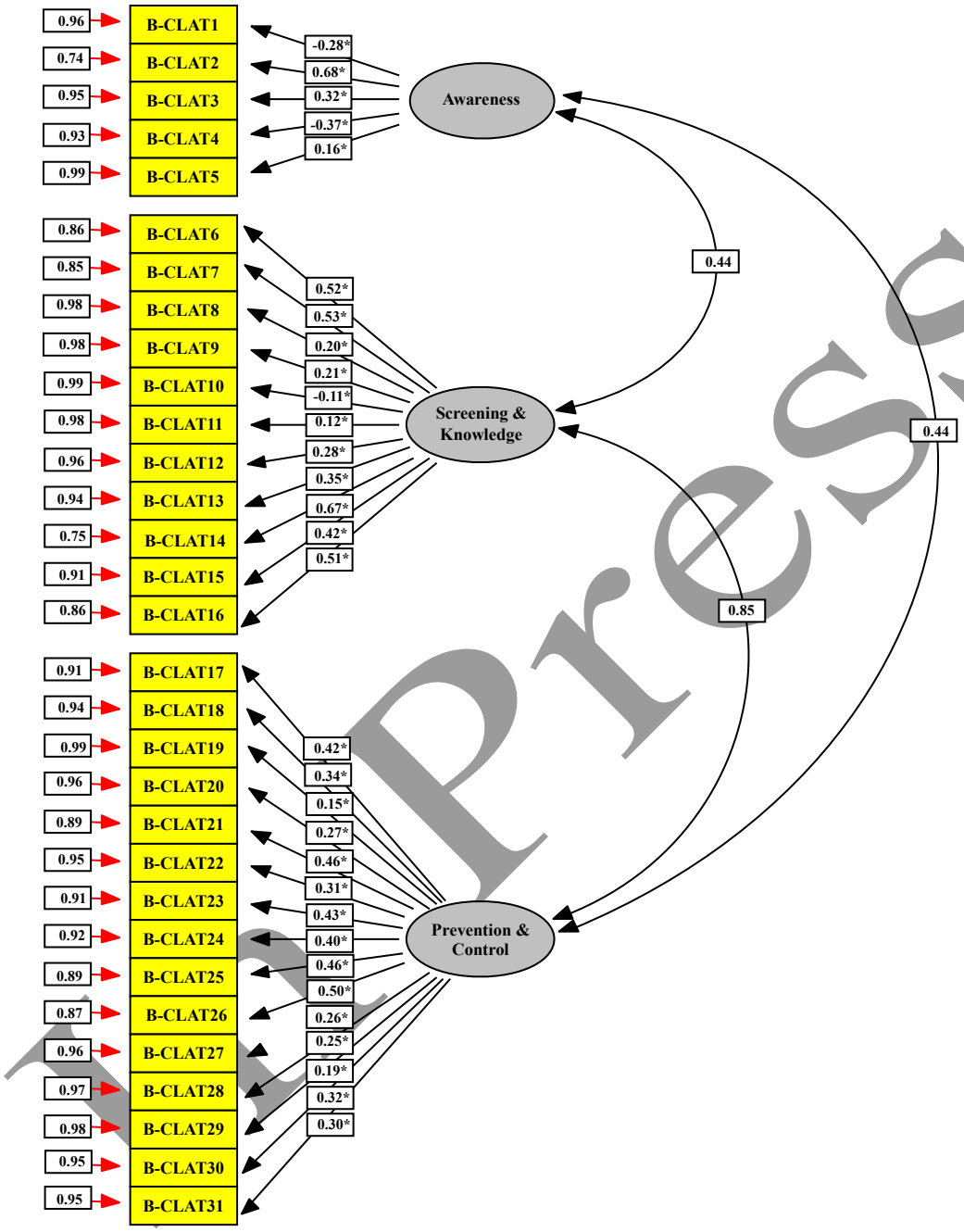

Diagram 1. The Results of Confirmatory Factor Analysis of IB-CLAT 31-Item

Discussion

In this study, the translation and cross-cultural adaptation of the tool were performed using the translation and back-translation method to ensure the original meanings were accurately

preserved in Persian. From the perspective of Nutbeam's model (36), this process supports functional, interactive, and critical health literacy by ensuring clarity, cultural relevance, and conceptual integrity. Following the reconciliation of both versions and the incorporation of necessary cultural and linguistic adjustments, the final Persian version of the tool was developed, maintaining the original intent of the items for the target population. This careful adaptation process supports the content validity of the tool and ensures that it accurately measures the intended constructs across cultural contexts.

The content validity of the research tool was evaluated using both qualitative and quantitative approaches, involving a panel of experts. Expert feedback led to substantial revisions aimed not only at enhancing item clarity but also at improving response accuracy and ensuring the tool's cultural and contextual relevance for the Iranian population. For instance, the inclusion of the response options "I don't know" and "I have no opinion" across all items was guided by both psychometric principles and cultural considerations. These options reduce forced-choice responses and guesswork, which can compromise data validity, and align with cultural tendencies in Iran where ambiguity tolerance is low and individuals prefer to acknowledge uncertainty rather than make potentially inaccurate assumptions (37). therefore, including options like "I don't know" or "I have no opinion" accommodates culturally-influenced decision-making, reduces social desirability bias in responses to sensitive questions, and improves data quality. Ensuring anonymity and informing participants about confidentiality can reduce respondent bias and encourage them to provide honest answers. From a theoretical perspective, providing such options supports response validity by mitigating social desirability bias and accommodating culturally-informed decision-making patterns in ambiguous situations, which is particularly relevant for sensitive topics influenced by stigma (38). From the perspective of Nutbeam's health literacy model (36), providing response options such as "I don't know" or "I have no opinion" not only facilitates accurate comprehension of items (functional literacy) but also enables participants to engage thoughtfully with the questions (interactive literacy) and make informed,

culturally-appropriate decisions (critical literacy). This alignment further enhances the validity of the tool in capturing meaningful responses within the Iranian cultural context.

Another important revision involved adding the term “radiologist” in parentheses following “X-ray technician” in relevant items. This modification reflects common terminology in Iran, where “radiologist” is frequently used interchangeably with “X-ray technician,” and mammography is generally performed by radiologists. This adjustment enhances construct validity by ensuring that respondents accurately understand the professional role being referenced, thereby reducing misinterpretation and potential measurement error. From the perspective of Nutbeam’s health literacy model (36), this clarification supports functional health literacy by enabling participants to correctly comprehend the professional role, interactive health literacy by facilitating accurate interpretation and application of this information, and critical health literacy by reducing misunderstanding and supporting informed evaluation of professional responsibilities.

Structural differences in breast cancer screening programs between Iran and the United States—the context in which the original tool was developed—necessitated specific modifications to relevant items. In Iran, clinical breast examinations are available free of charge at public health centers, whereas mammography typically requires referral to external facilities and incurs additional costs. Consequently, the original term “program” in item 31 did not accurately reflect the Iranian screening context. Following expert panel recommendations, the term was replaced with “centers,” improving both clarity and cultural relevance for respondents. From a psychometric perspective, such culturally and contextually informed adjustments are essential to maintain content validity and construct equivalence, ensuring that items measure the intended constructs accurately across different healthcare systems. The integration of expert feedback in this process highlights the importance of tailoring research instruments to the target population’s cultural and systemic conditions. Quantitative assessment using the Content Validity Index (CVI) and Content Validity Ratio (CVR) further confirmed the tool’s adequacy, with an overall CVI of 0.942, well above the acceptable threshold of 0.79 (31). These steps collectively

enhance the reliability, interpretability, and validity of the collected data, supporting robust and meaningful study findings.

Following the removal of three items (1, 15, and 18), the IB-CLAT comprises 31 items and demonstrates strong content validity. Item 1 was excluded because it was overly broad and insufficiently aligned with the tool's focus on functional health literacy related to breast cancer. Item 15 was removed due to content redundancy with earlier questions, its exam-like structure, and concerns about potentially patronizing respondents. Item 18 was discarded because of conceptual inconsistency between its two parts and prior coverage of mammography in earlier items. Despite these removals, the questionnaire maintains comprehensive coverage of functional health literacy, as the remaining items encompass the most relevant dimensions: awareness, screening and knowledge, and prevention and control. From the perspective of Nutbeam's health literacy model (36), the refinement of the questionnaire by removing items that were redundant, overly broad, or conceptually inconsistent enhances the tool's focus on functional health literacy. This ensures that the remaining items effectively capture the key dimensions of awareness, screening and knowledge, and prevention and control, thereby supporting participants' accurate comprehension and engagement with breast cancer–related health information.

Notably, items 3 ("If someone hits my breast, I will get breast cancer") and 5 ("Women who have large breasts are more likely to get breast cancer than women who have small breasts") were retained despite CVR scores below the conventional threshold (0.62). These items address prevalent misconceptions among Iranian women (39, 40) and globally (41-44), and were preserved based on expert consensus due to their conceptual importance and high CVI scores, particularly in relevance. From the perspective of Nutbeam's health literacy model (36), retaining these items supports functional health literacy by addressing prevalent misconceptions and ensuring that participants can accurately comprehend core concepts related to breast cancer awareness, screening, and prevention. Considering that this tool assesses functional health literacy across three domains—awareness, screening and knowledge, and prevention and

control—it is possible that if more detailed and comprehensive explanations of these domains had been provided to the expert panel, higher scores would have been assigned to the necessity of these items in assessing functional health literacy regarding cervical cancer. These cases underscore the importance of ensuring precise conceptual and structural alignment of items with the study's objectives and framework. Comparable adjustments have been reported in other adaptations; for instance, Shan and Ji (2023) also removed items 1 and 18 in the Chinese version of B-CLAT (45). Furthermore, related studies demonstrate robust psychometric properties of breast cancer literacy tools, with CVI and CVR values consistently exceeding acceptable thresholds (46-48). Collectively, these findings support the psychometric robustness of tools designed to assess breast cancer awareness and literacy. In summary, the IB-CLAT exhibits strong conceptual and semantic equivalence with the original tool, effectively assessing functional health literacy related to breast cancer, while the integration of expert feedback ensures both psychometric rigor and cultural relevance.

In this study, the content validity of the IB-CLAT was assessed qualitatively using participant feedback. Insights from the women informed targeted revisions that enhanced both the clarity and the cultural-linguistic appropriateness of the items. Notably, the phrase "How often?" was added to items 7, 11, and 13. This modification improved alignment between item wording and response options, addressing a conceptual gap in the original version. From a psychometric perspective, this change enhances construct validity by ensuring that respondents accurately interpret the frequency-related questions, thereby reducing measurement error and supporting the collection of more reliable and meaningful data (25).

Participant feedback indicated that certain phrases in the tool elicited negative emotional responses. For example, item 19 originally included the phrase "my chance of death," which was revised to the more neutral and culturally appropriate "the probability of my death," minimizing emotional discomfort and potential response bias. Similarly, in item 31, the term "resources" was perceived as vague and potentially confusing; it was replaced with "healthcare center" and supplemented with examples such as hospitals, clinics, and laboratories, enhancing clarity and

interpretability. These refinements not only improve comprehensibility and respondent comfort but also support content and construct validity by ensuring that items are interpreted as intended within the cultural context. Overall, the revisions made to the Persian version of the B-CLAT demonstrate the critical role of participant feedback in culturally and linguistically adapting research instruments, thereby enhancing the accuracy, reliability, and meaningfulness of the collected data.

The CFA findings demonstrate that the proposed measurement model achieves an acceptable and theoretically coherent fit to the data. In addition to satisfying conventional statistical criteria—such as CFI, GFI, IFI, TLI, and MFI values exceeding 0.90, RMSEA ≤ 0.08, and CMIN/DF falling between 1 and 3 (35)— the full set of fit indices consistently supports the model's adequacy. Taken together, these indices indicate that the underlying factor structure corresponds well with the observed response patterns. Although several items exhibited factor loadings below the commonly recommended threshold of 0.50, this pattern should be interpreted within the broader theoretical context of instrument validation. As emphasized in psychometric theory, item retention should not rely solely on statistical indicators but should also consider conceptual relevance and consistency with the foundational framework of the construct (25). Consistent with the original findings by Williams et al. (21), the lower-loading items in this study still represent essential dimensions of breast cancer literacy. Their content captures nuances that may not always yield high loadings but remain theoretically indispensable for ensuring domain coverage. Moreover, the decision to retain these items is supported by the acceptable overall fit indices, particularly CFI = 0.903 and RMSEA = 0.063, which indicate that the overall model performs adequately even with the inclusion of these items (49). Removing them could risk narrowing the scope of the construct and compromising the theoretical integrity of the instrument. Maintaining these items also increases the tool's potential for broader applicability in future studies, where contextual or population-specific factors may lead to stronger item performance and improved representation of sub-dimensions across diverse samples.

The fit indices obtained in the present study, together with the statistically significant factor loadings across all items, provide strong evidence of the instrument's construct validity. The positive and significant correlations among the extracted factors further suggest that the dimensions of the tool—Awareness, Knowledge and Screening, and Prevention and Control—are not only internally consistent but also conceptually interconnected. This pattern is consistent with psychometric theory, which emphasizes that distinct yet related factors should exhibit meaningful associations when they collectively represent a broader construct such as health literacy (25). The findings also align with prior validation studies. In the original work by Williams et al., confirmatory factor analysis supported a well-fitting three-factor model for the B-CLAT (TLI = 0.91, RMSEA = 0.04) (21), demonstrating a structure comparable to that observed in the current study. Similarly, Kawthaisong et al. reported satisfactory CFA indices for their colorectal cancer literacy instrument (CFI = 1.00, GFI = 0.93, AGFI = 0.91, RMSEA = 0.014), further confirming the suitability of multi-factor literacy frameworks in cancer research (50). The convergence of evidence across these studies reinforces the stability and appropriateness of the three-factor configuration identified here. Beyond these empirical parallels, the structure of the instrument corresponds closely with theoretical models of functional health literacy. Functional health literacy encompasses essential skills such as understanding disease characteristics and risk factors, recognizing appropriate screening and prevention strategies, lifestyle modifications, engaging effectively with healthcare providers, and navigating health systems. Within this conceptual framework, the Awareness factor in the present study captures basic comprehension of breast cancer and its risks; the Knowledge and Screening factor reflects understanding of screening procedures and access to health services; and the Prevention and Control factor represents knowledge of preventive behaviors and lifestyle modifications. These domains align with the core dimensions highlighted in Altin et al.'s (2014) systematic review of health literacy assessment tools, which emphasized the importance of information processing, interaction with healthcare systems, and effective communication (51). Taken together, these findings demonstrate that the developed tool possesses strong construct validity and appropriately represents the multidimensional nature of functional breast cancer literacy.

The known-groups comparisons further supported the construct validity of the instrument. The findings showed that educational level had a significant impact on breast cancer literacy, whereas no significant differences were observed across age groups. From the perspective of Nutbeam's health literacy model (36), the observed association between education level and breast cancer literacy reflects the impact of foundational knowledge and comprehension abilities on functional health literacy, highlighting that educational attainment enhances individuals' capacity to access, understand, and use preventive health information effectively. This pattern aligns with the results of Batooli et al. (52) reinforcing the notion that breast cancer literacy is strongly shaped by individuals' exposure to health information—an element more closely linked to education than to chronological age. Likewise, Almoajel et al. (2022) reported similar trends when assessing eHealth literacy and breast cancer literacy with the B-CLAT, identifying significant differences by education level but not by age (53), which is fully consistent with the results of the present study. In contrast, Danaei et al. found significant associations with both age and education level (54). This discrepancy can be understood in light of differences in study design and target populations. Danaei et al.'s research focused on women diagnosed with breast cancer recruited from treatment centers, and the instrument used was tailored to assess literacy among patients navigating diagnosis and treatment. Such individuals typically interact more frequently with healthcare professionals and engage more deeply with cancer-related information, making age a potentially more influential factor. In the present study, however, the sample consisted of healthy women attending primary healthcare centers, and the tool was specifically designed to evaluate preventive breast cancer literacy. In this context, educational attainment may play a more dominant role than age in shaping individuals' access to, comprehension of, and engagement with early detection and prevention information. Overall, these results indicate that the instrument performs as expected across known groups, demonstrating its suitability for assessing breast cancer literacy—including awareness, knowledge and screening, and prevention and control—among Iranian women in community and primary care settings.

Journal of Health Literacy

Another important finding of this study concerns the acceptable reliability of the IB-CLAT. Reliability was assessed using two main methods: internal consistency, measured through Cronbach's alpha, and temporal stability, evaluated via the ICC. The overall Cronbach's alpha obtained in the present study (α = 0.722) indicates satisfactory internal consistency, closely aligning with the value reported by Williams et al., who found an alpha of 0.73 for the original instrument (21). This consistency across studies suggests that the underlying construct is measured reliably across different populations.

Comparable results have been reported in other validation studies. For instance, Shan and Ji observed improved reliability of the subscales after removing several items with weak performance in their context, ultimately achieving an overall Cronbach's alpha of 0.607 (45). Although their value was slightly lower, the pattern supports the broader observation that cancer literacy tools tend to maintain acceptable internal consistency even when adapted across different cultural or linguistic settings. Likewise, Dumenci et al. reported high internal consistency for the CHLT-30 (α = 0.87), further demonstrating that cancer literacy constructs can be measured reliably with well-structured instruments (55). In the present study, the Screening and Knowledge subscale yielded a slightly lower alpha coefficient (α=0.687), marginally below the conventional threshold of 0.70. However, values above 0.60 are generally considered acceptable for newly adapted or exploratory instruments, particularly in the early phases of cross-cultural validation (56). This suggests that while the subscale performs reasonably well, some variability among its items may reflect differences in respondents' familiarity with screening procedures or access to health information. Overall, the reliability analyses provide solid support for the internal coherence and stability of the IB-CLAT. Nevertheless, the marginally lower internal consistency of the Screening and Knowledge subscale highlights an area for further refinement. Future studies should investigate item-level performance more deeply—potentially through item response theory (IRT) or cognitive interviews—to enhance the reliability and precision of this subscale.

Finally, the test–retest analysis demonstrated strong temporal stability, with an ICC of 0.868. Given that an ICC value of 0.70 is typically considered the minimum acceptable threshold for reliability in psychometric evaluations (57), the value obtained in this study reflects excellent stability over time. This high level of consistency suggests that participants' responses to the IB-CLAT remain stable across measurement occasions, indicating that the tool reliably captures relatively enduring aspects of breast cancer literacy rather than transient or situational knowledge. Comparable findings have been reported in other validation studies. Shan and Ji, for example, documented ICC values ranging from fair to excellent for the Chinese adaptation of the B-CLAT, underlining the stability of cancer literacy constructs across different cultural settings (45). The alignment of the present results with previous research further strengthens the evidence supporting the IB-CLAT's reliability and confirms that the instrument possesses robust test–retest properties.

This study confirms the validity and reliability of the IB-CLAT. Compared to existing tools, the IB-CLAT demonstrates notable differences. For instance, the HELBA tool is an Iranian tool designed and psychometrically validated to assess breast cancer literacy. HELBA is structured across five dimensions: evaluation, reading, access, decision-making/behavior, and understanding. It includes questions that measure the abilities of women with breast cancer in these five dimensions, focusing on treatment processes, post-surgery care, and other treatment-related management (22). This tool is primarily suitable for use at secondary and tertiary prevention levels. In contrast, the IB-CLAT is designed around three dimensions: awareness, screening, and control and prevention. It contains questions that assess the knowledge and awareness of individuals about the disease and preventive and screening methods. Therefore, this tool is suitable for primary prevention, aiming to prevent disease onset and increase screening rate. The P-HLS-EU-Q47 tool is designed to assess adult health literacy and represents the Persian version of the European health literacy survey (HLS-EU) (58). It evaluates health literacy across three dimensions: healthcare, disease prevention, and health promotion, providing an overall profile of adult health literacy. In contrast, the IB-CLAT specifically focuses on breast cancer literacy and

can be used to identify educational needs related to primary prevention interventions for breast cancer. Although multidimensional health literacy instruments are increasingly recommended, the use of a disease-specific and focused tool remains appropriate when the research objective is prevention-oriented. The IB-CLAT assesses functional breast cancer literacy through awareness, screening, and prevention-related domains, making it particularly suitable for primary prevention among healthy women. This targeted approach complements, rather than replaces, multidimensional instruments by capturing preventive literacy demands directly linked to screening uptake and risk reduction.

This study demonstrated that the three-factor model of the IB-CLAT aligns well with the priorities of Iran's healthcare system and can serve as a valid tool for designing educational interventions and informing related policymaking. A 2022 scoping review in Iran reported that the rates of breast self-examination, clinical breast examination, and mammography among Iranian women ranged from 0% to 79.4%, 4.1% to 41.1%, and 1.3% to 45%, respectively (59). These findings not only reveal generally low participation in screening practices but also highlight significant disparities in access to and utilization of screening services among Iranian women. Improving health literacy is recognized as an effective strategy to increase participation in breast cancer screening programs (60). One of Iran’s recommended cancer risk reduction policies is to raise public awareness and organize cancer prevention campaigns (61). The initial step in designing any intervention or educational program involves conducting a needs assessment and evaluating the community’s baseline status regarding the target characteristic (62). Therefore, having valid tools is essential to guide the design and implementation phases of such programs. The findings of this study provide critical resources to support policymakers and planners in advancing and developing breast cancer literacy initiatives within Iran’s public health framework. Moreover, this tool can be utilized in national health literacy screening programs, as well as mobile-based self-evaluation and screening, needs assessments and implementation of educational programs in workplaces and schools for female employees and teachers. Additionally, it can be used in assessment of community health workers’ knowledge, psychometric studies to evaluate

convergent validity with similar instruments and predictive validity for forecasting actual screening behaviors, as well as research facilitating international comparisons.

In the present study, which aimed to translate and psychometrically evaluate the IB-CLAT, several important achievements were made. However, there are also notable limitations that should be clearly considered when interpreting the results and designing future research. These limitations, including the sampling area, participants' literacy levels, and the generalizability of the findings, are important for users and evaluators to understand the context and applicability of the results. First, the data were collected through self-report tools, which are inherently susceptible to certain biases. In such tools, individual response styles can influence the accuracy of the data. For instance, participants may provide answers that reflect socially desirable behaviors rather than their true beliefs or actions. Moreover, some individuals may exhibit acquiescence bias, tending to agree with statements regardless of their actual opinions. These factors can introduce measurement bias and must be considered when interpreting the findings. To reduce the impact of bias, it is recommended that researchers use a triangulation approach to enhance the confidentiality of responses. Mixed-method strategies, such as incorporating objective measures alongside this tool, may also be useful for this purpose. Second, it is important to note that the potential influence of participants' baseline knowledge on their responses was not examined in this study. This is a relevant factor in breast cancer literacy research and should be addressed in future studies to better contextualize the results. Third, the sample was limited to participants residing in Tehran. As a result, the findings may not be generalizable to rural populations, regions with lower literacy rates, or areas with different cultural or geographical characteristics. Therefore, validating the tool in rural and diverse sociocultural settings is strongly recommended. Additionally, due to financial and time constraints, this study did not include comparisons with other established health literacy tools, such as the HLS-EU, to assess convergent validity. Future research should incorporate such comparisons to provide a more comprehensive validation of the IB-CLAT. Another limitation is the exclusion of illiterate individuals from the study. This restricts the applicability of the measurement tool to literate populations only, which is

particularly relevant in areas with lower literacy rates. In future studies, it is recommended that adapted versions of the tool—such as oral administration, the use of visual aids, or employing pictorial format scales—be developed and psychometrically evaluated for illiterate populations to assess the tool's validity and applicability in these groups. Finally, although a multistage sampling method using random selection was employed in the earlier phases to ensure representation from various urban areas and to enhance the representativeness of the sample, the use of convenience sampling in the final stage may have affected the generalizability of the findings. As the participant profiles indicate, the study included a broad and reasonably acceptable diversity in terms of demographic characteristics such as education, occupation, and more; however, caution should be exercised when interpreting and generalizing the results to the wider population of Iranian women, particularly in regions with different literacy levels or sociocultural conditions.

Conclusion

The present study provides a culturally grounded Persian version of the B-CLAT that is suitable for use in Iranian contexts. By offering a rigorously adapted and conceptually clear instrument, this work supports more accurate assessment of breast cancer–related health literacy. Importantly, the validated tool has practical and policy implications: it can guide health policymakers and public health planners in designing culturally appropriate breast cancer prevention and screening programs, inform resource allocation, and support evidence-based decision-making aimed at improving women's health outcomes in Iran. This validated tool can be effectively used in the development of educational programs and interventions aimed at increasing public awareness of breast cancer, promoting preventive behaviors, and enhancing participation in screening practices. Policymakers and healthcare professionals may use the results of this study to tailor breast cancer screening and educational strategies that align with the cultural context and specific needs of the Iranian population. It is recommended that policymakers consider integrating the IB-CLAT into national breast cancer initiatives to support early detection efforts and improve public health outcomes. Furthermore, future research is encouraged to explore the relationship between health literacy and breast cancer-related

preventive behaviors using this tool. Furthermore, future research is encouraged to explore the relationship between health literacy and breast cancer–related preventive behaviors using this tool, providing additional evidence to inform policy and practice.

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Availability of data and materials: All data that support the findings of this study are not publicly available due to participants' confidentiality.

Conflicts of interest: The authors declare no conflicts of interest.

Consent for publication: Not applicable.

Ethics approval and consent to participate: This study was performed in line with the principles of the Declaration of Helsinki and has been approved by the Research Ethics Committee of School of Public Health and Safety-Shahid Beheshti University of Medical Sciences (ethics code from IR.SBMU.PHNS.REC.1403.027). Informed consent Informed consent was obtained from all individual participants included in the study.

Supplementary Files 1. Table of demographic characteristics of participants in face validity assessment, 2. IB-CLAT dimensions and items with related factor loadings.

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