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Original Article

Development of an assessment scale for treatment compliance in type 2 Diabetes Mellitus in Turkish population: Psychometric evaluation

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ABSTRACT

Objectives: Compliance to treatment is important for the management of type 2 diabetes mellitus (DM) and the prevention of complications. The purpose of the study was to develop a scale and test its psychometric properties for the treatment compliance of the diabetic Turkish population.

Methods: This multicenter study was conducted in four training and research hospitals. The convenience sample consisted of 350 patients with type 2 DM. The items of the scale were determined after a literature review and qualitative interviews with the patients. Items were psychometrically analyzed. Content validity of the scale was evaluated using opinions from experts and a pilot study. Principal component analysis and the varimax rotation technique were used to evaluate construct validity in exploratory factor analysis. Criterion validity was evaluated with the Attitudes Towards Diabetes Scale, a subgroup of the Diabetes Care Profile scale. Reliability was evaluated with Cronbach's α coefficient and test-retest analysis of internal consistency.

Results: The scale consisted of 7 factors that explained 47.36% of the total variance. The KMO test was conducted to determine whether the sample size was sufficient before the factor analysis. The KMO test result of the data was 0.75. The Cronbach's α value of the sample was 0.77. The test-retest reliability analysis result was $r = 0.991$. We found a positive correlation between total scores of the developed scale and the Attitudes Towards Diabetes Scale ($r = 0.31$).

Conclusion: The results of the study demonstrated that the scale with 30 items is a valid and reliable scale for the evaluation of patient compliance with type 2 DM treatment. Thus, by using this scale, nurses and healthcare providers can evaluate the treatment compliance of patients with type 2 DM.

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1. Background

Diabetes mellitus (DM) is one of the most important healthcare problems threatening public health with an increasing global incidence and can be defined as an epidemic [1].

According to the first World Health Organization (WHO) Global report in 2014, adults over 18, living with diabetes has reached to a number of 422 million with a percentage of 8.5 by nearly quadrupling the number of 1980. This is caused by the increase in type 2 DM as a result of overweight and obesity [2].

The International Diabetes Federation (IDF), the number of the type 2 DM patients is estimated as 415 million now and 642 million in 2040. Also diabetes prevalence has been rising more rapidly in

middle- and low-income countries. These countries spend between 5% and 20% of their total health expenditure on diabetes [3]. Diabetes also has a high financial cost. The American Diabetes Association states that 116 billion dollars are spent annually and 68 billion dollars indirectly for diabetes management [4].

The most common form of diabetes is type 2 diabetes. Type 2 DM makes up 85% of all diagnosed diabetes cases around the world [5]. Another interesting point is the increasing incidence of type 2 diabetes in young children [6]. The diabetes incidence in the Turkish adult population has been reported to increase to 13.7% and affect a minimum of 10% of the population in the 40–44 years age group [7].

Compliance to treatment is a primary determinant of treatment success. The term compliance describes the extent to which patients follow treatment recommendations given by their health care providers. The rate of treatment compliance varies according to the disease characteristics, treatment regime and patient features. The noncompliance rate in chronic disorders is known to be

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about 50% on average [4]. The diabetic patients goes through a lifelong difficult and complex process to control and manage the disorder. The patient plays a key role in successful diabetes management but may encounter many complications and may be forced to receive more difficult and intensive care in case of bad management [8,9]. Compliance with treatment is very important in managing diabetes. Patients requiring a change in their usual life-style to comply with the rules of treatment may experience compliance problems [10]. In diabetic patients, noncompliance means poor glycemic control and long-term health complications, such as retinopathy, neuropathy, and renal disease [4].

The conceptual framework of this study was influenced by Cox's interaction model of client health behavior that is related to adaptation. The model assigns an important role to healthcare providers for the health of the individuals. It also directs nurses towards multidimensional care models from traditional care models. It demonstrates that the healthcare-related behavior of individuals has psychological, environmental and sociological aspects. These factors are important in the patient's adaptation to the disorder. The model is reported to be influenced by the individual being well informed and deciding independently and competently regarding health-related behaviors. In turn, these behaviors of the individual are said to be influenced by the individual's characteristics and his/her communication with the healthcare providers. It has been reported that nursing procedures should be conducted in accordance with the individual's characteristics if success is desired regarding health-related issues in this model. The model also accepts the intrinsic motivation concept as an important determinant of an individual's behavior [11,12].

The conceptual structure of this model is used in this study as it is important to know the individual's characteristics, to make specific care plans for the individual, and to provide motivation with insight to ensure compliance in diabetic patients.

Health care professionals, responsible for measuring patients' compliance to treatment. Patients compliant with treatment perceive the care provided by healthcare workers as supportive and satisfactory. Less compliant individuals may have difficulty with self-care and can misperceive compliance-related obstacles, which can decrease their self-confidence [13]. Health care professionals should therefore support and evaluate their patients as regards compliance with their treatment.

Using measurement tools in the evaluation of the abstract concept of compliance to disease enables expressing the features to be measured with numerical data and obtaining more objective and standard results. Another advantage of measurement tools is the ease of use and administration [14].

For a good management of the treatment, acceptance of the illness is very important. Sometimes patients may believe the health care professionals about the management of the treatment. For this reason objective instruments to evaluate the patient are needed. Evaluation by measuring instruments may show the right way in management of the treatment to patients and the healthcare personnel.

There is also a scale to evaluate the compliance to the Type 2 DM in Turkey. But this scale is adapted to Turkish from English [15,16]. Because of cultural differences, adapted scales may cause some issues in understanding and interpretation. A special, simple and understandable scale for Turkish population which will evaluate Type 2 DM treatment and show the compliance status (like diet, exercise, drug usage, emotional factors, foot care, change in life style) cannot be found in Turkey. For this reason the present study is done and the scale developed. The scale developed as a result of the study will help the healthcare providers in understanding the patient, making an objective evaluation, determining the needs and

providing the necessary healthcare.

The aim of this study was to develop a new and standard measurement tool for the evaluation of treatment compliance of type 2 DM patients. This tool will make it easier for healthcare providers and nurses to evaluate the compliance of Type 2 DM patients with treatment.

2. Materials and methods

2.1. Study design

This study used a methodological study design.

2.2. Setting and sample

This was a multicenter, methodological study conducted at the diabetes outpatient departments and clinics of endocrine and metabolic disorder units of various training and research hospitals in Ankara Turkey, between May 2013 and March 2014.

The sample size was calculated as follows: "number of items \times number of patients per item" [17]. The sample size was calculated in order that there would be at least 10 patients for each item in the scale. The scale for which the validity and reliability was tested contained 33 items with 5-point Likert type answers for each of the items. The study was completed with 350 patients [17,18].

The data were collected with face-to-face interviews; they lasted 15–45 min for each participant. Inclusion criteria for the study were a) having been diagnosed with type 2 DM for at least one year, b) being 18 years of age or above, and c) being able to communicate in Turkish.

Ethical consideration

Ethical approval for this study protocol, which adhered to the principles of the Declaration of Helsinki was given by the university's ethics council prior to the study (approval no. 1491-249-12/1539-549) [19]. The management of the hospitals where the study was conducted also provided written permission.

All the participants were made to complete the "Volunteer Information and Consent Form" before the intervention.

2.3. Measurements/instruments

For data collection, three forms were used. The first form was used to collect the patients' demographic and descriptive features. This form was created by the researchers after a literature review. Basic socio-demographic characteristics such as age, gender, marital status, educational status, and income status were collected with 12 questions. The second part of this form related to medical characteristics, which included 10 questions on disease duration, disease information, other diseases being treated, and the type of antidiabetic drug used.

The second form was the scale itself. The scale was administered to 101 patients for reliability assessment, and was reapplied to the same group for test-retest analysis. The patients were selected among those who had come to the hospital for treatment or a follow-up visit.

A third form, the "Attitudes Towards Diabetes Scale" (ATDS), a subgroup of the "Diabetes Care Profile" (DCP) scale, was administered to 155 patients for validity analysis.

2.4. Development process

2.4.1. Item generation, item selection, and content validity

First, the literature was reviewed before creating the items of this scale. The information revealed that the main points of interest

for compliance with type 2 diabetes treatment were drug usage, physical exercise, diet, diabetes management, and psychological acceptance of the disorder [9,10]. Researchers prepared semi-structured questions related to these areas and performed qualitative interviews with 42 patients, which were recorded with a voice recorder and analyzed using content analysis after being transferred to the computer environment. An item pool consisting of 54 items was created as a result of the analysis. The items were delivered by hand or sent by e-mail to 19 experts in their field who were conducting a study or providing education related to the subject of this study. The opinions of 5 medical doctors, 8 nursing faculty members, 1 psychologist, 4 diabetes nurses, and an individual who had been living with type 2 DM for 10 years were obtained. A lecturer in Turkish and Turkish literature reviewed the scale regarding language, expression, and punctuation.

The experts were asked to evaluate whether each candidate item represented the characteristic to be measured, and whether the items were expressed in simple and clear language and would be understood by the target audience. Further, each item was asked to be evaluated as follows:

1. The item is necessary and should remain in the item pool.
2. The item is beneficial but not adequate.
3. The item is not necessary.

Content validity ratios (CVR) and content validity indexes (CVI) were calculated for the items retained after the expert review.

The following formula was used for the calculation of CVR.

$$CVR = \frac{N_e - N/2}{N/2}$$

N_e = The number of the experts who marked the item as “necessary”. N = The overall number of experts [20,21].

Among the candidate scale items, those with a negative or “0” CVR value were removed. The significance level of $\alpha = 0.05$ led to a minimum CVR of 0.42 according to the number of experts for the “Type 2 DM Treatment Patient Compliance Scale.” Items with a calculated CVR below 0.42 were removed from the scale. This led to the removal of 21 items.

The final version of the scale included 33 items. The researchers made a final evaluation using the content validity index (CVI) (Σ CVR/Number of items), which was 0.68 for the 33 items [21].

The content validity for a scale is accepted as statistically significant when $CVI \geq CVR$ or $CVI/CVR \geq 0$ [22]. Our result of 0.68 (CVI) was ≥ 0.42 (CVR) and $0.68 (CVI)/0.42 (CVR) \geq 0$. Therefore, the content validity of the scale was found to be statistically significant with this result.

The pilot study was conducted with 20 type 2 DM patients who met the inclusion criteria. The patients were asked about the clarity of the items in the scale and whether there was a problem in answering them. The content of certain scale items was reviewed based on patient feedback and changes were made accordingly. No item was removed from the scale after the pilot study. However, the items underwent some revision. For example, the expression “I go to physician follow-ups once a year even if I have no symptoms” was changed to “I have my physician follow-ups done regularly at the recommended frequency” because most of the patients went for follow-up according to their physician’s recommendations. The statement “I exercise regularly at least 150 min a week” was replaced by “I exercise regularly in both winter and summer as recommended” because exercise patterns varied depending on the season.

The data of the 20 patients who were interviewed during the

pilot study were not included in the final data. With the modifications made after this stage, the scale was found to be clear and applicable in terms of the number of items and measuring quality for the individual’s compliance to treatment.

2.4.2. Psychometric testing

Reliability of the scale: The internal consistency and test-retest reliability were evaluated.

Validity of the scale: Content validity, criterion validity, and construct validity were evaluated for the scale. Content validity has been explained above in the development process.

2.4.3. Statistical analysis

The descriptive statistics were presented as frequencies, percentages, means, and standard deviations. The Pearson correlation coefficient and Cronbach’s α were calculated for reliability analysis of the items. A paired-sample t-test was applied for test re-test analysis and the correlation coefficient was calculated.

CVR and CVI were calculated to determine the content validity of the scale. The Pearson correlation coefficient was used to evaluate criterion validity. Principal component analysis and the varimax rotation technique were used to evaluate construct validity in exploratory factor analysis. The Keiser-Mayer-Olkin (KMO) test of sampling adequacy and the Bartlett sphericity test were used to understand whether the scale was appropriate for factor analysis. The SPSS for Win. ver. 15.00 (SPSS Inc. Chicago, IL, USA) package software was used in the evaluation of the data and for statistical analyses. A P value ≤ 0.05 was accepted as an indicator of a significant difference in statistical decisions.

3. Results

3.1. Sample characteristics

The mean age of the 350 participants forming the study sample was 59.00 ± 10.31 years and 62.3% ($n = 218$) were in the 45–64 years age group. Of the participants, 74.6% ($n = 261$) were female, 78.3% ($n = 274$) were married, 40.6% ($n = 142$) were primary school graduates and 84.9% ($n = 297$) were not working. Most of the participants (63.1%, $n = 221$) were diabetic for 1–10 years. HbA1c was tested in 126 of the participants and was under 6.6–8.9 in 48.4%. ($n = 61$). Oral antidiabetics were being used by 58% ($n = 203$) (Table 1).

3.2. Item analysis

Participants gave 0–5 points for each item of the Likert-type draft scale and the mean score of each item was calculated according to the answers of all participants. The mean overall score for the scale was 2.65 ± 0.50 .

“Corrected item-total score correlation coefficients” were calculated in the item analysis based on correlation. Total score correlation coefficients are seen to be between 0.40 and 0.44 for Items 3, 5, 20, 28, and 30 and between 0.21 and 0.39 for Items 1, 7–11, 13, 14, 16, 18, 21–25, 27, 29 and 31. Items 19 (–0.009), 32 (–0.0096) and 33 (–0.177) were excluded (Table 2). For the reason that; a) corrected item total score correlation coefficients were under 0.20 and negative b) the Cronbach’s α value would increase if they were extracted from the scale. But, Item: 2 (0.12), Item: 4 (0.12), Item: 6 (0.16), Item: 12 (0.18), Item: 15 (0.10), Item: 17 (0.10), and Item: 26 (0.10) were included because they increase the Cronbach’s α value although their correlation coefficients were low.

Table 1
Characteristics of study participants ($n = 350$).

Characteristics	<i>n</i>	%
Age		
18–44	32	9.1
45–64	218	62.3
65 and older	100	28.6
Gender		
Female	261	74.6
Male	89	25.4
Marital status		
Married	274	78.3
Single	76	21.7
Education status		
Illiterate	66	18.9
Literate	29	8.3
Elementary school	142	40.6
High school	61	17.4
University	48	13.7
Master degree and higher	4	1.1
Job status		
Working	53	15.1
Not working (retired,unemployed, housewife)	297	84.9
Duration of Disease (year)		
1–10	221	63.1
11–20	105	30.0
21–30	22	6.3
31–40	2	0.6
HbA1c % ($n=126$)		
6.5 and under	44	34.9
6.6–8.9	61	48.4
9 and higher	21	16.7
Treatment regimen		
Oral antidiabetic	203	58
Oral antidiabetic + Insulin	86	24.6
Insulin	61	17.4

3.3. Reliability findings of the scale

3.3.1. Internal consistency

Cronbach's α coefficient was 0.72 for the initial scale with 33 items. After item analysis, 3 items were excluded from the scale. The Cronbach's α value calculated for the remaining 30 items was 0.77.

3.3.2. Test-retest reliability

According to the data obtained with the test-retest procedure, the Cronbach's α value was 0.73 for the 33-item scale but 0.76 when some items were removed (for 30 items).

The mean total scale score from the first test of the 101 participants who underwent a re-test was 80.07 ± 14.64 and the mean re-test scale score was 80.04 ± 14.97 ($t = 0.14$). Therefore, a statistically highly significant and positive correlation found between the initial test and the re-test results in the test-re-test reliability analysis of the scale ($r = 0.99$; $P < 0.001$).

3.4. Validity findings of the scale

The findings regarding the content validity have been explained in the section titled development process.

3.4.1. Criterion validity

The "Attitudes toward diabetes scale" (ATDS), which is a subgroup of the "Diabetes Care Profile" (DCP) scale, was used in order to evaluate the criterion validity of patient compliance with Type 2 DM treatment in the study. The aim was to evaluate the correlation coefficient of the total scores obtained with this study and the total scores obtained from ATDS.

Table 2
The results of item analysis ($n = 350$).

Items	Scale Mean Score if Item Deleted	Scale Variance if Item Deleted	Corrected Item/Total Correlation	Cronbach's α If Item Deleted
Item 1	85.34	210.58	0.31	0.71
Item 2	85.12	217.60	0.12	0.72
Item 3	86.03	209.61	0.44	0.71
Item 4	84.42	219.08	0.12	0.72
Item 5	84.74	208.68	0.43	0.71
Item 6	84.60	216.97	0.16	0.72
Item 7	85.87	212.69	0.29	0.71
Item 8	85.75	211.80	0.29	0.71
Item 9	84.90	213.14	0.22	0.72
Item 10	85.35	213.96	0.21	0.72
Item 11	86.09	216.32	0.20	0.72
Item 12	84.54	215.45	0.18	0.72
Item 13	85.75	212.46	0.33	0.71
Item 14	85.53	208.41	0.39	0.71
Item 15	86.56	222.16	0.10	0.72
Item 16	85.02	215.79	0.24	0.72
Item 17	86.18	220.36	0.10	0.72
Item 18	85.69	213.91	0.21	0.72
Item 19	86.17	224.10	–0.01	0.73 (Deleted)
Item 20	84.60	207.99	0.40	0.71
Item 21	85.90	211.04	0.34	0.71
Item 22	85.25	211.07	0.28	0.71
Item 23	85.79	212.42	0.28	0.71
Item 24	85.44	211.15	0.30	0.71
Item 25	84.92	210.15	0.27	0.71
Item 26	85.79	218.76	0.10	0.729
Item 27	85.39	209.31	0.38	0.71
Item 28	84.52	207.26	0.40	0.71
Item 29	85.04	208.23	0.34	0.71
Item 30	85.72	208.83	0.44	0.71
Item 31	85.34	214.52	0.21	0.72
Item 32	85.12	228.14	–0.09	0.74 (Deleted)
Item 33	86.03	232.09	–0.17	0.74 (Deleted)

Note: Cronbach's $\alpha = 0.72$.

DCP was developed in 1996 by Fitzgerald et al. in order to evaluate the psychosocial factors related to diabetes and the care in diabetic patients [15]. DCP consists of 16 subgroups and 234 items. The researchers who developed the scale reported that it was possible to select and separate one or more subgroups of DCP for independent use. The scale items are scored with 5-item Likert type scoring. A high score shows a good attitude of the individual regarding diabetes. The Turkish validity and reliability of the scale was conducted by Özcan in 1999. The Cronbach's α value of the original scale was 0.60–0.95. Özcan found the Cronbach's α value of the scale to be between 0.54 and 0.98 [16]. The results were similar to the original study results.

This analysis was conducted with the 150 patients in the study. A positive correlation was found between the scores of this scale and the ATDS scores ($r = 0.31$; $P < 0.001$).

3.4.2. Construct validity

The KMO test was conducted to determine whether the sample size was sufficient or not before the factor analysis. The KMO test result was 0.75. The Bartlett Sphericity test results ($\chi^2 = 1930.488$ $P < 0.001$) was significant like KMO and it was concluded that factor analysis could be performed for the scale.

The exploratory factor analysis conducted to evaluate the construct validity of the Type 2 DM treatment compliance scale revealed 7 factors with an eigenvalue over 1. These factors explained 47.36% of the overall variance. The first item explained 14.92% of this variance, the second 7.52%, the third 6.39%, the fourth 5.61%, the fifth 4.76%, the sixth 4.22% and the seventh 3.94% (Table 3).

The factor loads of the items varied between 0.30 and 0.77. The items, which were close in meaning were merged to form factors. Accordingly, the factor names were determined as follows: factor 1, emotional difficulties in compliance, factor 2, physical difficulties in compliance, factor 3, changing difficulties of habits in compliance, factor 4, acceptance difficulties in compliance, factor 5, awareness difficulties in compliance, factor 6, diet difficulties in compliance and factor 7, denial difficulties in compliance.

4. Discussion

It is important for a scale to be valid and reliable for it to provide standardized and correct information. The scale developed was found to be valid and reliable in the evaluation of treatment compliance in type 2 DM patients in this study.

A reliable scale is one that provides a measurement that is as accurate as possible. Since a fully accurate measurement is not possible, increasing the reliability of a measurement will be possible by minimizing the error [22]. Therefore, "Cronbach's α internal consistency coefficient calculation" was performed to evaluate internal consistency. Cronbach's α coefficient was used as a measure of internal consistency (homogeneity) for the items in the scale [14,21]. Cronbach's α coefficient is considered undesirable between 0.60 and 0.65, minimally acceptable between 0.65 and 0.70, respectable between 0.70 and 0.80 and very good between 0.80 and 0.90 [23,24]. Cronbach's α coefficient was 0.77 in our study, indicating sufficient reliability and a respectable result.

Another method for determining the reliability coefficient was test-retest analysis. Test-retest reliability analysis which was found

Table 3
Result of exploratory factor analysis showing internal structure of scale ($n = 350$).

Item#	Items	Factor/Factor Loading						
		1	2	3	4	5	6	7
28	I am sad because I have to endure my disease.	0.649						
23	I can easily live with diabetes by doing everything that is required.	0.648						
29	I feel strong enough to fight the disease.	0.591						
20	I am angry because I have to eat special food and have special needs.	0.577						
22	I feel anxious when it is medication/insulin time	0.573						
14	I always feel depressed about my future due to my disease	0.534						
12	I am more nervous and furious due to the difficulties of diabetes.	0.365						
11	I arrange my oral antidiabetic medication/insulin dose myself according to my food intake.	0.307						
26	I started caring for my feet after I was diagnosed with DM.		0.656					
13	I always try to improve my knowledge about DM.		0.596					
7	I think that nothing bad will happen even if my blood sugar is high.		0.480					
16	After I was diagnosed with DM. I quit my bad habits.		0.472					
3	I regularly take my oral antidiabetics/insulin.		0.454					
8	I visit the doctor with the recommended frequency.		0.397					
19	I regularly exercise in both winter and summer as recommended.			0.772				
27	I usually have a defence for not doing exercises.			0.656				
5	I eat the amount of food in the recommended manner as advised by health care professionals.			0.623				
18	I do not trust health staff; they do not help me.				0.747			
21	I am very angry that I have this disease.				0.627			
10	I get angry with my friends and relatives more easily after my diagnose.				0.623			
17	I feel when my blood sugar is low.					0.747		
25	I feel when my blood sugar is high.					0.668		
15	I can easily tell everyone that I am a diabetic.					0.500		
1	I check my blood sugar regularly.					0.445		
30	I believe that my diabetes will cure if I strictly follow to my diet.						0.696	
6	I want to manage my disease by making dietary changes rather than using oral antidiabetics or insulin.						0.606	
24	I wish there was no special diet for the disease.						0.544	
4	I believe that my disease will completely cure when my worries or stress is over.							0.598
2	I do not feel like a diabetic.							0.469
9	Nothing has changed in my life after I was diagnosed with DM.							0.448
	Eigenvalue	4.47	2.25	1.91	1.68	1.42	1.26	1.18
	Percentage of variance explained (Total:47.36%)	14.92	7.52	6.39	5.61	4.76	4.22	3.94
	Cronbach's α	0.71	0.62	0.63	0.58	0.49	0.44	0.45

to be quite high, was conducted to determine the ability of the scale; to provide consistent results at different applications and to be stable over time. This analysis also determines to what degree the scale measures the permanent characteristics of the individual [14,21]. It is recommended that the time between two administrations is long enough to prevent a significant effect on the test scores from the second administration due to the person answering becoming familiar with the test content at the first administration. However, the time between two administrations should also be short enough to prevent a significant change in the characteristics of the individual being measured [25]. It is believed, the most reasonable duration was 2 weeks as it ensured accessibility of the patients and the test-retest analyses were conducted within these limits. The analysis revealed a highly significant and positive correlation between the scale scores obtained by the participants as a result of the first administration and repeat administration ($r = 0.99$; $P < 0.001$). Thus, the scale was found to show stability over time.

One of the determinants of scale reliability was the item analysis based on correlation that is an internal consistency analysis. This ended in removing items 19, 32, and 33 from the scale. After these items were extracted, there was an increase in the scale's Cronbach's α value.

The validity of a measurement tool indicates what is measured by the tool and how well it is measured. In other words, it is the degree a measurement tool measures the characteristics it intends to measure completely and accurately and without leading to confusion with another characteristic [14,26].

The scale's initial 33 items were decreased to 30 after 3 items were eliminated as a result of content validity analyses. It was concluded that the scale was clear and applicable in terms of the number of items and the quality of measuring the compliance with treatment characteristics of the individual.

The criterion validity of the scale has been shown with another (equivalent) scale that evaluated the same conceptual structure with the same qualifications. The desirable result when evaluating criterion/compliance validity is finding a correlation coefficient when the results obtained with the developed test or scale for a measure are compared with the scores determined in a standard manner [14,21]. A positive correlation was found between the scores of this scale and the ATDS scores in the analyses conducted to determine criterion validity of the scale ($r = 0.31$; $P < 0.001$). According to literature (Şencan, 2005) validity coefficient is not as high as reliability coefficient. If r value is between 0.30 and 0.50, the test is accepted as valid. In conclusion, the measure validity coefficient of over 0.30 in this study was accepted to indicate success in ensuring criterion validity [21].

The factor analysis method was used to evaluate the structure validity of this scale. The sample must have a certain size to be able to use the factor analysis method in a scale development study. The KMO and Bartlett tests were first used to understand whether the scale was suitable for factor analysis. The KMO test measurement result should be 0.60 or higher and the Bartlett Sphericity test result statistically significant in this regard. The KMO test result of the study was 0.75 indicating that factor analysis could be conducted on the scale.

Factor analysis was used to reveal the factor construction of the scale. Exploratory factor analysis is conducted to see how the measurement variables are grouped or, in other words, which factors are present in the background of the scale items [14,21,25]. The factor loads of the items in this scale were between 0.30 and 0.77. Factor loads being higher than 0.30 and all items being merged by meaning under the factors indicate that the structure analysis of

the scale has been conducted well.

Some experts recommend a minimum of three variables to be loaded for each factor in exploratory factor analysis. The 'more is better' philosophy may not apply to exploratory factor analysis. A large number of similar variables can mask the essential factors. A smaller number of significant factor loads can enable better and clearer explanation of the characteristic by the researcher [27,28]. Therefore, a 3-variable structure was used that explained factor 6 and 7 in this study. These factor loads are consistent with the meaning and contribute to the explanation of the structure.

Ten, three, and five-factor analyses were conducted to evaluate the construct validity of the scale in this study. Firstly, 5 factors, with eigenvalues over 1 that explained 40.068% of the total variance were used. Evaluating these factors revealed that they did not merge to provide a consistent meaning and the total variance of the items was lower. The same problems were also detected in the 10 and 3-factor analyses. Finally, 7 factors, explaining 47.36% of the total variance were found, which explains the scale with factor analysis and defined their meanings accordingly (Table 3).

When the form of the factors were examined, it was seen that there is significant merging of various aspects. It is especially noteworthy that emotional difficulties related to the compliance of the individual are present together. The patient's behaviors related to his/her emotional and psychological conditions are important in managing diabetes. Relevant versatile care provided by the healthcare providers may enable the individual to cope with the disease in the best possible way [29]. It was seen that the factors 1, 4 and 7 were especially based on the emotional problems experienced while complying with the different aspects of the treatment. Behaviors related to treatment compliance have been grouped in factors 2 and 3. Items regarding awareness of the disorder are grouped in factor 5. Awareness of the disease is important in the compliance of the individual with the treatment. The patients can especially be supported to develop awareness with training in order to avoid diabetes complications [9,30]. Behaviors related to awareness were grouped in the 5th factor in this scale.

The factor analysis revealed that the numerical data were acceptable and that the items had been groups in terms of their meaning. Thus, the structure validity of the scale was provided. Evaluation of the draft scale was successfully performed in this context and made sure the scale could be used safely.

This scale can be used to determine compliance of the patient with the treatment and is of the 5-item Likert type, which is the most commonly, used type and provides optimum information. The participants reflect the degree of their attitude related to the statement content when replying to the statements in the scale items. The scale score consists of the scores of these grades. The subjects were asked to answer each of the items in the form of 1 = I strongly agree, 2 = I agree, 3 = I partially agree, 4 = I disagree and 5 = I strongly disagree. A score of 5 was accepted as indication of an unfavorable attitude and 1 as a favorable attitude. The scale includes 13 items containing positive and 17 items containing negative attitudes. Items including negative expressions (2, 4, 6, 7, 9, 10, 11, 12, 14, 18, 20, 21, 22, 24, 27, 28, and 30) are scored from 5 to 1. The scale score will be low in patients with good treatment compliance and high in noncompliant patients. In addition, a directive is prepared for those who will use this scale. It includes how scoring, calculation and interpretation should be done.

Culture is an important concept that shows how patients interact with self-directed and health care workers [31]. Although

there are a lot of scales about Diabetes Mellitus, There is no scale for Turkish culture and society [32]. In recent years, there is an increased awareness about the importance of culture specific care and cultural data collection. For this reason, scales are being developed especially for Turkish people.

Scales, used for Turkish people, were adapted versions of International scales by validity and reliability studies. But these scales were insufficient in detailed data collection for nursing care. This situation causes insufficiency in nursing care and individual assessments. Nurses should evaluate patients according to their cultural patterns and consider this in nursing approaches [33]. According to Leininger, Transcultural nursing is defined as: a substantive area of study and practice focused on comparative cultural care values, beliefs, and practices of individuals or groups of similar or different cultures with the goal of providing culture-specific and universal nursing care practices in promoting health or well-being or to help people to face unfavorable human conditions, illness, or death in culturally meaningful ways [34]. While developing the items of this scale by qualitative interviews, participants are observed to be effected by religious beliefs about their compliance to their diseases. They were noticed to use their beliefs particularly in accepting and coping with their disease. The items of this scale are the compound of items effected by religious, historical, economical, familial and educational situation as mentioned before. The usage of these items in the assesment of compliance will help us to evaluate the patients better by their cultural characteristics.

5. Limitations of the study

In Likert type scales, individuals may sometimes hide the data that they find objectionable or show themselves to others in the way they want to be. This is the disadvantage of Likert type of scales. Additionally, the scale was developed for only type 2 DM patients who volunteered for the study.

6. Conclusion

A scale evaluating patient compliance with type 2 DM treatment was developed with this study. This scale was found to be a “valid” and “reliable” scale for the evaluation of the compliance of Turkish type 2 diabetes patients with treatment. The scale will be guide the healthcare providers and nurses regarding which kinds of treatment noncompliance are experienced and requires support. This scale may also be used in other countries following the cultural scale adjustment and the validity and reliability analyses.

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Conflict of interest

No conflict of interest has been declared by the authors.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.ijnss.2017.06.002>

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