Source and Grant Number: Self- funded

Clinical Research Protocol for Development and Reliability and Validity Testing of a Health Literacy Assessment Scale for Nursing Assistants

Sponsor: Xijing Hospital

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Protocol Summary

Study Title	Development and Reliability and Validity Testing of a Health Literacy Assessment Scale for Nursing Assistants
Study Objective	To develop a health - literacy assessment scale for nursing assistants based on their occupational characteristics and care-work requirements.
Study Design	Mixed-methods study. Based on the Timing It Right framework, semi-structured interviews combined with Delphi expert consultation will be adopted to develop the health-literacy assessment scale for nursing assistants and test its reliability and validity.
Total Sample Size	Prospective recruitment of no fewer than 300 participants
Subject Selection	Inclusion Criteria ① Engaged as a nursing assistant in medical institutions for ≥ 3 months ② Aged 18-65 years with basic communication and questionnaire-comprehension abilities ③ Informed of the study and willing to participate ④ No imminent job change recently; able to complete the survey and retest
	Exclusion Criteria ①Interns, temporary supporting staff, or informally employed nursing assistants

	②Subjects with severe hearing, speech or cognitive impairments that prevent effective communication ③Subjects with frequent leave-taking within the past month or about to leave their post ④Subjects who refuse or are unable to complete questionnaires
Treatment Regimen	Not applicable
Efficacy Evaluation	This is an assessment-instrument development study with no clinical efficacy evaluation. Only psychometric evaluation of the scale will be performed, including reliability-validity testing and quality assessment for expert consultation.
	Safety Evaluation Indicators This study consists solely of questionnaires and health-literacy assessments. No invasive procedures, pharmaceutical interventions or biological-sample collection will be performed. The informed-consent principle will be followed throughout the study. Before investigation, participants will be clearly informed of study objectives, procedures, confidentiality rules and the right to withdraw voluntarily. No physical or psychological risks are anticipated.
Statistical Methods	Data analyses will be performed using SPSS 27.0 and AMOS 28.0. Measurement data will be presented as mean ± standard

	deviation or median (interquartile range). Enumeration data will be described by frequency and percentage. Item analysis will be conducted using the critical-ratio method, item-total correlation and homogeneity test. Exploratory factor analysis and confirmatory factor analysis will be used to evaluate construct validity. Content validity, convergent validity and discriminant validity will be assessed via content-validity index, average variance extracted and composite reliability respectively. Reliability assessment will include internal-consistency reliability (Cronbach's α coefficient), split-half reliability and test-retest reliability (intraclass correlation coefficient). All statistical tests will be two-tailed with a significance level of $\alpha = 0.05$; $P < 0.05$ is regarded as statistically significant.
Study Period	June 2026 – August 2027

1 Background

With the accelerating global population aging, public attention to and demand for health-related factors keep rising, creating a substantial gap in health-service supply and resulting in a severe shortage of nursing staff in medical institutions. According to *The State of the World's Nursing 2025* released by the WHO, a global shortfall of 4.1 million nurses is projected by 2030[1]. Against this backdrop, the nursing-assistant market has emerged as an emerging occupation to ease the shortage of nursing human resources and meet family care demands. Nursing assistants refer to personnel employed by patients or their family members to provide activities-of-daily-living care for hospitalized patients[2]. Nevertheless, as a product of social needs and refined occupational division, nursing assistants have not yet been formally incorporated into China's occupational catalogue for health-technical personnel[3].

Health literacy is defined as the capacity of individuals to effectively apply reading, writing, verbal expression and numeracy skills to actively promote their own health-care outcomes[4]. Domestic studies indicate that adequate health literacy contributes to sound health beliefs, modification of unhealthy lifestyles and improvement of psychological status[5-6]. Previous research has demonstrated that patients with low health literacy have higher odds of emergency-department revisits. Since nursing assistants deliver daily-life care for patients, their satisfactory health literacy is conducive to improving service quality for patients. Existing domestic and international studies on health literacy mainly focus on residents, patients with specific diseases, young adults and medical staff, while few investigations target nursing assistants[2].

Current generic health-literacy assessment scales cannot reflect the occupational characteristics of nursing assistants, namely "providing daily-life care for inpatients, delivering basic health assistance, and transmitting information between physicians and patients". Therefore, developing a targeted health-literacy assessment scale is of great

significance for accurately evaluating the health- literacy level among nursing assistants, improving relevant training programs, formulating occupational standards and implementing industrial supervision.

二、Objectives

1、Primary Objective：To develop a health- literacy assessment scale for nursing assistants based on their occupational characteristics and care- work requirements.

2、Secondary Objective：To describe the health- literacy level of nursing assistants and identify relevant influencing factors, so as to provide evidence for subsequent formulation of training standards, occupational specifications and industrial supervision policies.

三、Research Design, Principles and Study Procedures

1、Research Design

1.1 Study Type

This is a mixed-methods, non-interventional methodological study. Guided by the Timing It Right (TIR) theory, semi-structured interviews combined with the Delphi expert consultation method were used to develop a health literacy assessment scale for nursing assistants and to test its reliability and validity.

1.2 Research Sites

The study participants are nursing aides working in general hospitals and long-term care facilities; general hospitals at Level III or above were selected as the research sites.

1.3 Sample Size Calculation

Purposeful sampling was used to conduct semi-structured interviews with 10 – 15 nursing aides, with each interview lasting 20 – 30 minutes. Based on the requirements for scale development: Number of items: Sample size = (1:5) to (1:10); exploratory factor analysis: sample size ≥ 150 cases; confirmatory factor analysis: sample size ≥ 200 cases. Considering the possibility of invalid data during the research process, an additional 10% was

added to the base sample size. Therefore, the preliminary sample size selected for this study is N ≥ 300 cases.

4. Case Selection

Study Population: Active nursing assistants employed at medical institutions

4.1 Inclusion Criteria

① Have been working as a nursing assistant at a medical institution for ≥3 months

② Are between 18 and 65 years of age and possess basic communication skills and the ability to understand the questionnaire

③ Have provided informed consent to participate in this study

④ Have not recently changed positions and are able to cooperate in completing the survey and follow-up assessments

4.2 Exclusion Criteria

① Interns, temporary support staff, or non-regular nursing assistants

② Individuals with severe hearing, speech, or cognitive impairments that prevent communication

③ Individuals who have taken frequent leave within the past month or are about to leave their positions

④ Individuals who refuse or are unable to complete the questionnaire

4.3 Culling Criteria

① Missing ≥10% of key questionnaire items

② Responses exhibiting obvious patterns or selecting the same option for all questions

③ Responses completed too quickly or containing logical contradictions.

④ Incomplete data rendering statistical analysis impossible

4.4 Criteria for Terminating the Study

Participants who experience sudden illness, accidental injury, severe discomfort, psychological stress, emotional breakdown, or other conditions rendering continued participation inappropriate; those with extremely poor compliance who are unable to cooperate in completing the survey; participants who voluntarily request to withdraw; or cases where the researcher determines that continued participation may endanger the participant’s physical or mental health.

5 Research Methods and Technical Approach

This study focuses on the development of a health literacy scale for nursing aides and the testing of its reliability and validity. It is a non-interventional methodological study and does not involve any investigational drugs, control drugs, placebos, or drug-related content.

Technical Approach

① Overview: Elaborate on the research background, objectives, and overall framework

② Model Development: Based on the Theory of Opportunity and health literacy, an initial item pool was formed through literature analysis and semi-structured interviews; items were then screened and revised through two rounds of Delphi expert consultation

③ Model Evaluation: Through a pilot survey and a large-scale, multicenter survey, item analysis and validity and reliability testing (including content, construct, convergent and discriminant validity, as well as reliability measures such as Cronbach’s α), and statistical analysis was performed using SPSS 27.0 and AMOS 28.0

④ Strategic Application: The target population and administration guidelines for the scale were defined; it was applied to clinical assessments and training interventions, and an empirical study on the health literacy of nursing aides was conducted

⑤ Conclusions: The results regarding the scale’s reliability and validity, along with its innovative features, were summarized, and prospects for dissemination and future research were proposed

6. Observation Items and Timing of Data Collection

Timing of data collection for general demographic characteristics and occupational characteristics of care workers: collected in a single instance during the formal survey; timing of health literacy assessment: cross-sectional on-site survey; retest reliability survey conducted 14 days after the initial survey; timing of expert consultation evaluation: during the two rounds of Delphi expert consultations; timing of scale reliability and validity evaluation: statistical tests completed after the formal survey data were collected.

7 Criteria for Efficacy Assessment

This study is designed to develop an assessment tool; it does not involve clinical efficacy evaluation. It focuses solely on the scientific validation of the scale, including reliability and validity testing and quality evaluation through expert consultation.

8 Monitoring of Adverse Events

This study employs only non-invasive methods, such as questionnaires, interviews, and expert consultations. It involves no medications, no invasive procedures, and no risk of adverse events; therefore, it does not involve the definition, monitoring, recording, management, or reporting of adverse events.

9 Quality Control and Quality Assurance

Investigators, interviewers, and data managers will undergo standardized training to ensure consistent procedures and standardized protocols. Literature analysis, semi-structured interviews, Delphi surveys, questionnaire surveys, data entry, and statistical analysis will be conducted in strict accordance with the study protocol; One-on-one guidance is provided for form completion, with on-the-spot verification of completeness and logical consistency, and missing items are promptly filled in; dual data entry and logical checks are employed to

eliminate invalid questionnaires; expert qualifications are rigorously screened, standardized inquiry forms are used, and the processes for collection, organization, and feedback are standardized; full informed consent and voluntary participation are ensured to guarantee the cooperation of caregivers and the authenticity of the data.

10 Statistical Analysis

Data analysis was conducted using SPSS 27.0 and AMOS 28.0 software. Quantitative data are presented as mean ± standard deviation or median (interquartile range), while categorical data are presented as frequency and percentage. Item analysis was performed using the critical ratio method, item-total correlation, and homogeneity tests. Structural validity of the scale was evaluated using exploratory and confirmatory factor analysis. Content validity, convergent validity, and discriminant validity were assessed using the content validity index, average variance extracted, and composite reliability, respectively. Reliability tests included internal consistency (Cronbach's α coefficient), split-half reliability, and test-retest reliability (intra-group correlation coefficient). All statistical tests were two-tailed, with a significance level of $\alpha = 0.05$; a P-value < 0.05 was considered statistically significant.

11 Ethics of Clinical Research

The clinical research will comply with relevant regulations, including the Declaration of Helsinki adopted by the World Medical Association. The clinical research may only be conducted after the study protocol has been approved by the Ethics Committee prior to the start of the study. Before each participant is enrolled in this study, the investigator is responsible for providing the participant or their legal representative with a complete and comprehensive explanation of the study's purpose, procedures, and potential benefits and risks. A written informed consent form must be signed, and participants must be informed of their right to withdraw from the study at any time. The informed consent form shall be retained as part of the clinical study documentation for future reference. Participants' personal privacy and data confidentiality will be protected throughout the study.The study

protocol was approved by the Ethics Committee of the First Affiliated Hospital of Air Force Medical University (Xijing Hospital) on June 18, 2026 (Approval Number: KY20262267-C-1)

12 Research Timeline

April 20, 2026 – May 31, 2026: Complete literature review, construct the theoretical framework, conduct semi-structured interviews, establish an initial item pool, and complete the first round of Delphi expert consultations.

June 1, 2026 – September 31, 2026: Complete the second round of Delphi expert consultations, conduct a small-sample pilot study, optimize the scale, and finalize the formal version of the Caregiver Health Literacy Assessment Scale.

October 1, 2026 – December 30, 2026: Conducted a multicenter, large-sample questionnaire survey; completed data collection, entry, and processing; and simultaneously conducted a test-retest reliability study.

January 1, 2027 – February 31, 2027: Use SPSS 27.0 and AMOS 28.0 to complete item analysis, reliability and validity testing, and statistical analysis, and finalize the scale.

March 1, 2027 – May 31, 2027: Draft the research paper, organize the research findings, and submit the paper for publication.

13 Participants

Name	Title/Specialty	Responsibilities	GCP Training (Yes/No)
Zhang Xin	Registered Nurse/Nursing	Comprehensively coordinate project implementation; lead the development of assessment scales, conduct interviews,and carry out the preliminary survey; be responsible for data collection, entry, and organization, as well	Yes

		as document archiving; independently complete the writing of the paper and the organization of materials.	
Feng Ting	Associate Chief Nurse/Public Health	Oversee overall technical aspects of the project; guide questionnaire optimization and validity testing; review questionnaire items and the full text of the paper;provide research quality control and academic guidance throughout the process.	Yes

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Exemption from Informed Consent Statement

Study Title: Development and Reliability and Validity Testing of a Health Literacy Assessment Scale for Nursing Assistantsl

Investigator: Zhang Xin Responsible Department: Nursing Department Study Design: Mixed-methods research design Study

Objective: To develop a health-literacy assessment scale for nursing care workers based on the occupational characteristics and care-delivery requirements of nursing care workers. Sample Size: 300-400 participants Study

Subjects: Nursing care workers / nursing assistants employed in the author's hospital as well as in hospitals in other provinces and cities.

Application Rationale for Exemption from Informed Consent: Part of the survey will be conducted via online questionnaires. Obtaining written informed consent is not feasible under such online data-collection circumstances. Therefore, an application is submitted for exemption from the requirement for informed consent.