The Health Information Technology Usability Evaluation Scale: Translation, cross-cultural adaptation, and psychometric validation in China

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Abstract

Background: The dramatic growth of digital health applications has posed an urgent demand for rigorous usability assessment tools. While the Health Information Technology Usability Evaluation Scale (Health-ITUES) has been increasingly utilized as a validated tool to evaluate the usability of digital health applications, there is no validated Chinese version available.

Objective: To translate and culturally adapt the Health-ITUES into Chinese, revise its customized parts to cater to both service consumers and professional care providers, and evaluate its reliability and validity in the Chinese context.

Methods: Following the Guideline for the Process of Cross-Cultural Adaptation of Self-Report Measures, the original Health-ITUES was translated and cross-culturally adapted into the Chinese version and then customized to the Care Receiver Version (Health-ITUES-R) and Professional Care Provider Version (Health-ITUES-P) based on the overall objectives and functional components of the SMART application. Older individuals and nurses were subsequently included in the validation test from December 2020 to February 2021. Content validity, internal consistency reliability, construct validity, convergent validity, discriminant validity, and criterion validity were used to evaluate the psychometric attributes of the Health-ITUES-R and Health-ITUES-P.

Results: A Chinese version of the Health-ITUES comprising 20 items across 4 dimensions was formulated. Based on this, the Health-ITUES-R and Health-ITUES-P were customized. Both the Health-ITUES-R and Health-ITUES-P demonstrated satisfactory content validity, internal consistency reliability, convergent validity, and discriminant validity. Confirmatory factor analysis results indicated a four-dimension model consistent with the original scale structure and exhibited acceptable model fit. Furthermore, Pearson's correlation coefficients between the Health-ITUES-R and reflected a high between the Health-ITUES-R and Patient Acceptance Questionnaire for Mobile Health Application reflected a high criterion validity.

Conclusions: The Chinese version of the Health-ITUES is a valid and reliable tool to evaluate the usability of digital health applications for both care receivers and professional care providers. Clinical Trial: Not Applicable

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and reflected a high between the Health-ITUES-R and Patient Acceptance Questionnaire for Mobile Health Application reflected a high criterion validity.

Conclusions: The Chinese version of the Health-ITUES is a valid and reliable tool to evaluate the usability of digital health applications for both care receivers and professional care providers.

Keywords: digital health application, reliability, translation, usability, validity

1. Introduction

The global realm of digital health Applications (Apps) has grown dramatically, particularly since the onset of the Corona Virus Disease 2019 (COVID-19) pandemic in early 2020 [1, 2]. As of the first quarter of 2021, more than 53000 Apps were available on the Google Play Store, representing a notable increase of over 25% compared to about 42000 Apps on the same platform during the same period of the previous year [3]. These Apps offer a feasible alternative to face-to-face communication between healthcare professionals and patients, assist healthcare professionals in diagnosing and managing various medical conditions by providing quick access to health data, disseminate health-promoting knowledge, and facilitate patients' self-management, thus improving the efficiency of the healthcare system worldwide [4,5].

Despite the growing popularity of digital health Apps, users frequently encounter difficulties in selecting the appropriate Apps that would benefit their health, primarily due to a lack of rigorous quality and efficacy evaluation before the release of these Apps to the major stores [6]. The star rating and user review provided on the App Store are subjective and cannot accurately reflect the true usefulness and effectiveness of a digital health App [7]. In contrast, usability, defined as the extent to which users can use an App to achieve specific objectives with efficiency, satisfaction, and effectiveness in a specified usage context, is crucial to reflect the quality and efficacy of digital

health Apps [8,9]. Therefore, a rigorous and validated usability evaluation tool is urgently warranted to produce objective usability results of digital health Apps before their release, thereby aiding consumers and researchers in choosing reliable Apps quickly and efficiently.

Several questionnaires have been developed previously for usability testing, such as the System Usability Scale (SUS) [10], the Post-Study System Usability Questionnaire (PSSUQ) [11], the Software Usability Measurement Inventory (SUMI) [12], and the Computer System Usability Questionnaire (CSUQ) [13]. However, these questionnaires were intended for general information technology systems without considering the characteristics of digital health Apps, such as the specificity of content, users' high requirements for the App accuracy, and the involvement of both service consumers and professional providers, making it challenging to reliably identify the specific problems that may arise when using the digital health Apps [14].

To bridge this gap, researchers developed the Health Information Technology Usability Evaluation Scale (Health-ITUES) based on a web-based communication system for scheduling nursing staff, Bidshift [15]. It has been increasingly utilized as a validated tool to specifically evaluate the usability of digital health Apps by clearly considering tasks [16]. The Health-ITUES also supports the customization at the item level to align with the specific tasks and expectations of the health systems while retaining comparability at the construct level [17]. The original English version of the Health-ITUES has been validated through exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) among nurses [16] and community-dwelling adults with Human Immunodeficiency Virus [18]. Although a validated Korean version of Health-ITUES already exists [19], a Chinese version is currently unavailable.

Therefore, this study aimed to translate and culturally adapt the Health-ITUES into Chinese, revise its customized parts to cater to both service consumers and professional care providers, and evaluate its reliability and validity in the Chinese context.

2. Materials and methods

2.1 Study design

This study followed the Guideline for the Process of Cross-Cultural Adaptation of Self-Report Measures by Beaton and his colleagues [20]. Before initiating the translation process, we obtained permission from the original author of the Health-ITUES via email to translate it into Chinese (refer to Supplementary File 1).

2.2 The original Health-ITUES

The Health-ITUES was originally designed to measure the usability of a web-based communication system for scheduling nursing staff. Derived from the Health Information Technology Usability Evaluation Model, a theoretical framework to guide usability evaluations of digital health technologies [21], the Health-ITUES has recently been increasingly utilized to accurately assess the usability of digital health Apps [18, 19]. The tool allows for customization of the items to match the specific tasks and expectations of the health systems. It comprises 20 items from 4 dimensions: quality of work life (3 items), perceived usefulness (9 items), perceived ease of use (5 items), and user control (3 items). Each item is rated from 1 (strongly disagree) to 5 (strongly agree) on a 5-point Likert scale [15]. The total scores range from 20 to 100, with higher scores indicating better perceived usability. The English version of the Health-ITUES demonstrated satisfactory reliability and validity, with Cronbach's α coefficients and criterion validity indexes of 0.85-0.92 and 0.46-0.70, respectively [16].

2.3 Translation and cross-cultural adaptation of the Health-ITUES

2.3.1 Forward translation and synthesis of the forward translations

Two bilingual native Chinese speakers who were proficient in English and had passed the College English Test Band Six produced two forward Chinese translations of the Health-ITUES independently (T1 and T2). One of the translators was familiar with the Health-ITUES contents,

while the other was unaware of the concepts being quantified. Subsequently, the two translations were meticulously reviewed for any ambiguity until a consensus was reached. In the process, we also invited a third translator to resolve disagreements. Through iterative comparison and refinement, a synthesized Chinese version, T3, was achieved.

2.3.2 Back translation

The synthesized Chinese version T3 was independently back-translated into English versions (BT1 and BT2) by another two experienced translators who were native English speakers and had a good command of Chinese. Both of the back-translators were blinded to the original Health-ITUES. The research team then compared the two back translations, analyzed the similarities and differences between them, and provided feedback to the original author of the Health-ITUES for verification. The basic information of the translators was summarized in Supplementary Table S1.

2.3.3 Cross-cultural adaption

All translated versions of the Health-ITUES (including the two forward translations, the synthesized version, and the two back translations) were thoroughly discussed and evaluated by a panel of six experts with varied research fields, encompassing older welfare technology, clinical nursing, nursing information, Chinese and American culture, and data science and engineering (see detailed information in Supplementary Table S2). Through the adoption of a self-evaluation method (see Supplementary Table S3), the authority coefficient (Cr) was determined by considering the familiarity coefficient (Cs) and the judgment coefficient (Ca). The formula for calculating the Cr is $Cr = (Cs + Ca) / 2$ [22].

Based on their professional theoretical knowledge and practical experience, the experts evaluated each item independently on semantic equivalence, conceptual equivalence, experiential equivalence, and idiomatic equivalence. Any items with ambiguity were reworded until all expert queries were addressed, eventually resulting in the final Chinese version of the Health-ITUES.

2.4 Validation of the Health-ITUES

The validation test was approved by the Institutional Review Committee of the Capital Medical University (Approval No. 2015SY49). We utilized the SMART App (known in Chinese as Aifuxing App), developed in the early stage, as a digital health App for the Health-ITUES validation. In short, the SMART App was primarily designed to facilitate personalized integrated home-based care for older people [Error: Reference source not found]. Considering that older individuals and professional care providers are the main users of the App, this study aimed to validate the effectiveness of the Chinese version of the Health-ITUES among both older people and professional care providers.

2.4.1 Customization of the care receiver and professional care provider versions of the Health-ITUES

Based on the overall objectives and functional components of the SMART App, the research team engaged in multiple rounds of discussions to refine the customized components within the Chinese version of the Health-ITUES, formulating initial care receiver and professional care provider versions of the Health-ITUES (Health-ITUES-R and Health-ITUES-P). Subsequently, a panel of 6 experts from pertinent fields (refer to specific details in Supplementary Table S4) were tasked with reviewing the 2 initial customized scales and assigning ratings for the correlation between each item and the corresponding dimension on a four-level scale: 1 - uncorrelated, 2 - weakly correlated, 3 - strongly correlated, and 4 - highly correlated. The research team then iteratively modified the items according to expert suggestions until a consensus was reached among all experts on the finalized Health-ITUES-R and Health-ITUES-P.

2.4.2 Study participants

The validation test was conducted in a geriatric ward of a comprehensive hospital in Beijing, China from December 2020 to February 2021. Older adults were included consecutively if they: (1) were aged 60 or older; (2) possessed normal communication and interaction abilities; (3) obtained at

least a primary school education; (4) had an Android-based smartphone for Internet access; (5) expressed willingness to participate. Older individuals with dementia or other mental illness were excluded. To validate the Health-ITUES among professional care providers, nurses, considered as the primary professional care providers, were included. In-service nurses holding Nurse Qualification Certificates were enrolled in the study if they had an Android-based smartphone and were willing to participate. All participants provided written informed consent on enrollment.

2.4.3 Instruments

2.4.3.1 General information collection

Demographic information including age, gender, education, and monthly income was collected from both older individuals and nurses. Besides, we gathered data on nurses' professional titles and years of employment. To measure participants' usage frequency of common functions on mobile phones, a Mobile Phone Usage Experience Questionnaire was utilized. This questionnaire, derived from the Questionnaire on Computer Experience, consists of 8 items, each rated on a 5-point Likert scale ranging from 1 (never) to 5 (very frequently). The total scores range from 8-40, with 8-16, 17-32, and 33-49 indicating low, moderate, and abundant mobile phone usage experience, respectively. The questionnaire exhibited satisfactory reliability, with a Cronbach's α coefficient of 0.922 [24].

2.4.3.2 The Health-ITUES-R and Health-ITUES-P

The finalized Health-ITUES-C and Health-ITUES-P adapted from the Chinese version of the Health-ITUES were used to collect the perceived usability of the SMART App among older individuals and nurses, respectively. Respondents rate these items on a 5-point Likert scale from 1 (completely disagree) to 5 (completely agree). Total scores for both versions are calculated by summing the scores of each item, with higher scores reflecting better perceived usability.

2.4.3.3 Patient Acceptance Questionnaire for Mobile Health Application

The Patient Acceptance Questionnaire for Mobile Health Application was utilized as a reference standard to evaluate the criterion validity of the Health-ITUES. This questionnaire, designed to

evaluate patients' acceptance of mobile medical products, consists of 32 items covering six dimensions: usefulness, ease of use, trust, usage attitude, system/interface, and usage tendency. Respondents provide ratings for each item on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree), resulting in a total score of 160. The questionnaire had satisfactory reliability and validity, with Scale-Content Validity Index (S-CVI), Cronbach's α coefficient, and split-half reliability of 0.97, 0.96, and 0.99, respectively [25]. Given its focus on users of medical Apps, the questionnaire was only administered to older people.

2.4.4 Data collection procedures

After providing a comprehensive explanation of the study's purpose, significance, and procedures, the research team assisted the participants in downloading and installing the SMART App and completing registration and login. Training materials, including instructional videos and user manuals, were made available to the participants until they felt confident in using the App. Subsequently, the participants were encouraged to use the SMART App for 24 hours to complete the assigned tasks before filling out the Health-ITUES-R, Health-ITUES-P, and Patient Acceptance Questionnaire for the Mobile Health Application as appropriate. The detailed tasks assigned to older adults and nurses were listed in Supplementary Table S5.

2.4.5 Sample size calculation

To achieve adequate statistical power, the sample size should be 5-10 times the number of items [26]. With a total of 20 items in the Health-ITUES, the study necessitated a minimum of 100 participants. Taking a 20% dropout rate into consideration, at least 110 older individuals and nurses were needed for the study.

2.4.6 Statistical analysis

Continuous variables with a normal distribution were presented as mean ± standard deviation, and

comparisons between groups were conducted using the Student's t-test or ANOVA test. For non-normally distributed continuous variables, the median (25% percentile, 75% percentile) was used and the Mann-Whitney U test was applied for between-group comparison. Categorical variables were expressed as frequencies or proportions (%) and comparisons were conducted using chi-square or Fisher's exact test as appropriate.

The content validity of the finalized Health-ITUES-R and Health-ITUES-P was assessed by the Content Validity Index of Items (I-CVI) and S-CVI based on expert ratings. I-CVI is the ratio of the experts ranking the item for 3 or 4 scores, and the S-CVI is the average value of all the I-CVI scores [27]. A scale with an I-CVI of > 0.78 and a S-CVI of ≥ 0.90 is considered satisfactory [28].

The internal consistency reliability was determined by Cronbach's α, McDonald's ω, and corrected item-total correlation coefficient (CITC). Values of Cronbach's α and McDonald's ω ≥ 0.70 are considered adequate, while a value of CITC < 0.30 indicates a low correlation [29,30]. While the test-retest reliability could assess measurement consistency under consistent conditions, the fluctuating nature of users' perceived usability of the digital health Apps over time makes this indicator unsuitable [31]. Furthermore, due to inherent variations in user perceptions of the App's usability, inter-rater reliability was not examined in the study.

CFA with maximum likelihood estimation was performed to explore the structure validity. The analysis provided standardized factor loading to estimate the relationship strength between items and dimensions [32], together with model fit indices, including χ^2/df, root mean square error of approximation (RMSEA), root mean square residual (RMR), standardized root mean square residual (SRMR), parsimonious goodness-of-fit index (PGFI), parsimonious normed fit index (PNFI), and parsimonious comparative fit index (PCFI). Acceptable structure validity was evaluated using recommended cut-offs characterized as standardized factor loading ≥ 0.60, χ^2/df < 3, RMSEA ≤ 0.10, RMR ≤ 0.05, SRMR ≤ 0.80, PGFI ≥ 0.50, PNFI ≥ 0.50, and PCFI ≥ 0.50 [33].

To determine the convergent validity, the composite reliability (CR) and average variance

extracted (AVE) were calculated through Fornell and Larcker's approach [34] with a CR ≥ 0.70 and AVE ≥ 0.50 indicating satisfactory convergent validity. The square root of the AVE exceeding each of its correlations with other dimensions indicates appropriate discriminant validity [35]. The discriminant validity was also tested by the Hetereotrait-Monotrait ratio (HTMT), where a value < 0.85 is acceptable [36]. Additionally, the criterion validity between the Health-ITUES and Patient Acceptance Questionnaire for Mobile Health Application was analyzed through Pearson's correlation, with correlation values > 0.50 deemed adequate [37].

Statistical analyses were performed using AMOS version 26.0 (IBM, Armonk, New York, USA) for CFA and SPSS version 26.0 (SPSS, Inc., Chicago, IL, USA) for the remaining analyses. A two-sided *p*-value < 0.05 was considered statistically significant.

3. Results

3.1 Translation and cross-cultural adaptation versions of the Health-ITUES

The detailed summary of the forward translations T1 and T2, synthesized version T3, and back translations BT1 and BT2 was provided in Supplementary Table S6. Following the first and second rounds of consultations with the expert panel, a total of 6 and 5 modifications were made, respectively, to formulate the final Chinese version of the Health-ITUES. The dimension "quality of work life" was deemed inadequate in reflecting the corresponding items accurately. Under the expert guidance, we changed it to "impact". Further details of expert suggestions and specific modifications on the synthesized version T3 were summarized in Supplementary Tables S7 and S8. The Cr of the expert panel was 0.89, indicating a high level of expert authority.

3.2 Validation of the Health-ITUES

3.2.1 Customization of the Health-ITUES-R and Health-ITUES-P

Based on the final Chinese version of the Health-ITUES, the research team proceeded to customize the Health-ITUES-R and Health-ITUES-P to align with the specific tasks and expectations of the

SMART App after extensive discussions. Subsequently, according to the suggestions from the expert panel with a Cr of 0.95, the research team made revisions to 6 and 4 items in the initial Health-ITUES-R and Health-ITUES-Provider to formulate the finalized versions for further validation. The expert suggestions and revisions as well as the finalized Health-ITUES-R and Health-ITUES-P were shown in Supplementary Tables S9-S12.

3.2.2 Validation of the Health-ITUES-R and Health-ITUES-P

3.2.2.1 Baseline characteristics of older individuals and nurses

A total of 110 and 124 eligible older adults and nurses were included in the validation test, respectively. Table 1 showcases their baseline characteristics. The median age of the older participants was 67.00 (64.00, 71.00) years with 67.27% being male. The enrolled nurses were largely female (112, 90.32%) with a median age of 26.00 (24.00, 28.00) years. 52.73% of the older participants were reported to have limited experience in using mobile phones, while the rest (52, 47.27%) exhibited moderate experience. In contrast, nurses exhibited more experience in using mobile phones, with 91.13% (113) having moderate usage experience and 8.87% (11) possessing abundant experience. Furthermore, older people tended to spend less time on their mobile phones every day, with only 10.00% (11) using their mobile phones for more than 3 hours per day, while 69.35% (86) of nurses reported using mobile phones for more than 5 hours per day.

Table 1. Baseline characteristics of the older adults and nurses in the validation study

Characteristics	Older adults (n=110)	Characteristics	Nurses (n=124)
Age	67.00 (64.00,71.00)	**Age**	26.00 (24.00,28.00)
Male	74 (67.27%)	**Male**	12 (9.68%)
Education		**Education**	
Primary school and below	28 (25.45%)	**Junior college or below**	63 (50.81%)
Junior high school	51 (46.36%)	**Undergraduate or above**	61 (49.19%)
Senior high school and above	31 (28.18%)	**Monthly income (□)**	
Monthly income (□)		**≤5000**	29 (23.39%)
≤1000	16 (14.55%)	**5001-10000**	66 (53.23%)
1001-3000	41 (37.27%)	**>10000**	29 (23.39%)
3001-5000	42 (38.18%)	**Years of work experience**	

Characteristics	Older adults (n=110)	Characteristics	Nurses (n=124)
>5000	11 (10.00%)	**<4**	64 (51.61%)
History of chronic diseases		**4-9**	50 (40.32%)
Hypertension	75 (68.18%)	**>9**	10 (8.06%)
Diabetes mellitus	37 (33.64%)	**Professional titles**	
Hyperlipidemia	31 (28.18%)	**Junior level**	93 (75.00%)
Stroke	38 (34.55%)	**Intermediate level**	29 (23.39%)
Coronary heart diseases	9 (8.18%)	**Senior level**	2 (1.61%)
Usage experience of mobile phones		**Usage experience of mobile phones**	
Less experience	58 (52.73%)	**Less experience**	0 (0.00%)
Moderate experience	52 (47.27%)	**Moderate experience**	113 (91.13%)
Abundant experience	0 (0.00%)	**Rich experience**	11 (8.87%)
Daily mobile phone usage duration		**Daily mobile phone usage duration**	
<1 hour	52 (47.27%)	**<5 hours**	38 (30.65%)
1-3 hours	47 (42.73%)	**5-7 hours**	64 (51.61%)
>3 hours	11 (10.00%)	**>7 hours**	22 (17.74%)

3.2.2.2 Reliability and validity evaluation results

As shown in Table 2, the I-CVI for both the Health-ITUES-R and Health-ITUES-P ranged from 0.83 to 1.00, while the S-CVI for both versions were 0.99, indicating satisfactory content validity.

Table 2. The content validity and modified kappa agreement of the Health-ITUES (n = 6)

Items	Health-ITUES-R			Health-ITUES-P		
	Ne	I-CVI	Modified kappa	Ne	I-CVI	Modified kappa
AQ1/BQ1	5	0.83	0.81	6	1.00	1.00
AQ2/BQ2	6	1.00	1.00	5	0.83	0.81
AQ3/BQ3	6	1.00	1.00	6	1.00	1.00
AQ4/BQ4	6	1.00	1.00	6	1.00	1.00
AQ5/BQ5	6	1.00	1.00	6	1.00	1.00
AQ6/BQ6	6	1.00	1.00	6	1.00	1.00
AQ7/BQ7	6	1.00	1.00	6	1.00	1.00
AQ8/BQ8	6	1.00	1.00	6	1.00	1.00
AQ9/BQ9	6	1.00	1.00	6	1.00	1.00
AQ10/BQ10	6	1.00	1.00	6	1.00	1.00
AQ11/BQ11	6	1.00	1.00	6	1.00	1.00
AQ12/BQ12	6	1.00	1.00	6	1.00	1.00
AQ13/BQ13	6	1.00	1.00	6	1.00	1.00
AQ14/BQ14	6	1.00	1.00	6	1.00	1.00
AQ15/BQ15	6	1.00	1.00	6	1.00	1.00
AQ16/BQ16	6	1.00	1.00	6	1.00	1.00
AQ17/BQ17	6	1.00	1.00	6	1.00	1.00
AQ18/BQ18	6	1.00	1.00	6	1.00	1.00
AQ19/BQ19	6	1.00	1.00	6	1.00	1.00
AQ20/BQ20	6	1.00	1.00	6	1.00	1.00

Health-ITUES, Health Information Technology Usability Evaluation Scale; Health-ITUES-R, Health Information Technology Usability Evaluation Scale (Care Receiver Version); Health-ITUES-P, Health Information Technology Usability Evaluation Scale (Professional Care Provider Version); Ne, number of experts with a rating of 3/4; I-CVI, item-level content validity index; AQ, questions in the Health Information Technology Usability Evaluation Scale (Care Receiver Version); BQ, questions in the Health Information Technology Usability Evaluation Scale (Professional Care Provider Version).

As shown in Table 3, we found a satisfactory internal consistency of the Health-ITUES-R, with Cronbach's alpha and McDonald's ω values of 0.880 and 0.899 for the overall scale, and 0.770-0.891 and 0.798-0.887 for the individual items. Similarly, the internal consistency of the Health-ITUES-P was excellent (Cronbach's alpha = 0.939 for the overall scale and 0.833-0.939 for individual items, McDonald's ω = 0.946 for the total scale and 0.901-0.931 for individual items). Besides, the CITC of each item in both of the versions was greater than 0.30, reflecting an acceptable correlation of each item with the sum of the other items in the scales.

Table 3. The internal consistency reliability and convergent validity of the Health-ITUES

Dimensions	Health-ITUES-R					Health-ITUES-P				
	Cronbach's α	McDonald's ω	CITC	AVE	CR	Cronbach's α	McDonald's ω	CITC	AVE	CR
Impact	0.778	0.871	-	0.544	0.781	0.844	0.907		0.649	0.847
AQ1/BQ1	0.878	0.898	0.362			0.936	0.944	0.647		
AQ2/BQ2	0.879	0.898	0.336			0.937	0.944	0.651		
AQ3/BQ3	0.875	0.895	0.480			0.936	0.944	0.676		
Perceived usefulness	0.888	0.911	-	0.478	0.891	0.914	0.931	-	0.556	0.918
AQ4/BQ4	0.873	0.894	0.523			0.935	0.943	0.722		
AQ5/BQ5	0.875	0.895	0.473			0.935	0.943	0.720		
AQ6/BQ6	0.877	0.896	0.416			0.936	0.943	0.697		
AQ7/BQ7	0.872	0.892	0.582			0.936	0.943	0.691		
AQ8/BQ8	0.875	0.894	0.486			0.936	0.944	0.647		
AQ9/BQ9	0.870	0.892	0.607			0.936	0.944	0.682		
AQ10/BQ10	0.875	0.895	0.482			0.935	0.943	0.694		
AQ11/BQ11	0.875	0.895	0.463			0.935	0.943	0.737		
AQ12/BQ12	0.875	0.895	0.493			0.937	0.945	0.609		
Perceived ease of use	0.891	0.921	-	0.633	0.895	0.867	0.906	-	0.581	0.873
AQ13/BQ13	0.874	0.895	0.535			0.937	0.944	0.624		
AQ14/	0.871	0.893	0.598			0.938	0.945	0.566		

Dimensions	Health-ITUES-R					Health-ITUES-P				
	Cronbach's α	McDonald's ω	CITC	AVE	CR	Cronbach's α	McDonald's ω	CITC	AVE	CR
BQ14										
AQ15/	0.872	0.894	0.564			0.938	0.945	0.536		
BQ15										
AQ16/	0.871	0.894	0.579			0.938	0.945	0.562		
BQ16										
AQ17/	0.873	0.895	0.516			0.939	0.947	0.452		
BQ17										
User control	0.770	0.867	-	0.527	0.768	0.833	0.901	-	0.647	0.845
AQ18/	0.874	0.895	0.494			0.936	0.943	0.696		
BQ18										
AQ19/	0.876	0.897	0.427			0.937	0.944	0.631		
BQ19										
AQ20/	0.879	0.900	0.314			0.937	0.945	0.596		
BQ20										
Total scale	0.880	0.899	-			0.939	0.946	-		

Health-ITUES, Health Information Technology Usability Evaluation Scale; Health-ITUES-R, Health Information Technology Usability Evaluation Scale (Care Receiver Version); Health-ITUES-P, Health Information Technology Usability Evaluation Scale (Professional Care Provider Version); CITC, corrected item-total correlation coefficient; AVE, average variance extracted; CR, composite reliability; AQ, questions in the Care Receiver Version; BQ, questions in the Professional Care Provider Version.

The path diagram and standardized factor loadings of the Health-ITUES were illustrated in Figure 1. The CFA confirmed a four-factor model consistent with the dimensions and items of the original Health-ITUES. The item scores from both the Health-ITUES-R and Health-ITUES-P exhibited adequate psychometric properties, with standardized factor loadings all exceeding 0.60, except for one item (AQ12) in the Health-ITUES-R (0.59). Moreover, according to the model fit indices (Table 4), both versions of the Health-ITUES showed acceptable fit, despite a slightly higher RSMEA value (0.122) for the Health-ITUES-P.

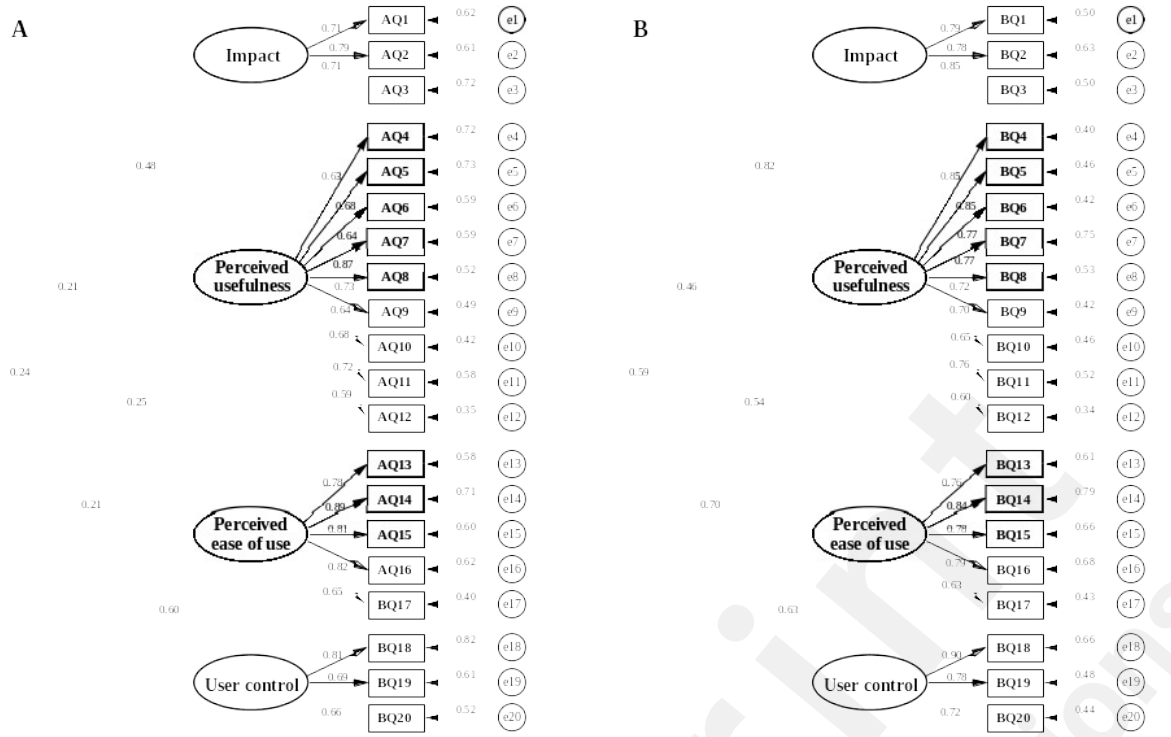

Figure. 1. Path diagram and standardized factor loadings for Health Information Technology Usability Evaluation Scale scores. (A) Path diagram and standardized factor loadings for the Health-ITUES-R; (B) Path diagram and standardized factor loadings for the Health-ITUES-P. The large oval is the latent construct, with the rectangles representing measured variables, and the small circles with numbers representing the residual variables (variances). The path factor loadings were determined by critical ratios (all $p < 0.001$).

Table 4. Overall CFA model fit indices of the Health-ITUES

Model fit indices	χ^2/df	RMSEA	RMR	PGFI	PNFI	PCFI	SRMR
Observed Value of the Health-ITUES-R	1.621	0.075	0.031	0.629	0.676	0.778	0.076
Observed Value of the Health-ITUES-P	2.841	0.122	0.033	0.571	0.652	0.711	0.079
Level of acceptance	< 3	≤ 0.10	≤ 0.05	≥ 0.5	≥ 0.5	≥ 0.5	≤ 0.1

Health-ITUES, Health Information Technology Usability Evaluation Scale; Health-ITUES-R, Health Information Technology Usability Evaluation Scale (Care Receiver Version); Health-ITUES-P, Health Information Technology Usability Evaluation Scale (Professional Care Provider Version); CFA, confirmatory factor analysis; RMSEA, Root Mean Square Error of Approximation; RMR, Root Mean Square Residual; PGFI, Parsimonious Goodness-of-Fit Index; PNFI, Parsimonious Normed Fit Index; PCFI, Parsimony Comparative Fit Index; SRMR, Standardized Root Mean Square Residual.

According to Table 3, both the Health-ITUES-R and Health-ITUES-P displayed satisfactory convergent validity, with AVE values exceeding 0.5 and CR values surpassing 0.7, except for a slightly lower AVE value (0.478) for the second dimension in the Health-ITUES-R. Besides, the greater square root of AVE values for all four dimensions than correlation coefficients and HTMT values below 0.85 suggested a good discriminant validity (see Table 5 and Table 6).

Table 5. Discriminant validity of the Health-ITUES

Dimensions	Health-ITUES-R				Health-ITUES-P			
	D1	D2	D3	D4	D1	D2	D3	D4
D1	0.738				0.806			
D2	0.484	0.691			0.747	0.746		
D3	0.215	0.248	0.796		0.461	0.545	0.762	
D4	0.237	0.210	0.602	0.726	0.594	0.702	0.630	0.804

Health-ITUES, Health Information Technology Usability Evaluation Scale; Health-ITUES-R, Health Information Technology Usability Evaluation Scale (Care Receiver Version); Health-ITUES-P, Health Information Technology Usability Evaluation Scale (Professional Care Provider Version); D1, dimension 1 (impact); D2, dimension 2 (perceived usefulness); D3, dimension 3 (perceived ease of use); D4, dimension 4 (user control); the values on the diagonal are the square root of average variance extracted.

Table 6. HTMT values between the four dimensions of the Health-ITUES

HTMT values	Health-ITUES-R	Health-ITUES-P
Impact - Perceived usefulness	0.506	0.845
Impact - Perceived ease of use	0.240	0.463
Impact - User control	0.262	0.604
Perceived usefulness - Perceived ease of use	0.281	0.589
Perceived usefulness - User control	0.214	0.753
Perceived ease of use - User control	0.631	0.687

HTMT, Hetereotrait-Monotrait; Health-ITUES, Health Information Technology Usability Evaluation Scale; Health-ITUES-R, Health Information Technology Usability Evaluation Scale (Care Receiver Version); Health-ITUES-P, Health Information Technology Usability Evaluation Scale (Professional Care Provider Version).

Regarding the criterion validity, Pearson's correlation coefficients for the perceived usefulness dimension, perceived ease of use dimension, and overall scale of the Health-ITUES-R and Patient Acceptance Questionnaire for Mobile Health Application were 0.587, 0.647, and 0.743, respectively (all $p < 0.01$), indicating a significant correlation between them. Further details were provided in Table 7.

Table 7. Criterion validity of the Health-ITUES-R concerning the Patient Acceptance Questionnaire for Mobile Health Application

Health-ITUES-R	Patient Acceptance Questionnaire for Mobile Health Application						
	Usefulness	Ease of use	System/ Interface	Reliability	Usage attitude	Usage tendency	Overall scale
Impact	0.383**	0.181	0.288**	0.275**	0.323**	0.317**	0.389**
Perceived usefulness	0.587**	0.222*	0.320**	0.401**	0.531**	0.492**	0.563**
Perceived ease of use	0.453**	0.647**	0.417**	0.087	0.492**	0.393**	0.576**
User control	0.456**	0.406**	0.310**	0.107	0.368**	0.335**	0.452**
Overall scale	0.696**	0.546**	0.488**	0.330**	0.657**	0.580**	0.743**

Health-ITUES-R, Health Information Technology Usability Evaluation Scale (Care Receiver Version); *$p < 0.05$; **$p < 0.01$.

4. Discussion

4.1 Principle findings

Based on the original Health-ITUES, we meticulously translated and culturally adapted it to develop the Chinese version of the Health-ITUES. The validation test conducted among the main users of the SMART App (older people and nurses) confirmed satisfactory reliability and validity of the Chinese version of the Health-ITUES in evaluating the usability of digital health Apps. To our understanding, this represents the first exploration of a valid usability evaluation instrument that specifically designed for digital health Apps considering both care receivers and professional care providers in China, which can provide evidence supporting the use of the Chinese version of the Health-ITUES as a validated tool for evaluating the usability of digital health Apps.

Following the Guideline for the Process of Cross-Cultural Adaptation of Self-Report Measures [20], we carefully selected appropriate translators for both forward and back translations of the Health-ITUES and determined the Chinese version through numerous rounds of discussions within the research team [38]. Simultaneously, our iterative modification process under consultations with the expert panel until obtaining verification of the original author, enabled us to adjust the dimensions and items from a professional perspective and ensure that the original meanings of the Health-ITUES items were retained, thereby improving the effectiveness and practicality of the Chinese version of the Health-ITUES [39].

Furthermore, the customized Health-ITUES-R and Health-ITUES-P were validated as effective tools with good content validity, internal consistency reliability, and discriminant validity in measuring the usability of the SMART App. The CFA results also indicated an adequate structure validity, expect for a slightly higher RMSEA value of the Health-ITUES-P. It is worth noting that the RMSEA value is calculated based on non-centrality parameters for representing the absolute measure of fit, and its calculation heavily depends on the sample size [40, 41]. Models with smaller sample sizes were generally believed with the potential to artificially large RMSEA values, which can

explain the overestimated RMSEA value in our validation test to some extent [42]. Regarding the convergent validity, the slightly lower AVE value for the second dimension in the Health-ITUES-R (0.478) could be attributed to the limited understanding and short usage time of the SMART App among older individuals. This may result in less precise responses to the 9 questions in this dimension and a lower AVE value [43]. Additionally, the Health-ITUES-R exhibited high criterion validity compared to the Patient Acceptance Questionnaire for Mobile Health Application.

To the best of our knowledge, our study, for the first time, formulated the Chinese version of the Health-ITUES and validated its utility for evaluating the usability of digital health Apps in the Chinese context by considering both care receivers and professional care providers [8]. In addition to the commonly used validation measures such as content validity, internal consistency reliability, structure validity, and criterion validity, we also examined the convergent and discriminant validity for a comprehensive validation of the Chinese version of the Health-ITUES. Given its strong psychometric properties, we postulate that the Chinese version of the Health-ITUES can serve as a valuable instrument in evaluating the usability of digital health Apps for both professional healthcare providers and receivers.

4.2 Limitations

There are several limitations in this study. Firstly, the validation of the Chinese version of the Health-ITUES relied on the SMART App, a platform designed for personalized integrated home-based older care, while the Health-ITUES applies to all types of digital health Apps. Consequently, it cannot be ruled out that the validation results could have differed with another App. Secondly, there may be a selection bias in the sample selection, since the validation test were conducted in the geriatric ward of a comprehensive hospital, where individuals tended to spent more time using digital health Apps to manage health status compared to the general population[44]. Furthermore, our validation study was constrained by relatively small sample sizes and inadequate usage time of the SMART App due to the COVID-19 pandemic. The generalizability of the findings should be approached with caution.

Further research with a larger sample and adequate usage time of the digital health Apps is needed.

4.3 Conclusions

This study formulated a Chinese version of the Health-ITUES with satisfactory reliability and validity in evaluating the usability of the digital health Apps for both care receivers and professional care providers. The Chinese version of the Health-ITUES can serve as a valuable tool to identify reliable and effective digital health Apps for end users.

Authors' Contributions

Rongrong Guo conducted the formal Analysis and wrote the original draft, Ziling Zheng collected the data and participated in the data analysis process, Fangyu Yang designed the study, and Ying Wu conceptualized the methodology, reviewed the manuscript, and supervised the whole process.

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Conflicts of Interest

None declared.

Abbreviations

Health-ITUES: Health Information Technology Usability Evaluation Scale

Health-ITUES-R, Health Information Technology Usability Evaluation Scale - Care Receiver Version

Health-ITUES-P, Health Information Technology Usability Evaluation Scale -Professional Care Provider Version

App: applications

COVID-19: Corona Virus Disease 2019

SUS: System Usability Scale

PSSUQ: Post-Study System Usability Questionnaire

SUMI: Software Usability Measurement Inventory

CSUQ: Computer System Usability Questionnaire

EFA: exploratory factor analysis

CFA: confirmatory factor analysis

Cr: authority coefficient

Cs: familiarity coefficient

Ca: judgment coefficient

S-CVI: Scale-Content Validity Index

I-CVI: Content Validity Index of Items

CITC: corrected item-total correlation coefficient

RMSEA: root mean square error of approximation

RMR: root mean square residual

SRMR: standardized root mean square residual

PGFI: parsimonious goodness-of-fit index

PNFI: parsimonious normed fit index

PCFI: parsimonious comparative fit index

CR: composite reliability

AVE, average variance extracted

Data availability statement

The data that support the findings of this study is available from the corresponding author upon reasonable request.

Ethics Statement

The study was approved by the Institutional Review Committee of the Capital Medical University (Approval No. 2015SY49).

Multimedia Appendix

Multimedia Appendix 1 CONSORT-EHEALTH checklist

Multimedia Appendix 2 File 1 included permission from the original author of the Health Information Technology Usability Evaluation Scale. Table S1 provided an overview of the translators involved in the forward translation, synthesis of the forward translations, and back translation. Table S2 outlined the basic information of the expert panel for cross-cultural adaption. Table S3 detailed the methods and rules to assess the expert authority coefficient. Table S4 summarized the basic information of the experts involved in the customization of the Health Information Technology Usability Evaluation Scale. The specific SMART App operation tasks assigned to older individuals and nurses were listed in Table S5. Table S6 summarized the original version, forward translation versions, synthesized version, and back translation versions of the Health Information Technology Usability Evaluation Scale. The expert suggestions and specific modifications from the two rounds of expert consultation of the synthesized forward translation version were presented in Tables S7 and S8, while the expert suggestions and specific changes made to the initial scale for older people and

nurses were summarized in Tables S9 and S10, respectively. The finalized customized scale for older people and nurses along with their confirmatory factor analysis results were presented in Tables S11-14. Table S15 described the Patient Acceptance Questionnaire for Mobile Health Application.

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Supplementary Files

Multimedia Appendixes

Reporting Guideline Checklist.
URL: http://asset.jmir.pub/assets/278659b158d8c96b2f420a9614d19ddf.docx

Other detailed analysis results.
URL: http://asset.jmir.pub/assets/93b5b5bc1fb052a7aca3b5fd1700eb30.docx