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ORIGINAL RESEARCH

Psychometric Validation of the Dampness Syndrome Scale of Chinese Medicine for People in China

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Background: Dampness syndrome is a basic syndrome of many major and chronic diseases. Early screening and identification of dampness syndrome are important. The Dampness Syndrome Scale of Chinese Medicine (DSSCM) was developed to measure the occurrence and severity of dampness syndrome. The measurement characteristics of the DSSCM should be further validated. The objective of this study is to evaluate the reliability and validity of the DSSCM based on a cross-sectional survey.

Methods: The development of DSSCM was based on the traditional Chinese medicine (TCM) theory, expert consensus and clinical investigations. Participants were recruited from Guangdong Provincial Hospital of Chinese Medicine and Guangzhou Cadre Health Management Center in Guangdong Province, China. All participants completed the baseline questionnaire and DSSCM. The reliability of the DSSCM was evaluated by internal consistency reliability and test–retest reliability. The factor structure was tested with confirmatory factor analysis (CFA), while discriminant validity was evaluated by calculating the difference between the total score of the DSSCM and its four dimensions for participants with or without dampness syndrome. We used a clinician's diagnosis of dampness syndrome as a criterion to evaluate the criterion validity. Multivariate regression analysis was used to analyze the associations among gender, age, height, and weight and dampness syndrome.

Results: A total of 880 participants were enrolled for psychometric validation and 869 participants were included in the final analyses after exclusion. The mean age of the participants was 42.62±12.86 years. The Cronbach's alpha coefficients for the four dimensions of the DSSCM were 0.809, 0.891, 0.816 and 0.780. The ICCs for the four dimensions of the DSSCM were 0.806, 0.674, 0.780 and 0.760. For validity, the results showed that the DSSCM had good content validity, discriminant validity and criterion validity. For the CFA, the root mean square error of approximation (RMSEA) was 0.091; the standardized root mean square residual (SRMR) was 0.074; the comparative fit index (CFI) was 0.766; and the Tucker–Lewis index (TLI) was 0.745. Weight was found to be associated with the total scores of the DSSCM and its three dimensions.

Conclusion: The DSSCM has good reliability and validity to support its use as a tool for assessing the severity of dampness syndrome. This study provides empirical evidence for future updates to the DSSCM.

Keywords: dampness syndrome, dampness syndrome scale of Chinese medicine, reliability, validity

Introduction

Dampness syndrome is one of the basic syndromes of traditional Chinese medicine (TCM). According to the TCM theoretical system, it is defined as feeling external dampness or abnormal water-liquid transportation in the body, resulting in the formation of dampness turbidity, which obstructing the movement of qi, and mainly manifested as body heaviness, limb soreness, abdominal distention or diarrhea, poor appetite and digestion, slippery tongue coating and soggy pulse.[1,2] The slippery tongue coating means that the surface of the tongue has a lot of moisture, making it drip and

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slippery to touch.[1] The characteristic of the soggy pulse is that the pulse conditions is floating thin, weak and soft.[2] The tongue pictures and pulse conditions performed an important role in the diagnosis of dampness syndrome, which needed one veteran doctor to assess these signs. Dampness pathogens may damage the skin, body hair, muscles, sinews, Zang-fu organs, bone marrow, qi or blood.[1] Dampness is regarded as omnipresent in humid, semi humid and nonhumid regions.[3]

Occult onset, lingering and difficulty healing are key characteristics of dampness pathogens, which means that the onset of dampness syndrome is slow and occult, and the symptoms are relatively mild at the beginning.[4] It is not easy to be noticed by patients. Once it is taken seriously, the disease has lasted for a long time. Meanwhile, the characteristic of dampness is sticky and stagnant, which makes it difficult to recover when feeling dampness, and the duration of the disease will be long,[4] which is also the reason dampness syndrome is considered an important factor for some major or chronic diseases, such as rheumatic immune disease, cardiovascular and cerebrovascular diseases, and metabolic diseases.[5–7] Some studies have shown that dampness syndrome is a basic syndrome of metabolic diseases, such as obesity or hyperlipidemia; other studies have implied that it is a crucial element of a variety of syndromes related to cardiovascular diseases.[8–10] It has been observed that dampness syndrome lasts through the early, middle and late stages of the above diseases and is involved in their pathological evolution.[11] If scientific and reasonable assessment can be conducted in the early stage of the disease to provide an alert for the early recognition and warning of dampness syndrome, it may significantly prevent the occurrence of diseases, reduce the disease recurrence rate or even decrease mortality.

TCM is a typically individualized type of medicine that determines the diagnosis by summarizing the clinical signs and symptoms exhibited by the patient to guide treatment strategies.[12] Therefore, the diagnosis is subjective and empirical and is easily influenced by the doctor's educational level and clinical experience. A previous study showed that diagnostic consistency was less than 30% among TCM practitioners,[13] which impedes the development of the clinical efficacy system of TCM. TCM has shown the potential to treat dampness syndrome using Chinese herbal medicine, acupuncture, moxibustion, cupping and other methods.[14–16] Most treatment effects were not assessed directly by TCM but by biochemical indicators or generic health-related quality of life measures. To solve these problems, researchers developed a number of TCM syndrome-specific instruments, such as the Kidney Deficiency Syndrome questionnaire, Damp Phlegm Pattern and Blood Stasis Pattern questionnaire, and Qi-Deficiency Self-Rating Scale.[17–19] The development of these TCM syndrome-specific instruments enriches the efficacy evaluation of TCM. To date, no scale for dampness syndrome has been developed based on well-recognized approaches.

The Constitution in Chinese Medicine Questionnaire (CCMQ), developed by Wang,[20–22] is the most comprehensive and widely used instrument to evaluate body constitution. The CCMQ contains nine types of body constitutions; among them, phlegm-dampness (8 items) and damp-heat (6 items) can be used to evaluate whether individuals have "dampness" or "no dampness". The scale is mainly evaluated from the perspective of body constitution. It includes other kinds of body constitutions and is inappropriate to be used alone to evaluate dampness syndrome. From the perspective of TCM, the concepts and properties of phlegm and dampness are different. The phlegm is defined as thick and turbid pathological product, while the dampness is the water vapor dispersed in the organs and tissues.[23] Questionnaires in regards of phlegm pattern[24] may not be suitable for dampness syndrome evaluation.

Based on this reason, we developed the Dampness Syndrome Scale of Chinese Medicine (DSSCM)[1,25] in 2021 to evaluate the severity of dampness syndrome. The DSSCM has been used in clinical practice and plays an important role in the early identification and prediction of dampness syndrome. However, its reliability and validity have not been well verified. Thus, the objective of the present study was to evaluate the psychometric properties of the DSSCM in a larger number of people using a cross-sectional survey.

Materials and Methods

Study Design

The cross-sectional survey was designed by Guangdong Provincial Hospital of Chinese Medicine. Participants were recruited from two hospitals in southern China. Participants who presented to the outpatient clinic or performed a physical examination were invited to participant in this study. After obtaining the written or electronically informed consent, the participants were invited to fill out a questionnaire under the supervision of interviewers. This study complied with the Declaration of Helsinki. Ethics approval was obtained from the both ethics committees at

Guangdong Provincial Hospital of Chinese Medicine (Approval No. BE2021-222-01, BE2021-222-02, BF2022-119-01) and Guangzhou Cadre Health Management Center (Approval No. K2022-04).

Participants

Participant recruitment was performed in Guangdong Provincial Hospital of Chinese Medicine and Guangzhou Cadre Health Management Center in Guangdong Province, China, from January 2022 to June 2022. Inclusion criteria included 1) age 18–75 years; 2) primary school education or above; and 3) signed informed consent and voluntary participation in the investigation. Exclusion criteria included 1) participants with any of the following complications and unable to complete the questionnaire independently: cardiovascular and cerebrovascular diseases, respiratory failure, renal insufficiency, malignant tumors and other acute and critical diseases and mental diseases; 2) participants with a confused state of mind or who were unable to express their opinions clearly.

All participants provided written or electronically confirmed informed consent. When the participants came to the clinic, trained investigators explained the purpose of the study, the study procedures, and potential risks and benefits in detail to each of them and identified their willingness to participate. All private information of the participants was kept confidential and used for survey purposes only.

Measurements

Demographic and Clinical Characteristics

Ten data collectors were responsible for collecting data. A printed questionnaire was provided to collect demographic and clinical characteristics in Guangdong Provincial Hospital of Chinese Medicine, including gender, age, height, weight, family history, and disease history. We used an electronic questionnaire to survey the Guangzhou Cadre Health Management Center in Guangdong Province. The content of the printed and electronic questionnaires was exactly the same. The electronic questionnaire was administered using an electronic data collection system. The participants scanned the QR code into the system using a smartphone or iPad and completed the basic information and questionnaire. Each participant completed the questionnaire in the presence of an interviewer.

The Dampness Syndrome Scale of Chinese Medicine (DSSCM)

The DSSCM was developed under the guidance of TCM theory, including the following steps: (1) Establish a research team consisting of the experts who were skilled in TCM syndrome research, scale development, clinical practice and psychometrics; (2) Define the measurement concept of dampness syndrome and form a theoretical framework; (3) Establish item pool based on TCM dampness syndrome monograph or textbooks, as well as standards or guidelines related to dampness syndrome; (4) Screen items to form a preliminary scale; (5) Optimize items based on expert consensus and form a pre-survey scale; (6) Conduct clinical preliminary test; (7) Conduct clinical investigation and form a formal scale. Finally, the DSSCM consisting of 30 items was developed (see Supplementary Table 1).[1,25]

The DSSCM is a self-report questionnaire and provides an overall severity assessment of dampness syndrome for participants 18 years of age and above across four dimensions: (1) characteristic of dampness being heavy and turbid (6 items); (2) characteristic of dampness being sticky and stagnant (14 items); (3) characteristic of dampness being descending (4 items); (4) dampness pathogen being apt to damage yang qi (6 items). A 5-point Likert scale was used to calculate the scores for each item. For the first three dimensions, each item was scored 0="not at all", 1="light", 2="mild", 3="severe", and 4="extremely heavy". For the last dimension, that is, the dampness pathogen being apt to damage yang qi, each item was scored 0="not at all", 1="light", 2="mild" and "severe", 3="extremely heavy". Each item was answered by the respondents according to their experiences and feelings in the last two weeks. The total score of the DSSCM ranges from 0 to 114; the higher the score, the more serious the degree of dampness syndrome is. Specifically, if the total score of the DSSCM ranges from 0 to 19, it is considered non-dampness syndrome; 20 to 39 is regarded as mild; 40 to 59 is regarded as moderate; and 60 to 79 is judged as severe. If the total score is equal to or greater than 80, it is judged as extremely severe dampness syndrome. Participants completed the DSSCM in 5 to 10 minutes on average.

Statistical Analysis

Statistical analysis was performed using SPSS 19.0 and LISREL 8.8 statistical software. A two-sided P<0.05 indicated statistical significance. The sociodemographic and clinical characteristics of the participants were presented as numbers (%) for categorical variables and means (standard deviations, SDs) for continuous variables. Multivariate regression analysis was conducted to explore the independent variables underlying dampness syndrome. Multicollinearity was carried out by variance inflation factor (VIF) method, with a VIF greater than 10 roughly indicating the presence of multicollinearity.[26]

The reliability of the DSSCM was evaluated by internal consistency reliability and test–retest reliability. The evaluation of the internal consistency reliability included Cronbach's alpha and corrected item-total correlation. The time stability of the scale was evaluated through test–retest reliability. In this study, the retest interval of the DSSCM was 7 days. The interclass correlation coefficients (ICCs) were used to calculate test–retest reliability. The recommended acceptable value of Cronbach's alpha coefficient and the ICC was greater than 0.70,[27,28] and the corrected item-total correlation was performed using 0.3 as the inclusion criterion.[29]

The content validity refers to whether the designed scale or item can represent the topic to be measured or whether the participants' understanding of and responses to the scale are consistent with the original intentions.[30] In this study, we used the item-dimension correlation and dimension-total correlation to evaluate the content validity.

We conducted a confirmatory factor analysis (CFA) to assess the suitability of the four-factor structure classification. Model fit was assessed using a combination of fit indices, including χ^2 ratio to degrees of freedom (χ^2/df), comparative fit index (CFI), Tucker–Lewis index (TLI), root mean square error of approximation (RMSEA) and standardized root mean square residual (SRMR). The model fit indices are acceptable if χ^2/df<3, CFI>0.90, TLI > 0.90, RMSEA < 0.08 and SRMR≤0.08.[31,32]

The purpose of discriminant validity is to judge whether there is good discriminant ability between different latent variables.[33] Based on the total score of the DSSCM, participants whose total scores were less than 20 were assigned to the non-dampness syndrome group, and those whose scores were equal to or greater than 20 were assigned to the dampness syndrome group. Discriminant validity was evaluated by calculating the difference between the total score of the DSSCM and its four dimensions for participants with dampness syndrome and for non-dampness syndrome. A two-tailed independent-samples *t* test was used to analyze these differences. If the scores in the 2 groups reached the significance level (P<0.05), it indicated that the discriminant validity was good.

The clinician's diagnosis as the criterion to confirm the criterion validity of the DSSCM. The clinician's diagnosis of dampness syndrome was based on criteria identified by national syndrome standards and books related to dampness syndrome.[2,34,35] All clinicians were required to have an education background in TCM and some of them have been working for over 10 years. Before the study started, the training courses were conducted for clinicians on the diagnosis of dampness syndrome to improve the consistency. We calculated Spearman's rho correlation coefficients between the DSSCM's judgment and the clinician's diagnosis to evaluate criterion validity. Due to the limitation of personnel, we conducted the criterion validation study only in samples recruited from the Guangdong Provincial Hospital of Chinese Medicine.

Results

Participants' Demographic and Clinical Characteristics

A total of 880 participants were recruited in Guangdong Provincial Hospital of Chinese Medicine and Guangzhou Cadre Health Management Center from January 2022 to June 2022, of whom 9 were ineligible and 2 were excluded for a response rate of the questionnaire less than 80% which meant that more than 6 out of 30 items were not completed by the participants. After exclusion, a total of 869 participants were included in the final analyses, of whom 401 completed the paper version and 468 completed the electronic version (Figure 1).

The mean age of the 869 participants was 42.62±12.86 years. There were more female than male participants and more younger than older participants. Most of the participants had no chronic disease history (61.1%) or family medical history (86.5%). The participants' mean height and weight were 164.2±8.0 cm and 62.2±12.3 kg, respectively. More details are shown in Table 1.

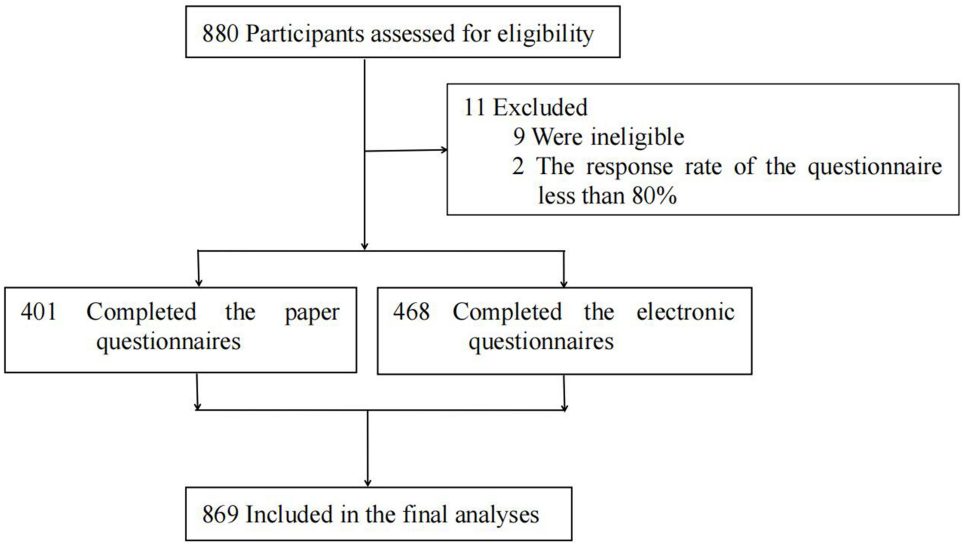

Figure 1 Participants recruitment flow diagram.

Internal Consistency Reliability

The Cronbach's alpha coefficients for the four dimensions of the DSSCM were 0.809, 0.891, 0.816 and 0.780. All Cronbach's alpha coefficients were greater than the minimum acceptable value of 0.7, indicating that the DSSCM had good internal consistency reliability. The corrected item-total correlation for individual items ranged from 0.342 to 0.657 (see Table 2), showing that these items were suitable for scale construction.

Table 1 Demographic and Clinical Characteristics of the Participants

Variable	Total sample (N=869)
Gender (N[%])	
Male	364(41.9)
Female	505(58.1)
Age (N[%])	
18–35 years old	307(35.4)
36–50 years old	327(37.6)
51–65 years old	174(20.0)
66–75 years old	61(7.0)
Height (cm) (Mean[SD])	164.2(8.0)
Weight (kg) (Mean[SD])	62.2(12.3)
Chronic disease history (N[%])	
No	531(61.1)
Yes	322(37.1)
Unknown/Missing	16(1.8)
Disease classification*	
Hypertension	82
Diabetes	49
Hyperlipidemia	42
Coronary heart disease	14
Kidney diseases	14
Thyroid diseases	41
Other diseases#	188

(*Continued*)

Table 1 (Continued).

Variable	Total sample (N=869)
Family medical history (N[%])	
No	752(86.5)
Yes	100(11.5)
Unknown/Missing	17(2.0)

Notes:* The total number of patients was greater than 322, as some participants may suffer from multiple diseases. #These diseases included spleen and stomach diseases, cerebrovascular diseases, lung diseases, gynecological diseases, breast diseases, osteoarthritis, etc.

Table 2 The Corrected Item-Total Correlation (N=869)

Dimensions /Item Number	Corrected Item-Total Correlation
Characteristic of dampness being heavy and turbid	
DSSCM1	0.342
DSSCM2	0.644
DSSCM7	0.643
DSSCM18	0.574
DSSCM19	0.470
DSSCM20	0.586
Characteristic of dampness being sticky and stagnant	
DSSCM3	0.582
DSSCM4	0.584
DSSCM8	0.559
DSSCM9	0.628
DSSCM10	0.523
DSSCM11	0.657
DSSCM12	0.599
DSSCM14	0.469
DSSCM25	0.441
DSSCM26	0.553
DSSCM27	0.591
DSSCM28	0.560
DSSCM29	0.542
DSSCM30	0.550
Dampness pathogen being apt to damage yang qi	
DSSCM5	0.623
DSSCM6	0.594
DSSCM13	0.523
DSSCM15	0.616
DSSCM16	0.550
DSSCM17	0.490
Characteristic of dampness being descending	
DSSCM21	0.491
DSSCM22	0.457
DSSCM23	0.552
DSSCM24	0.556

Test–Retest Reliability

To assess the test–retest reliability, 55 participants were selected from all participants to answer the paper version of the DSSCM again after 7 days; 3 participants failed to complete the questionnaire. A total of 52 respondents completed repeated measurements after an interval of 7 days. The ICC for the total score was 0.801 (P<0.001), exceeding the recommended standard of 0.70.[28] The ICCs for the four dimensions of the DSSCM were 0.806, 0.674, 0.780 and 0.760, which indicated acceptable test–retest reliability.

Content Validity

The correlation coefficients of the dimension-total score were 0.810, 0.927, 0.840 and 0.735. Table 3 lists the correlation coefficient of the item-dimension. The correlation coefficients between the four dimensions of the DSSCM and the corresponding items ranged from 0.464 to 0.850.

Construct Validity

CFA was conducted to test the four-factor structure of the DSSCM. The χ^2 test was significant (p<0.001, χ^2=3272.628, 399 df), and the χ^2/df of 8.202 suggested that the model did not fit the data well. The SRMR was 0.074, indicating that the model had reasonable model fit. However, the other fit indices with a CFI of 0.766, a TLI of 0.745 and an RMSEA of 0.091 were below the desired levels. The standardized factor loadings of all 30 items ranged from 0.353 to 0.857 (see Table 4).

Table 3 The Correlation Coefficient of the Item-Dimension (N=869)

Dimensions	Item Number	Correlation Coefficient
Characteristic of dampness being heavy and turbid	DSSCM1	0.567
	DSSCM2	0.784
	DSSCM7	0.668
	DSSCM18	0.737
	DSSCM19	0.690
	DSSCM20	0.748
Characteristic of dampness being sticky and stagnant	DSSCM3	0.598
	DSSCM4	0.625
	DSSCM8	0.642
	DSSCM9	0.686
	DSSCM10	0.579
	DSSCM11	0.697
	DSSCM12	0.686
	DSSCM14	0.542
	DSSCM25	0.464
	DSSCM26	0.674
	DSSCM27	0.728
	DSSCM28	0.655
	DSSCM29	0.645
	DSSCM30	0.653
Dampness pathogen being apt to damage yang qi	DSSCM5	0.772
	DSSCM6	0.794
	DSSCM13	0.629
	DSSCM15	0.766
	DSSCM16	0.717
	DSSCM17	0.587
Characteristic of dampness being descending	DSSCM21	0.819
	DSSCM22	0.680
	DSSCM23	0.850
	DSSCM24	0.663

Table 4 The Factor Loading of All 30 Items of the DSSCM (N=869)

Dimensions	Item Number	Factor Loading
Characteristic of dampness being heavy and turbid	DSSCM1	0.353
	DSSCM2	0.687
	DSSCM7	0.704
	DSSCM18	0.727
	DSSCM19	0.676
	DSSCM20	0.761
Characteristic of dampness being sticky and stagnant	DSSCM3	0.579
	DSSCM4	0.584
	DSSCM8	0.575
	DSSCM9	0.663
	DSSCM10	0.556
	DSSCM11	0.692
	DSSCM12	0.637
	DSSCM14	0.494
	DSSCM25	0.478
	DSSCM26	0.661
	DSSCM27	0.702
	DSSCM28	0.643
	DSSCM29	0.631
	DSSCM30	0.647
Dampness pathogen being apt to damage yang qi	DSSCM5	0.711
	DSSCM6	0.714
	DSSCM13	0.575
	DSSCM15	0.706
	DSSCM16	0.662
	DSSCM17	0.546
Characteristic of dampness being descending	DSSCM21	0.798
	DSSCM22	0.589
	DSSCM23	0.857
	DSSCM24	0.537

Discriminant Validity

The results of the discriminant validity analysis are presented in Table 5. The total score of the DSSCM and its four dimensions for participants with dampness syndrome were higher than those for participants without dampness syndrome, and the difference was statistically significant ($p < 0.001$). This indicated that the DSSCM and each dimension had good discriminant ability.

Table 5 Score Comparison Between Dampness Syndrome and Non-Dampness Syndrome Groups

Dimensions/Total Score	Participants with Dampness Syndrome, Mean (SD)	Participants Without Dampness Syndrome, Mean (SD)	t	*P*
Total score	36.16±11.96	10.63±5.20	42.32	<0.001
Characteristic of dampness being heavy and turbid	8.46±4.04	2.85±2.28	25.87	<0.001
Characteristic of dampness being sticky and stagnant	16.44±6.80	4.50±3.02	34.64	<0.001
Dampness pathogen being apt to damage yang qi	6.58±2.79	2.04±1.82	28.93	<0.001
Characteristic of dampness being descending	4.68±2.94	1.24±1.43	22.67	<0.001

Criterion Validity

A total of 401 participants were evaluated by both the paper DSSCM and the clinician's diagnosis. The correlation coefficient between the DSSCM's judgment and the clinician's diagnosis of dampness syndrome was 0.430 (95% CI, 0.342–0.523). The correlation coefficient was greater than 0.4 and showed that the criterion validity of the DSSCM was good.

Relations Among Dimensions

The correlation coefficients among the dimensions (see Table 6) presented moderate to high relations, supporting their commonality in measuring individuals' dampness syndrome. The correlation coefficient between the characteristic of dampness being sticky and stagnant and the dampness pathogen being apt to damage yang qi was 0.700, which indicated high correlation. The correlations with the remaining dimensions were moderate.

Multivariate Regression Analysis

The multivariate regression analysis of the total scores of DSSCM and scores of the four factors are presented in Table 7. The VIFs with a gender of 2.267, a age of 1.131, a height of 2.684 and a weight of 2.119 were less than 10, indicating that there was no multicollinearity problem among these indicators. The DSSCM total score correlated with gender and weight. However, we found no statistically significant associations between age and height.

Table 6 Correlations Among Dimensions Scores in DSSCM

Dimensions	Characteristic of Dampness Being Heavy and Turbid	Characteristic of Dampness Being Sticky and Stagnant	Dampness Pathogen Being Apt to Damage Yang Qi	Characteristic of Dampness Being Descending
Characteristic of dampness being heavy and turbid	1			
Characteristic of dampness being sticky and stagnant	0.624	1		
Dampness pathogen being apt to damage yang qi	0.657	0.700	1	
Characteristic of dampness being descending	0.494	0.613	0.540	1

Table 7 The Result of the Multivariate Regression Analysis

Model	B	SD	Beta	t	*P*
Overall					
Constant	7.040	16.803	/	0.419	0.675
Gender	−4.130	1.605	−0.128	−2.574	0.010
Age (years)	−0.035	0.044	−0.028	−0.809	0.418
Height	−0.018	0.110	−0.009	−0.163	0.871
Weight	0.387	0.063	0.296	6.149	<0.001
Characteristic of dampness being heavy and turbid					
Constant	8.151	4.432	/	1.839	0.066
Gender	−2.447	0.423	−0.276	−5.782	<0.001
Age (years)	0.008	0.011	0.023	0.694	0.488
Height	−0.076	0.029	−0.137	−2.639	0.008
Weight	0.178	0.017	0.494	10.705	<0.001

(*Continued*)

Table 7 (Continued).

Model	B	SD	Beta	t	P
Characteristic of dampness being sticky and stagnant					
Constant	−0.391	8.551	/	−0.046	0.964
Gender	−0.779	0.817	−0.048	−0.954	0.341
Age (years)	−0.006	0.022	−0.010	−0.289	0.773
Height	0.015	0.056	0.014	0.264	0.792
Weight	0.157	0.032	0.237	4.905	<0.001
Dampness pathogen being apt to damage yang qi					
Constant	0.631	3.536	/	0.178	0.859
Gender	−0.788	0.338	−0.118	−2.332	0.020
Age (years)	−0.033	0.009	−0.130	−3.633	<0.001
Height	0.030	0.023	0.071	1.282	0.200
Weight	0.014	0.013	0.051	1.035	0.301
Characteristic of dampness being descending					
Constant	−1.350	3.151	/	−0.428	0.668
Gender	−0.116	0.301	−0.020	−0.387	0.699
Age (years)	−0.004	0.008	−0.015	−0.430	0.667
Height	0.014	0.021	0.038	0.689	0.491
Weight	0.038	0.012	0.159	3.261	0.001

Weight was found to be statistically correlated with the characteristic of dampness being heavy and turbid, characteristic of dampness being sticky and stagnant and characteristic of dampness being descending. In addition, we found that the characteristic of dampness being heavy and turbid correlated with gender and height, and the dampness pathogen being apt to damage yang qi correlated with age.

In summary, weight correlated with the total scores of DSSCM and its factors, except for the dampness pathogen being apt to damage yang qi. Similarly, gender was found to be associated with the total scores of the DSSCM and the characteristic of dampness being heavy and turbid and the dampness pathogen being apt to damage yang qi, whereas age and height were only associated with certain dimensions.

Discussion

In this study, we validated the reliability and validity of the DSSCM. This was the first study to evaluate the psychometric properties of the DSSCM in a large sample population. The results exhibited satisfactory reliability, content validity, discriminant validity and criterion validity to assess the population's dampness syndrome.

The internal consistency and test–retest reliability of the DSSCM were good. The overall Cronbach's alpha coefficient and its four dimensions of the DSSCM were all within a desirable range. The corrected item-total correlations were also greater than 0.3, showing that these items could measure the same underlying concept. Otherwise, these items did not add exploratory power to the measure if the correlations were below 0.3.[36] Additionally, the DSSCM exhibited acceptable test–retest reliability; the ICC for the total score exceeded the recommended threshold of 0.70. The ICCs for the characteristic of dampness being sticky and stagnant was less than 0.70 but higher than 0.60, indicating marginally acceptable reliability. The possible reason is that some items in this dimension, such as heavy eye discharge or bad breath, were easily affected by some factors (eg, dietary habits, lifestyle), which led to a low reliability value.

The content validity showed that the correlation coefficients of the dimension-total score were all greater than 0.7 and the correlation coefficients between the four dimensions of the DSSCM and the corresponding items ranged from 0.464 to 0.850, which indicated that the DSSCM had good content validity.

Based on the four characteristics of dampness syndrome, the DSSCM was divided into four dimensions when the scale was developed.[1,25] In this study, we further verified the rationality of the four-factor structure. The results of CFA showed that the fit indices were not ideal. Although the development of the DSSCM strictly followed the standard of the scale, the development of TCM syndrome scales is different from that of modern medical scales, which are guided by Western medical theory and focus on capturing specific indicators and main symptoms to reflect a problem.[37] However, TCM symptoms are complex and involve multiple aspects. When developing the TCM syndrome scale, some supporting items are designed to determine the corresponding TCM syndrome along with main symptoms, which could lead to low factor loading for some items.[38] Similar problems were found in other TCM syndrome scales.[38] Further development work on the factor structure of the scale is warranted.

In multivariate regression analysis, weight was found to be associated with the total scores of the DSSCM and its factors, except for the dampness pathogen being apt to damage yang qi. Obesity has always been associated with dampness or phlegm in Chinese medicine theory, and phlegm-dampness is considered the key pathogenesis of obesity.[39,40] Another finding of this study was that gender had a significant influence on dampness syndrome; specifically, men were more likely to suffer from dampness syndrome than women. This result was in line with a previous study showing that the proportion of the phlegm-dampness type in males was higher than that in females by nearly 10 percentage points.[41] The possible reasons are that males are more likely to have the habits of tobacco and alcohol consumption and a preference for a greasy and salty diet, which might induce the accumulation of phlegm dampness in the body.[41]

This study has some limitations that need to be further considered. First, we did not follow the principle of random selection of samples, which limited the representativeness of the samples. Second, criterion validity was performed only for 401 samples. Although we included 869 participants, only 401 participants included in Guangdong Provincial Hospital of Chinese Medicine were evaluated by clinicians for a dampness diagnosis. Therefore, the result of criterion validity should be interpreted with caution. Third, some factors, such as alcohol consumption, dietary habits, humid level of long-term living or working environment and lifestyle, which may closely related to the degree of dampness were not involved in the investigation due to limited resources. These factors shall be taken into consideration in future DSSCM studies. In addition, in this study, some participants answered the survey questionnaire with a printed questionnaire, while others answered the survey questionnaire with an electronic questionnaire using a mobile phone or iPad. Considering the impact of different versions on the results, we further analyzed the psychometric properties of both versions and found that the main results were similar (see Supplementary Tables 2–5). We will further compare the difference between the electronic and paper versions in future studies.

Conclusions

This study evaluated the reliability and validity of the DSSCM with a sufficiently large sample size of participants. While only one index supported model fit in CFA, the DSSCM displayed good reliability, content validity, discriminant validity and criterion validity to support its use as a tool for assessing the severity of participants' dampness syndrome. Furthermore, this study also provides guidance for clinicians who have difficulty in decision-making. It is valuable for clinicians to make better decisions in the diagnosis, intervention and prognosis of dampness syndrome, especially for clinicians who have high decisional conflict and need extra support in the identification of dampness syndrome.

Abbreviations

CCMQ: Constitution in Chinese Medicine Questionnaire; CFA, Confirmatory factor analysis; CFI, Comparative fit index; DSSCM: Dampness Syndrome Scale of Chinese Medicine; GFI: Goodness of fit index; ICC: Interclass correlation coefficients; RMSEA, Root mean square error of approximation; SRMR: Standardized Root Mean Squared Residual; TCM: Traditional Chinese medicine; TLI: Tucker–Lewis Index.

Data Sharing Statement

All the data obtained and materials analyzed in this study are available with the corresponding author upon request.

Ethics Approval and Informed Consent

This study complied with the Declaration of Helsinki. Ethical approval was obtained from the ethics committees of Guangdong Provincial Hospital of Chinese Medicine (Approval No.: BE2021-222-01, BE2021-222-02, BF2022-119-01) and Guangzhou Cadre Health Management Center (Approval No.: K2022-04). All the respondents provided written or electronic informed consent before answering the survey questionnaire.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that they have no competing interests.

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