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## 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  $\alpha$  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  $\alpha$  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 lifestyle 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.

#### 2.2.1. 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

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