



## Development and Validation of the “Treatment Satisfaction with Traditional Medicines” Questionnaire (TSTMQ)

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### Abstract

To develop and validate “Treatment Satisfaction with Traditional Medicines” Questionnaire (TSTMQ), a preliminary 22-item instrument was designed. Content validity ratio (CVR), content validity index (CVI), Intra-class correlation (ICC), and Cronbach alpha were measured, and exploratory and confirmatory factor analysis (EFA and CFA) were conducted. Data were analyzed using SPSS (17) and LISREL softwares (8.8). Finally, TSTMQ with 14 items and in three domains were confirmed after measuring CVR (> 0.62), CVI (> 0.79) and EFA. ICC for the entire questionnaire was 0.99 (95% CI: 0.95-0.99) (P<0.001), and Cronbach alpha was also 0.87. In CFA, all factor loadings and t-values were greater than 0.3 and 1.96, respectively. Also,  $\chi^2/df$ , RMSE and GFI were 2.6, 0.062, and 0.94, respectively. This study showed that the TSTMQ is a standard tool to measure treatment satisfaction with traditional medicine.

**Keywords:** Satisfaction; Traditional medicine; Questionnaire; Iran; Persian medicine

### Introduction

Reduction of communicable diseases and childhood illnesses, increased human life expectancy and increased frequency of chronic diseases have changed patient's requirements from health care services. Measuring accessibility to health care services is not sufficient, and attention to the clients' satisfaction, especially in the treatment of chronic diseases has been paid in recent decades more than ever [1]. Patient satisfaction (PS) is associated with all aspects of healthcare, and includes satisfaction with medical care and various therapeutic methods prescribed by

the therapist [1-3]. Treatment satisfaction affects patient's preferences and adherence to treatment; therefore, as a quality indicator, it can be used to promote health care [2-6].

Many efforts have been conducted for measuring PS and developing its measurement tools. Several questionnaires are available to assess PS with the service quality provided at clinics [2,7-10]; however, there are a few questionnaires to evaluate PS with the effectiveness or convenience of the therapeutic methods. The “Treatment Satisfaction Questionnaire for Medication (TSQM)” examines the effectiveness, convenience,

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and side effects of treatments, and the global satisfaction with treatment [11-13]. The “Treatment Satisfaction with Medicines Questionnaire (SATMED-Q)” examines some other aspects of medical care in addition to the TSQM [14].

These questionnaires are not in Persian language, and do not address all aspects of treatment satisfaction; their contents are not appropriate enough to be applied in practice and research in Persian medicine. Persian medicine is one of the branches of complementary/alternative medicine. In Persian medicine, a treatment package is usually prescribed, including lifestyle changes, dietary recommendations, different medicines, massage, cupping, leech therapy, etc.

In many studies on traditional medicine, treatment satisfaction has been investigated, but there is no standard questionnaire in this field. There is a clear lack of a standard and valid questionnaire to evaluate PS with prescribed treatments. Accordingly, this study was conducted to design a valid and reliable tool to examine PS with treatments through traditional medicine.

## Methods

This cross-sectional study was performed during 2016-2018 for development and standardization of Treatment Satisfaction with Traditional Medicine Questionnaire (TSTMQ).

### *Development of Items*

Initially, related texts and similar questionnaires were extracted [8,11,14]. Then, the initial questions were developed by a team of 10 experts (seven in the field of Persian medicine, all of whom were faculty members with the history of clinical work, plus three methodologists with the history of questionnaire designing) by the Delphi method. The questionnaires and checklists were sent to them by email; they were followed by email and telephone.

Ten patients referring to the clinics of the Iran University of Medical Sciences were also interviewed to determine the different aspects of treatment satisfaction for developing the questionnaire. For each section, relevant, understandable and unambiguous questions were designed, such that each question represented one aspect of satisfaction. The first questionnaire included 22 items in the fields of efficacy, convenience, side effects and the overall satisfaction with medications. The answer to all questions was Likert-type, and scored as 1 for totally disagree, 2 for disagree, 3 for no idea, 4 for agree and 5 for totally agree.

### *Participants*

Patients with chronic diseases referring to the traditional Medicine Clinic of the Iran University of Medical Sciences were included in the study, by a convenience method. The inclusion criteria were age over

18, outpatients of both genders with chronic diseases, who had been under treatment for more than two months with the recommended treatments of Persian medicine.

The first sample consisted of 50 patients, who were included in the pilot study to assess the content validity, exploratory factor analysis and reliability of the questionnaire. On the other hand, the second sample consisted of 470 patients, whose data were used to conduct the confirmatory factor analysis (CFA).

### *Face and Content Validity*

To assess the face validity of the TSTMQ, experts were asked to evaluate the questionnaire in terms of grammatical accuracy, the use of proper words, phrases, scoring, ambiguity and the difficulty in understanding the concept. In addition, in the pilot study on 50 patients, phrases or words that were ambiguous or difficult to comprehend were identified; in the next step, all ambiguities were resolved.

To assess the content validity quantitatively, the TSTMQ was reviewed by the expert team, and CVR (content validity ratio) and CVI (content validity index) were calculated. To measure the CVR, the experts were asked to indicate which item was essential, required but not essential, or not required [15,16]. Scores of answers were considered as 3 for essential, 2 for required but not essential and 1 for not required. Then CVR was calculated for each question by the equation 1.

$$\text{Equation 1.} \quad [\text{CVR} = [\text{ne} - (\text{N}/2)] / (\text{N}/2)]$$

In this formula, ne represents the number of experts selecting “is essential” and N refers to the total number of experts. Based on the Lawshe table, questions with CVR greater than 0.62 were retained and the rest were excluded [15].

To measure the CVI, the experts were asked about the relevance of each question with the subject of the questionnaire, as well as the simplicity and clarity of the phrases. Scores were 1 for “not relevant”, 2 for “relatively relevant”, 3 for “relevant” and 4 for “completely relevant”. Similarly, scores 1 to 4 were considered for answers to simplicity and clarity. Waltz and Bausell methods were used to calculate the CVI. The CVI for each question was calculated from the following formula:  $\text{CVI} = \text{number of answers 3 and 4} / \text{number of experts}$  [17]. Questions with CVI above 0.79 were kept, those with CVI in the range of 0.79-0.7 were changed or modified, and items with CVI less than 0.7 were excluded. Then, the average of CVI was calculated.

### *Construct validity*

For determining the underlying factors (domains) of

the 14-item questionnaire, Exploratory Factor Analysis (EFA) was done. The principal component analysis and the varimax rotation method were used for extraction. Kaiser-Meyer-Olkin (KMO) was assessed for sampling adequacy. Bartlett’s test for sphericity was utilized to test the identity formation of the correlation matrix. Finally, for confirming the developed questionnaire, it was fulfilled by 470 participants, and CFA was done.

Standardized loading factors, t-values, and variance of error (1-r<sup>2</sup>) were calculated for each question. The acceptable limit for the standardized loading factor was higher than 0.3, and for the t-value was greater than 1.96. Chi-square/degree of freedom ( $\chi^2/df$ ) less than 3, Root Mean Square Error of Approximation (RMSEA) less than 0.08, and the goodness of fit (GFI) greater than 0.9, were considered as a reasonable model [8,18].

**Reliability**

The internal consistency was evaluated by Cronbach’s alpha. Cronbach’s alpha coefficient of more than 0.7 was considered as an optimal level. The repeatability

of the questionnaire was determined by calculating the Intra-class correlation coefficient (ICC) in a test-retest on a 50-member sample with a 2-week interval [16]. Data were analyzed using LISREL (version 8.8) and SPSS (version 17) software. The mean ( $\pm$  standard deviation) was reported to describe the quantitative variables.

**Results**

In the main study, 431 from 470 questionnaires were completed (response rate: 91.7%). Table 1 reports the characteristics of patients in the main study. Table 2 shows the causes of referral to traditional medicine clinics (the main problem of patients). The mean ( $\pm$  SD) duration of using traditional medicine (for the most recent and important problem) was 6.5 ( $\pm$  6.7) months.

After checking the CVR and CVI, a 14-item questionnaire remained. The results of the validity and reliability of the final questionnaire and the ICC calculated in the test-retest are presented in table 3. F-values were 13, 11.94, 9.01, and 134.22 ( $P < 0.001$ ) for sections a, b, and c, and for the whole questionnaire, respectively.

**Table 1.** Participants’ characteristics

Variable	
Age	39.7 $\pm$ 11.5 years
(Mean $\pm$ Standard Deviation)	
Sex	Male: 145 (33.6)
n (%)	Female: 286 (66.4)
Education	Illiterate: 72 (16.7)
n (%)	Under the diploma:118 (27.3)
	Diploma: 176 (40.8)
	Higher than diploma: 65 (15)
Job	Housekeeper: 226 (52.4)
n (%)	Eemployee:83 (19.2)
	Other: 122 (28.3)

**EFA**

KMO was 0.806 and Bartlett’s test of sphericity was significant ( $\chi^2 (100) = 374.5, p < 0.001$ ). The communalities were 0.54-0.8 in the first model. The first three Eigenvalues were above one, which indicated the first three factors explained 63% of variance cumulatively.

Analyzing the principal components factor of the remaining 14 items was handled using the varimax rotation. Table 4 shows the factor loadings for every 14

**Table 2.** The causes of referral of the patients to traditional medicine clinics

n (%)	Type of disease
54(12.52)	Musculoskeletal diseases
147(34.1)	Gynecology
25(5.8)	Endocrine and metabolism
20(4.64)	Respiratory
3(0.69)	Hematology
79(18.32)	Gastro-intestine and liver
51(11.83)	Neurology and psychiatry
23(5.33)	Dermatology
3(0.69)	Cardiology
5(1.16)	Renal
11(2.55)	Other

items, and all three factors named efficacy, convenience, and overall satisfaction, respectively.

**CFA**

The standardized factor loadings for each question, the t-value, and the variance error are shown in Table-5. Figure 1 shows the standardized factor loadings for each item. The fitness indices were as follows:  $\chi^2/df = 2.6$ , RMSEA = 0.062 and GFI = 0.94 [8,18,19].

**Table 3.** CVR, CVI, Cronbach’s Alpha and ICC of the TSTMQ

Domain	Code	Question	CVR	CVI	Cronbach’s Alpha
Satisfaction with efficacy	a1	Reduction of symptoms following interventions	1	0.8	0.87
	a2	Feeling better following interventions	1	1	0.87
	a3	The time to effect	1	0.8	0.9
	a4	Ability to perform daily living activities	0.8	0.8	0.87
	a5	Ability to perform leisure activities	0.8	0.8	0.88
a	$\alpha=0.9$ ICC= 0.92 95% CI= 0.88-0.95 F=13, P<0.001				
Satisfaction with convenience	b1	Taste and odor of the prescribed drugs	1	0.8	0.78
	b2	Duration of interventions	1	0.9	0.75
	b3	Amount of prescribed drugs per day	1	0.8	0.75
	b4	Times to take drugs per day	1	0.8	0.76
	b5	Number of prescribed orders	0.8	0.8	0.80
	b6	Tolerance of complications	0.8	1	0.77
b	$\alpha=0.81$ ICC=0.91 95% CI=0.87-0.94 F=11.94, P<0.001				
Overall satisfaction	c1	Intention to continue interventions	1	1	0.9
	c2	Intention to return for treatment of other diseases	0.8	0.8	0.79
	c3	Intention to recommend these interventions to others	1	1	0.78
c	$\alpha=0.88$ ICC=0.88 95% CI=0.83-0.93 F=9.01, P<0.001				
The whole questionnaire	$\alpha=0.87$ ICC= 0.99 95% CI=0.95-0.99 F=134.22, P<0.001				

CVR: content validity ratio, CVI: content validity index. ICC: Intra-class correlation coefficient,  $\alpha$ = Cronbach’s Alpha, CI=confidence interval, F: F-value for probable bias, P: P value for F test, a, b, c: the whole domain

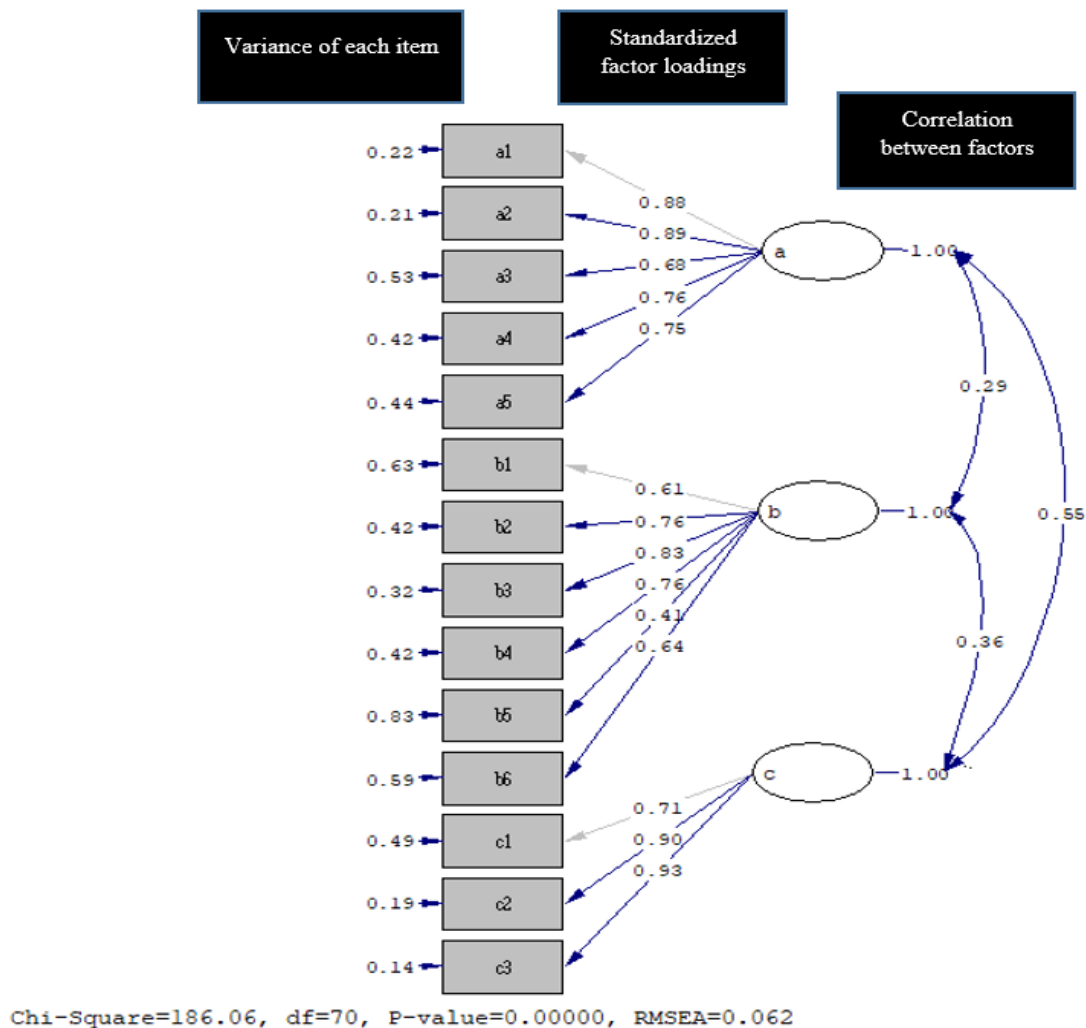
**Discussion**

The aim of this study was to develop and explore the psychometric properties of a new instrument for measuring treatment satisfaction to use in the clinical practice of traditional medicine; the results revealed that the 14-item TSTMQ had appropriate validity and internal consistency. Although the ICC was high in all sections of the questionnaire, F-values were significant; these significant F-values showed the probable existence of bias in the test-retest, which may be due to the small number of questions or the short period between the test and retest.

One of the questionnaires in the field of treatment satisfaction is TSQM, which was developed in 2004; it consists of four sections of effectiveness, side effects, convenience and global satisfaction [11]. The 9-item TSQM was designed and validated in 2009; it also

consists of three sections of effectiveness, convenience and global satisfaction [12]. The SATMED-Q, which is another questionnaire for measuring treatment satisfaction was developed and validated in 2008; it consists of 17 items in 6 sections of effectiveness, convenience, impact on daily activities, medical care, side effects, and global satisfaction [14].

We only had the published articles of SATMED-Q and TSQM, and some general information about their items, sections and indices of validity and reliability. These questionnaires have not been standardized in Iran; therefore, we did not have any gold standard questionnaires to compare with TSTMQ. We designed our own questionnaire and finally, the TSTMQ was presented with 14 items in three sections of efficacy (5 items), convenience (6 items) and overall satisfaction (3 items). The present study showed that all validity



**Figure 1.** Standardized item loadings  
 [Grey boxes show the items of the questionnaire, a = efficacy, b = convenience, c = overall satisfaction (see table 3)]

**Table 4.** The factor loadings for each 14 items for three factors after varimax rotation of variance matrix

Code	Question	Components		
		A: Satisfaction with efficacy	B: Satisfaction with convenience	C: Overall satisfaction
a1	Reduction of symptoms following interventions	0.816		
a2	Feeling better following interventions	0.750		
a3	The time to effect	0.574		
a4	Ability to perform daily Living activities	0.726		
a5	Ability to perform leisure activities	0.733		
b1	Taste and odor of the prescribed drugs		0.730	
b2	Duration of interventions		0.870	
b3	Amount of prescribed drugs per day		0.852	
b4	Times to take drugs per day		0.712	
b5	Number of prescribed orders		0.474	
b6	Tolerance of complications		0.520	
c1	Intention to continue interventions			0.519
c2	Intention to return for treatment of other diseases			0.699
c3	Intention to recommend these interventions to others			0.826

and reliability indices of TSTMQ were appropriate. The TSTMQ has one question about the tolerance of complications. Other questions in the domain of side effects were deleted due to low CVR. There are some detailed questionnaires, that can be used to check the complications of the treatment, which was not the objective of the present study.

The present questionnaire could be used to assess the PS with treatments, but not with medical care services. PS with the services offered at the clinic or office is also an important aspect of satisfaction, and there are several available questionnaires to assess it. In these questionnaires, PS with facilities and equipment, physician and staff behavior, waiting time, respect for the patient’s opinion, physician’s skill in diagnosing and treating the disease, accessibility and costs have been

evaluated [14,19,20].

Compliance or adherence, which means following the orders of the physician is very important in the effectiveness of various therapies. If the prescribed treatment is not effective, the first question to be asked is whether the patient has had enough compliance with the prescriptions. Note that assessment of treatment satisfaction should be evaluated alongside the adherence. If the patient is not satisfied, the association between dissatisfaction and non-adherence should be suspected, and reasonable conclusions must be drawn [21,22].

Another issue that must be considered is patients’ expectations of the treatment outcomes. Indeed, what patients expect to happen can influence their treatment satisfaction. Clinicians need to clarify patients’ expect-

tations, and support them to have appropriate expectations of recovery [23]. The results of studies suggest that patients with more positive therapeutic expectations benefit medical treatments more, and have higher treatment satisfaction than others [24]. For example, in the study of Habibovic et al., the frequency of depression and anxiety was higher in patients with implantable cardioverter defibrillators and negative expectations about outcomes [25].

The relationship between patient’s expectations and the treatment outcomes depends on the type of disease and the measured outcomes. As mentioned above, physicians need to identify patients’ expectations, and help them to have reasonable expectations from treatment [23]. This issue should be taken into account in traditional medicine, and physicians should explain the possible outcomes to the patient reasonably and honestly. For example, the experience of traditional medical practitioners and existing studies suggest, that traditional therapies do not improve the sensory and motor symptoms of patients with Multiple Sclerosis (MS); they only improve their quality of life [26]. With this knowledge, patients will not expect to improve the sensory and motor symptoms by traditional therapies, and they will probably be more satisfied.

Using questionnaires such as TSTMQ will help therapists and researchers to manage chronic diseases efficiently, and make appropriate decisions. Treatment satisfaction can be disturbed in the presence of several diseases comorbidities and drug interactions of several medications. It is an important issue to be taken into account; in such cases evaluation of the treatment satisfaction needs to be conducted more cautiously.

This questionnaire was the first standard questionnaire designed to assess treatment satisfaction in traditional medicine. There was no gold standard for comparison; therefore, criterion validity could not be verified. Conducting a study to examine patients’ expectations from traditional therapies and their relationship with their outcomes and satisfaction is suggested. In addition, a prospective study is needed to evaluate the influence of low treatment satisfaction on clinically relevant outcomes.

### Conclusions

The TSTMQ is a patient-reported outcome measure to assess treatment satisfaction. The findings of the present study suggested that TSTMQ had satisfactory psychometric properties.

### Conflict of Interests

None to declare.

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