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ORIGINAL ARTICLE

TURKISH ADAPTATION, VALIDITY AND RELIABILITY STUDY OF TREATMENT BURDEN QUESTIONNAIRE IN GERIATRIC PATIENTS

Abstract

Introduction: This study aimed to adapt the Turkish Treatment Burden Questionnaire, test its validity and reliability, and predict the treatment burden in the geriatric population.

Materials and Method: This methodological study included individuals aged 65 years and older from the geriatric population attending routine outpatient clinic examinations at the Ankara Bilkent City Hospital Geriatrics Department between June 1, 2022, and June 1, 2023. The sample consisted of 150 geriatric individuals who spoke and understood Turkish, could managed their illness, had no disease complications, were communicative, and did not have any physical or mental illnesses that would hinder their participation. The study data were collected using the 'Individual Information Form' and the Turkish version of the 'Treatment Burden Questionnaire.' Descriptive and confirmatory factor analysis were performed, and Cronbach's α coefficient was calculated for the Turkish version of the scale.

Results: Analyzing the factor structure of the Treatment Burden Questionnaire, a three-factor, 11-item structure with an eigenvalue above 1 explained 53.227% of the variance. In the assessment of the internal consistency of the scale, four items were eliminated because of low item-total correlations and inter-item correlations. The reliability analysis for the 11-item Treatment Burden Scale yielded a Cronbach's α coefficient of 0.645.

Conclusion: The Turkish adaptation of the Treatment Burden Questionnaire demonstrated validity and reliability in for assessing the extent of treatment burden in the geriatric population.

Keywords: Treatment; Geriatrics; Chronic Disease; Questionnaire.

INTRODUCTION

Non-communicable diseases (NCDs), also called chronic illnesses, are characterized by a gradual and progressive deviations in various physiological functions that do emerge suddenly, often featuring remissions and relapses and necessitating irreversible medical care and treatment (1,2). Globally, 76.4% of all deaths are attributed to NCDs. NCDs, encompass a broad range of conditions, including cardiovascular diseases, cancer, respiratory diseases, and metabolic disorders (3). According to the World Health Organization (WHO) 2014 NCD data for Turkiye, cardiovascular diseases account for 47% of deaths, cancer for 22%, respiratory diseases for 8%, diabetes for 2%, and other diseases for 21% (4). The proportion of these deaths in geriatric individuals is 38% due to circulatory system diseases, 19% due to malignant tumours, and 12% due to respiratory system diseases (3).

Considering epidemiological research conducted in Turkiye, it is evident that the incidence of chronic diseases increases with age, particularly in the geriatric population, requiring enhanced treatment, specialized care, and rehabilitation (5). Risk factors such as poverty, poor living conditions, unhealthy nutrition, exposure to ultraviolet rays, viruses, physical inactivity, tobacco and alcohol use, overweight/obesity, and high blood sugar and pressure create a conducive environment for the development of chronic diseases (3). As individuals age in the geriatric population, various structural changes occur in the chest cavity and lung parenchyma, abnormalities in lung function tests, ventilation and gas exchange abnormalities, decreased exercise capacity, decreased respiratory muscle strength (6), reduction in lean mass such as muscles and bones, increase in fat mass, decrease in muscle functions, strength, and mass (7), decreased blood flow in the liver, decreased activity of liver enzymes, increased stiffness in the vascular

wall, impaired circulation, structural changes in the heart, increased insulin resistance, decreased beta-adrenergic response leading to decreased vasodilation of catecholamines, decreased glomerular filtration rate, renal artery stenosis, and decreased renin levels are among the many factors contributing to the increased prevalence of chronic diseases (8).

The burden of treatment encompasses the impact of the disease, specific treatments, and their side effects, as well as the functioning of healthcare services and their effects on patient well-being (9). Another definition involves the patients' efforts to access and use healthcare services and perform self-care activities, expressing the adverse effects of these efforts on patients. In short, the treatment burden focuses on the individualized load of treatment and care experienced by individuals with chronic illnesses during treatment, excluding any consideration of the burden on the healthcare system (10). Based on these definitions, the burden of treatment encompasses all the healthcare activities undertaken by patients to maintain their health. These include doctor visits, blood pressure monitoring, self-monitoring, laboratory tests, treatment management, the use of medical devices, bearing certain costs in particular situations, access to care, and the ability to coordinate care. Treatment burden in the context of an acute illnesses may be temporary. The patient could easily tolerate it while temporarily achieving a healthcare goal. Likewise, the burden of multiple oral medications may be acceptable in chronic diseases. However, self-injection, taking new medications, undergoing additional laboratory tests, and making lifestyle changes will begin to increase the burden of treatment and care on patients (11). Harmony between geriatric individuals and healthcare professionals is crucial during treatment. In geriatric patients, in addition to the pharmacological treatment approach to manage the disease, avoid disability, and maintain their quality of life, lifestyle

changes such as diet, exercise, smoking cessation, and alcohol abstinence are also recommended. These care activities increase the burden on geriatric patients (12).

Regular monitoring of elderly individuals at appropriate intervals, as specified by healthcare professionals, should be performed using appropriate techniques and documentation. The importance of paying attention to regular health check-ups (eye, kidney, cardiovascular, etc., and organ/system examinations) in this patient group should be emphasized. The group of medications used by these patients as well as the possible side effects of these medications should be discussed (8). There may be differences in the skills of individuals to manage health problems, defined as health capacity, and follow these treatments. Factors such as geriatric individuals' medication use, treatment follow-up situations, sociocultural status, cognitive functions, and overall health status need to be considered, especially the presence of problems such as the excessive use of medications (13). When the number of healthcare activities required to manage chronic diseases increases, the treatment burden on patients will also increases. As a result, a decrease in therapeutic adherence, an increase in hospitalization rates, and mortality may occur. These conditions indicate that patients must invest effort, attention, and time in managing their diseases (9,11).

In the literature, a measurement tool for assessing the burden experienced by individual patients during treatment in Turkiye has yet to be developed. This study was conducted to determine the content validity, construct validity, and internal consistency reliability coefficient of the Treatment Burden Questionnaire AU1.1 version and to contribute to the literature by establishing its characteristics for the valid and reliable measurement of the treatment burden and predicting the treatment burden in the geriatric population.

MATERIALS AND METOD

Study design

This is a methodological study.

Participants

The study population was comprised of geriatric patients aged 65 years and older who attended routine outpatient clinic examinations at the Geriatrics Department of Ankara City Hospital, Bilkent Campus, between June 2022 and June 2023. The sample size was determined based on the recommendation in the literature that at least 5-10 times the number of items in validity and reliability studies should be included (14). Considering this, 150 geriatric individuals were included in the study, ten times the number of items in the 15-item scale. The sample was selected using a non-probability random sampling method, and participants were required to be aged 65 years or above, able to manage their disease, free of disease complications, physically and mentally healthy enough to participate, speak and understand Turkish, and willing to participate in the study.

Data collection

Research data, along with patient demographic characteristics, were collected using face-to-face interviews with the Treatment Burden Questionnaire. Each Scale took approximately 15-20 minutes to complete.

Data collection tools

The data collection form included the Individual Introduction Form and the Treatment Burden Questionnaire.

Individual Introduction Form: The Individual Introduction Form, consisting of 12 questions in a single section, was designed by the researchers inspired by the studies of Değer and Ordu (2022) (15). It included demographic information such as

age, gender, marital status, education, occupation, income status, smoking and alcohol use, exercise, and diet-related characteristics (lifestyle and habits); disease and disease durations (disease characteristics) were also queried for each geriatric individual.

Treatment Burden Questionnaire: The Treatment Burden Questionnaire (TBQ-AU1.0 version), developed in France, consists of 15 items and a single dimension. There are no reverse items on the scale. Each item on the scale is scored on a scale ranging from '0-10' ('not a problem' to, 'a significant problem'). The lowest possible score on the scale was '0,' and the highest score ranged between '0' and '150.' A high score indicated that an individual was experiencing a high level of treatment burden. The Cronbach's α coefficient for the scale was found to be 0.89 (16). As no validity and reliability studies have been conducted for the TBQ-AU1.1 version in Turkiye, the Turkish language and context adaptation for this version were translated, and validity and reliability tests were performed within the scope of this study.

Language and content validity

The translation-back-translation method was used to test the language validity of the Treatment Burden Questionnaire. In the first stage, the researchers appropriately adapted the English version of the Treatment Burden Questionnaire into Turkish. The English form and the Turkish-translated form of the scale were presented to seven expert faculty members in the nursing field who were both familiar with the scale and fluent in English. After adjustments were made based on expert opinions, the entire scale was reviewed again. The translation based on the original version was then presented to the researchers, and the final Turkish version of the scale was created according to their suggestions. A pilot study was conducted with 50 patients in this study.

Internal consistency

The Treatment Burden Questionnaire showed homogeneous relationships, and Cronbach's α coefficients were examined.

Construct validity

'Explanatory and Confirmatory Factor Analysis' was performed to determine the construct validity of the Treatment Burden Questionnaire. The Kaiser-Meyer-Olkin (KMO) value and Bartlett's sphericity test were used for the exploratory factor analysis. After determining the suitability of the data for exploratory factor analysis, the fit criteria for confirmatory factor analysis, including root mean square error of approximation (RMSEA), comparative fit index (CFI), goodness of fit index (GFI), adjusted goodness of fit index (AGFI), incremental fit index (IFI), non-normed fit index (TLI), and chi-square/degrees of freedom (x^2/df) tests, were evaluated, and varimax rotation methods were used.

Statistical analysis

The data and analyses of the scale were performed using IBM SPSS (Statistical Package for Social Sciences) version 27.0 and Amos 26.0 statistical package program. Continuous data were calculated as mean, standard deviation, minimum, and maximum, whereas categorical data were calculated as percentages. Kolmogorov-Smirnov, skewness, and kurtosis tests were used to investigate the normal distribution of the data. Since the data showed a normal distribution, one-way analysis of variance (ANOVA) and independent sample T test were used. Statistical significance was set at $p < 0.05$.

Ethical dimension

Official permissions to conduct this study was obtained by signing a license agreement via email with the authors who developed the scale and its owner. This study was conducted in accordance with

the principles of the Declaration of Helsinki. This study was reviewed and approved by the Clinical Research Ethics Committee of the Ministry of Health of Ankara City Hospital 1 (Approval Number: E. Kurul-E1-22-2671). Informed consent was obtained from the geriatric individuals participating in the research in advance to provide information about the study procedures at each stage.

RESULT

Sociodemographic Characteristics of Geriatric Individuals

The average age of geriatric individuals (n=150) was 77.79 ± 8.19 years (min=65, max=98), 54% were female, 83.3% were married, 34.7% had elementary school education, and 80.7% had income matching their expenses. It was found that 5.3% of geriatric individuals used cigarettes, and 0.7% used alcohol. While 22.7% of the geriatric patients engaged in physical activity, 27.3% followed a diet. The most common diseases among geriatric individuals were a combination of cardiovascular and endocrine diseases (40.0%). The average duration of geriatric individuals' diseases was 8.31 ± 4.76 years (min=1, max=20).

Treatment Burden Questionnaire Results

The treatment burden score for geriatric individuals was calculated as 45.68±15.83 (min=2, max=95), indicating that they experienced a low level of treatment burden. Among the components contributing to treatment burden in geriatric patients, the most significant feature was the financial burden (7.57±2.62). In contrast, the least impactful factor on treatment burden was the burden related to appointments (frequency of visits, problems encountered when going to visits, inability to undergo examination after attending the appointment) (0.40±1.39).

When evaluating the Treatment Burden Questionnaire scores based on gender, a statistically significant difference was found between females (42.77±16.24) and males (49.10±14.72) (p=0.014).

Assessing the Treatment Burden Questionnaire scores based on chronic diseases revealed no significant differences between the diseases (p=0.386). Upon examining the scores, it was determined that patients with respiratory system diseases (58.00±18.57) experienced the highest burden.

Validity of the Treatment Burden Questionnaire

Data were collected from a study group of 150 individuals to assess the validity and reliability of the Treatment Burden Questionnaire. Initially, the KMO Index and Bartlett's tests were employed to assess the adequacy of the sample size and the appropriateness of the data. The KMO value was found to be 0.661, and the results of the Bartlett Sphericity test were x^2=278.372, p=0.000 (Table 1).

Exploratory Factor Analysis (EFA)

EFA was applied to a 15-item scale within the scope of the study. After confirming the suitability of the data for analysis, a varimax rotation was performed using principal components analysis to examine the scale's factor structure. Rotation was applied to the scale, and a five-factor structure was identified by reviewing the results. However, four scale items that overlapped and had low factor loadings were excluded from the analysis. After excluding these items, factors with eigenvalues exceeding one were included in the study. A three-factor structure emerged using a Scree Plot (Figure 1).

For factors with eigenvalues exceeding 1, the factorization of the scale was considered appropriate for the study, and as a result of the Exploratory Factor Analysis (EFA), a three-factor factor matrix was obtained, explaining 53.227% of the total variance. According to the EFA results, the Treatment Burden Questionnaire yielded a

Figure 1. Slope gradient graph of the EFA result
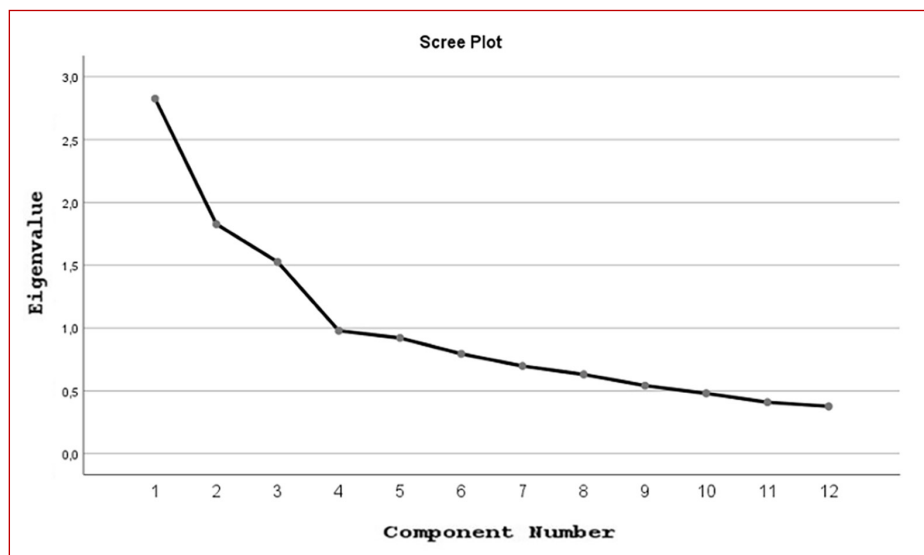
Table 1. Factor Analysis Results of Treatment Burden Questionnaire Items

Treatment Burden Questionnaire (TBQ) Items:	TBQ 1 (Economic and Social Context)	TBQ 2 (Treatment)	TBQ 3 (Medical Follow-ups)
1. Financial burden related to your healthcare	0.815		
2. Administrative burden related to healthcare	0.747		
3. Burden related to diet changes	0.621		
4. Burden related to engaging in physical activity	0.579		
5. Daily medication intake burden		0.721	
6. Burden related to the taste, shape, etc., of tablets/medications		0.715	
7. Burden related to laboratory tests		0.625	
8. Burden related to the need for regular medical care		0.562	
9. Burden related to doctor appointments			0.843
10. Burden related to interactions with healthcare professionals			0.662
11. Burden related to self-monitoring			0.657
Eigenvalue	2.825	1.826	1.525
Explained Variance Ratio	19.079	17.741	16.408
KMO = 0.661, $X2$ = 278.372; Bartlett Sphericity Test (p) = 0.000 **Total Explained Variance Ratio = 53.227**			

three-factor structure comprising 11 items. In this study, factor loadings ranged from 0.562 to 0.843 in the factor analysis. All items gathered from the factor, Factor 1 (TBQ 1), with an eigenvalue of 2.825, consisted of four items and explained 19.079% of the variance. Factor 2 (TBQ 2), with an eigenvalue of 1.826, comprised of four items and explained 17.741% of the variance. Factor 3 (TBQ 3), with an eigenvalue of 1.525, consisted of three items and explained 16.408% of the variance (see Table 1).

Confirmatory Factor Analysis (CFA)

CFA was applied to determine the fit indices of the structure consisting of 11 items and three factors obtained from the results of the EFA, and to assess its appropriateness. The fit indices obtained from the CFA results of the Treatment Burden Questionnaire are presented in Table 2.

The Treatment Burden Questionnaire CFA results yielded the following goodness-of-fit indices: x2/

Table 2. CFA Results of the Treatment Burden Questionnaire

Index	Excellent Fit Criterion	Acceptable Fit Criterion	Treatment Burden Questionnaire
/sd	$0 \leq \chi^2/df \leq 3$	$3 \leq \chi^2/df \leq 5$	1.792
RMSEA	0.000.05	0.05	0.073
CFI	$0.95 \leq CFI$	$0.85 \leq CFI$	0.863
GFI	$0.90 \leq GFI$	$0.85 \leq GFI$	0.922
AGFI	$0,90 \leq AGFI$	$0.85 \leq AGFI$	0.871
IFI	0.901.00	0.80	0.872
TLI	$0.90 \leq TLI$	$0.80 \leq TLI$	0.812

Chi-Square/Degrees of Freedom (X^2/df), Root Mean Square Error of Approximation (RMSEA), Comparative Fit Index (CFI), Non-Normed Fit Index (NNFI) or Tucker-Lewis Index (TLI), Goodness of Fit Index (GFI), Adjusted Goodness of Fit Index (AGFI)
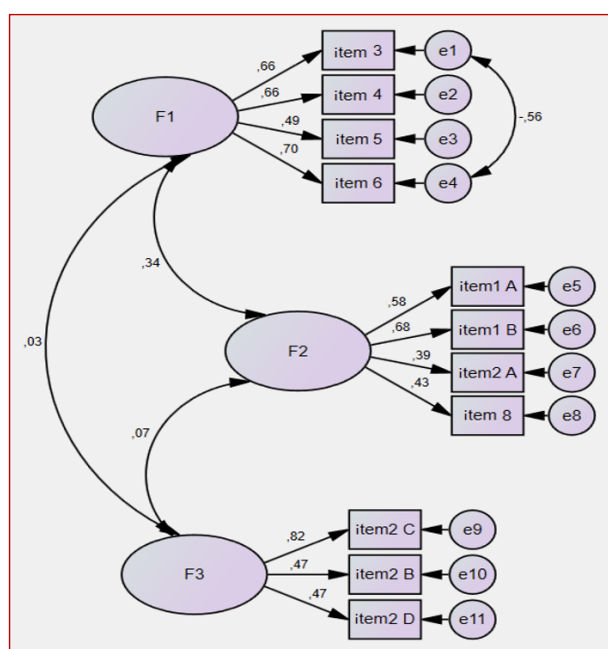
Figure 2. Path Diagram for the Treatment Burden Questionnaire

Table 3. Total Correlations and Cronbach a Coefficients of the Burden of Treatment Questionnaire (n=150)

Scale and Subdimension	Cronbach α coefficient
TBQ 1	0.673
TBQ 2	0.589
TBQ 3	0.549
Treatment Burden Questionnaire	0.645

df=1.792, RMSEA=0.073, CFI=0.863, GFI=0.922, AGFI=0.871, IFI=0.872, TLI=0.812. In this instance, Figure 2 shows a Path Diagram tailored to the Treatment Burden Questionnaire.

Reliability Analysis of the Treatment Burden Questionnaire

The Cronbach's α coefficient was calculated based on the data obtained from 150 geriatric individuals in this study. The analysis resulted in a Cronbach's α internal consistency coefficient of 0.645 for the Treatment Burden Questionnaire (Table 3).

DISCUSSION

This study aimed to translate and adapt a scale measuring the treatment burden of individuals into Turkish and conduct reliability and validity analyses to determine the dimensions in which geriatric individuals experience treatment burden. Language and content validity were assessed according to these objectives, and EFA was applied. After the EFA, four overlapping items were excluded, and the validity and reliability findings of the scale consisting of 11 items with three factors were discussed.

Discussion of Language and Content Validity

According to the literature, it is recommended to consult expert opinions, with at least three experts, to determine the language and content validity. The opinions of seven faculty members were obtained for this study. Using the Davis technique, the scale

was sent to experts, who evaluated the clarity and cultural appropriateness of the questions, providing scores as follows: "1 point: Not appropriate; 2 points: Slightly appropriate (items/expressions need to be shaped appropriately); 3 points: Quite appropriate (appropriate, but minor changes are needed); 4 points: Very appropriate (no need for changes, can remain as is)" (17). Kappa's coefficient of agreement (K.G.I.) was used to evaluate each question by dividing the number of experts who scored three and four points by the total number of experts (18). The K.G.I. for the 15 items on the scale was greater than 0.80. The scale was reviewed in its entirety based on expert suggestions. Following the analysis of expert recommendations, necessary adjustments were made to the scale without removing any items.

In scale adaptation studies, conducting a pilot application with at least 30-40 people is recommended to test the understandability of the questions (17). In the planned study, a pilot application was conduct with 50 participants to assess their language, expression, comprehensibility, and application difficulties. At the end of the application, the questionnaire items were found to be understandable and did not require correction.

Discussion of the Construct Validity of the Treatment Burden Questionnaire

KMO value and Bartlett's sphericity tests were used to evaluate the appropriateness of the data and adequacy of the sample size. The literature

suggests that the KMO value should be> 0.60, and the Bartlett's test should be significant, indicating good factor analysis and a sufficient sample size (19). According to this information, our study's sample size was sufficient (KMO = 0.661) (Bartlett sphericity test; x2 = 278.372, p = 0.000).

Discussion of the Reliability Analysis of the Treatment Burden Questionnaire

Reliability is the first condition that must be satisfied in scaled studies. The most important method to assess the reliability is to calculate Cronbach's α coefficient. This allowed us to determine the scale's degree of consistency. If this α value is below 0.40, the scale is not reliable. Values between 0.40 and 0.60 indicate low reliability, 0.60 and 0.80 are moderately reliable, and 0.80 and 1.00 are highly reliable (19). In the study, the Cronbach's α internal consistency coefficient of the Treatment Burden Questionnaire was found to be 0.645, indicating that the scale is moderately reliable.

EFA

The literature emphasizes that the total explained variance should be 40-60% (20). Consistent with the literature, the 3-factor scale structure explained 53.227% of total variance. This finding is further supported by a similar 3-factor structure obtained in a Spanish validity and reliability study where the Treatment Burden Questionnaire (TBQ_AU1.1 version) was administered to patients with Multiple Sclerosis (10).

When selecting scale items in EFA, the factor loads should be at a certain level. Tabacknick and Fidell defined this threshold value as 0.32 (21). Another study stated that the factor loads of scale items should be at least 0.30 or higher (22). In our study, when examining the factor loads in the EFA, it was observed that they varied between 0.562 and 0.843. According to the results, the factor loadings of the included items were sufficient.

CFA

The critical values that CFA must satisfy are x2/df, RMSEA, CFI, GFI, AGFI, IFI, and TLI, which are shown in Table 2 (20). In our study, the obtained fit indices were calculated as x2/df = 1.792, RMSEA = 0.073, CFI = 0.863, GFI = 0.922, AGFI = 0.871, IFI= 0.872, TLI = 0.812. These results showed that the fit indices examined with CFA were at sufficient levels, confirming the 3-factor 11-item structure.

Limitations of the study

In our study, the KMO values and Bartlett's sphericity tests were applied, and it was observed that the sample size needed to be at a sufficient level but not excellent (20). This situation led to the Cronbach's α coefficient being 0.645 (quite reliable) which is not a high level of reliability (0.80-1.00).

CONCLUSION

As a result of this research,

- Geriatric individuals experience a low treatment burden.

- There was a statistically significant difference in treatment burden between female (42.77±16.24) and male (49.10±14.72) geriatric individuals (p=0.014).

- When evaluated according to chronic diseases, there was no significant difference in the treatment burden questionnaire scores (p=0.386).

- Among the chronic diseases, it was determined that patients with respiratory system diseases (58.00±18.57) experienced the highest-burden according to treatment burden scores.

Validity and reliability analyses of the Turkish version of the Treatment Burden Questionnaire (Version A.U1.1) indicated sufficient validity and reliability. Based on the results obtained at the end of the study, it can be clearly stated that the 3-factor 11-item Treatment Burden Questionnaire is high-

ly reliable for evaluating the treatment burden on geriatric individuals in Turkey. We recommend conducting this validity and reliability studies in other sample groups with a larger sample sizes.

Competing interest: There is no conflict of interest among the authors.

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