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Evidence-based Study

Development and evaluation of a Traditional Chinese Medicine syndrome questionnaire for measuring sub-optimal health status in China

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Abstract

OBJECTIVE: Sub-optimal health status (SHS), in which a person's mind and body exists in a low-quality state of being between disease and health, has become a public health problem that cannot be ignored in China. SHS measurement presents a challenge to the academic fields. We developed and evaluated a questionnaire from the perspective of traditional Chinese medicine (TCM) that embodies the features of TCM syndrome diagnosis for measuring SHS in China.

METHODS: The construction of the theoretical framework of the questionnaire was based on a literature review, an expert questionnaire survey and group interviews. The subscales and questionnaire items were screened through a pilot study using statistical means and qualitative analysis. Reliability tests that were used included test-retest reliability, Cronbach's α coefficient, split-half reliability; validity tests included content validity, criterion validity, discrimination validity and construct validity.

RESULTS: The final questionnaire, the SHSQ-50, included 50 five-class quantifiable items that encompassed nine subscales: liver stagnation syndrome, liver-Qi deficiency syndrome, spleen-Qi deficiency syndrome, liver-fire syndrome, heart-fire syndrome, stomach-fire syndrome, heart-Qi deficiency syndrome, lung-Qi deficiency syndrome and dampness syndrome. Questionnaires were completed by 268 of the 288 SHS subjects (93.0%) and by 86 of the 94 healthy subjects (91.5%). The Cronbach α coefficients, split-half coefficients and stability coefficients ranged from 0.70 to 0.95, 0.67 to 0.87 and 0.88 to 0.98, respectively, for the overall scores and subscales. The Wilcoxon rank test showed statistically significant differences in the subscales and overall scores between the SHS group and the healthy group (P<0.01). Twelve factors with an eigenvalue greater than one were extracted by factor analysis and merged into nine factors, for which the cumulative contribution rate was 63.63%. The nine factors were corresponded to the overall structure of the questionnaire.

CONCLUSION: The SHSQ-50 is a reliable and valid

instrument for measuring TCM syndrome diagnosis of SHS in China.

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Key words: Sub-optimal health status; Questionnaire; TCM syndrome; Reliability; Validity

INTRODUCTION

In the mid 1980s, a kind of intermediate state of existence in which the body hovers between health and disease was discovered. It was not characterized by a specific disease, but instead by a general discomfort, various uncomfortable feelings and symptoms, low energy and overall weakness. In China, this state of being is called sub-optimal health status (SHS)^[11]. Its main characteristics are fatigue, dry eyes, irritability, depression, headache, insomnia and poor appetite, among others. This state of being has become a common problem that seriously interferes with people's personal lives, work and study^[2].

According to a global survey conducted by the World Health Organization, approximately 75% of people live with varying degrees of SHS^[3], an especially serious health problem in developed regions. In China, where social competition has become increasingly fierce, the rhythms of work and life are accelerating and environmental and noise pollution are worsening, statistics show that 60%-70% of people currently suffer from SHS^[4]. It has become a public health problem that can no longer be ignored. However, measuring SHS has presented quite a challenge to the academic fields because the concept of SHS is very general, its causes are complex and unclear, its clinical manifestations are varied and it shows no abnormal results in laboratory tests^[5].

Several scholars developed a questionnaire to measure SHS in urban Chinese from a Western medicine perspective. They queried a large cross-sectional study of 3,000 people in sub-par health and it proved a reliable and effective instrument^[6].

Guided by holistic concepts and syndrome differentiation, traditional Chinese medicine (TCM) has shown the potential to modulate sub-health using Chinese medicine, acupuncture, massage, health care and other methods^[7]. A syndrome is a functional status following the body's response to pathogenic factors. It would be helpful to consider TCM syndrome diagnosis as one of the factors in the questionnaire designed to investigate sub-health. Therefore, in the preliminary studies conducted from the perspective of TCM, a literature review^[5,8-12],expert questionnaire survey, group interviews and a pilot study were performed. Then using statistical methods and qualitative analysis to analyze and screen subscales and items, we developed the SHSQ- $50^{[13]}$, a questionnaire that embodies the features of TCM syndrome diagnosis, in the effort to find an effective method of judging and measuring SHS.

This study assessed the reliability and validity of the 50-item SHSQ so as to evaluate its measurement capability and improve its design and application.

METHODS

Study participants

From December 2008 to February 2009, sub-healthy and healthy subjects were recruited from Dongfang Hospital, which is affiliated with the Beijing University of Chinese Medicine (BUCM, Beijing, China), the Guoyitang Outpatient Department of BUCM (Beijing, China) and the Health Services Center of Yongwai Community at Chongwen District (Beijing, China). The sub-healthy participants were included if they: 1) had no physical or mental disease, according to their medical history, their physical examination report and after checking with their physicians; 2) had fatigue for more than 3 months; and 3) were aged 18-49 years. Individuals were excluded if they: 1) were pregnant, breastfeeding or preparing for pregnancy; or 2) had an error or omission rate of more than 0.05 on the questionnaire upon answering all the questions. The selection criteria for healthy participants were the same as those for sub-healthy ones, with the exception of not having had fatigue for more than three months.

The ethical committees of both the hospital and the university approved the study, and written informed consent was obtained from each of the participants before they answered the questionnaire. The procedures used for protecting participant privacy were described in the questionnaire.

Questionnaire

There are 66 items in the SHSQ-50, 50 five-class quantifiable items and 16 non-quantifiable items. The 50 quantifiable items were self-rated and divided into nine dimensions: liver stagnation syndrome, liver-Qi deficiency syndrome, spleen-Qi deficiency syndrome, liver-fire syndrome, heart-fire syndrome, stomach-fire syndrome, heart-Qi deficiency syndrome, lung-Qi deficiency syndrome and dampness syndrome. Some of the 50 quantifiable items overlapped dimensions. All self-rated items were designed for interviewees to rate how often they suffered various specific complaints in the preceding three months on a 5-point Likert-type scale of 1) never; 2) occasionally; 3) often; 4) very often; 5) always. The scores of quantifiable items were recoded as 0 to 4 according to the items asked forwardly or reversely, and subscale scores were calculated for each respondent by totaling the ratings for the component subscale items. The 16 non-quantifiable items included mental status, complexion, coating on the tongue, the conditions of the pulse and the female including menopause, breast pain before menstruation, menstrual cycle, the color and quantity of menstruation and leucorrhea were the basis for judging TCM syndrome, but were not used in the scoring.

Data collection

The participants completed the self-rated items in the questionnaire and the investigators finished the interview portion. The average time taken to fill out the questionnaire was 10 to 15 min. Quality control activities included appointing quality control inspectors, coordinating meetings between the three participating organizations and providing professional training for the researchers. Epidata software (the EpiData Association, Odense, Denmark) was used to build the database and to screen invalid questionnaires. Sixty-five sub-healthy people were randomly selected to complete the SHSQ-50 a second time and 63 healthy people were asked to complete the WHO Quality of Life Scale-BREF (WHOQOL-BREF) to measure criterion validity.

Statistical analysis

For data processing and analysis, SPSS v15.0 (IBM, Armonk, NY, USA) was used. The specific statistical methods used were as follows: 1) the Spearman rank correlation coefficient (r_s) was used to analyze the test-retest reliability. It is generally thought that a correlation coefficient above 0.6 indicates good test-retest reliability and if it is greater than 0.75, the test-retest reliability is extremely $good^{[14]}$; 2) with the Cronbach α coefficient, a split-half coefficient was applied to analyze the internal consistency reliability. It is believed that when the α coefficient is above $0.6^{[15]}$ and the split-half coefficient is above 0.7^[16], it shows better internal consistency reliability; 3) the Spearman rank correlation was used to analyze criterion validity; 4) two independent samples of the Wilcoxon rank test were used to analyze the discrimination validity; 5) an exploratory factor analysis was performed to analyze the construct validity, ensuring it met two conditions: a. the cumulative variance contribution rate factor was at least 40%; and b. each item corresponded to one of the factors for which one factor loading was more than 0.4, while the other was lower^[17].

RESULTS

Characteristics of participants

After screening out 28 invalid questionnaires, we obtained 268 valid cases of sub-healthy subjects (a 93.0% response rate), in which 90 were male (33.58%) with a mean age of 35.03 (SD, 9.38), and 178 were female (66.42%) with a mean age of 36.23 (SD, 8.85). There were also 86 valid cases of healthy people (a 91.5% response rate), in which 48 were male (55.82%) with a mean age of 32.33 (SD, 8.50) and 38 were female (44.18%) with a mean age of 32.13 (SD, 8.83).

Test-retest reliability

Seventy respondents were included in the test-retest study. Two weeks after answering the first questionnaire, 65 people completed a second questionnaire (92.9%), 16 men (24.62%) with a mean age of 39.06 (SD, 6.70) and 49 women (75.38%) with a mean age of 40.51 (SD, 7.17). The overall r_s of the questionnaires was 0.98; the minimum r_s of all subscales was lung-Qi deficiency (r_s =0.88) and the maximum r_s was heart-fire (r_s =0.98), which indicated the test-retest reliability of the overall and nine subscales was good (Table 1).

Internal consistency

All 268 cases of sub-health were included in the split-half reliability and Cronbach α coefficient method tests. The total split-half coefficient was 0.874; the minimum split-half coefficient of all subscales was stomach-fire (0.67) and the maximum was liver-fire (0.81). The total α coefficient was 0.95; the subscale with the minimum α coefficient was stomach-fire ($\alpha = 0.70$), the maximum, liver-Qi deficiency ($\alpha = 0.87$). The split-half and α coefficient for the overall and domains were good for the sample (Table 1).

Content validity

Professional knowledge of TCM, a literature review, an expert questionnaire survey, group interviews and a pilot study were used to repeatedly screen domains and items^[13], which ensured that the content validity was excellent.

Table 1 Results for 9 subscales of the 50-item SHSQ					
Subscale	No of items	r _s	Guttman Split-half	Cronbach' s α	
Liver-Qi deficiency	17	0.93	0.80	0.87	
Heart-Qi deficiency	8	0.90	0.68	0.76	
Lung-Qi deficiency	9	0.88	0.69	0.72	
Spleen-Qi deficiency	12	0.93	0.70	0.79	
Liver stagnation	7	0.96	0.76	0.85	
Liver-fire	11	0.97	0.81	0.84	
Heart-fire	6	0.98	0.70	0.71	
Stomach-fire	4	0.94	0.67	0.70	
Dampness	5	0.95	0.74	0.75	
Total	50	0.98	0.87	0.95	

Criterion validity

TCM syndromes include the psychological conditions and symptoms of the disorders, which are consistent with the basic notion of quality of life. TCM syndromes and the quality of life are just two different expressions for the same thing^[18]. Therefore, it was considered helpful to objectively compare the health status of sub-healthy subjects using a comprehensive analysis of quality of life and TCM syndromes. We chose to use the WHOQOL-BREF criterion, due to its brevity and convenience. The WHOQOL-BREF is divided into 4 domains that comprehensively assesses an individual's health status: physiology, psychology, environment and social relations^[12].

Of the 86 healthy respondents included in the study, 63 completed the WHOQOL-BREF (92.9%). There were 17 men (26.98%) with a mean age of 35.23 (SD, 8.84) and 46 women (73.02%) with a mean age of 36.52 (SD, 7.69). The r_s between the total score of Table 2 Results for the criterion validity test of SHSO-50

SHS and the WHOQOL-BREF was -0.34 (P<0.01). The subscale of liver-Qi deficiency negatively correlated to the overall and four domains of the WHO-QOL-BREF and the correlation coefficient was lower (r_s <0.5; P<0.05 or P<0.01). Most of the other subscales had no statistically significant correlations with the overall and four domains of the WHOQOL-BREF (P>0.05). The results indicated the criterion validity of the nine domains and the total was not good (Table 2).

Discrimination validity

Discrimination validity was tested in 268 cases of sub-healthy subjects and 86 cases of healthy subjects. Results revealed that there were significant differences (P<0.01) in total scores and in scores for the nine subscales between the two groups, which indicated that the discrimination ability of the overall and nine subscales was good (Table 3).

Subscale	Physiology	Psychology	Environment	Social relations	Total
Liver- <i>Qi</i> deficiency	-0.41*	-0.32 [△]	-0.42*	-0.30	-0.43*
Heart-Qi deficiency	-0.31	-0.23	-0.26 [△]	-0.17	-0.29
Lung-Qi deficiency	-0.30 [△]	-0.15	-0.24	-0.10	-0.22
Spleen-Qi deficiency	-0.25 [△]	-0.07	-0.19	-0.10	-0.22
Liver stagnation	-0.23	-0.18	-0.33*	-0.30 [△]	-0.32
Liver-fire	-0.23	-0.11	-0.20	-0.07	-0.20
Heart-fire	-0.18	-0.09	-0.16	-0.06	-0.16
Stomach-fire	-0.25	-0.07	-0.19	-0.08	-0.20
Dampness	-0.29	-0.08	-0.22	-0.21	-0.29
Total	-0.36	-0.18	-0.33*	-0.20	-0.34

Note: $^{A}P < 0.01, ^{\Delta}P < 0.05.$

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Subscales	Sub-healthy people (<i>n</i> =268)	Healthy people (<i>n</i> =86)	t	Р
Liver-Qi deficiency	43.85±8.30	31.91±6.01	-10.78	< 0.0001
Heart-Qi deficiency	20.84±4.18	15.06±2.83	-10.41	< 0.0001
Lung- <i>Qi</i> deficiency	23.12±4.46	16.73±3.16	-10.81	< 0.0001
Spleen-Qi deficiency	29.45±5.55	21.53±4.13	-10.48	< 0.0001
Liver stagnation	16.99±4.58	12.17±3.11	-8.75	< 0.0001
Liver-fire	25.87±5.96	18.98±4.39	-9.11	< 0.0001
Heart-fire	14.48±3.47	10.67±2.70	-8.76	< 0.0001
Stomach-fire	8.94±2.46	6.78±1.95	-7.09	< 0.0001
Dampness	11.75±3.10	8.37±2.23	-8.71	< 0.0001
Total	120.29±22.72	88.36±17.17	-10.40	< 0.0001

Construct validity

Principal component factor analysis with varimax orthogonal rotation was used to extract factors with an eigenvalue above one. The KMO (Kaiser-Meyer-Olkin) measure of the sampling adequacy of the 12 factors was 0.90, the Bartlett test of sphericity was significant Table 4 Results for the factor analysis (varimax orthogonal rota $(\chi^2=6286.64; P<0.01)$ and the cumulative contribution rate was 52.10%, which meant the data were appropriate for factor analysis. Twelve factors were merged into nine, which mostly corresponded to the nine subscales of the questionnaire and showed a better construct validity (Table 4).

Serial number of factor	Representative meaning	Maximum loading	Minimum loading	Contribution rate
The first factor	Heart-Qi deficiency	0.697	0.697 0.632 7.639	
The second factor	Stomach-fire 0.535 0.424		7.619	
The third factor	Liver stagnation	0.616	0.406	7.182
The fourth, seventh and ninth factors	Liver-Qi deficiency	0.778	0.485	14.696 (cumulative)
The fifth and twelfth factors	Spleen-Qi deficiency	0.714	0.4	7.575 (cumulative)
The sixth factor	Dampness	0.779	0.592	5.789
The eighth factor	Heart-fire	0.779	0.544	4.305
The tenth factor	Liver-fire	0.677	0.662	3.988
The eleventh factor	Lung-Qi deficiency	0.729	0.697	3.758
Cumulative				63.632

DISCUSSION

In this study, the SHSQ-50 was shown to be reliable and valid in a cross-sectional health status survey of sub-healthy subjects in Beijing. In addition, the percentage of those who fully completed questionnaires was high, with 93% of sub-healthy subjects and 91.5% of healthy subjects responding, indicating that participants carefully responded to the questions.

The overall Cronbach's α (0.95) and split-half coefficient (0.87) were good, with the α for nine subscales greater than or equal to 0.7 (0.70 to 0.87) and nine subscales of split-half coefficient ranging from 0.67 (close to 0.7) to 0.81, indicating that the questionnaire had good internal consistency reliability. The total test-retest was 0.98, while the test-retest for the nine subscales was above 0.8 (0.88 to 0.98), indicating it was a better test-retest. The α and the split-half coefficient in the stomach-fire subscale was the lowest (0.70 and 0.67, respectively), which may have been due to the small number of questionnaire items included. However, increasing the number of items would have made the questionnaire too lengthy, causing participants to be less likely to complete it. Moreover, the test-retest validity of the stomach-fire subscale was excellent (0.94). These results indicate that the questionnaire achieved a stable reliability.

As for the discrimination validity, there were statistically significant differences in the overall and nine subscales' scores between the two groups of sub-healthy and healthy subjects (P<0.01), which shows a better discrimination validity.

Criterion validity

The criterion validity was not good, as shown by the

criterion validity test, but the negative correlation trend was reflected in the whole. This was because the scoring system of the WHOQOL-BREF is positive, namely, the higher the score, the better the quality of life, whereas the SHSQ-50 scores negatively, i.e., the higher the score, the worse the status of health. However, this negative correlation was not obvious in the statistical evidence, which suggests that further research is needed about how to reflect a person's quality of life using the SHSQ-50. The content of the SHSQ-50 was not nearly as comprehensive as the WHOQOL-BREF; social environments, social relationships, personal beliefs and other quality of life indicators were not included. The WHOQOL-BREF focuses on evaluating the consequences of symptoms, while the SHSQ-50 places more emphasis on self-evaluation of the occurrence and frequency of somatic symptoms. Each assessment instrument evaluates health from a different angle, thus it is necessary to further explore the correlation between them and to select other appropriate criterion. One of the goals of the factor analysis was to determine

One of the goals of the factor analysis was to determine whether we could extract the underlying dimensions that would support our conceptual model. The analysis resulted in 12 factors with an eigenvalue above one and a cumulative contribution rate of 63.63%. When the 4, 7, and 9 factors were merged with liver-Qi deficiency, the cumulative contribution rate was 14.696%. The first factor was heart-Qi deficiency and its cumulative contribution rate was 7.639%; the second factor was stomach-fire, and its cumulative contribution rate was 7.619%. The fifth and ninth factors merged into spleen-Qi deficiency, for which the cumulative contribution rate was 7.575%; the third factor was liver stagnation, whose cumulative contribution rate was 7.182%. The contribution rate of the other factors decreased successively.

Twelve factors were merged into nine, which corresponded to the majority of the questionnaire, suggesting that it had a clear structural design. However, it did not achieve ideal results between the number of items (12) and the cumulative contribution rate (63.63%). In addition, there were a few items with low factor loading or that were not a good fit for those factors they were designed to represent. Therefore, the structure and content of the SHSQ-50 can still be modified, simplified and improved for future revisions.

Based on the above research results and aside from poor criterion validity, the Cronbach α coefficients, stability coefficient and split-half coefficient were higher. The discrimination validity was excellent and the structural validity was reasonable and practical. This showed that the SHSQ-50 obtained satisfactory results in evaluating the reliability and validity of the overall and nine subscales and achieved its goals for measuring TCM syndrome diagnosis of SHS.

The study had some limitations; for instance, the participants were recruited only from the Beijing area, there was a gender imbalance, and the sample size of the formal investigation was not large. Because the participants were recruited from Beijing and their demographic characteristics might differ from those of other regions of China, the generalizability of the results might be limited. The reason there were more female than male subjects in this study was because of the age limit of 49 as an inclusion criterion; more premenopausal women with sub-health manifestations volunteered to fill in the questionnaire with informed consent. According to the general rule of multiple factors analysis, sample size should be approximately 5 to 10 times the number of all variables^[19]. Fifty of the SHSO-50 variables were used in the statistical analysis.

so the minimum sample size should have been 250; the valid sub-healthy sample was 268 cases, which ensured the statistical efficacy of this study. In future studies, however, it would be more valuable to test the questionnaire on a larger representative sample of sub-healthy subjects in China using epidemiological surveys from multiple regions.

This study aimed to develop assessment tools for the quantifiable evaluation of TCM syndrome diagnosis in groups and individuals suffering from sub-optimal health. The goal was to establish specific and unified diagnostic criteria of SHS, the better to treat sub-optimal health symptoms. In the questionnaire developed in this study, sub-optimal health status was divided into numerous TCM syndromes. Compared with the authoritative studies on TCM syndromes in sub-optimal ly healthy people conducted by other scholars in China^[20,21], the SHSQ-50 covers all the common syndromes of sub-par health described by those scholars, except for liver-kidney yin deficiency and phlegm-heat disturbance.

However, studies in this field are still in their infancy. Further work is necessary to improve the systematic use and measuring precision of the SHSQ-50 questionnaire.

APPENDIX

Sub-optimal health status questionnaire (SHSQ-50)

The following questions inquire about the common symptoms of traditional Chinese medicine during the last 3 months. Answer every question by marking the appropriate box with an " $\sqrt{}$ ". Please choose one of the following answers according to your true feelings. 1 means never; 2 means occasionally; 3 means often; 4 means Very often; 5 means always.

How often did the following occur?	1	2	3	4	5
1.You were easily exhausted.					
2. Your fatigue could be alleviated by rest.					
3. Your hands and feet were weak.					
4. You felt short of breath.					
5. You could not respond quickly.					
6. You had trouble with your memory.					
7. Your eyes felt dried.					
8. Your eyes felt acidic and swollen.					
9. You felt that misfortunes will happen.					
10. Your heart felt empty.					
11. You felt depressed and nothing could make you cheer up.					
12. You felt confident.					
13. You suffered from palpitations.					
14. You felt a choking sensation in your chest.					
15. You sweated easily when doing only a little activity.					
16. You sweated when asleep.					
17. You felt averse to wind (for example: you were unable sit near blowing air conditioning or fans in summer).					

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18. You easily caught a cold.			
19. You felt tired after saying only a few words.			
20. You had a poor appetite.			
21. You had a bloated feeling in your stomach after dinner.			
22. You suffered from dizziness.			
23. You suffered from giddiness.			
24. You suffered from tinnitus.			
25. You suffered from nausea.			
26. You suffered from soft stool (like noodle sauce).			
27. You desired to defecate, but had no or very little stool.			
28. You felt depressed.			
29. You were easily irritated.			
30. You felt nervous.			
31. You felt anxious.			
32. You sighed.			
33. You felt bloated or ached in costal region (lateral chest under your armpits).			
34. You felt bloated or ached in lower abdomen (both sides below your navel).			
35. You suffered from bitter mouth.			
36. You suffered from dry throat.			
37. You had difficulty falling asleep.			
38. You had difficulty concentrating and remembering due to poor sleep.			
39. You had constipation.			
40. You had yellow urine or a burning sensation.			
41. You felt upset.			
42. You suffered from ulcerated mouth and tongue.			
43. You suffered from swelling and aching gums.			
44. You suffered from sore throat.			
45. You suffered from halitosis.			
46. You suffered from sour regurgitation.			
47. You had a heavy feeling in your head.			
48. You had a sticky feeling in your mouth.			
49. You had a heavy feeling in your legs when walking.			
50. You had an uncomfortable and sticky feeling when you defecated.			

Subscale	No of items	Serial number with items
Liver-Qi deficiency	17	ITEM (1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 28, 29, 32, 33, 34)
Heart-Qi deficiency	8	ITEM (1, 2, 3, 4, 13, 14, 15, 16)
Lung-Qi deficiency	9	ITEM (1, 2, 3, 4, 15, 16, 17, 18, 19)
Spleen- <i>Qi</i> deficiency	12	ITEM (1, 2, 3, 4, 20, 21, 22, 23, 24, 25, 26, 27)
Liver stagnation	7	ITEM (28, 29, 30, 31, 32, 33, 34)
Liver-fire	11	ITEM (22, 24, 29, 33, 34, 35, 36, 37, 38, 39, 40)
Heart-fire	6	ITEM (37, 38, 39, 40, 41, 42)
Stomach-fire	4	ITEM (43, 44, 45, 46)
Dampness	5	ITEM (47, 48, 49, 50, 14)
Total	50	

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