European Journal of Therapeutics

DOI: 10.5152/eurjther.2020.19132

Original Research

Validity and Reliability of the Turkish Version of the 8-Item Morisky Medication Adherence Scale in Patients With Type 2 Diabetes

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ABSTRACT

Objective: Diabetes mellitus (DM) is a common disorder that causes undesirable medical and economic consequences. A simple, reliable, and validated self-report instrument could provide a better understanding of non-adherence to treatment and may help identify new treatment modalities. Thus, the eight-item Morisky Medication Adherence Scale (MMAS-8) was developed. The aim of this study was to evaluate the validity and reliability of the MMAS-8 among Turkish diabetes mellitus patients.

Methods: This cross-sectional descriptive study enrolled 199 patients. The Turkish translation of the Morisky-8 item scale consisted of forward translation, reconciliation, back translation, back translation review, developer review, pilot testing, and final translation.

Results: Cronbach's alpha test of internal consistency was calculated at alpha=0.890 for the eight items of the MMAS-8 scale. CFA demonstrated the scale fitted CMIN/DF=1.194, GFI=0.970, CFI=0.995, RMSEA=0.031. Poor glycemic control (HbA1c<7) was significantly higher in the low-adherence group than in the high- and medium-adherence groups (p=0.001, LR=21.79). Approximately 94% of the low-adherence group patients were in the poor glycemic control group.

Conclusion: The MMAS-8 Turkish version was found to be a valid and reliable scale in diabetic patients. This self-reported scale could function as a screening tool in busy clinics to identify patients with low adherence to medication treatment. Moreover, the MMAS-8 Turkish version could help improve adherence and develop new treatment strategies.

Keywords: Diabetes mellitus, reliability, treatment adherence, validity

INTRODUCTION

Diabetes mellitus (DM) is a common disorder that causes undesirable medical and economic consequences. The International Diabetes Federation has predicted that there will be 380 million people with diabetes in 2025 (1). Poor glycemic control leads to increased mortality and morbidity with significant direct and indirect costs to the healthcare system. Therefore, effective DM treatment is essential (2-4). Various factors affect the glycemic control of diabetic patients. Several studies have demonstrated that therapy with multiple drugs, poor patient physician communication, low patient education, local culture, religious affiliation, and medication adherence status are factors that affect the treatment outcome (5, 6). Non-adherence to treatment is a major problem faced by physicians today. Several studies have reported unsatisfactory medication adherence among type 2 DM patients (7-9). Many studies have tried to improve methods for assessing adherence to therapy (10, 11). One of the methods to evaluate adherence is to measure the patient's plasma drug level. However, it is difficult to access the drug levels; further, drug levels are not measured at every center; thus, this method appears impractical (12-14).

Prescription and pill-count follow up are other methods; however, their methodology and practicability require teamwork, and so they are rarely used (15). A simple, reliable and validated self-report instrument could provide a better understanding of non-adherence and may identify new treatment modalities (16). Therefore, the 8-item Morisky Medication Adherence Scale (MMAS-8) was developed (17). The MMAS-8 has been validated in some studies with patients diagnosed with type 2 DM (18,

How to cite: Sayiner ZA, Savaş E, Kul S, Morisky DE. Validity and Reliability of the Turkish Version of the 8-Item Morisky Medication Adherence Scale in Patients With Type 2 Diabetes. Eur J Ther 2020; 26(1): 47-52.

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Received: 18.12.2019 • **Accepted:** 26.12.2020

19). However, few studies have been conducted among Turkish diabetic population, and the scale has not been validated with diabetic patients in Turkey. A cross-sectional population based survey showed that the prevalence of the type 2 DM was 13.7% in the Turkish population in 2010 (20). Consequently, it is essential to improve the treatment outcome and facilitate the evaluation of medication adherence status for Turkish patients. To our knowledge, this is the first study of MMAS-8 validation and reliability survey among diabetic patients in Turkey. The aim of this study was to evaluate the validity and reliability of the MMAS-8 in Turkish diabetes mellitus patients.

METHODS

Study Design

This cross-sectional descriptive study aimed to evaluate the validity and reliability of the MMAS-8 in Turkish diabetes mellitus patients. The study was performed at the Gaziantep University Department of Endocrinology and metabolism. The study was performed from November 2013 to March 2014. The study was approved by Gaziantep University Council's Ethic Committee (NO: 408). All patients provided informed consent for study participation. The study design included patient selection, screening, interview, self-reported questionnaire survey, and data collection. The data were collected primarily using self-administered questionnaires.

Participants

Patients were selected from the Gaziantep University Internal Medicine outpatient clinic. The inclusion criteria for this study were as follows: 1. age ≥ 18 years 2. diagnosis of diabetes (type 1 or 2) established at least 1 year previously 3. literate status 4. consumption of at least one anti-diabetes drug 5. willingness to participate in the study and provision of written informed consent 6. willingness to schedule blood test at the laboratory at the time of the visit 7. and ability to understand the questions and instruction.

A target sample size of 160 patients was estimated by a ratio of 20:1 for each item but a larger sample size of 199 patients was enrolled to increase the reliability of the conclusion (21).

Instrument: The eight-item Morisky Medication Adherence Scale (MMAS-8)

The MMAS-8 is a diagnostic adherence assessment instrument, consisting of 8 items. The range of the scale is from 0-8 with 0 indicating low adherence and 8 showing high adherence. The first 7 questions require a dichotomous response, and the last item has a Likert scale. A categorical frequency distributes the scale into the following three parts: 0 to <6 is low adherence, 6 to <8 is moderate adherence, and a score of 8 indicates high adherence. The Turkish version was obtained with the permission of the scale copyright owner (Appendix 1).

Main Points:

- Diabetes mellitus (DM) is a common disorder that causes undesirable medical and economic consequences.
- A simple, reliable and validated self-report instrument could provide a better understanding of non-adherence.
- The MMAS-8 Turkish version was found to be a valid and reliable scale in diabetic patients.
- This self-reported scale could function as a screening tool in busy clinics to identify patients with low adherence to medication treatment.

Instrument translation

Step 1 concept elaboration

The agency project manager develops a concept elaboration document that describes the intentions of each question in the scale and offers definitions of key words and terms. These aided the translators in choosing the appropriate wording in the target language. This report is typically reviewed by the instrument developer before being sent to the translators.

Step 2 forward translations

The source scale is translated by two translators (T1, T2). The translators are both native speakers of the target language or are qualified to translate into that language by a creditable institution. The translators work independently of each other.

Step 3 reconciliation

The first translator (T1) combines the two forward translations into a third translation (T3) to maximize harmonization with the source document.

Step 4 back translation

The reconciled translation (T3) is translated back into English by two translators (T4, T5). The translators are both native speakers of English or qualified to translate into English by a creditable institution. The translators work independently of each other and work with no prior knowledge of the source version.

Step 5 back translation review

The Oxford outcomes project manager reviews the back translations (T4, T5) against the source documents and works with the first translator (T1) in order to a) refine the translation (T6) where necessary and b) clarify any ambiguities that have resulted from the back translations.

Step 6 developer review

The instrument developer reviews the back translation review. Any questions or comments are reviewed by the first translator (T1) and the project manager, and discussions continue until the time all the involved experts are satisfied with the outcome (T7).

Step 7 cognitive debriefing (pilot testing)

The first translator (T1) recruits 5 patients in the target population and asks them to complete a copy of the translated scale (T7). After they have completed the scale, the subjects are asked a series of questions to gauge their understanding of the translation. Any issues are discussed among the translator (T1) and the project manager until resolved (T8).

Step 8 the final translation

T8 is formatted in the preferred format of the client/developer and sent to two proofreaders. The proofreaders work sequential-

ly and independently. Both the proofreaders are native speakers of the target language and are briefed to avoid making suggestions that would invalidate the previous work. Thus, they are only required to point out spelling mistakes, and refrain from making stylistic or preferential changes.

Step 9 step 8 results in the final translation
This version is sent to the client and the instrument developer who reviews each item in the scale for its face and constructs validity.

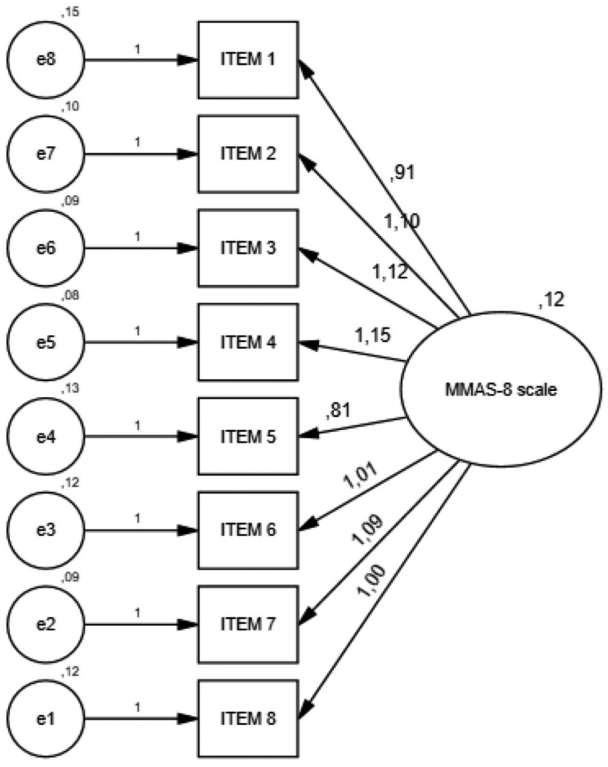
This translation process was performed by Dr. Morisky, the developer of the MMAS-8.

Patient Recruitment Procedure
We enrolled 200 diabetes patients, 199 of whom completed the full questionnaire. Patients were chosen from the internal medicine outpatient clinic. While obtaining written consent, we assessed the participants' literacy level by asking them whether they were able to complete the questionnaires independently or had used assistance. The patients who needed assistance mostly had a literacy issue; therefore, we excluded them from the study. Each survey required 15-20 min to complete.

Statistical Methods
The psychometric properties of the MMAS-8 were evaluated by using confirmatory and explanatory factor analysis (Figure 1).

Figure 1. Path diagram for the MMAS-8

[a]The MMAS (8-item) content, name, and trademarks are protected by US copyright and trademark laws. Permission for use of the scale and its coding is required. A license agreement is available from Donald E. Morisky, ScD, ScM, MSPH, 14725 NE 20th St Bellevue, WA 98007, USA; dmorisky@gmail.com.



Principle component analysis was used as the extraction method in the explanatory factor analysis. Cronbach's alpha was used to assess the reliability of the scale. In order to evaluate the correspondence between the MMAS-8 adherence groups and other clinical parameters, chi-square tests were used. All the univariate analyses and explanatory factor analysis were performed in IBM Statistical Package for the Social Sciences (IBM SPSS Corp.; Armonk, NY, USA) version 22.0 software. and confirmatory factor analysis was performed by using IBM AMOS version 22.0 package. A two-sided p-value <0.05 was considered to indicate statistical significance.

RESULTS

Clinical and Demographic Data
Recruitment was performed between September 2013 and March 2014, and 199 of the 200 participants completed the questionnaire. For the study group, 60.3% of the patients were women, within the age range of 18-87 years. The mean age of the study population was 55.02 years (SD 13.05). The socio-demographic and clinical characteristics of the participants are shown in Table 1.

Exploratory Factor Analysis and Internal Consistency
The Kaiser-Meyer-Olkin measures of sampling adequacy was 0.912, demonstrating marvelous inter-correlation among items for factor analysis. Bartlett's test of sphericity showed statistical significance (p=0.001), indicating that the inter-correlation matrix comes from a population wherein the variables are collinear. Table 2 presents factor loadings, which are the correlation between a variable and a factor that has been extracted from the data, for clinical samples for Morisky scale. According to the result of the explanatory factor analysis, only one component was extracted, and the solution cannot be rotated. Total variance explained by single factor solution was 58.60%. Internal consistency was assessed by using Cronbach's alpha, and values >0.8 indicate satisfactory internal consistency. The Cronbach's alpha value of our sample was 0.89, indicating high internal consistency (22). The Cronbach's alpha values decreased for each deleted item (Table 2). In addition, that item total correlation coefficients were high for each item, ranged from 0.599 to 0.758 (Table 2).

Confirmatory Factor Analyses
In the confirmatory factor analysis, user model versus baseline model p-value must be <0.05 for an acceptable model. Our model was statistically significant (p=0.001) according to the result of the confirmatory factor analysis. Many different criteria were considered to evaluate the result of the confirmatory factor analysis. The thresholds were determined from Hu and Bentler. CMIN/DF was 1.194 smaller than 4, the comparative fit index was 0.995 higher than the desired level of 0.90, the Tucker-Lewis Index was 0.993, and the GFI was 0.970 also higher than the desired level of 0.95. The root mean square error of approximation was 0.031 (90% CI=0.000-0.072); the desired level is <0.05. Furthermore, standardized root mean square residual was 0.028, quite smaller than 0.08. According to all the evaluated criteria, the reliability and validity of the scale were very high.

Table 1. Socio–demographic and clinical characteristic of the participants

Characteristics (n=199)		n	%
Sex	Female	120	60.3
	Male	79	39.7
Marital status	Married	160	80.4
	Single	39	19.6
Education level	Primary school	132	66.3
	High school or higher	67	33.7
Employment status	Employed	64	32.2
	Non–employed	135	68.8
Monthly income ($)	<500	123	61.8
	>500	76	39.2
Disease duration (years)	1–5	60	30.2
	5–10	57	28.6
	>10	82	41.2
Treatment modalities	Oral antidiabetics	74	37.2
	Oral antidiabetics+insulin	83	41.7
	Insulin	42	21.1
Number of anti–diabetic drugs	1	49	24.6
	2	95	47.7
	3	42	21.1
	≥ 4	13	6.5
Insulin administration Frequency (during the day)	0	74	37.2
	1	30	15.1
	2	49	24.6
	3	14	7.0
	4	32	16.1
Regular control visit	Yes	149	74.9
	No	50	25.1
Co–morbidity	Yes	89	44.7
	No	110	55.3
End organ damage	Yes	77	38.7
	No	122	61.3

External (Known Groups) Validity

This study assessed the known group validity through an association of glycemic control state. Poor glycemic control was defined as fasting plasma glucose (FPG) <130 and HbA1c <7 (20). The total score of MMAS-8 ranged from 0-8 for adherence. The MMAS-8 scores were categorized into three groups as follows: high adherence (score=8), medium adherence (score, 6 to <8), and low adherence (score, <6) (23).

Table 2. Factor loadings, item total correlations, and Cronbach's alpha values if item was deleted

Variables	Factor loadings	Item total correlation	Cronbach's alpha if the item was deleted
Question 1	0.698	0.599	0.893
Question 2	0.791	0.722	0.881
Question 3	0.816	0.739	0.880
Question 4	0.813	0.758	0.878
Question 5	0.689	0.580	0.894
Question 6	0.749	0.661	0.887
Question 7	0.811	0.736	0.880
Question 8	0.747	0.660	0.887

Table 3. Relationship between the level of adherence and glycemic control

Patient characteristics	Low adherence (<6)	Medium adherence (6 to <8)	High adherence (=8)
Good glycemic control	6 (6%)	26 (30%)	1 (34%)
Poor glycemic control	102 (94%)	62 (70%)	2 (66%)
Total	108 (100%)	88 (100%)	3 (100%)

In our sample, 18.2% of the participants had low adherence, 78.8% had medium adherence, and 3% had high adherence. The mean score for medication adherence was 4.3.

MMAS-8 categories using Chi square and likelihood ratio, assuming that patients with poor adherence level also report poor glycemic control. As shown in Table 3, Chi square test showed a significant relationship between the adherence levels as determined by the MMAS-8 and glycemic control (p=0.001). Poor glycemic control (HbA1c <7) was significantly more common in the low adherence group than in the high- and medium-adherence groups (p=0.001, LR=21.79). Around 94% of the low-adherence group patients were in the poor glycemic control group. Using a cutoff point of <8, the sensitivity of the MMAS-8 for identifying patients with poor glycemic control was estimated to be 61% and specificity was estimated at 81%.

DISCUSSION

To our knowledge, this is the first report on the translation and validation of the MMAS-8 into the Turkish language for use in diabetic patients. The Turkish version of the MMAS-8 has provided satisfactory evidence of the reliability and validity features in diabetic patients. Studies have reported the following Cronbach's alpha values for the translated versions of MMAS-8: 0.61, 0.73, and 0.68 (18, 24-26). In addition, only three studies that were performed on patients with diabetes mellitus have used the MMAS-8 (27, 28). The overall Cronbach's alpha for the Turkish MMAS-8 was 0.89, higher than that reported previously. The original MMAS-8 was tested by Morisky et al, in 1367 hypertension patients; the mean value was 6.6 (SD=1.6), and Cronbach's alpha was 0.61 (28).

In this study, the internal consistency of the MMAS-8 was higher than that in previous studies and the original MMAS-8 reported by Dr. Morisky. One reason for this might be the homogenous distribution of our participants' features. This study was performed at the University hospital, potentially resulting in a homogenous distribution of subject characteristics. Socio-cultural and health system differences may be other reasons for the scores. In contrast, 7 out of 8 items on the scale used binary responses (yes/no), and this tends to lower the Cronbach's alpha score (28); the score may be improved by increasing the number of response choices. In another study conducted on hypertension patients in Uganda, the Cronbach's alpha score was 0.65, lower than our value (29). These differences may also be attributable to differences in the physicians' education level as well as the cultural and educational level of the study participants. Moreover, in Uganda, there is limited supply of medication, making it less easily accessible to the patients. This situation does not exist in Turkey where patients have easy access to their drugs. Another study from sub-Saharan Africa reported a Cronbach's alpha score of 0.47, much lower than our Cronbach's alpha score (30). A Persian study on hypertensive patients reported a Cronbach's alpha value of 0.69 (31). However, most of the subjects in this study were illiterate, while our study excluded illiterate patients.

A Portuguese study on 937 subjects (more than that in our study) reported a Cronbach's alpha value of 0.68 (32). Moreover, the Portuguese study enrolled patients from 6 different centers across the country. The diversity of the patients may have caused the difference in the Cronbach's alpha values.

Because the factor loadings of the survey questions are very close to each other, we consider that there will not be significant difference in Cronbach's alpha score even if this question is removed. This situation can be assessed as positive evidence related to the reliability of the survey. The specificity and sensitivity of the MMAS-8 was 81% and 61%, respectively (likelihood ratio=21.79, p=0.001). These results showed that the MMAS-8 was strongly reliable for patients with high medication adherence and moderately reliable for those with low medication adherence. In many studies by Dr. Morisky, the sensitivity of MMAS-8 was higher than its specificity (28); this result may be attributable to the sample distribution and disease characteristics.

For known groups validity, three studies with patients with diabetes mellitus showed a significant association between adherence levels and glycemic control (27, 29, 33). In our study, the Turkish version of the MMAS-8 was able to differentiate strongly between patients with controlled and uncontrolled blood glucose levels based on their HbA1c levels. In our study, the number of subjects with high adherence was significantly lower than that of those with moderate and low adherence. One explanation for this could be the fact that Gaziantep (the city where this study was conducted) has one of the highest diabetic populations in Turkey (30, 34).

Study Limitations

Cronbach's alpha score is affected by sample characteristics; therefore, it is important to test the internal reliability for each different sample group.

CONCLUSION

The MMAS-8 Turkish version was determined to be a valid and reliable scale in diabetic patients. This self-reported scale could function as a screening tool in busy clinics to identify patients with low adherence to medication treatment. Moreover, the MMAS-8 Turkish version could help improve adherence and develop a new treatment strategy.

You can reach the questionnaire of this article at https://doi.org/10.5152/eurjther.2020.19132.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Gaziantep University (number 408 year 2013).

Informed Consent: All patients provided informed consent for study participation.

Peer-review: Externally peer-reviewed.

Acknowledgment: Authors agreed to adhere all copyright requirements. The MMAS (8-item) content, name, and trademarks are protected by US copyright and trademark laws. Permission for use of the scale and its coding is required. A license agreement is available from Donald E. Morisky, ScD, ScM, MSPH, 14725 NE 20th St Bellevue, WA 98007, USA; dmorisky@gmail.com.

Author contributions: Concept - E.S., Z.A.S.; Design - E.S., Z.A.S.; Supervision - E.S., D.E.M.; Resource - E.S., D.E.M., Z.A.S.; Materials - E.S., D.E.M., Z.A.S.; Data Collection and/or Processing - Z.A.S., S.K.; Analysis and/or Interpretation - E.S., D.E.M., S.K.; Literature Search - Z.A.S.; Writing - Z.A.S.; Critical Reviews - E.S., D.E.M., S.K.

Conflict of Interest: Donald E. Morisky receives honorarium for use of the copyrighted MMAS-8 diagnostic assessment instrument.

Financial Disclosure: The authors declared that this study has received no financial support.

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APPENDIX 1

The required citations and copyright acknowledgement for the Morisky scale are available on the final license contract and copyright agreement. Required citation and acknowledgement for the 8-item MMAS are as follows:

Morisky DE, Ang A, Krousel-Wood M, Ward H. Predictive validity of a medication adherence measure for hypertension control. J Clin Hypertens (Greenwich) 2008; 10: 348-54

Krousel-Wood MA, Islam T, Webber LS, Re RS, Morisky DE, Muntner P. New medication adherence scale versus pharmacy fill rates in seniors with hypertension. Am J Manag Care 2009; 15: 59-66.

Morisky DE, DiMatteo MR. Improving the measurement of self-reported medication nonadherence: Final response. J Clin Epidemiol 2011; 64: 258-63.