Original Article

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Design and Validation of the Questionnaire to Determine the Warmness and Coldness of the liver Mizaj (Temperament): A Self-Report Scale

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ABSTRACT

Background & Objective: Traditional medicine use is growing, highlighting the need to standardize diagnostic indices and treatment methods. In Persian medicine (PM), the concept of Mizaj (temperament), especially the Mizaj of major organs such as the heart, brain, and liver, has an important role in diagnosing and treating diseases. The present study aimed to provide a standard tool for diagnosing the warm-cold Mizaj of the liver.

Materials & Methods: A two-stage exploratory study reviewed literature and interviewed PM specialists to identify and construct questions related to liver Healthy Mizaj and Su-e-Mizaj (dystemperament). After assessing the preliminary questionnaire's validity and reliability, the final questionnaire's sensitivity, specificity, and cutoff point were determined. The normal distribution was tested with Kolmogorov-Smirnov. ANOVA, post-hoc tests, and the Mann-Whitney test were used for normal distribution data.

Results: Twenty PM specialists, methodologists, and 245 volunteers participated in this study. The initial questionnaire was regulated based on 180 items in the data pool and after different stages of validity and reliability assessment, 13 items remained. Sensitivity and specificity according to the cutoff point were, respectively, 79 and 74 for the warm liver Mizaj, 80 and 74 for the cold, and so 70 and 77 for the moderate liver Mizaj.

Conclusion: For diagnostic and research purposes, this is the first self-report questionnaire that assesses the warm and cold liver Mizaj in people aged 20 to 60.

Keywords: Persian medicine, Mizaj, Temperament, Traditional Iranian medicine, liver, Questionnaire

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Introduction

According to the World Health Organization, traditional, complementary, and alternative medicine (TCAM) is a collection of knowledge and skills based on theories and beliefs that can be promoted if their rational and evidence-based use is supported (1).

PM (Persian medicine) or Iranian Traditional Medicine (ITM) is among the oldest medical paradigms, extending back several millennia. Based on PM specialists' observations and experiences, this school presents disease signs, symptoms, and diagnostic methods. PM prescribes lifestyle changes and disease diagnosis and treatment based on temperament or physiological, physical, and mental traits (2). According to PM, all beings, including humans, are composed of four basic components: fire, water, air, and earth, called elements. Each element is somehow cold, warm, wet, or dry. The above elements exist in the form of four vital mixtures called four humors in the bodies of organisms, including humans. Once food enters the body in the first stages of digestion, it turns into four humors. The humors are Blood (warm and wet), Phlegm (cold and wet), Black bile (cold and dry), and Yellow bile (warm and dry (3)).

Each person's body and organs contain a proportion of senses of humor, and the aggregate of these traits produces Mizaj (temperament). Thus, each person's disposition fluctuates between warm and cold and wet and dry. The mentioned temperaments are four simple Mizajes (warm, cold, wet, dry), four compound Mizajes (warm/dry, warm/wet, cold/dry, cold/wet), and a temperate Mizaj (3). PM holds that everyone is born with an innate Mizaj that can alter with age, environment, and nutrition. This temperament is deemed healthy if the person is healthy. Temperament imbalance causes Su-e-Mizaj (dystemperament), a major illness group (4). In PM, in addition to the general Mizaj of the body, the organs also have their own Mizaj (5). PM literature states that the liver, the basic organ, creates humors from gut nutrients and transfers them to the other organs for energy and growth. Thus, this organ's Mizaj affects the whole body (6). PM literature states that the liver, the basic organ, creates humors from gut nutrients and transfers them to the other organs for energy and growth. Thus, this organ's Mizaj affects the whole body (7, 8). In “The Canon of Medicine,” Avicenna listed numerous liver illnesses, including liver Su-e-Mizaj (9).

Recent studies have shown that liver diseases such as cirrhosis impose high costs of treatment and care (10) and that non-alcoholic fatty liver, the most common liver disease, is a health priority (11). The effectiveness of health and treatment methods in PM can be confirmed through clinical research. Therefore, research related to liver Mizaj, timely intervention to prevent liver Su-e-Mizaj, and PM-based treatment can help reduce the burden of related diseases. Moreover, the PM specialists believed that the criteria for diagnosing Mizaj were of various degrees of importance (12).

To our knowledge, no standard tool or method has ever been provided to determine liver Mizaj. Therefore, the present study aimed to provide a valid and reliable diagnostic tool in the form of a self-report questionnaire to diagnose the cold and warm Mizaj of the liver for diagnostic purposes and research projects.

Materials and Methods

This study is a two-stage exploratory research project conducted from 2017 to 2020 at Shahid Beheshti University of Medical Sciences. The first stage was a qualitative study using a hybrid model, and the second was a quantitative study in which the psychometric properties of the instruments were evaluated.

Qualitative phase

The symptoms of liver warm and cold Mizai and Su-e-Mizaj were retrieved from 11 authentic PM texts using hybrid concept analysis to create a data pool. The second stage involved semi-structured interviews with PM specialists to assess their clinical experiences after a literature study. We also designed questions utilizing frequent phrases in semi-structured public interviews. A thorough diagnosis of warm and cold liver dysfunction based on signs and symptoms was presented after collecting and classifying all the elements. MaxQ software entered all signs and symptoms and built a tree chart to determine subgroups.

Item Generation

The researchers created one to two Likert items for each sign and symptom subset. In order from cold to warm, the first choice scored 1 in all items, while the fifth option scored 5. Thus, a preliminary liver coldness and wetness instrument design was created (13).

Face Validity

PM specialists and volunteers of both sexes with varying education levels were interviewed in stages till data saturation to determine face validity. This level examined difficulty, irrelevancy, and ambiguity. The research team eliminated redundant, confusing, or

problematic questions throughout many group discussions (14).

Content Validity

About 15 PM specialists from various medical universities received a content validity form. The professionals were asked for qualitative and quantitative feedback on the questionnaire's content validity. For face validity, we requested experts to review language, wording, item allocation, scale, simplicity, and clarity. The content validity ratio (CVR) and the content validity index (CVI) were examined to establish the item's necessity and relevance. Specialists were also asked to rate each item's CVR as "necessary", "useful" but "not necessary" or "not necessary."

Specialists were asked to rate the CVI as "relevant," "completely relevant," "relatively relevant," or "not relevant." CVR was calculated using Lawshe's table. For that, items for which over 70% of professionals voted “relevant” or “completely relevant” were chosen (15).

Reliability Assessment

Test-retest reliability examined questionnaire reliability. To test reliability, a questionnaire was given to 35 men and women of various education levels. Three weeks following the first stage, 21 subjects completed the questionnaire again. Both sexes aged 20–60 were eligible. However, liver illnesses such as cirrhosis or cancer, pregnancy, and drug and alcohol addiction were excluded. The weighted kappa coefficient was measured for each question. In this study, we accepted items above the 0.4 kappa coefficient (16).

Critertion Validity

Specialist-determined liver temperament was the gold standard before criterion validity testing. During a discussion with 14 Persian medical doctors, symptoms from written sources and interviews were refined, and major and minor liver warmness and coldness criteria were identified to improve diagnosis agreement (17).

The criterion validity was determined using the known-groups validity approach. Five to ten individuals were requested to participate in the study for each item that reached this stage. Three PM doctors with over ten years of clinical expertise were invited to collaborate. Specialists visited subjects and independently determined their liver temperament (coldness and warmness) using the stated criteria and their clinical diagnosis. In total temperament specialist agreement circumstances, the determined temperament becomes the gold standard (18). If there is a relative agreement, signs and symptoms will be discussed. Volunteers with conflicting temperaments were excluded. Volunteers with liver temperament were also given a reliability-stage self-report questionnaire. The results were then examined using SPSS.

The association between volunteers' item choices and temperament was examined using specialists' diagnoses as the gold standard. The alternatives were divided into two modes to compare each item to coldness, warmness, and moderateness. At each stage, each item's alternatives were changed to warm and non-warm, cold and non-cold, moderate and non-moderate, and the Spearman coefficient was found once for each question in general and then for warmness, coldness, and moderateness. Questions with Spearman coefficients below 2 were eliminated. The ROC curve was generated for coldness, warmness, and moderateness to determine the best cutoff point using specialists' diagnosis as the gold standard and the questionnaire's total score. All three modes—coldness, moderateness, and warmness—were tested for cutoff point sensitivity and specificity. Kolmogorov-Smirnov test for normal distribution (19) ANOVA and post-hoc test for normal distribution (20). Also calculated was the Mann-Whitney test (21).

Results

Items Generation

We categorized the symptoms of the warm and cold temperaments of the liver into 17 items, extracting a total of 60 symptoms for the warm temperament and 75 for the cold temperament, including symptoms of Mizaj and Su-e-Mizaj.

Quantitative phase

Preliminary questionnaire

A self-report questionnaire had one hundred and eighty items. All items had five Likert options. We designed at least one item for each sign and symptom.

Face Validity

A qualitative facial validity study involved 10 PM specialists and 30 participants over three stages. In the third stage, volunteers approved the remaining 93 questions for difficulty, irrelevancy, and ambiguity after 87 questions were removed and some revised.

Content Validity

Twelve traditional medicine specialists responded to send forms on required questionnaire items to determine the CVR. Lawshe's table extracted 61 items

for which more than 56% of specialists chose "necessary" and 24 items that did not score well.

Two stages of the CVI study involved 15 PM Doctors. In the first step, we deleted 12 items and changed 10. Two more questions were excluded in the second round, and 55 items were selected for reliability review by specialists.

Reliability Assessment

At least 21 of 35 invited volunteers completed the questionnaire twice, and weighted Kappa was measured. The questionnaire entered criterion validity with 37 items after removing 18 questions with a weighted Kappa below 0.4.

Critertion Validity

In criterion validity, nine of 225 people invited to measure liver temperament were excluded due to exclusion criteria. Persian medical experts analyzed the remaining 216 subjects' liver Mizaj for coldness and warmness. Out of the 208 volunteers, 48 had a cold liver Mizaj, 79 had a warm liver Mizaj, and 81 had a moderate liver Mizaj. Eight volunteers whose temperament was not agreed upon were deleted. Volunteers completed the 37-item questionnaire from the previous step. Based on the Spearman correlation, 13 items with a significant link to warmness, coldness, or moderateness were selected for the final questionnaire.

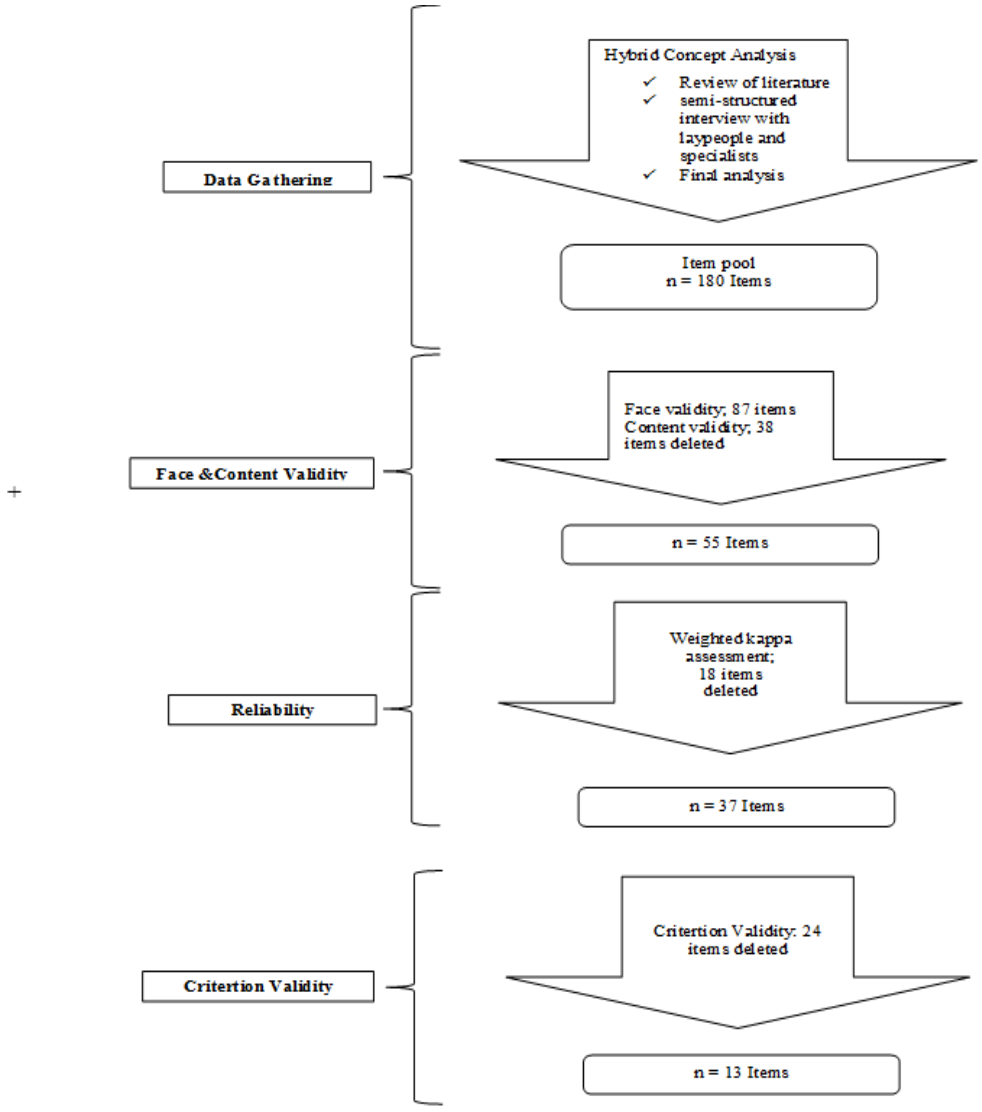

Figure 1. Displays the entire item creation process and adjustments during the study. The final questionnaire has 13 items: 8 connected to the main criteria, 2 to minor criteria, and 3 unrelated.

Scoring

According to Kolmogorov-Smirnov and Mann-Whitney tests, the questionnaire findings had a normal distribution, and ANOVA and posthoc testing showed a significant mean difference between coolness, moderateness, and warmness. The specialists separated volunteers into groups for the three stages based on liver Mizaj. The first stage was warm and non-warm, the second moderate and non-moderate, and the third cold and non-cold. Based on the total score of the thirteen final questionnaire items, the Roc Curve was formed for warmness, moderateness, and coldness, and the best levels below the curve determined the sensitivity and specificity of these three parameters (Figure 2). All warmness, coldness, and moderateness cutoff points have above 70% sensitivity and specificity, as shown in Table No.

Table 1. 13-item questionnaire analysis results

No.	Item	Options					wk	CVR	CVI1	CVI2	Spearman	Correlation
1.	My face is thinner than before.	Strongly agree	Agree	Neither agree nor disagree	disagree	Strongly disagree	0/5	0/2	0/57	0/53	0/2	coldness
2.	My facial skin has become more sagging.	Strongly agree	Agree	Neither agree nor disagree	disagree	Strongly disagree	0/6	o	0/57	0/53	0/26	warmness
3.	I am pale.	Strongly agree	Agree	Neither agree nor disagree	disagree	Strongly disagree	0/4	0/8	0/7	0/8	0.21	coldness
4.	I feel an annoying heat in my body.	Never	Rarely	Sometimes	Usually	Always	0/5	0/8	0/81	1	0.24	Coldness & warmness
5.	I feel hot in my body by eating foods with warm temperament like honey or dates or cinnamon.	Never	Rarely	Sometimes	Usually	Always	0/3	0/8	0/81	0/93	0/2	warmness
6.	By eating food with a cold temperament, like buttermilk, cucumber, or yogurt, I feel refreshed	Never	Rarely	Sometimes	Usually	Always	0/2	0/8	0/7	0/73	0/22	coldness
7.	Warm weather bothers me more than cold weather.	Never	Rarely	Sometimes	Usually	Always	0/5	0/55	0/7	0/8	0.46	Coldness & warmness
8.	I feel better in warm weather.	Always	Usually	Sometimes	Rarely	Never	0/3	0/8	0/41	0/57	0.47	Coldness & warmness
9.	In winter, I wear more clothes than other people.	Always	Usually	Sometimes	Rarely	Never	0/6	0/8	0/29	0/6	0.51	Coldness & warmness
10.	I usually drink several glasses of water and liquids in a row.	Never	Rarely	Sometimes	Usually	Always	0/4	0/6	0/57	0/8	0.22	warmness
11.	I feel thirsty all day long.	Never	Rarely	Sometimes	Usually	Always	0/4	1	0/7	0/93	0.26	Coldness & warmness
12.	When shaking hands with me, others tell me my hands are warm.	Never	Rarely	Sometimes	Usually	Always	0/7	0/8	0/91	0/8	0.31	Coldness & warmness
13.	My hands and feet are cold.	Always	Usually	Sometimes	Rarely	Never	0/5	0/8	0/41	0/67	0.44	Coldness & warmness

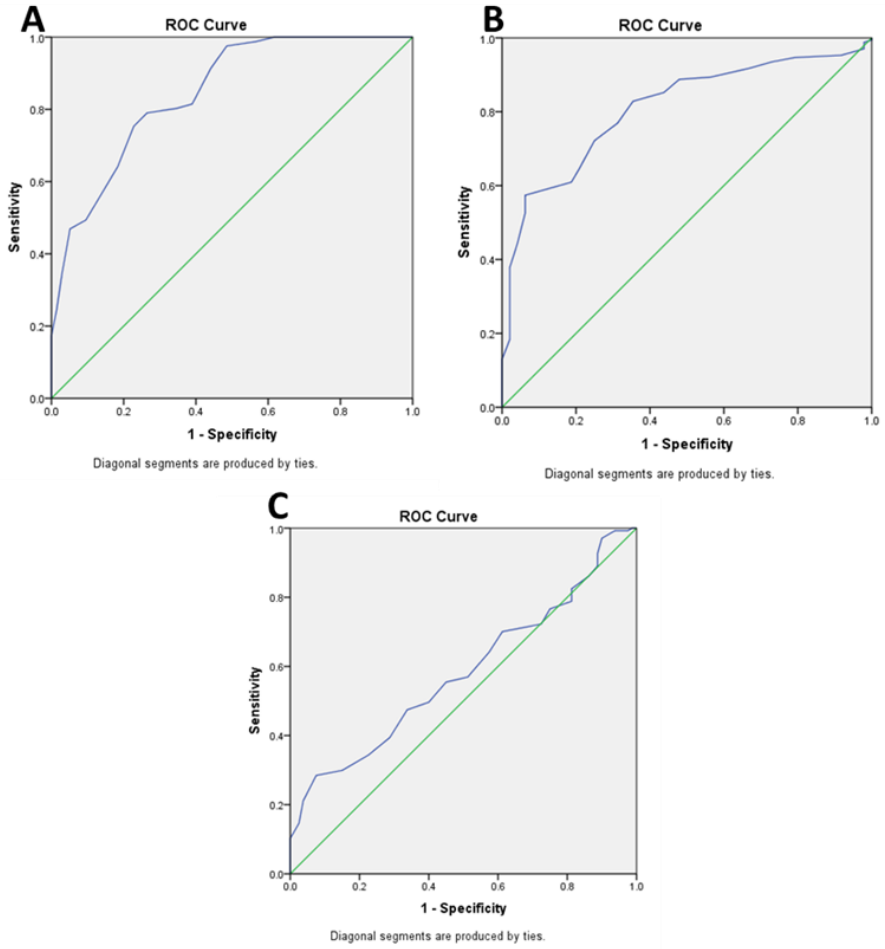

Figure 1. A) Roc Curve for Warmness B) Roc Curve for Coldness C) Roc Curve for Moderateness

Table 2. Warmness, coldness, moderateness cutoff points, sensitivity and specificity.

Quality	Cutoff point	Area under the curve (%)	Sensitivity (%)	Specificity (%)	Positive Predictive Value (PPV) (%)	Negative Predictive Value (NPV)(%)
Warmness	38≤	85(79-89) P=0.00	79(70-88)	74(66-81)	64(55-73)	**85(79-92)**
Moderateness	34-37	21(12-20) P=0.04	80(73-86)	74(66-81)	38(24-52)	**63(56-71)**
Coldness	33≥	81(74-87) P=0.00	70(56-82)	77(71-83)	46(34-57)	**90(85-90)**

Table 3. The number of items for each theme in the validation process.

NO.	Theme	Number of Items After Each Step				
		Primary Tool	Face validity	Content validity	Reliability	**Criterion Validity (Final Version)**
1.	Weight changes	7	4	2	0	**0**
2.	Touching	4	2	2	2	**2**
3.	Vein Conditions	4	2	1	0	**0**
4.	taste changes in the mouth	5	2	0	0	**0**
5.	Tongue, mouth, and lips change	14	8	4	2	**0**
6.	Appetite changes	6	3	1	0	**0**
7.	Changes in thirst	13	7	6	5	**2**
8.	characteristics of diarrhea and vomiting	13	3	0	0	**0**
9.	Abdominal pain or discomfort	8	3	0	0	**0**
10.	bowel habits and stool characteristics	10	5	2	0	**0**
11.	Changes in urine color	6	3	3	1	**0**
12.	impressibility of cold or warm weather	7	6	6	5	**3**
13.	impressibility of cold or warm food	18	12	10	8	**2**
14.	Specific symptoms of liver warm Sue-Mizaj	15	5	1	1	**1**
15.	Specific symptoms of liver cold Sue-Mizaj	12	6	7	5	**2**
16.	Skin and hair changes and problems	20	11	8	6	**1**
17.	Behavioral changes: The speed and slowness of the body movements	18	11	2	2	**0**
18.	Total	180	93	55	37	**13**

Discussion

There is a deficit of research in instrument Standardization in PM. In this regard, the questionnaire developed by Mojahedi et al. In this study, which was performed with the cooperation of healthy volunteers aged 20–40 years, the opinions of 3 specialists with an agreement of more than 70% were considered the gold standard (22).

Furthermore, Roshandel et al. developed a questionnaire to assess present, acquired, and hereditary or congenital temperaments. No construct validity standard was used, and moderate temperament was not considered when separating temperament types (23). Anoushirvani et al. also created a validated PM-based depression questionnaire. After face, content, and reliability testing, the instrument has 27 self-report items and 6 examination-only items. This study's construct validity and scoring mode were unclear (24).

The questionnaire that detected Mizaj using the ten Mizaj indicators was evaluated by Salmannejad et al. at various phases. A three-person PM team deemed 221 healthy participants' temperament the best standard for criterion validity. This questionnaire covers 20–60-year-olds (25).

Hosseinzadeh et al. (2018) described creating and validating a digestive system dystemperament questionnaire. 49 items were made utilizing textual sources and expert views in this investigation. They found some items by examination and others by patient response. Two PM professionals determined ten patients' temperament and concurrent validity assessed. Software-based grading was not disclosed by the questionnaire's creators (26). In addition, Fattahi Masoum et al. (2020) used a 35-item self-report questionnaire to assess brain temperament and reported content validity and reliability. Criterion and construct validity assessment are lacking in this study (27).

In the study of Akhtari et al. (2024), a self-report questionnaire was designed to check the temperament of older adults. In this study, the temperament determined by experts was the gold standard (28).

In the literature review of the articles about the design and validation of temperament questionnaires, several studies had not passed all of the standardization stages. This was especially true for the stages that dealt with construct and criterion validity.

Hakimi et al. (2019) retrieved, rated, and reported the liver temperament criterion utilizing PM sources, face-to-face interviews, and group discussions with PM specialists. Thirst, body color, impressibility to warm and cold foods and air, skin lesions, and problems like itching, acne, and edema were major criteria, while tongue color, body temperature and location of the liver, urine color, appetite, obesity and thinness, and lip color were minor criteria (28). Since no other research has been done on liver mizaj criteria, the questionnaire items from this study are discussed based on Hakimi et al.'s main and minor criteria.

Major Criteria

Thirst

Thirst with the highest score is Hakimi's study's first major criterion for determining liver warmness and coldness (29). Only two of the 13 thirst-related items in this study remained in the final questionnaire. Due to the association between the thirst index and other organs, particularly the stomach, Persian medical sources have developed differential signs to detect changes in the temperament of the member causing the thirst (30). The next two items in the final questionnaire focus on liver temperament-induced thirst alterations in coldness and warmness (31, 32). In their standard digestive system temperament questionnaire, Hosseinzadeh et al. (2018) incorporated a daytime thirst item (26).

Skin color

Avicenna considers skin color as one of the important symptoms for diagnosing liver diseases and states that an experienced doctor diagnoses liver

diseases based on stomach disease only via color and does not need any other symptoms (8). PM books describe the types of skin color and how they change with each type of liver temperament and dystemperament. Only one of the twenty items designed for skin changes remained in the final questionnaire. Since skin color is one of the indicators for determining general temperament, there is an item related to body color in Salmannejad's questionnaire (25). In Mojahedi et al.'s study, the skin color index, one of the indices for determining general temperament, did not exhibit a strong correlation with the final temperament determination by specialists, leading to its elimination during the validation process (33). According to the importance of skin color, there is an item in the questionnaire of Akhtari et al. (28).

Impressibility of cold or warm weather and food

The third and fourth cases of major criteria for determining liver temperament in Hakimi's study were the impressibility of cold or warm food and weather (29). According to PM, warm or cold foods can worsen or relieve liver ailments. People with warm livers react faster to warm foods and vice versa (7). In 2014, Mohammadi Farsani studied the association between warm and cold foods, the thermic effect of food (TEF), basal metabolism, sympathetic and parasympathetic activity, and thyroid function (34, 35). In Mojahedi et al.'s temperament determination indices investigation, the speed of impacting attributes was more strongly correlated with general temperament warmness and coldness (33). The final questionnaires of Salmannejad and Mojahedi included one item related to food and air (22, 25).

Hosseinzadeh et al. prepared a questionnaire on the temperament of the digestive system, which includes questions about the improvement and aggravation of digestive symptoms with different foods (26). In the Akhtari et al. study, there is one item related to the impressibility of weather and one item related to impressibility of food (28).

In this study, PM sources and interviewed specialists considered the importance and many features of this index. Therefore, the items were constructed with closer attention to interviews with patients with cold or warm livers. Due to the range of pros and cons, the initial questionnaire had at least 18 items on the cons of warm or cold food and 7 on cold weather, of which five remained in the final questionnaire.

Regarding the other two major criteria in Hakimi's study, including skin problems and edema, in the initial questionnaire designed, 10 items were allocated to skin lesions and four items to edema, but these items were removed due to insufficient scores in the validation process. Therefore, no items are related to these two indicators in the final questionnaire.

Minor Criteria

Hakimi's study's seven minor criteria were covered by several questions in the initial questionnaire. We assigned four items to tongue color, one to liver warmness and coldness when touched, six to urine color, six to appetite and its fluctuations, seven to obesity, thinness, and weight changes, three to lip color, and three to body warmness and coldness. The final questionnaire included only two general touching items. Mojahed's temperament assessment included a question about bodily coldness and warmness when touched. There are also two items in the Akhtari elderly temperament questionnaire about the coldness and warmth of the body when touched (28).

This study is the first to create a self-report liver warmness and coldness questionnaire, although it has significant disadvantages. The investigation was hampered by PM Doctors' disagreement on liver temperament indices. We held many expert panel sessions to resolve this issue. Another study flaw was the failure to give weights to indications to determine beginning item counts. Future research should include more and less significant aspects to construct index components.

The qualitative stages of this investigation revealed indicators beyond the major and minor criteria. In the final questionnaire, we included three topics on facial slimming, skin loosening, and a discomforting feeling of warmness in the body. However, hair under the ribs and abdomen, hair characteristics, pulse, fever, taste and moisture of the mouth, tongue characteristics, behavioral changes, factors causing cold liver, including consumption of cold water after physical activity and fasting warm baths, body excreta, and abdominal obesity were not included in the major and minor criteria and did not score high enough to be included.

Conclusion

Using standard tools to organize logical and evidence-based research and development in PM is necessary. This study is the first to provide a standard tool for diagnosing warm and cold livers. Most of the items in this study's final questionnaire correspond to the major and minor criteria extracted from the opinions of PM specialists to determine the warmness and coldness of the liver. We recommend using this questionnaire in PM research and clinical activities related to liver temperament. Because some of the indicators that were considered important from the perspective of the primary sources of the questionnaire were removed in the questionnaire standardization process, it is suggested to determine the exact relationship between these indicators and liver temperament using metric and standard methods of determining liver temperament.

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Conflict of Interest

The authors declare no conflict of interest.

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Ethics approval and consent to participate

The Ethics Committee of Shahid Beheshti University of Medical Sciences approved the study with the code IR.SBMU.RETECH.REC.1395.624

Authors' Contribution

P. J.: Conceptualization, Investigation, Resources, Writing original draft, Review and Editing. F.H., M.Ch.R. and E.P.: Resources, Software, Review and Editing. M. M. and R. M.: Conceptualization, Project Administration, Investigation, Review and Editing. M.T., R. I. and A. A.: Conceptualization, Investigation, Validation, Supervision. M. Sh. and H. N.: Conceptualization, Validation, Supervision. M.S.I., A. Z., A. E. and H. Sh.: Methodology, Validation, Supervision.

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