Treatment Satisfaction Questionnaire for Medication (TSQM Version II): A Psychometric Properties Analysis

Mahin Eslami Shahrbabaki  
Neurology research center, Shahid Beheshti hospital, Kerman university of medical sciences, Kerman

Habibeh Ahmadipour  
Social determinants of health research center, Kerman university of medical sciences, Kerman

Narjes Yousefi  
Shahid beheshti hospital, kerman university of medical sciences, kerman

Parisa Divsalar (✉ pdivsalar@yahoo.com)  
Neuroscience research center, Institute of neuropharmacology, Kerman university of medical sciences  
https://orcid.org/0000-0002-9695-724X

Research

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Abstract

Background: Methadone or buprenorphine maintenance therapy is an effective treatment for opioid dependence. Since the satisfaction of Patients who use Methadone Maintenance therapy (MMT) services plays an important role in their therapeutic success, it seems important to evaluate the satisfaction of methadone usage with multidimensional psychometric tools. This study aimed to investigate the psychometric properties of the Persian version of the Treatment satisfaction questionnaire for medication (TSQM) version II.

Methods: A cross-sectional study carried on 288 opioid dependent patients of Shahid Beheshti MMT clinic in Kerman. Data was collected using a questionnaire containing the demographic characteristics of the participants and the Persian version of the Treatment Satisfaction Questionnaire for Medication version II (TSQM). TSQM has 11 questions in four subscales including effectiveness, side effects, convenience of use and overall satisfaction. The sum of the scores of each subscale is displayed as a number from zero to 100.

Face and content validity of the questionnaire was confirmed. Exploratory and confirmatory factor analysis methods were used to evaluate the construct validity. Internal consistency of TSQM Version II was determined by Cronbach's alpha and its repeatability using test-retest method. Data were analyzed by Statistical Package for the Social Sciences (SPSS) software version 20.0 and linear structural relations (LISREL) software version 8.80.

Results: The mean age of 46.24± 11.5 years and the majority of them (85.4%) were male. Internal consistency of the Persian version of TSQM Version II was determined by the Cronbach's alpha 0.80. Its repeatability using test-retest method was calculated as 0.9.

Exploratory factor analysis revealed the adequacy of sampling and justifiability of the analysis (KMO= 0.82, P = 0.001, χ² = 1507.02, df = 28) In CFA, the Goodness of Fit Statistics were in an appropriate level.

Conclusion: The Persian version of TSQM Version II had appropriate psychometric properties and can be used as a valid, and reliable tool to assess the treatment satisfaction in the clinical settings.

Background:

Since 2000, the World Health Organization (WHO) has focoused strongly and seriously on evaluation and measurement of treatment's satisfaction and suggested the conduction of improvement plan across health care delivery (Li et al, 2017). During the last two decades the treatment Satisfaction has been highlighted not only as an important parameter in measuring the quality but also a reasonable result of our expectations and experiences of health services (Tran, Nguyen, Phan&Latkin, 2015). One of the questionnaires related to the topic of treatment satisfaction with the particular aim of development and evaluation of treatment satisfaction among the patients already undergoing treatment is the TSQM.
(Treatment Satisfaction Questionnaire for Medication). TSQM is a valid scale of patients' satisfaction of pharmacological treatment (Atkinson et al, 2004).

It was shown that patient’s satisfaction affects their health and treatment-related behaviors, which in turn, affects the success of treatment results (Taylor, 2000). Satisfaction with the received services, predicts success of treatment, medical compliance, follow-ups and Proper use of services among patients. In other words, Patient’s satisfaction from their prescribed medicine predicts continuity of drug treatment, proper use of medication and medicine adherence. Among patients with chronic disease, adverse effects of medications such as ongoing side effects, and the inconvenience of long-term use could cause a patient cease to use their medicine without getting medical advice from their physician. Since, more emphasis is on dissatisfaction with side effects and discomfort, poor adherence may jeopardize the effectiveness of a drug, thus, increases the rate of disease progression (Atkinson et al, 2004 & Dunbar-Jacob et al, 2000).

Substance use disorder is currently a public health issue with high rate of morbidity and mortality. Maintenance therapy with methadone or buprenorphine is an effective treatment for opioid dependence in the community (Peles, Schreiber S& Adelson, 2006). Due to the increasing prevalence of substance abuse disorder in our country (Iran) and its destructive effects on the quality of life of patients, attention to quality of life as an important factor in evaluating treatment outcomes and the effectiveness of treatment in physical and mental illnesses has been improved during the last 3 decades (Brown, Zueldorff, 2007). Since the satisfaction of patients who use Methadone Maintenance Treatment (MMT) services plays an important role in their therapeutic success and harmony, hence realization of dosage adequacy, treatment satisfaction, side effects and ease of use seems to be necessary (Trujols et al, 2012a). Therefore, it seems important to evaluate the satisfaction of opioid agonists usage as a medicine with psychometric tools.

Many Studies have been conducted worldwide on the validity and reliability of the TSQM questionnaire (Peles et al, 2006, Liberato, Rodrigues, São-João, Alexandre,& Gallani, 2016, Pérez de Los Cobos et al, 2018, Regnault, Balp, Kulich, Viala-Danten, 2012, 12- Watanabe-Fujinuma et al, 2019). A study conducted in the United States on 8 different groups of patients showed that this questionnaire can be a good predictor of drug treatment in different patients that the reliability coefficient was acceptable with Cronbach's alpha coefficient of the questionnaire (Peles et al, 2006). In 2016, the validity and reliability of the treatment satisfaction questionnaire in cardiovascular patients were assessed in Brazil and showed evidence of the acceptability and practicality of TSQM (Liberato et al, 2016). A 2018 study evaluated satisfaction with buprenorphine-naloxone treatment in heroin addicts. The result of this study that conducted with the help of TSQM questionnaire and evaluated general satisfaction, drug treatment, mental status, physical condition, personal performance, acceptance and anti-addictive effects of secondary substances showed acceptable internal consistency and correlation coefficients among all studied factors. The results supported the validity and reliability of the questionnaire (Pérez de Los Cobos et al, 2018).
Considering both the role of buprenorphine and methadone maintenance therapy as an effective treatment method in controlling opioid dependence and the importance of treatment satisfaction in the success and therapeutic alliance, there is a serious requirement to measure treatment satisfaction for periodic care, using a valid and multi-dimensional tool. According to our knowledge, there has not been a previous study conducted in Iran using TSQM. The present study was conducted to evaluate the validity and reliability of the Persian version of the treatment satisfaction questionnaire in patients referred to the methadone clinic of Shahid Beheshti Hospital in 2020.

**Methods:**

The current research was a cross-sectional study carried out between February and March 2020, on 288 opioid dependent patients undergoing maintenance treatment with opioid agonists referred to Shahid Beheshti MMT clinic affiliated to Kerman University of Medical Sciences, Kerman, Iran. The participants were selected using convenience sampling method.

Inclusion criteria were having morphine test approval, indication of maintenance therapy and having the minimum physical and cognitive ability to participate in psychological interventions and also consent to participate in the study. Patients who completed the questionnaire incompletely (more than 10% of unanswered questions) were excluded.

Data collected using a questionnaire containing the demographic characteristics of the participants (age, gender, economic status, occupation, personal and family history of mental disorders, the substance was consumed, type of treatment) and the Persian version of the Treatment Satisfaction Questionnaire for Medication version II (TSQM). TSQM Version II examines different aspects of treatment satisfaction and has 11 questions in four subscales including effectiveness (1, 2), side effects (4, 5, 6), convenience of use (7, 8, 9) and overall satisfaction (10, 11). Each item scored from 1 (strongly disagree) to 7 (strongly agree), except for the fourth which checks the experience of side effects in the patient as Yes / No (3).

The sum of the scores of each subscale is displayed as a number from zero to 100. In this way, the sum of the scores of each subscale minus the number of questions in that subscale is divided by maximum score minus minimum score of that subscale multiplied by 100.

After obtaining permission, the original version of the questionnaire was translated into Persian separately by two professors fluent in English. Then, while comparing the text of the two translated versions, a Persian version was prepared. In the next step, the Persian to English translation was done by someone who did not know anything about the original version. In the last step, by comparing the two versions prepared in Persian and English, the required corrections were applied and the instrument adapted culturally.

Face and content validity of the questionnaire was confirmed by the panel of experts (Five psychiatrists who were faculty members of Kerman University of Medical Sciences). Exploratory and confirmatory factor analysis methods were used to evaluate the construct validity. Principal component analysis (PCA)
conducted on the items using Kaiser Criterion and scree plot. Confirmatory factor analysis also employed using main model fit indices; the goodness-of-fit index (GFI), adjusted GFI (AGFI), comparative fit index (CFI), root mean squared error of approximation (RMSEA), non-normed fit index (NNFI), and standard root mean square residual (SRMR).

Internal consistency of TSQM Version II was determined by Cronbach’s alpha and its repeatability using test-retest method. To do so, twenty participants completed the questionnaire in an interval of 2 weeks.

Data were analyzed by SPSS software version 20.0 (SPSS Inc., Chicago, IL, USA) and LISREL version 8.80 (Scientific Software International, Chicago, IL, USA).

It took about five minutes for the participants to complete the questionnaire anonymously and voluntarily and they were assured that the data would be used only for research purposes.

The study approved by the Ethics Committee of Kerman University of Medical Sciences with ethics approval code of IR.KMU.AH.REC.1396.141.

**Results:**

In total, 288 addicts were assessed with the mean age of 46.24 ± 11.5 years. The majority of them (85.4%) were male with moderate economic status (58.0%). Table one shows the characteristics of the participants. (Table 1)
Table 1
The characteristics of the participants undergoing maintenance treatment referred to Shahid Beheshti MMT clinic, Kerman University of Medical Sciences

| Age Mean (SD)        | 46.24(11.5) |
|----------------------|-------------|
| Gender N (%)         |             |
| Male                 | 246(85.4)   |
| Female               | 42(14.6)    |
| Employment status N (%) |        |
| Employed             | 75(12.5)    |
| Self employed        | 154(53.5)   |
| Unemployed           | 27(9.4)     |
| Retired              | 73(25.03)   |
| Missing              | 4(1.4)      |
| Household socioeconomic status N (%) | |
| Low                  | 114(39.6)   |
| Moderate             | 167(58.0)   |
| Good                 | 6(2.1)      |
| Missing              | 1(0.3)      |
| Family history of psychiatric disorder N (%) | |
| Yes                  | 114(39.6)   |
| No                   | 174(60.84)  |
| Concurrent psychological disorder N (%) | |
| Yes                  | 166(57.6)   |
| No                   | 122(42.4)   |
| Type of MT           |             |
| Methadone            | 207(71.9)   |
| Buprenorphine        | 81(28.1)    |

Table 2 shows the means and Standard deviations for each of the four TSQM subscales and measures of variability. The mean values on the different TSQM factors stood within the variety of intermediate to high values of each subscales. (Table 2)
Table 2
TSQM subscales Measures of variability and central tendencies

|                  | Global Satisfaction | Convenience | Side Effects | Effectiveness |
|------------------|---------------------|-------------|--------------|---------------|
| Mean             | 80.67               | 79.79       | 79.09        | 79.97         |
| SD               | 12.15               | 11.99       | 12.14        | 11.7          |
| Median           | 83.33               | 83.33       | 83.33        | 83.3          |
| Minimum          | 33.33               | 33.33       | 44.44        | 41.6          |
| Maximum          | 100                 | 100         | 100          | 100           |

Internal consistency of the Persian version of TSQM Version II was determined by the Cronbach's alpha 0.80. Its repeatability using test-retest method was calculated as 0.9.

Kaiser-Meyer-Olkin Measure (KMO) was 0.82 and Bartlett's test of sphericity was statistically significant ($P = 0.001$, $\chi^2 = 1507.02$, df = 28) which indicating the adequacy of sampling and justifiability of the analysis. Three factors were extracted and the proportion of the variance which explained by these factors was 82.41% (58.74%, 15.28%, and 8.39 for the first, second, and third factor, respectively). Table three shows exploratory factor loading of the Persian version of TSQM Version II.

In CFA, the Goodness of Fit Statistics, Root Mean Square Error of Approximation (RMSEA) = 0.15, Standardized Root Mean Square Residual = 0.05, Goodness of Fit Index (GFI) = 0.9, Adjusted Goodness of Fit Index (AGFI) = 0.8, Comparative Fit Index (CFI) = 0.95, Incremental Fit Index (IFI) = 0.95, and Non-Normed Fit Index (NNFI) = 0.92, showed that the model had a reasonable fit to the data. (Table 3)
Table 3
Exploratory factor loading of the Persian version of TSQM Version II.

| Items Number | Items                                | Factor | Factor loading |
|--------------|--------------------------------------|--------|----------------|
| 1            | Preventing or treating condition      | 1      | 0.86           |
| 2            | Relief of symptoms                   | 1      | 0.87           |
| 4            | Interference w/physical function     | 2      | 0.70           |
| 5            | Interference w/mental function       | 2      | 0.86           |
| 6            | Interference w/mood or emotions      | 2      | 0.67           |
| 7            | Ease of medication use               | 3      | 0.88           |
| 8            | Planning for medication use          | 3      | 0.89           |
| 9            | Frequency of medication use          | 3      | 0.78           |

Discussion:

The current study aimed to determine psychometric properties of the Persian version of Treatment Satisfaction Questionnaire for Medication (TSQM Version II). In our analyses, the Persian version of the instrument had acceptable Psychometric Properties. In terms of reliability, the instrument had appropriate internal consistency and excellent repeatability. Atkinson et al found TSQM v. I and v. II had good internal consistency in all its subscales (Atkinson et al, 2004). Our values are, nevertheless, slightly lesser than those stated by Atkinson et al. In our study the highest variability subscale was global satisfaction followed by effectiveness, convenience and side effects. Murtuza Bharmal et al found, also, 9-items Treatment Satisfaction Questionnaire for Medication (TSQM-9) in which the items related to side effects were not included, had acceptable reliability (Bharmal et al, 2009). Trujols et al (2012b) evaluated the psychometric properties of the Spanish version of the Treatment Satisfaction Questionnaire for Medication in a sample of methadone-maintained patients. He presented acceptable level of internal consistency (0.70) which is a small amount lower than the results of our study.

In terms of validity, EFA showed justiability of the analysis and the Goodness of Fit measures, in CFA, indicated that the model had a reasonable fit to the data which was similar to the study done by Atkinson et al. (2004) Furthermore, most of the Goodness of Fit indices in TSQM-9, had acceptable level.

This research showed the mean satisfaction score of effectiveness, side effects, convenience and the global satisfaction score is an acceptable high score of approximately 80% and these results are consistent with Fiellin et al (2008) study conducted on 53 opioid-dependent patients to assess the long-term treatment with buprenorphine.
One of the limitations of the present study remains the accuracy of data as the questionnaires may not have been completed with sufficient honesty. Furthermore, it is only performed among the patients of the methadone clinic of Shahid Beheshti mental hospital in Kerman, and cannot be generalized to other populations. Moreover, this is a cross-sectional study, and further longitudinal studies in this field are necessary.

**Conclusions:**

It seems that different versions of TSQM (including Persian version) in different studies and populations had appropriate psychometric properties and can be used as a simple, valid, and reliable tool to assess the treatment satisfaction in the clinical settings.

With precise use, this tool provides a method to evaluate and compare patients' satisfaction from different types of medication and may be a useful reference for physicians not only in better understanding of patients' experiences of specific medicine side effects or discomforts but also in optimizing drug dosage or medication guide, Thus, the clinical care turns to be further effective.

**Abbreviations**

AGFI: Adjusted GFI

CFA: Confirmatory Factor Analysis

CFI: Comparative Fit Index

GFI: Goodness-of-Fit Index

IFI: Incremental Fit Index

LISREL: Linear Structural RELations software

KMO: Kaiser-Meyer-Olkin Measure

MMT: Methadone Mainenance Therapy

NNFI: Non-Normed Fit Index

PCA: Principal Component Analysis

RMSEA: Root Mean Squared Error of Approximation

SPSS: Statistical Package for the Social Sciences software

SRMR: Standard Root Mean Square Residual
Declarations

Ethical Approval and Consent to participate

The study approved by the Ethics Committee of Kerman University of Medical Sciences with ethics approval code of IR.KMU.AH.REC.1396.141

Consent for publication

Not Applicable

Availability of supporting data

Data are available upon request.

Competing interests

Not Applicable

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Authors' contributions

All authors have made contribution to all sections of this research however the most significant part of contributions are as following:

M.E. S. had substantial contribution to conception and design of the work, H.A. substantially contributed to interpretation and analysis of data, N.Y had made significant contribution to, acquisition and primary analysis of data, and P.D. have drafted the article and revised it and as the corresponding author coordinated the work and revisions among all authors.

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