




Developing a Valid and Reliable Questionnaire of the Stages of Change in Self-management of Patients With Type 2 Diabetes Among the Iranian Population

Maryam Zare¹, Maryam Rafraf², Abdolreza Shaghghi³, Mohammad Asghari Jafarabadi⁴,
Ali Tarighat-Esfanjani^{2*}

Abstract

Objectives: The present study aimed to develop a valid and reliable questionnaire regarding the stages of change in the self-management of patients with type 2 diabetes mellitus (T2DM).

Materials and Methods: In the first section of this cross-sectional study, the stages of change in self-management of patients with T2DM questionnaire were developed by the researcher. The questionnaire included eight questions in the field of using medication, a healthy diet, and physical activity. In the second section, the content validity and face validity of the questionnaire were assessed by the opinions of 11 expert panelists in the field of health education and nutritional sciences. Finally, construct validity was carried out by exploratory factor analysis (EFA) among 206 patients with T2DM in an outpatient clinic in Ardabil in the northwest of Iran.

Results: The total content validity index (CVI), content validity ratio (CVR), and face validity were 0.60-0.91, 0.81-1, and 4.32-4.82, respectively. The number of questions increased up to 10. In addition, EFA results showed that Kaiser-Meyer-Olkin and the total variance extracted were 0.69 and 23.6, respectively, and Bartlett tests were statistically significant ($P=0.000$). Finally, reliability analysis indicated a moderate level of internal consistency ($ICC = 0.89$) and Cronbach's alpha of 0.63.

Conclusions: This questionnaire with 10 items and one factor was found to be valid and reliable as a simple and effective tool for self-care on the stages of change in patients with T2DM.

Keywords: Type 2 diabetes mellitus, Surveys and questionnaires, Self-management, Iran

Introduction

Diabetes mellitus (DM) as one of the most important health problems is characterized by high and suddenly rising blood glucose levels (1-3). One out of three people in the world is expected to have type 2 diabetes mellitus (T2DM) by 2050 (4). In patients with T2DM, self-management behaviors affect the compliance of medical procedures and decrease their consequences. Thus, assessing the success of self-management programs seems essential in this regard. Self-management in diabetes requires a dynamic process including using blood glucose-lowering drugs and insulin injections, a healthy diet consisting of low saturated fat intake, sufficient amounts of fruits and vegetables, and physical activities (5,6).

In DM, the disorder occurs in carbohydrate, protein, and fat metabolism (7). The objectives of diet therapy in diabetes include providing all the essential components of foods (i.e., macronutrients, vitamins, and minerals), achieving and maintaining healthy weight, providing the required energy, preventing severe changes in

blood glucose concentration, obtaining normal levels of glucose as much as possible (without increasing the risk of hypoglycemia), and adjusting the serum level of lipoproteins (8).

Exercise reduces blood glucose and has a major role in improving the efficacy of insulin. In addition, exercise reduces the blood glucose level while it improves bloodstream and muscle tuning by enhancing the uptake of glucose by the muscles and improving the function of insulin. Thus, exercise is introduced as one of the treatment procedures for diabetes (9).

Nowadays, with the development of research in medical, social, and educational science and research, several measures are performed using questionnaires for quantifying individuals and societies' behaviors (10). Considering that most of the behavioral studies are in this scope and questionnaires are required for their assessment, measurement tools need to be both valid and reliable. Currently, there are various instruments for assessing management and self-management behaviors

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¹Department of Nutrition, Khalkhal University of Medical Sciences, khalkhal, Iran. ²Nutrition Research Center, Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences, Tabriz, Iran. ³Health Education and Promotion Department, Faculty of Health, Tabriz University of Medical Sciences, Tabriz, Iran. ⁴Road Traffic Injury Research Center, Tabriz University of Medical Sciences, Tabriz, Iran.

*Corresponding Author: Ali Tarighat-Esfanjani, Tel: +98-41-33362117, Email: Tarighata@tbzmed.ac.ir, Tarighat45@gmail.com



such as the Management Self Efficacy Scale (11,12).

Recent studies have applied self-management behaviors in accordance with behavioral change models (13). The trans-theoretical model (TTM) is one of these behavioral change models. By applying this practical approach, one can understand how different people are susceptible to healthy behavior changes. One of the structures of this model is the *stages of change*, in which individuals pass five different stages (i.e., pre-contemplation, contemplation, preparation, action, and maintenance) to achieve behavior interactions (14).

In general, controlling the consequences of diabetes is a multi-behavioral change approach. Thus, TTM may correspond to behavioral changes related to blood glucose control and the consequences of diabetes (5).

The validity and reliability of questionnaires must be confirmed since they are used as measurement tools in studies (15). Few studies are conducted to survey the validity and reliability of the self-management questionnaire among patients with T2DM (15-17).

To the best of our knowledge, no valid and reliable questionnaire for TTM exists with regard to patients diagnosed with T2DM among Iranian adults. Thus, the present study intended to develop a questionnaire related to the stage of change in the self-management of patients with T2DM (QSOCSMD). The study further aimed to assess the validity and reliability of the QSOCSMD questionnaire among the Iranian population.

Materials and Methods

Study Design

The study population was recruited by using the simple and convenience sampling method in this cross-sectional study.

Instruments

First Section: Designing QSOCSMD

A literature review was accomplished to design the questions for the QSOCSMD. After revising the resources and data, three major factors in the self-management of patients with T2DM were included, namely, the appropriate use of blood glucose-lowering drugs, healthy diet, and physical activity. According to the stages of change construct and the three major factors, eight questions were designed for assessing self-management among patients with T2DM. As shown in Figure 1, one question was about using blood glucose-lowering drugs and one question about physical activity, and six questions were related to a healthy diet (5, 18-20). To apply the stages of change in the questionnaire, each question was given five choices and each choice reflected the constructs of the stages of change (i.e., pre-contemplation, contemplation, preparation, action, and maintenance).

In the blood sugar-lowering drugs and physical activity section of the self-management questionnaire, the first, second, third, fourth, and fifth choices of the

multiple-choice questions referred to pre-contemplation, contemplation, preparation, action, and maintenance, respectively. In addition, the Likert-type scale was used in the healthy diet section and the mean scores were taken into account for subject allocation in each stage. Therefore, those who obtained scores between 8 and 14 were the pre-contemplation section while the scores of 15-20, 21-26, 27-32, and 33-40 indicated the contemplation, preparation, action, and maintenance sections, respectively.

Second Section: Assessing the Content and Face validity of QSOCSMD-I

A panel of experts was asked to assess the content and face validity. The QSOCSMD-I was designed based on eight questions and handed to 15 members of the academic staff of health education (four members) and food science majors (11 members) of Tabriz, Isfahan, and Ardabil Medical Science Universities in Iran. Three faculty members received the questionnaire by email and the remaining staff obtained it in person.

The content validity index (CVI) and content validity ratio (CVR) were calculated for measuring content validity quantitatively. Furthermore, the faculty members were asked to assess the quantitative content and face validity of the questionnaire and answer each question according to the determined choices. The simplicity graded codes (i.e., completely simple, simple, somewhat complicated, and complicated), relevance graded codes (highly relevant, relevant, somewhat relevant, and irrelevant), and clarity graded codes (i.e., highly clarified, clarified, somewhat clarified, and not clarified) were 1, 2, 3, and 4, respectively, and were assessed for determining the CVI. Moreover, the CVR was assessed by asking questions about the necessity of the questionnaire (i.e., necessary, useful but not necessary, and not necessary), which were denoted by graded codes of 1, 2, and 3, respectively. The face validity was also checked using a question regarding the importance of question (i.e., very important, important, moderately important, slightly important, and not important) which was graded as 1, 2, 3, 4, and 5, respectively (6, 21).

Setting and Subjects

The medical records of patients with T2DM referring to a private clinic in Ardabil in the northwest of Iran were analyzed and 400 patients, who attended and cooperated regularly with the clinic, were recruited based on the inclusion and exclusion criteria.

Data Collection and Procedures

Assessing the Construct Validity (EFA) of QSOCSMD-I

In this study, the inclusion criteria were patients with T2DM aged 30-70 years, those who had diabetes for more than a year, consumed blood glucose-lowering drugs, showed willingness to participate in the study, as well as patients without kidney or liver diseases, without mental, learning, vision and hearing problems, and finally,

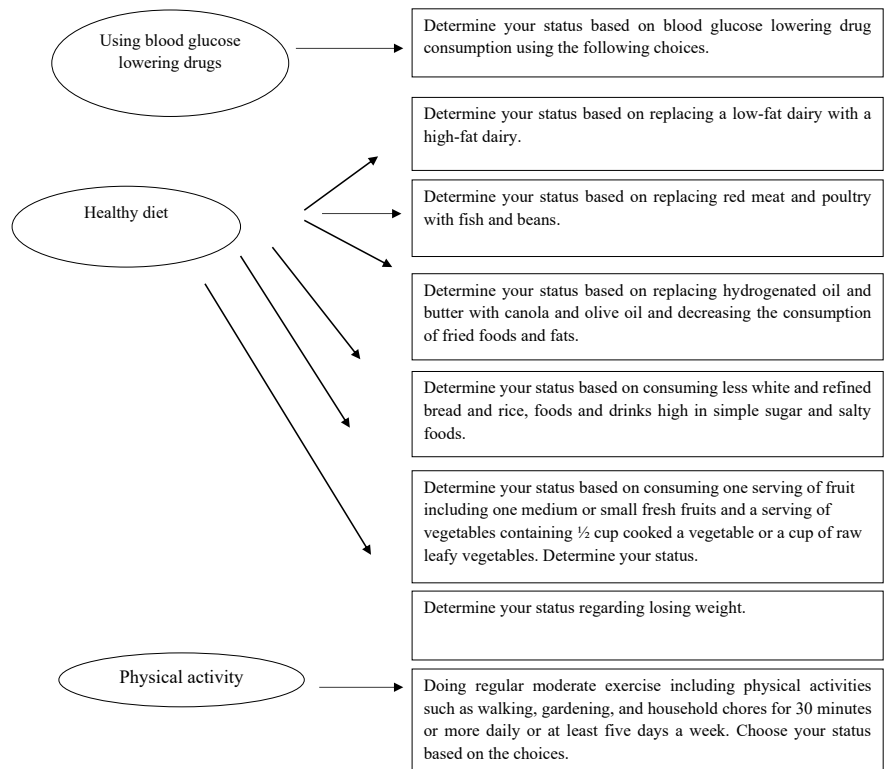


Figure 1. The Platform of QSOCSMD-I.

those who were literate. On the other hand, the exclusion criteria included patients using insulin, pregnant or breastfeeding women diagnosed with T2DM and those who were planning to get pregnant, and finally, patients who had undergone surgery for weight loss.

A total of 206 patients with T2DM from 400 participants completed written informed consent and questionnaire. After completing the questionnaire by the subjects, the questionnaire was evaluated using the exploratory factor analysis (EFA). EFA was used for summarizing and classifying data in the correlated groups (22).

Assessing the Reliability of QSOCSMD-I

In this study, 23 subjects with T2DM who met the inclusion and exclusion criteria completed the questionnaire twice within 15 days (5, 21). The internal consistency (Cronbach's alpha) was used to examine the reliability of the data, followed by applying the intra-class correlation coefficient (ICC) to assess the test-retest reliability.

Data Analysis

The following quantitative validity formula was used for measuring face validity:

$$\text{Impact Score} = \text{Frequency (\%)} \times \text{Importance}$$

The CVR of the questionnaire was measured using the following formula and by the Excel 2010 software:

$$\text{CVR} = \frac{nE - N/2}{N/2} \quad (21).$$

The demographic status of subjects was reported as mean

and standard deviation, as well as the percentage using the IBM SPSS Statistic 17 software (SPSS Inc. IL, Chicago, USA). The EFA was used to evaluate the construct validity with the principal axis factoring extraction method and Varimax rotation. The Kaiser-Mayer-Olkin (KMO) test, EFA, and Bartlett's test of sphericity were applied as well. Based on this diagram, value changes decreased from the second factor. Therefore, it was possible to extract one important factor with the most effect on variance determination.

After determining the factor load for each question, all questions had a factor load of more than 0.30 (criteria for choosing items). In addition, the Cronbach's alpha was utilized to assess the internal consistency and stability reliability of the questionnaire, respectively. A $P < 0.05$ was considered statistically significant.

Results

The questionnaire was given to 15 faculty members, of which 11 individuals read it and suggested a few comments for improvement.

Face and Content Validity of QSOCSMD-I

Face Validity of QSOCSMD-I

The score achieved from questions for face validity was within the range of 4.32-4.82. The questions were retained for subsequent analysis because their impact score was more than 1.5.

Content Validity of the Questionnaire (QSOCSMD-I)

The content validity of the questionnaire results are as follows:

Based on simplicity, the points for CVI, relevance, and clarity CVI of the questions were within the range of 0.4-0.9, 0.9-1, and 0.40-0.81, respectively.

Further, the total score of the questions for CVI was between 0.60 and 0.91 and the question acceptance was more than 0.79 based on CVI score. Among these questions, only the first and seventh questions gained scores equal to 0.85 and 0.91, respectively, which were both more than 0.79, and the remaining questions achieved scores less than 0.79.

The calculated CVR for questions was in the range of 0.81-1. Based on the CVR decision-making table or Lawshe table, in which the least validity criteria for the 11 people reading the questionnaire was 0.59, the acquired scores in this study were within the range of 0.81-1. The CVR was approved since this score was more than the required minimum content validity.

Given that the acquired scores for questions 2, 3, 4, 5, 6, and 8 were lower than 0.79, these items were revised based on the expert's remarks. Furthermore, the number of questions regarding self-care management in diabetes was increased up to 10 to meet both qualitative and face validity, including one question about the proper use of medicines, eight questions about a healthy diet, and one question related to physical activity (Figure 2). Eventually, the questions were handed to three experts for final approval. The CVI scores for items 2, 3, 4, 5, 6, 8, 9,

and 10 were obtained in the range of 0.81-0.87 and were confirmed accordingly.

Constructive Validity (EFA) of QSOCSMD-I

In the present research, 206 patients with T2DM completed the QSOCSMD-I to carry out the EFA and all of them completed the general information questionnaire (Table 1).

Table 2 presents data related to the placement of the subjects in the stages of the change construct regarding each of the processes of self-management.

Exploratory Factor Analysis

The results of EFA, in which 206 individuals participated, indicated that KMO was 0.69. Moreover, the KMO values and the variance percentage for the extracted factor was more than 0.5 and about 23.6, respectively. In addition, the significant results of the Bartlett test confirmed the adequacy of EFA for one of the extracted factors ($P=0.000$).

After determining the factor load for each question, all the questions were found to have a factor load of more than 0.3 (as the criteria for choosing the items). The EFA pattern matrix loading for QSOCSMD-I items is provided in Table 3.

Reliability of QSOCSMD-I

In this study, 23 subjects completed the QSOCSMD-I for assessing its validity and reliability after two weeks for the second time.

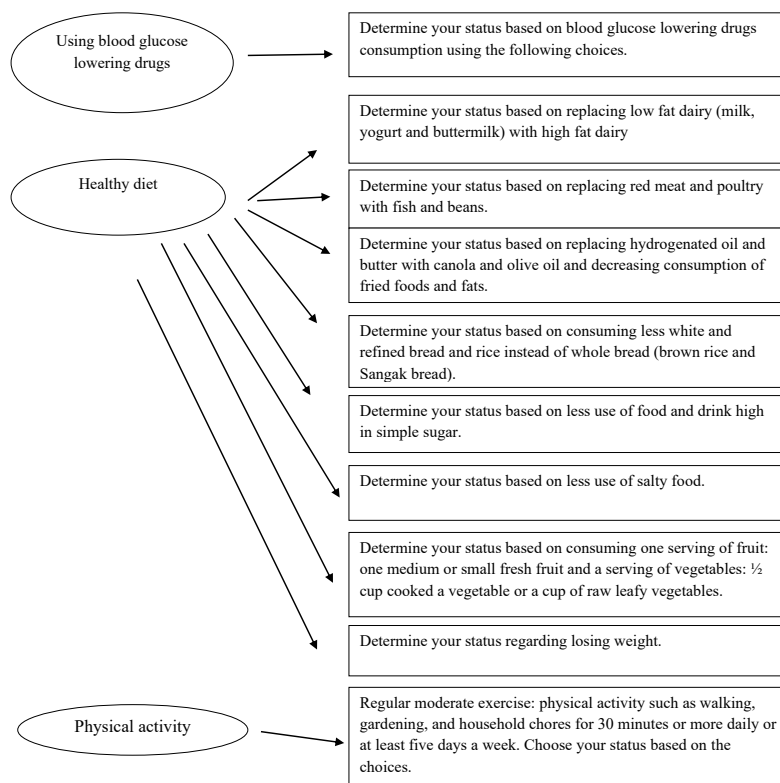


Figure 2. Final Platform of QSOCSMD-I.

Table 1. Participant Background Characteristics

Demographic Variables	Mean ± SD	No. (%)
Age (y)	52.51 ± 7.15	
Gender		
Male		86 (42.2)
Female		118 (57.8)
Education		
Higher education		19 (9.3)
High school diploma		42 (20.6)
Middle school diploma		142 (69.6)
Occupation		
Housewife		111 (54.4)
Employee		18 (8.8)
Self-employed		56 (27.5)
Retired		18 (8.8)
Disease duration (y)	6.65 ± 4.86	
Diabetes onset age (y)	45.29 ± 9	
Total		206

Note. SD: Standard deviation.

Table 2. Placement of Subjects in the Construct Regarding Each of Stages of Change Factors of Self-management

Stage	Proper Use of BGLDs	Healthy Diet	PA
	No. (%)	No. (%)	No. (%)
Pre-contemplation	23 (11.3)	11 (5.4)	50 (24.5)
Contemplation	2 (1)	45 (22.1)	22 (10.8)
Preparation	15 (7.4)	61 (29.9)	34 (16.7)
Action	15 (7.4)	59 (28.9)	19 (9.3)
Maintenance	149 (73)	28 (13.7)	79 (38.7)
Total			206

Note. BGLDs: Blood glucose lowering drugs; PA: physical activity.

The internal consistency reliability for the 10 questions was 0.58. By eliminating the eighth and ninth questions, the internal consistency reliability for the remaining questions was increased to 0.89. Additionally, the average measures ICC and 95% confidence interval were 0.89 and 0.75-0.95, respectively, while the Cronbach's alpha was 0.63. However, the questions were maintained since they

had relatively sufficient content and face validity and due to their necessity.

Discussion

After necessary revisions, QSOCSMD was designed and three effective processes in self-management were selected, including the appropriate use of blood glucose-lowering drugs, a healthy diet, and physical activity.

In the study conducted by de Oliveira et al, a questionnaire was designed from a meta-theory model using two constructs (i.e., the stages of change and change process). The validity results verified by the panel of experts were similar to our study, but the reliability results (Cronbach's alpha) and the factor load of the questions were higher (23). The reason for these differences is the large sample size of the study, the completion of the questionnaire by educated men, and differences in the content of the questions. The questions of our questionnaire were about the self-management of patients with T2DM, but in the above-mentioned study, the items considered the consumption of vegetables and fruits by healthy people. In addition, this study used a two-construct meta-theory model while only one of the constructs was assessed in our study.

In a survey on the validity and reliability of a self-efficacy questionnaire in patients with DM in Iran, the Cronbach's alpha of dietary factors, physical activity, and blood glucose measurements in self-efficacy was higher compared to those of our study (24). The reason for the high Cronbach's alpha of Haghayegh and colleagues' study was applying a large number of questions for each scale compared to the present study.

Similarly, Pilv et al studied the reliability and validity of the diabetes obstacles questionnaire (DOQ). This questionnaire contained items regarding the changes in lifestyle such as diet, as well as physical activity and medications. The measured factor load for diet was similar to the results of this study although the factor load of

Table 3. EFA Pattern Matrix Loading for SOCSMDQ-I Items

Component and Item Labels	Factor 1
Determine your status based on blood glucose lowering drugs consumption using the following choices.	0.46
Determine your status based on replacing a low-fat dairy (e.g., milk, yogurt, and buttermilk) with a high-fat dairy.	0.48
Determine your status based on replacing red meat and poultry with fish and beans.	0.63
Determine your status based on replacing hydrogenated oil and butter with canola and olive oil and decreasing the consumption of fried foods and fats.	0.58
Determine your status based on consuming less white and refined bread and rice instead of whole bread (i.e., brown rice and Sangak bread).	0.41
Determine your status based on less use of food and drink high in simple sugar.	0.56
Determine your status based on less use of salty food.	0.45
Determine your status based on consuming one serving of fruit containing one medium or small fresh fruit and a serving of vegetables including 1/2 cup cooked a vegetable or a cup of raw leafy vegetables.	0.42
Determine your status regarding losing weight.	0.39
Doing regular moderate exercise including physical activities such as walking, gardening, and household chores for 30 minutes or more daily or at least five days a week. Choose your status based on the choices.	0.54

physical activity and medications was higher than that of the present study. Further, the calculated Cronbach's alpha for diet, physical activity, and medications was higher than the present study. Nevertheless, the correlation coefficient of our study was higher (25). The reason for the differences between these two studies is because they investigated the self-management with regards to the stages of change. In the DOQ, in addition to diet, physical activity, and medications, there were other questions about family support, awareness, and acknowledgment, which increased the number of questions.

In another study, the reliability and validity of the patients with T2DM management evaluation tool (DMET) were assessed and the results revealed that regarding the constructing validity, the EFA for the obtained score of the factor load for diet and physical activity were similar to the results of our study. However, the scale reliability coefficients for diet and physical activity were more than those of our study (26). The difference between these two questionnaires was due to numerous sections and questions of DMET, along with the method of questionnaire completion. In Paddock's study, the DMET questionnaire was posted to the subjects and filled by them, but in our study, QSOCSMD was completed by the instructor by face-to-face interviews.

In a study, the Diabetes Intention, Attitude, and Behavior Questionnaire was assessed in the field of physical activity, diet, and weight control for reliability and factor analysis construct validity and the results indicated that Cronbach's alpha reliability was similar to our study. The similarities between these two studies were because of the infrequent number of questions (27).

In a study by Fappa et al, the Greek Version of the Diabetes Management Self-Efficacy Scale (GR-DMSES) was translated and its reliability and validity were assessed as well. The ICC and the stability of QSOCSMD for diet and physical activity were less than the reliability of GR-DMSES. Furthermore, the KMO, validity, and Bartlett's test of sphericity for EFA measured in QSOCSMD was acceptable and similar to that of the GR-DMSES (16). The reason for this difference is because QSOCSMD is a self-made questionnaire based on the stages of change while GR-DMSES is a translated questionnaire. Moreover, the numbers of participants for the EFA and the number of experts in the panel of the experts in our study were more than those of GR-DMSES.

Assessing the German version of the Summary of Diabetes Self-Care Activities measure (SDSCA-G) indicated that the obtained Cronbach's alpha from this questionnaire was similar to the present study. Additionally, the scary graph diagram determined only one factor but four factors were achieved, and rotated factor loadings from SDSCA-G were more than QSOCSMD (17). The reason for the similarity of ICC was the infrequent number of questions.

The Cronbach's alpha can be affected by the number of questions and the relationship between the questions (28).

In the study of Payo et al, the validity of the Motiva.Diaf-DM2 questionnaire was evaluated that included a healthy diet and physical activity. The reported KMO was more than that of the present study while the ICC of this study was similar to that of Payo et al (29). The reason for the similarity of these two studies is the number of subjects assessed for EFA and reviewing two lifestyle factors (i.e., healthy diet and physical activity) in both questionnaires. The number of items is the difference between the two questionnaires.

In another study, the validity and reliability of IT-DMSES were surveyed and it was found that KMO and reliability were more than QSOCSMD-I (30). This DMSES consists of 20 items with self-care activity in the field of using drug, diet adherence, body weight, feet condition, and correction serum glucose. Such a discrepancy between the two questionnaires is related to the number of items and self-care activity. In addition, IT-DMSES is a translated questionnaire while QSOCSMD-I is a self-made questionnaire.

Nowadays, using valid and reliable tools for assessing the stages of changes of the TTM in patients with T2DM self-management is of great necessity. Currently, different tools are used to assess patients with T2DM for self-management but they are not designed based on the stages of change and cannot measure self-management according to the stages of change. Another important factor is that the questionnaire must be in accordance with the objective of the study (31).

The present study evaluated three different independent factors of self-management activities including the appropriate use of blood glucose-lowering drugs, healthy diet, and physical activity (32). In the present questionnaire, there were no relationships between using blood glucose-lowering drugs or physical activity. In other words, they were completely independent. Thus, we should not expect a Cronbach's alpha more than 0.7. Another reason is the infrequent number of questions and their independency.

Suggestions for Further Research

Given the increasing number of items, QSOCSMD-I provides an appropriate instruction with high Cronbach's alpha for patients with T2DM. Therefore, it is recommended adding other factors to QSOCSMD-I such as a psychological and behavioral base in self-management.

Study Limitations

Conducting a simple and convenient sampling cross-sectional study while not measuring perspective validity are among the major limitations of this study. The infrequent number of questions also decreased the Cronbach's alpha score.

Highlights

Patients with type 2 diabetes mellitus need self-management in daily activities. The stages of change are among the structures of the TTM for assessing self-management and are effective in promoting a healthier lifestyle.

This questionnaire is the first valid and reliable questionnaire regarding self-management in diabetes according to the stages of change.

Conclusions

The present questionnaire was designed in the field of the stages of change in the self-management of patients with T2DM questionnaire (QSOCSMD). This 10-item questionnaire provides satisfactory face validity, CVR, and CVI. According to the results of EFA, all the questions had a factor load greater than 0.3. In addition, the internal consistency and stability of the questions were desirable and Cronbach's alpha was above 0.6. Thus, QSOCSMD is considered as a valid and reliable tool for assessing self-management in patients with T2DM among the Iranian population. Further, it is a short and easy-to-use tool that can indicate a subject's position in the stages of change in accordance with the objective of measuring individuals based on the stages of change.

Conflict of Interests

None to be declared.

Ethical Issues

The study objectives and procedures were thoroughly explained to the selected participants and written informed consent was completed for participants who represented a willingness for participation. This study was performed according to the ethical principles of the Declaration of Helsinki. The ethical approval was granted by the Medical Ethics Committee of the Tabriz University of Medical Sciences (approval code: IR.TBZMED.REC.1395.1012).

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