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Validation of the Iranian/Persian Version of the Perceived Therapeutic Efficacy Scale for Type 2 Diabetes

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Abstract

Background: The theory if self-efficacy is the central concept of social cognitive theory with emphasis on the constructs of efficacy expectation, outcome expectation. Efficacy expectation is defined as the person's confidence to carry out a specific behavior. Outcome expectation is beliefs that carrying out a specific behavior will lead to a specific outcome. While the benefit of measuring outcome expectations has been established, there has been no large scale within the Iranian context. The purpose of this study is to examine the reliability-validity of the Persian version of the Perceived Therapeutic Efficacy Scale (PTES).

Methods: This study was conducted among 160 patients with type 2 diabetes mellitus (T2DM) using a self-administered instrument measuring outcome expectation. We used a methodological study design to assess the validity and reliability of the translated Persian version of the instrument.

Results: The findings of the present study support the uni-dimensionality of the Persian version of the instrument. The 10 items of the scale account for 73.54% of the total variance and the un-rotated factor loadings ranged from 0.66 to 0.93. Moreover, this study offers support for convergent validity and internal consistency of the scale.

Conclusion: Our study demonstrated good convergent validity, factor structure and internal consistency in a sample of 160 Iranian adults with T2DM. Therefore, the Persian version of the scale is a valid and reliable instrument and can be used in research and clinical settings.

Keywords: Confirmatory factor analysis, Convergent validity, Exploratory factor analysis, Outcome expectation scale, Persian version of outcome expectation scale

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Introduction

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder associated with significant mortality and morbidity.[1] In 2015, the International Diabetes Federation (IDF) reported that there are 415 million adults with diabetes worldwide.[2] The incidence of diabetes is reaching potentially pandemic proportions, and it is estimated that this figure will rise to 642 million in 2040.[2] The overall growth of diabetes in Iran is projected to be greater than global trends. It is estimated that there are 4.6 million patients with diabetes in Iran (8.5% of the population). By 2040, estimated number of people with diabetes in Iran is projected to be twice as many people as there are today (9.2 million). Lifestyle changes including an increase in tendency toward sedentary lifestyle, urbanization, greater calorie intake and obesity, have contributed to a rapid rise in the incidence of diabetes in Iran.[2]

People with T2DM are at increased risk for serious complications such as cardiovascular and renal diseases, heart failure, lower limb amputation, blindness, and hypoglycemia/hyperglycemia attacks.[3] T2DM and its complications are preventable if rigorous attention is paid to manage the condition.[4] Diabetes is a self-managed disease that requires the patients to make a multitude of self-management decisions regarding prescribed medications regime, doing physical activities, monitoring diet and blood glucose levels, and foot care.[5] Low levels of self-efficacy and psychosocial support are considered as potential barriers to diabetes self-management.[6] Promoting patients' confidence in successfully carrying out a certain task or behavior is a critical element of effective self-management.[7] Research in diabetes affirms that individuals with higher levels of outcome expectation have better care practices.[6] Self-efficacy theory was developed by Albert Bandura as a part of social cognitive theory and was defined as "people's judgments of their

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capabilities to organize and execute courses of action required to attain designated types of performances".[8] Efficacy expectations and outcome expectations are the central constructs of Bandura's self-efficacy theory.[9] Both self-efficacy and outcome expectation play prominent roles in self-management of diabetes.[10] Among central constructs of the self-efficacy theory, outcome expectations are less studied than efficacy expectations.

In Iran, some standardized measurements have been developed to assess efficacy expectations.[11] However, very few studies have focused on measuring outcome expectations. There has been lack of evidence on outcome expectations towards management instruments within the Iranian context. The Perceived Therapeutic Efficacy Scale (PTES) measures participants' confidence (outcome expectations). The PTES was developed and validated by Dunbar-Jacob in 2000.[12] This scale was originally developed in the United States for patients with diabetes.[12] It focused on activities of people with T2DM who were taking prescribed medications. These activates has been incorporated into the PTES. The PTES is a 10-item questionnaire with 11-point scale ranging from "0"-"no confidence" to "10"-"highest confidence". This instrument was found to have acceptable measures of reliability and validity in the United Kingdom and United States. A high degree of internal consistency (0.94–0.96) and test-retest reliability (0.64–0.80) was reported.[12,13] To our knowledge, there is no validated Persian version of the PTES questionnaire to measure outcome expectations. Thus, this scale was chosen as the target scale for validation in this study.

Materials and Methods

Research Design

Our study used a methodological study design.

Instrument

Dunbar-Jacob et al developed the PTES in 2006 in the United States.[12] The scale was developed to measure outcome expectation (people's belief that a behavior has the desired effect). It focuses on activities of people with T2DM who are taking prescribed medications. This instrument is consisting of 10 items. Respondents will rate on an 11-point scale from "no confidence" (0 point) to "highest confidence" (10 points). The responses will be summed to produce a single (total) score for "confidence". Possible scores ranged from 0 to 100 points, with higher scores indicating greater confidence. Completing the questionnaire will take 10 minutes on average. The internal consistency of the scale which was developed by Dunbar-Jacob et al was >0.90, which is an acceptable value given the small number of variables. Permission to reuse the questionnaire was obtained from the author. The main purpose of this study was to assess validity and reliability of the Iranian version of the PTES, which measures outcome expectation towards diabetes self-management.

Development Process

Translation and Pre-test

The English version of the PTES was translated into Persian using backward-forward method. Iranian version of the PTES was developed according to the steps described in World Health Organization (WHO) guideline in order to assure equivalence.[14]

The PTES was translated by 2 independent professional bilingual translators (English-Persian). In a consensus meeting, both translations were compared with each other and also with the original English version. The questionnaire was then employed to assess face validity of the questionnaire by a panel of three diabetes educators and three patients with diabetes. The result showed a face validity index of 0.97. English back-translation from Persian was done by two professional translators unaware of the original version. Subsequently, the authors of the study compared the back-translated version with the original version for cultural relevancy and linguistic congruence (See Table S1, Supplementary Materials). This process aimed to ensure that different language versions measure the same construct. We then examined the psychometric properties of the Persian version of the PTES using the following approaches: construct and validity as well as internal consistency.

Study Setting and Sample

This is a cross-sectional study conducted over a period of 1 month from September to October 2016 among individuals with diabetes attending an urban outpatient endocrine clinic located within an academic teaching hospital (primary and secondary level of care) in Ilam, Iran. The sample size needed to perform factor analysis was calculated using ratio of at least 10 participants for each item in the instrument.[15] Included participants were Iranian adults with T2DM, aged above 18 years old who were willing to participate. Patients with reduced cognitive ability, hearing difficulties, speech disorders, mobility impairments, or who were too ill, illiterate and/or unable to speak Persian/Kurdish were excluded from the study.

Study recruitment was conducted through putting an advertisement on a notice boards of the clinic and also personal communication with the patients. Participants signed a written consent form prior to actual data collection. Subjects were informed about the study's aim, benefits and their voluntary participation rights. Anonymous self-reported questionnaires were used

to collect data on PTES. A total of 240 Iranian adult patients (aged ≥18 years) with T2DM were approached and invited to participate in this study. Out of 180 patients, 39 patients did not meet the study inclusion criteria. Twenty-one patients refused to participate and 180 patients were eligible and invited to participate. Of those invited patients, 2 did not respond (unsuccessful phone call after 6 repeated attempts or wrong phone number), 3 agreed to attend but did not, 9 were not interested after reading the information and 2 responded after deadline. The remaining 160 patients participated in this study.

Statistical Analysis

Two software packages of SPSS (version 21) and AMOS (version 21) were used to run the statistical analyses. The significance level was set at <0.05. The reliability of the PTES scale was measured via Cronbach α.

Exploratory factor structure and confirmatory factor analysis (CFA) were used to assess the psychometric properties of the PTES. The exploratory factor structure was run using principal component analysis with varimax rotation. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was used to ensure that data set is suitable for factor analysis.[16] Then, the Bartlett's test of sphericity[17] was applied. We permitted SPSS to extract dimensions with eigenvalue greater than 1, and the items with factor loading less than 0.40 were suppressed.[18]

Then CFA was conducted using AMOS 21,[19] and several indices were used to assess the usefulness of the model. The following criteria need to be met: goodness of fit index (GFI) >0.90,[20] root mean square error of approximation (RMSEA) with acceptance level of <0.08,[21] Tucker Lewis Index (TLI) with acceptance level of >0.90,[22] comparative fit index (CFI) with acceptance level of >0.90,[23] and finally normal fit index (NFI) with acceptance level of >0.90.[24] Finally, the convergent validity of the uni-dimensional PTES construct was evaluated. The formula to calculate[25] AVE has been described below:

$$AVE\ \left(Average\ Variance\ Extracted\right) = \frac{\sum_{i=1}^{n} \lambda^2}{n}$$

λ= standardized factor loading, n = number of items

Results

Sample's Background

The PTES with 10 items was applied to a sample of 160 diabetic patients with a mean age of 55.71 years ±12.58 (ranged from 22 to 85) with average diabetes duration of 6 years ± IQR 9. Nearly 66% of respondents were female, 46.3% had primary education and 57.5% of them were retired or unemployed. The average HbA1c was 9.15% ± 1.13% and 81.3% of them had at least one co-morbidity condition. Participants had moderate socioeconomic status, with a significant proportion (70.6%) having difficulty paying for basic needs. Approximately three quarter of the participants (73.1%) never smoked, 11.3% were smokers, and 15.6% were ex-smokers. Half of participants (N = 80) regularly checked their blood glucose levels (see Table 1).

Exploratory Factor Analysis

The exploratory factor structure was run using principal component analysis with varimax rotation, and items with factor loading less than 0.40 were not allowed to load in the respective component. Findings from exploratory factor analysis (EFA) showed a KMO of 0.94 which confirms the adequacy of sample size. Bartlett's test of sphericity was significant ($P<0.001$). There was only one eigenvalue more than one (6.81) which implies the uni-dimensionality of PTES. The 10 items of the PTES account for 73.54% of the total variance. Un-rotated factor loadings ranged from 0.66 to 0.93 (Table 2).

Reliability Analysis

We examined the factor-based internal consistency of the PTES using Cronbach α. Table 2 displays total alpha

Table 1. Characteristics of Participants in Pilot Testing of Instruments

Characteristics	Mean ± SD/ Median ± IQR	No. (%)
Age, years	55.71 ± 12.58	
Gender		
Male		54 (33.8)
Female		106 (66.3)
Marital status		
Married		132 (82.5)
Single (divorced/widow)		28 (17.5)
Educational status		
Primary education		74 (46.3)
Secondary education		24 (15)
Tertiary education		62 (38.8)
Occupation status		
Working		68 (42.5)
Not working		92 (57.5)
Having difficulty paying for basics		
Very hard		8 (5)
Somewhat hard		113 (70.6)
Not hard at all		39 (24.4)
Smoking status		
Current smoker		18 (11.3)
Never		117 (73.1)
X-smoker		25 (15.6)
Duration of diabetes, years	6 ± IQR 9	
Presence of at least one comorbidity		130 (81.3)
HbA1c	9.15 ± 1.13	
Use of SMBG		80 (50)

Abbreviations: SD, standard deviation; IQR, interquartile range; SMBG, self-monitoring blood glucose.

Table 2. Principal Component Analysis for the Perceived Therapeutic Efficacy Scale (N = 160)

Component Matrix		Mean	SD	Item Total Correlation	Cronbach if item deleted
Component					
PTES1	0.92	6.37	0.99	0.89	0.95
PTES2	0.91	6.45	1.03	0.88	0.95
PTES3	0.91	6.52	1.04	0.88	0.95
PTES4	0.91	6.48	1.06	0.87	0.95
PTES5	0.93	6.49	1.10	0.90	0.95
PTES6	0.82	6.63	1.03	0.78	0.96
PTES7	0.91	6.44	1.06	0.87	0.95
PTES8	0.88	6.39	1.03	0.85	0.95
PTES9	0.68	5.67	1.05	0.63	0.96
PTES10	0.66	5.21	0.91	0.61	0.96

Abbreviations: PTES, perceived therapeutic efficacy scale; SD, standard deviation.
Total PTES Cronbach alpha = 0.96.

Cronbach mean (0.96), standard deviation, item-total correlation and the "alpha Cronbach if item deleted".

Confirmatory Factor Analysis

We examined the one factor model extracted from EFA in AMOS 21 using maximum likelihood estimation method. The result of CFA (Figure 1) indicated the chi-square of 52.1 (df = 31, P = 0.018) which showed poor fitness. Some limitations exist for chi-square as a criterion to determine poor fitting or good fitting models. Since the chi-square test is sensitive to sample size, it is not a practical test of model of fitness for large samples. Therefore, other fit indices are considered for large samples.[26,27]

The alternative index to chi-square is GFI which determines the proportion of variance that is accounted for by the estimated population covariance.[20] The GFI in the current study was 0.94 which shows the good fitting of the uni-dimensional model of the PTES construct. Further indices are tested in this model which are RMSEA = 0.06, CFI = 0.98, NFI = 0.97 and TLI = 0.98. All of the reported indices indicate that the extracted model is a good fitting one for the perceived therapeutic efficacy scale.

Convergent Validity

The Fornell and Larcker[25] recommendation to assess the convergent validity of a construct by obtaining the average variance extracted (AVE) greater than 0.50 in every single construct was applied in this study. If the AVE falls below 0.50, it means that variance explained by that construct is smaller than variance explained by measurement error. Based on the mentioned formula, AVE for the uni-dimensional PTES construct was 0.70. Therefore, convergent validity of the uni-dimensional PTES is confirmed.

Discussion

This study aimed to assess the psychometric properties of the Persian version of the PTES. The outcomes from this study suggest that the instrument is appropriate for Iranian adults with T2DM. The fit indices of the CFA indicate a good model fit for the original English uni-dimensional model. Our findings were similar to Wu et al in which uni-dimensionality of the scale was confirmed.[28] CFA also indicated that the overall structure of the PTES scale is equivalent to the original instrument. Thus, this can confirm the ability of the instrument to measure the outcome expectation among Iranian adults with T2DM.

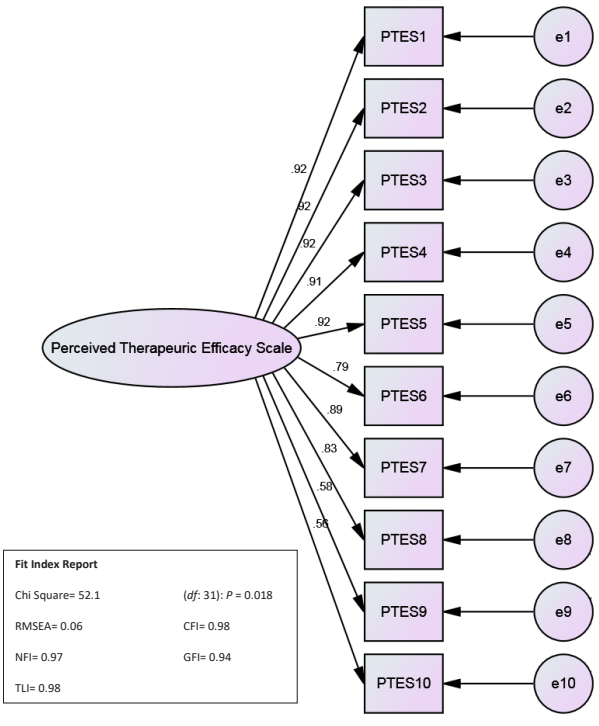

Figure 1. Confirmatory Factor Analysis of the Perceived Therapeutic Efficacy Scale.

CFA was conducted with the obtained data to determine factor loading of each item. Factor loading is defined as a set of regression statements from the latent variable to the indicators. A factor loading of 0.5 or higher is acceptable for one indicator.[29] The result of the CFA revealed one factor, which had factor loadings >0.66. The outcome of CFA was similar to the original version of the instrument, which also generated a single factor.

The internal consistency of the Persian version of PTES scale resulted in an acceptable alpha of 0.96. It is slightly higher than the internal consistency reported for the English ($\alpha = 0.94$) and Chinese ($\alpha = 0.95$) versions of the instrument.[13,28] The item-to-total correlations ranged from 0.61 to 0.90. The constant average inter-item correlations demonstrated that the scale is homogeneous.[30] However, high degree of correlation among items may suggest some redundancy in the scale.[31]

To date, this is the first study to assess the PTES scale's reliability and validity in adults with T2DM in Iran. Our study confirmed the reliability and validity of the Persian version of the instrument. Furthermore, it is a disease-specific instrument for evaluating efficacy expectation, and there are few questionnaires designed especially for use in people with T2DM. The high degree of similarities between Persian version and the original English version of the instrument provides a valid indication of questionnaire's ability to measure efficacy expectation.

Strengths and Limitations of the Study

This study has several limitations which must be acknowledged. We did not assess the test-retest reliability and convergent and divergent validity. This study examined the Persian version of the PTES scale among only adults with T2DM. Different types of diabetes and their key difference characteristics must be considered when measuring the level of efficacy expectation. Therefore, the reliability and validity study of the Persian version of the PTES scale in type 1 diabetes will offer an excellent opportunity for comparison between different types of diabetes. In spite of these limitations, the 10-item PTES scale is quite easy to administer and can be completed in a relatively short period of time. In this study, we found good evidence for reliability and construct validity of Persian version of the PTES. Our study provided necessary evidence for Iranian researchers who are interested in studying outcome expectations using a validated tool.

In conclusion, the PTES has shown to be a valid and reliable instrument in Iranian adults with T2DM. Explanatory factor analysis was conducted to assess the dimensionality of the Persian version of the PTES scale. Our results supported the uni-dimensionality, as was previously observed in the original PTES scale. Following explanatory factor analysis, we conducted CFA to evaluate the factor structure and convergent validity of the instrument. Our results confirmed the uni-dimensionality structure of the scale, and convergent validity was established. Finally, Cronbach's alpha showed a satisfactory internal consistency for PTES among Iranian adults with T2DM. In sum, this instrument provides an opportunity for healthcare professionals to detect factors that have negative impacts on self-efficacy. Alternatively, researchers will be able to enhance self-efficacy by developing interventions based on the results obtained from this scale.

Authors' Contribution

GA conceived the study, designed and obtained research funding. SKL, SG, S.Md.S, SA, MM, and HT supervised the conduct of the study and data collection. GA and SA undertook recruitment of participating centers and patients and managed the data, including quality control. SA, and S.Md.S provided statistical advice on study design and analyzed the data; SKL, SG and S.Md.S chaired the data oversight committee. GA drafted the manuscript and all authors contributed substantially to its revision. SKL and GA takes responsibility for the paper as a whole.

Conflict of Interest Disclosures

The authors have no conflicts of interest.

Ethical Statement

Ethical approval was obtained from the University Putra Malaysia (UPM) ethics committee for research involving human subjects, Malaysia (UPM/TNCPI/RMC/JKEUPM/1.4.18.2(, as well as the ethics committee of the Ilam University of Medical Sciences, Iran)22/40/94/5599(. Permission to reuse the instruments, as well as the director of the selected hospital, was obtained. After a complete description of the study was provided to the potential participants, all patients gave written informed consent prior to their inclusion in this study.

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Supplementary Materials

Table S1. Perceived Therapeutic Efficacy Scale (PTES).

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