

Translation and Cross-Cultural Adaptation of the Questionnaire of Sleep Health for Using in Chinese Older

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Research

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Abstract

Objective: to make the translation, cross-cultural adaption and content and face validation of Questionnaire of sleep health for use in Chinese elder, as well as measuring psychometric properties of the questionnaire.

Methods: A methodological study carried out in six steps: translation of the instrument, consensus of the translations, back-translation, analysis by an expert committee, pre-testing and then evaluation of psychometric properties. Psychometric properties, including item analysis (the extreme group comparison and item-total correlations), content validity (item-level content validity index (I-CVI) and scale-level content validity index (S-CVI)), construct validity confirmatory factor analysis (CFA) and internal consistency (Cronbach's α and test-retest reliability) were measured.

Results: The instrument was translated, transculturally adapted and its final version consisted of 12 items. The Q-USM has excellent internal consistency (Cronbach's $\alpha=0.76$). The test-retest reliability coefficient was 0.97. The I-CVI ranged from 0.80 to 1.00, and the S-CVI was 0.98. CFA showed that the three-factor model explained 56.54% of the total variance, with a good model fit (likelihood ratio $\chi^2/df=3.75$, incremental fit index=0.86, comparative fit index=0.86, goodness-of-fit index=0.89, adjusted goodness-of-fit index=0.84, standardized root mean square error of approximation=0.09 and root mean square residual=0.02).

Conclusion: The *Q-USM* was translated and adapted to Chinese elder, and the psychometric properties of the Chinese version of the questionnaire presented satisfactory. It's providing assessment instruments for community elderly health. As the questionnaire is applied for the first time in China, it needs to be continuously improved.

Introduction

Sleep disorder has become a common symptom of the elderly [1–3]. Studies have shown that it is characterized by difficulty in falling asleep, shallow sleep and easy to wake up [4–6]. Sleep disorders are extremely common among the elderly, impairing the sleep quality and becoming a public health problem [7, 8], seriously affecting the cognitive function of the elderly [9], increasing the risk of falls in the elderly [10]. The demand for sleep has not decrease, it is very common to take sleeping drugs [11–14].

Prescription and some over-the-counter drugs contain doxylamine and diphenhydramine, which can increase liver and kidney dysfunction, the risk of falls in order adults and adverse drug events in the elderly [15]. The elderly have poor awareness of drug safety, such as multiple diseases coexisting with multiple drugs [16], drug abuse [17], and poor drug compliance [18]. The simple medication evaluation tool is conducive to investigate the current situation of sleep medication use in the elderly and analyze the influencing factors.

The questionnaire of sleep health and use of sleep medications among older adults compiled by American scholar Olufunmilola Abraham et al [19], it contained 13 items and used to evaluate the use of over-the-counter sleep drugs(over-the-counter,OTC)and prescription sleep drugs among elderly, along with healthcare seeking behaviors, products of the names, frequency of use, knowledge of safety risks and active ingredients, and satisfaction with use sleep medication. The results show that 169 participants from the Pittsburgh Claude D in one urban region of Western Pennsylvania in the United States have all taken sleep medications in the past 30 days, and more than half (59%) of them used OTC drugs containing at least one DIPH/DOX. 80% had consulted a physician, with 21% consulting a pharmacist and about 5% reporting that they consulted a nurse practitioner when choosing their sleep medications. Effective questionnaires about use of sleep medications used for assessing the status of drug use in the elderly is necessary, there is no relevant questionnaire in China that limits the study of use of sleep medication among elderly.

The objectives of this study were to translated, cross-cultural adaptation and evaluate the reliability and validity of the Chinese version questionnaire.

Methods

This is a methodological development study involving the translation, cross-cultural adaptation and obtaining initial psychometric properties of the questionnaire, carried out between June 2019 and October 2019. The questionnaire of sleep health and use of sleep medications among older adults was prepared by American scholar Olufunmilola Abraham and others [19]. It contains 13 items, developed to collect information and characteristics including use of treatments or products used to alleviate sleep problems (primarily OTC sleep medications). To elicit responses indicating the use of OTC medications to improve sleep, participants were asked: "Do you use any over the counter (OTC) medications to help you fall asleep or stay asleep (OTC drugs include Benadryl, Tylenol PM, ect.)? Participants were also asked about any prescription taken to help fall or stay asleep. Survey items relating to consultation with a healthcare professional about choosing an OTC product for asleep and overall satisfaction with sleep (very dissatisfied, dissatisfied, neither satisfied nor dissatisfied, satisfied, very satisfied) were also collected. The questionnaire translation process was guided by the theoretical framework of cross-cultural adaptation, and comprised the following steps (Fig. 1; Page 18): translation, synthesis, back-translation, reviewed by the expert committee, pre-test measuring psychometric properties and cross-cultural adaptation process [20].

Step 1

Two independent translators translated the questionnaire from English to Chinese, the former is the subject researcher and the other is a doctor. Two translators reviewed the translated questionnaires from the professional and linguistic perspectives respectively to ensure that the translated version expressed the same meaning as the original English version. Both translators provided a written report of the

translation process, including challenging phrases, uncertainties and reasoning for their decisions. Step 1 resulted in 2 Chinese translations: T1 and T2.

Step 2

Both translators from step 1 combined the 2 translations of the questionnaire into 1 version of the questionnaire: T12. A report clarified the consensus process.

Step 3

The translation of the questionnaire (T12) was independently back-translated from Chinese to English by 2 translators. Both professional translators were bilingual, with English as their primary language. The translators had no knowledge of the concept the questionnaire aims to measure and were masked to the original English version of the questionnaire. Both translators provided a written report of the translation process, including challenging phrases, uncertainties and reasoning for their decisions. Step 3 resulted in 2 English translations: R1 and R2.

Step 4

The expert committee referred to in step IV was comprised of masters and doctors, all with experience in the theme and fluent in the English language. An expert group composed a pre final version of the questionnaire, on the basis of the translations and reported of the previous stage. The expert group consisted of 6 people: subject researcher, the 4 translators (Nursing experts and professors), neurologist with approximately 30 years of clinical experience. The expert group made a report of the process during step 4.

Step 5

In step V, the questionnaire was applied to 300 elderly adults over 60 years old with sleep disorders who were taking sleep medications. Participants that convenient sampling were asked for their opinions on the questionnaire by a survey. Questions were primarily with regard to comprehensibility and applicability. No personal or medical data were collected. Furthermore, this study was considered not to lead to infringement of the physical or psychological integrity of our participants. And then conduct preliminary investigation and reliability and validity test.

Step 6

The translation process was assessed during a process audit by means of review of the translations and reports of step 1 through 5 by one of the developers of the original English version of the questionnaire. The doctor judged the process and quality of the translation and created a report including comments to be considered by the expert group.

Data analysis

Data were analysis using SPSS 22.0. The categorical variables were counted using frequency and percentages, $P < 0.05$ was considered to be statistically significant. Item analysis was conducted based on the following analysis: (I) extreme group comparison, items should discriminate between the scoring group of the upper 27% and lower 27% [21] and (II) item-total correlations the correlation between the score of each item and the total score of the scale. Items with a critical ratio (CR) > 0.3 or an item-total correlation between 0.30 and 0.80 were retained [22]. Content validity was tested using the content validity index, including the item-level content validity index (I-CVI) and the scale-level content validity (S-CVI). I-CVI of 0.78 or higher and an S-CVI of 0.80 were considered acceptable [23]. Additionally, confirmatory factor analysis (CFA) was conducted using AMOS V.22.0. The Kaiser-Meyer-Olkin test and Bartlett's test of sphericity should be performed before CFA to determine whether factor analysis is suitable. When the Kaiser-Meyer-Olkin value ≥ 0.6 and Bartlett's test of sphericity is significant at $p < 0.05$, the scale is suitable for conducting factor analysis [24]. In addition, internal reliability and stability were tested through Cronbach α and test-retest reliability, respectively. Cronbach's α with a value higher than 0.7 demonstrate that the items would measure the same construct [25]. Test-retest reliability (2 weeks internal) in a convenience sample of 300 was examined using the Pearson's correlation coefficient.

Results

Baseline characteristics

A total of 300 subjects were interviewed, baseline characteristics of the population are shown in Table 1. (Page 19)

Table 1
Baseline characteristics of the participants (n = 300)

Variable	n	%	Mean ± SD
Gender			
Male	148	49.3%	
Female	152	50.7%	
Age (Years)			67.80 ± 9.14
60–74	196	65.3%	
≥ 75	104	34.7%	
Marital status			
Married	213	71.0%	
Divorced	5	1.7%	
Widowed	82	27.3%	
Education achievement			
Primary school	102	34.0%	
Middle school	96	32.0%	
High school	56	18.7%	
College or university	46	15.3%	

Stage 1 and 2 (Forward Translation)

Throughout the translation process, several arguments were taken into consideration. Simplicity and terms generally used by researchers in their communication with older adults were preferred, in order that questionnaire be comprehensible for participants. Moreover, consistency of terms and syntax was strived for throughout the questionnaire.

Personal reading ability is the most important factor affecting the reading of the elderly. The physical function of the elderly is gradually declining, and both vision and hearing are declining, which leads to an increase in dyslexia and weakens the subject's ability to understand the reading content. Therefore, in order to alleviate the reading and writing obstacles of the elderly, listing the most frequently used prescription and over-the-counter sleep drugs in the elderly through expert group discussions and social surveys.

In the original version item-1 “provide the following for each OTC medication you have used to help you fall asleep or stay asleep”, expert group list the most frequently used OTCs for the elderly, such as Anshen Bunao, Liermian capsule, Baile Mian Capsule et al.

In the original version item-8 “provide the following for each prescription medication you have used to help you fall asleep or stay asleep”, expert group list the most frequently used prescription drugs such as Zopiclone, Zolpidem, Diazepam Clonazepam, Phenobarbital, Estazolam tablets et al.

In the original version item-10, listing side effects mainly: (1) daytime sleepiness, slow response, decreased judgment; (2) wake up early, sleep is not complete; (3) respiratory disorders during sleep; (4) rebound insomnia

Stage 3 and 4 (Back-Translation and Expert Group)

The expert group addressed several fundamental remarks. Regarding cultural context, two items of original version that-12, 13 were modified. Original questionnaire that item-12 “How often do you have someone (like a family member, friend, hospital/clinic worker, or caregiver) help you read hospital or pharmacy materials?” Since the elderly are not familiar with some proper terms, the appearance of these terms may interfere with the judgment of the elderly. Therefore, the Expert Committee recommends that they be changed to “Drug Instructions” to facilitate understanding by the elderly. The item-13 “How often do you have problems learning about your medical condition because of difficulty understanding written information?” is modified by “Do you have difficulty understanding the disease because it’s difficult to understand the drug product or hospital diagnosis, if so the frequency is ?” to adapt to Chinese language and culture. Respect the semantic and cultural equivalences. The remaining 10 items had 100% agreement among the specialists. And the consensus among the specialists dictated that all the items were modified using second person singular.

Stage 5 (Pilot-Test)

300 older adults were recruited for the pilot-test. Respondents commented on multiple layout issues. They felt the layout was orderly and convenient after listing the most frequently used prescription and over-the-counter sleep drugs in the questionnaire. In addition, participants made content-related of comments, for example some listed medications lack of specificity. To retain comparability between the Chinese translation and the original English version, these did not lead to changes to the construct to be measured.

Stage 6 (Process audit)

The process auditor stated that the process had been comprehensive and valued the quality of the work. Based on comments of the process auditor, some additional changes were made.

The response options of item 8 were reconsidered. Considering the medical background and cultural differences, the purchase of some prescription medications is restricted, so the drugs listed in item8 are mainly: Zopiclone, Zolpidem, Diazepam et al and Tianmeng capsule

Item analysis

Item analysis based on the results of the expert consultation and cognitive interview, item 8 “If Yes, provide the following for each prescription medication you have used to help you fall asleep or stay asleep” from the original questionnaire was incorporate in the item 7 “Do you ever use prescription medications to help you fall asleep or stay asleep?”, and the first preliminary version of the questionnaire include 12 items.

Based on the results of the extreme group comparison, the CR value of all items exceeded 3.0; thus all of the items were temporarily retained. The Spearman’s correlation method was adopted to calculate the correlation between items and the total score. The coefficients all of the items were > 0.3, therefore the preliminary version of the questionnaire contained 12 items in Table 2.

Table 2 Results of Chinese version of questionnaire of sleep health and use of sleep medications items analysis (12 items)

Item	CR	Item-total correlations	Note
Item-1	41.42*	0.76*	Retained
Item-2	9.38*	0.53*	Retained
Item-3	19.80*	0.67*	Retained
Item-4	7.50*	0.39*	Retained
Item-5	9.50*	0.50*	Retained
Item-6	6.71*	0.36*	Retained
Item-7	14.47*	0.57*	Retained
Item-8	9.98*	0.51*	Retained
Item-9	6.30*	0.35*	Retained
Item-10	6.10*	0.39*	Retained
Item-11	14.24*	0.71*	Retained
Item-12	12.57*	0.64*	Retained
*P<0.01			

Validity

Content validity

The final version by committee of experts, named Questionnaire of sleep health and use of sleep medications among older adults (Q-USM), total 12 items. Five experts were select to evaluate the validity of the questionnaire, 3 professors of neurology, 2 doctors in neurology. I-CVI was calculated based on the number of people giving an expert rating of 3 or 4 for each item, and the S-CVI was calculated from the average of the I-CVI of all items. The results showed that the I-CVI ranged from 0.80 to 1.00 and that the S-CVI was 0.98, indicating that the Q-USM has excellent content validity, as show in Table 3. For the item 1 “provide the following for each OTC medication you have used to help you fall asleep or stay asleep”, the expert gives a revised opinion: please describe whether the over-the-counter drug is Chinese medicine or western medicine. All over-the-counter medicines exemplified are Chinese medicine or Chinese patent medicine.

Table 3 Content validity of Chinese version of questionnaire of sleep health and use of sleep medications among older adults (n=5)

Item	Number of experts rated 3 or 4	I-CVI
Item-1	4	0.80
Item-2	5	1.00
Item-3	5	1.00
Item-4	5	1.00
Item-5	5	1.00
Item-6	5	1.00
Item-7	5	1.00
Item-8	5	1.00
Item-9	5	1.00
Item-10	5	1.00
Item-11	5	1.00
Item-12	5	1.00
		S-CVI/Ave=0.98

Construct validity

The Kaiser-Meyer-Olkin measure of the Q-USM was 0.85, and Bartlett's test of sphericity was also satisfactory ($p = 0.00$), which means that the 12-item Q-USM was suitable for conducting factor analysis. According to the screen plot (Fig. 2) and the factor structure of the original scale, we decided that the number of common factors extracted from the scale and these three factors explained 56.54% of the total variance. The CFA results suggested that goodness of fit of the adjusted three-factor model was good. Specifically, likelihood ratio $\chi^2/df = 3.75$, incremental fit index = 0.86, comparative fit index = 0.86, goodness-of-fit index = 0.89, adjusted goodness-of-fit index = 0.84, standardized root mean square error of approximation = 0.09 and root mean square residual = 0.02.

Criterion-related validity

Criterion-related validity is one of the standards, the higher correlation, the higher validity of the questionnaire. In this study, the scale of Beliefs and Medicines Questionnaire (BMQ)[26] is the gold standard for assessment. The results of the spearman correlation analysis with the BMQ scale illustrate $r = 0.71(P < 0.01)$. Better confirmation of the good validity of the Chinese version of the questionnaire.

Reliability

Regarding the psychometric properties, Cronbach's α was 0.764, for all items of the translated and adapted version, indicating excellent internal consistency. The reliability of the Chinese-Q-USM according to the test-retest measured by the intra-class correlation coefficient (ICC) provided a global value of 0.97, CI 95% [0.96–0.98]. Table 4 shows the original questionnaire version besides the translated and transculturally adapted version to Chinese older adults and their psychometric properties.

Table 4
Original version and adapted version of Q-USM items.

Questionnaire of sleep health and use of sleep medications among older adults (<i>version original</i>)	Questionnaire of sleep health and use of sleep medications among older adults (<i>Q-USM, version adapted</i>)
<p>1. Do you use any over the counter (OTC) medication to help you fall asleep or stay asleep?</p> <p>If yes, provide the following for each OTC medication you have used to help you fall asleep or stay asleep?</p>	<p>1. Do you use any over the counter (OTC) medication to help you fall asleep or stay asleep?</p> <p>If yes, provide the following for each OTC medication you have used to help you fall asleep or stay asleep?</p>
<p>2. Have you used one of the above listed over the counter (OTC) medication to help you fall asleep or stay asleep in the last 30 days?</p>	<p>2. Have you used one of the above listed over the counter (OTC) medication to help you fall asleep or stay asleep in the last 30 days?</p>
<p>3. Do you know the active ingredient/s contained in your most recently used OTC medication for sleep?</p> <p>If yes, please list here</p>	<p>3. Do you know the active ingredient/s contained in your most recently used OTC medication for sleep?</p> <p>If yes, please list here</p>
<p>4. Did you consult your pharmacist or doctor when choosing this OTC medication for sleep?</p> <p>If Yes, who did you consult?</p>	<p>4. Did you consult your pharmacist or doctor when choosing this OTC medication for sleep?</p> <p>If Yes, who did you consult?</p>
<p>5. Do you believe there are any safety risks in taking OTC sleep medications, whether or not you use these medications?</p> <p>If yes, please describe any safety risks you are aware of below</p>	<p>5. Do you believe there are any safety risks in taking OTC sleep medications, whether or not you use these medications?</p> <p>If yes, please describe any safety risks you are aware of below</p>
<p>6. How satisfied are you with using this/these OTC sleep aid(s) to improve your sleep quality?</p>	<p>6. How satisfied are you with using this/these OTC sleep aid(s) to improve your sleep quality?</p>
<p>7. Do you ever use prescription medications to help you fall asleep or stay asleep?</p>	<p>7. Do you ever use prescription medications to help you fall asleep or stay asleep?</p> <p>If Yes, provide the following for each prescription medication you have used to help you fall asleep or stay asleep</p>
<p>8. If Yes, provide the following for each prescription medication you have used to help you fall asleep or stay asleep</p>	<p>8. Have you used one of the above listed prescription medications to help you fall asleep or stay asleep in the last 30 days?</p>
<p>9. Have you used one of the above listed prescription medications to help you fall asleep or stay asleep in the last 30 days?</p>	<p>9. Did you experience any side effects from using these prescription medications?</p> <p>If Yes, please describe these side effects (Day-time drowsiness, fragmented sleep, etc...)</p>

Questionnaire of sleep health and use of sleep medications among older adults (<i>version original</i>)	Questionnaire of sleep health and use of sleep medications among older adults (<i>Q-USM, version adapted</i>)
<p>10. Did you experience any side effects from using these prescription medications?</p> <p>If Yes, please describe these side effects (Day-time drowsiness, fragmented sleep, etc...)</p>	<p>10. Do you ever use any other prescription medications?</p> <p>If Yes, please list the prescription medications you are currently taking, what you are taking them for, and describe how you use these medications.</p>
<p>11. Do you ever use any other prescription medications?</p> <p>If Yes, please list the prescription medications you are currently taking, what you are taking them for, and describe how you use these medications</p>	<p>11. How often do you have someone (like a family member, friend, hospital/clinic worker, or caregiver) help you read drug directions?</p>
<p>12. How often do you have someone (like a family member, friend, hospital/clinic worker, or caregiver) help you read hospital or pharmacy materials?</p>	<p>12. Do you have difficulty understanding the disease because it's difficult to understand the drug product or hospital diagnosis, if so, the frequency is?</p>
<p>13. How often do you have problems learning about your medical condition because of difficulty understanding written information?</p>	

Discussion

The project resulted in a Chinese translation of the questionnaire, adapted for cross-cultural differences. The key strength of the project is the extensive procedure that was used for development of the translated questionnaire, consisting of duplicated forward as well as back-translations, criticism by an expert group, pilot testing, and a process audit. The approach was successful in capturing the relevant cross-cultural differences and making valid adaptations. Specifically, the expert committee discussions revealed remarkable insights. The number of participants of the pilot-test however, was small and the scope relatively narrow, which results in limited information on perception of the target population regarding the questionnaire.

The process of translation and cross-cultural adaptation was carefully conducted in the line of the criteria described by Guillemin et al. and Beaton et al [20, 27]. In step 1 and 2, considering factors such as reading ability and writing disabilities in the elderly, after discussion by the expert group, the handwritten answer is changed to options to make it easier for the elderly to answer. In step3 and4, the expert group follows the equivalence model proposed by Flaherty and Herdman [28, 29]: conceptual equivalence; Semantic equivalence; Content equivalence; Technical equivalence; Standard equivalence. Item-12, 13 of original version has been modified to suit Chinese culture. In general, the Q-USM had satisfactory internal consistency (Cronbach's $\alpha = 0.76$), test-retest reliability (coefficient = 0.97). The items' CVIs all achieved the standard of good content validity with CVI of 80% or above[30]. And the criterion-related validity is $r =$

0.71. This instrument provides an effective and comprehensive method for Community health care system.

The rational and safe drug use of the elderly is becoming well known to public and being valued by the healthcare system [31, 32]. In this study, the questionnaire was standardized and cross-culturally adjusted. Strictly follow the principle of translation, the pre-test and reliability-effectiveness test were conducted for the elderly who were consistent with the original English version of the questionnaire.

Conclusion

The Chinese Q-USM is promising to contribute to community health care system and as an outcome for research purposes, it provides a valuable addition to measure participation in elderly with sleep disorder and use sleep medications.

Declarations

Ethics Statement

The research project was approved by the medical ethics committee of the affiliated hospital of Beihua university (201910). The data source strictly abides by the principle of confidentiality and does not disclose the patient's privacy.

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Competing interests

The authors declare that they have no competing interests.

Author contributions

Study concept, design and translation, data collection, recording and analysis and manuscript preparation: He Tang, the study concept, design and translation, literature review and revising it critically:

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Figures

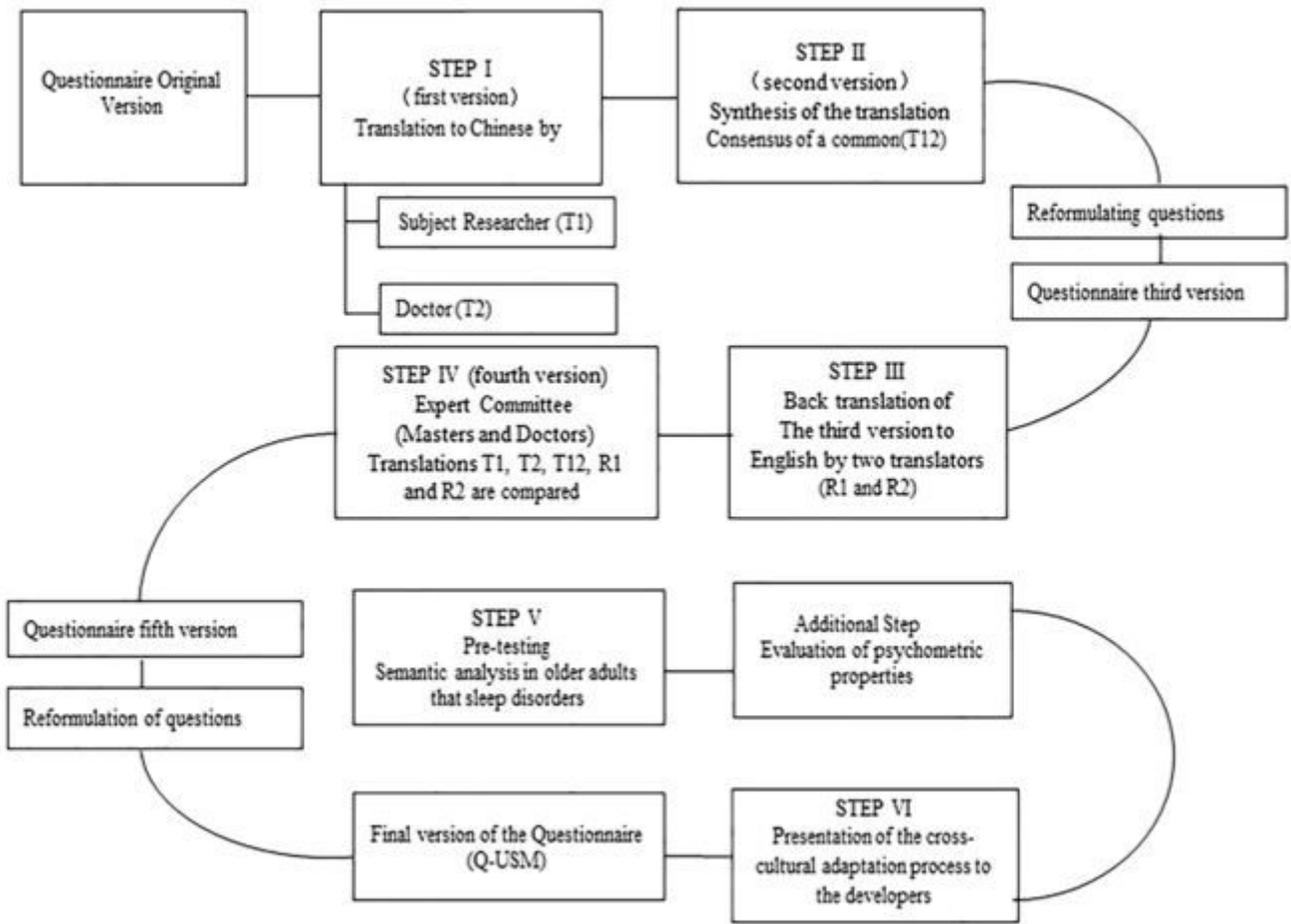


Figure 1

Methodological trajectory of the questionnaire cultural adaptation

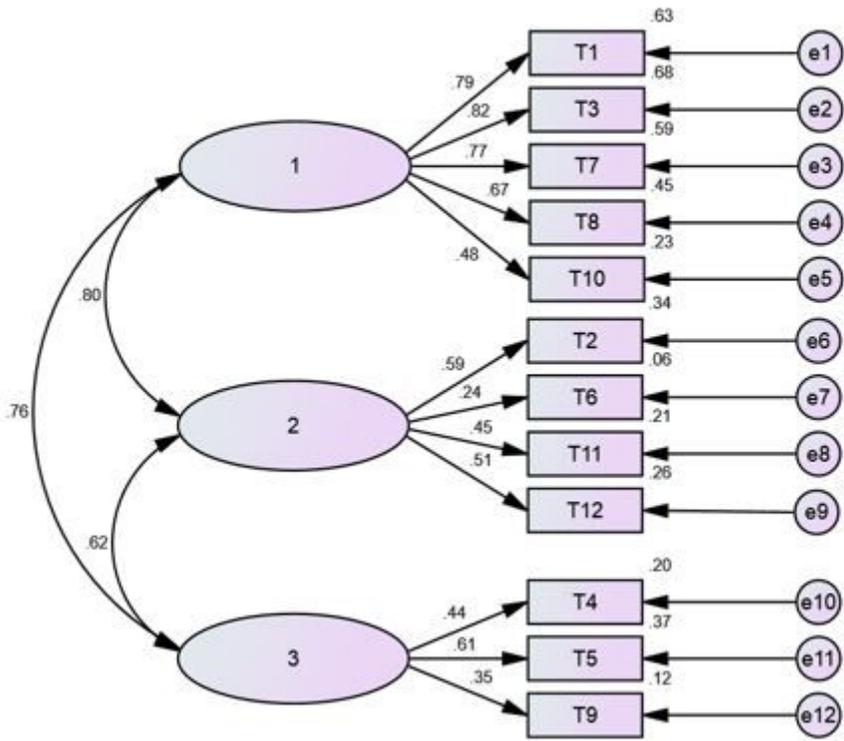


Figure 2

Standardized three-factor structural equation model diagram.