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Development of a Valid and Reliable Diabetes Self-management Instrument: An Iranian Version

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Abstract

Background: The aim of this study was to develop a valid and reliable instrument in order to measure self-management of type 2 diabetic patients.

Methods: Validity and reliability of Iranian version of Diabetes Self-Management Instrument (DSMI) measured through a cross-sectional study. Content validity, reliability, and cultural equivalency of Iranian version of DSMI were evaluated through a qualitative and quantitative study by 350 type 2 diabetic patients.

Results: Reliability and validity of the instrument and its 5 subscales, namely, "self-integration" (α=0.88), "self-regulation" (α=0.88), "interaction with health professionals and significant others" (α=0.79), "self-monitoring blood glucose" (α=0.92), and "adherence to recommended regimen" (α=0.87) were approved by a psychometric analysis. An intraclass correlation was satisfactory when a test-retest conducted among 150 patients by two weeks interval ($p< 0.001$). Criterion validity between total instrument and metabolic control Index (HbA1c) of type 2 diabetic patients was approved ($p< 0.001$).

Conclusion: Study findings supported the reliability and validity of the Iranian version of DSMI for measuring self-management among Iranian people with type 2 diabetes in order to set appropriate interventions.

Keywords: Self-Management, Type 2 Diabetes, Reliability, Validity, Iranian version

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Introduction

As a metabolic disease, type 2 diabetes is considered as major current health problem worldwide; its prevalence and burden is rapidly increasing in both developing and developed countries (1, 2). It is estimated that a 54% increase will occur in adult diabetic patients from 2010 to 2030 (3). According to the National Survey of Risk Factors for Non-Communicable Diseases in Iran, 2005, the prevalence rate of diabetes mellitus among 25–64-year-old Iranian citizens was estimated to be about 7.7% (4).

Diabetic patients provide most of their day to day activities by themselves, and they should be responsible about their self-management beh-aveiors (5). Effective diabetes self-management has an important role in diabetes control.

Diabetes self-management should integrate in diabetic patients ' life. This skill is a need to manage chronic disease like diabetes (6). At the same time of their self-care, diabetic patient make informed decisions; with measuring blood glucose they do self-monitoring and self-regulation (7).

Because self-management is the cornerstone of diabetes care, high prevalence of diabetes in Iran (4), and a great need for a valid and reliable instrument for interventional studies, we aimed to develop this instrument. Validation of the instrument developed by Lin et al. (2008) seems to be a necessity (8). In this paper the process of validation of the instrument is presented.

Methods

Study design and participants

A total number of 350 patients were required to provide a maximum of ten respondents per item on the F-DSMI-35 (9). Systematic random sampling was used vai recorded available list of patients in Omol-Banin diabetes center, Isfahan, Iran. The included participants were older than 30 years; had a confirmed diagnosis of type 2 diabetes for at least one year; and were affiliated to the diabetic center. A total number of 350 eligible patients selected during 8 months period of data collection (between December 2010 and May 2011). An explanation was made by researcher to patients about the nature and purpose of the study. Informed consents were obtained; and confidentiality of data was guaranteed. Then, information about HbA1c results of was collected from the last medical record of each patient. According to the World Health Organization criteria for metabolic control, HbA1c was divided in three parts as following: 1) Optimal control (< 7.0%) , Borderline control (7.0- 8.5%), and Poor control (> 8.5%) (10). This study included of two qualitative and quantitative parts (figure1).

Instrument

The DSMI is a 35-items self-report scale with subscales reflecting 5 domains: (1) Self-integration (10 items); (2) Self-regulation (9 items); (3) Interaction with health professionals and significant others (9 items); (4) Self-monitoring blood glucose (4 items); and (5) Adherence to recommended regime (3 items) (Table 1). The items of the scale are evaluated in a five-point Likert scale (1=never, 2=rarely, 3=sometimes, 4=usually, 5=always) (8).

Validity assessment

In qualitative part of the study (part 1), permission was attained from the providers of the instrument. The translation and back-translation of the original version of DSMI-35 was conducted. Back-translation reviewed by an expert committee in order to achieve a modified version of the original instrument. The translation committee (three researchers and two translators) reviewed and agreed upon the provided version of F-DSMI-35 as a comprehensive representative of the original version in terms of wording and content.

Two focus group discussions (FGD) (6 persons in each group) were assigned in order to achieve a consensus on the form and content of the translated version (11). The members of the groups were invited as key informers to assess and approve the translated version of F-DSMI-35 as culturally and linguistically appropriate. Provided version of F-DSMI-35 by FGDs reviewed by three independent researchers for content analysis. The analysis revealed that the version provided by FGDs was almost entirely the same as original version in content. The prepared version transferred to the panel of experts (included 5 people) which was responsible to final version of F-DSMI-35. This panel included one endocrinologist and 4 diabetes educators and was responsible for the

assessment of content validity of F-DSMI-35. The original F-DSMI-35 and the focus group F-DSMI-35 were sent to each member of the panel, who were bilingual. Furthermore, for face validity assessment, the panel was asked to make comments on individual items regarding the accuracy, clarity, style, question formatting and cultural relevance of the translated version. Minor changes were suggested and a panel-modified version was developed. Content validity was assessed by asking the members to rate each item as a valid measure of the construct using a five-point Likert scaling. A content validity ratio was calculated for each item and for the overall F-DSMI-35. In the pilot study, some patients needed more explanation about some utterances such as "self-integration and self-regulation" in their daily living activities. More clarifications and explanations were made to the participants. About 15-20 minutes was needed to complete the scale. Then after, the final version of the scale was developed.

According to assess construct validity, the suitability of the data for factor analysis was tested using the Kaiser–Mayer–Olkin (KMO) measure of sampling adequacy of 0.6 and Bartlett's chi-square test of Sphericity with $p<0.05$ (12). The original dimensional structure of the DSMI were confirmed with an EFA by the principal component extraction method using a Varimax rotation with Kaiser normalization as a usual descriptive method for analyzing grouped data (13). These criteria were followed: 1- Eigenvalue >1 (14), 2- Loading level greater than 0.50 to assess whether an item loaded on one factor or another (15), and 3- the explanation of the factor structure should be significant (16).

Also, Pearson correlation coefficient was used to evaluate criterion validity between total scale and metabolic control (HbA1C) of participants.

Reliability assessment

In quantitative part of the study (part 2), the final version applied for the study population (350 persons). Although applying this version to a subsample of the study population as a retest was acceptable, we retested the instrument in all the participants (350 persons).

Regarding reliability, the scale's internal consistency, reliability, Cronbach's alpha reliability coefficient, and test–retest reliability were evaluated. $\alpha=0.70$ was set as scale usefulness (17). For stability analysis, intraclass correlation coefficient (ICC) and test–retest reliability were used. Statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) version 11.5. The significance level was set at $p<0.01$.

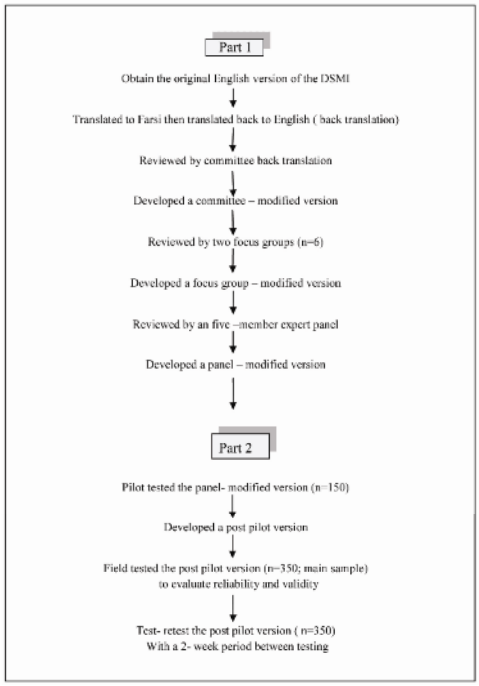

Figure 1. Flow chart for the development and evaluation of the F-DSMI-35

Results

The response rate was 89.9 %. The majority of the patients were between 50 and 60 years of age (55.52±8.42), and more than half of them diagnosed as diabetic during the past 8 years (6.36±4.37). More than half of the patients (54.3%) demonstrated borderline glycemic control (8.42±1.31 %) .Table 2 demonstrates the socio-demographic and health-related characteristics of the participants.

"Self-integration" demonstrated as the most important domain among domains analyzed by factor analysis. Eigenvalue for this domain was 9.55 which revealed in Table 1. Also, this table reveals descriptive statistics for the subscales.

The Cronbach's alpha was examined to calculate the homogeneity of the items in the scale. The Cronbach's alpha values for all the subscales were 0.91 and ranged from 0.79 – 0.92. The ICC was 0.91 ($p<0.001$ and 95% CI: 0.904–0.929).

Five certain domain items demonstrated by analyzing of spearman correlation coefficient and Cronbach's alpha in each five domains. Measured Cronbach's alpha for domains of "Self-integration", "Self-regulation"," Interaction with health professionals and significant others", "Self-monitoring blood glucose" and " Adherence to recommended regime" were 0.88, 0.88, 0.79, 0.92 and 0.87, respectively.

The KMO measure of sampling adequacy was 0.81, indicating adequate sample size, and Bartlett's test of Sphericity was statistically significant ($\chi^2 = 1126.08$, df = 545, $p< 0.001$), suggesting correlations between variables. There were five factors with 35 items in the model. The five factors explained 62.66% of the total variance. This finding reveals primary support for construct validity. Variances of each factor revealed in Table 1. A significant correlation was found between total self-management score and HbA1c among the respondents which indicated that the higher the F-DSMI-35 scores, the lower the HbA1c values ($r = - 0.64$, $p<0.001$). After controlling the effects of age, education level, and duration of living with diabetes, the correlation between total self-management score and HbA1c of type 2 diabetic respondents remained significant ($r = - 0.52$, $p<0.001$).

Table 1. Descriptive statistics for F-DSMI-35

Factors	Number of items	Means± SD (Range)	Eigenvalue	Variance (%)
Self-integration	10	3.36±0.63 (1.70- 5)	9.55	27.29
Self-regulation	9	3.23±0.65 (1.67- 4.78)	4.80	13.71
Interaction with health professionnals and significant others	9	3.00±0.53 (1.22- 4.78)	3.21	9.18
Self-monitoring blood glucose	4	2.92±0.97 (1- 5)	2.48	7.10
Adherence to recommended regime	3	3.82±0.96 (1.67- 5)	1.88	5.38
Total	35	11.29± 1.69 (6.80- 16.90)	-	-

Table 2. Sociodemographic and Health-related characteristics of study population

Variables	Frequency (%)	Variables	Frequency (%)
Age		Family Income(R/ annually)	
≤ 50	105(30)	Low(<36* 10^6)	58(16.6)
50-60	157(44.9)	Middle(36-72* 10^6)	216(61.7)
≥ 60	88(25.1)	High(>72* 10^6)	76(21.7)
Sex		Duration of diabetes(Years)	
Male	179(51.1)	≤ 3	97(27.7)
Female	171(48.9)	3-8	162(46.3)
		≥ 8	91(26)
Level of education			
Illiterate	52(14.9)	Type of treatment	
Up to diploma	109(31.1)	Oral Agents	277(79.1)
Diploma	156(44.6)	Insulin	16(4.6)
Post-graduated	33(9.4)	Oral Agents & Insulin	57(16.3)
Marital Status		History of Type2 Diabetes	
Married	286(81.7)	Yes	244(69.7)
Unmarried	64(18.3)	No	106(30.3)
General health status		Metabolic control(HbA1C)	
Very favorable	87(24.9)	Optimal control (< 7.0%)	32(9.1)
Favorable	148(42.3)	Borderline control (7.0- 8.5%)	190(54.3)
Unfavorable	115(32.9)	Poor Control (> 8.5%)	128(36.3)
Diabetes Complication		Co-morbidity	
Yes	207(59.1)	Yes	155(44.3)
No	143(40.9)	No	195(55.7)

Discussion

The aim of this study was to evaluate the validity and reliability of the F- DSMI-35. The primary study revealed appropriate internal consistency and construct validity for the scale. The F-DSMI-35 can be useful to measure the effects of self-management education programs.

Findings of the study support the construct validity and test-retest reliability of the F-DSMI-35. The coefficient for the five subscales and the total F-DSMI-35 was satisfactory. The test-retest reliability of the F-DSMI-35 was supported by Cronbach's alpha of the sub-sample of 350 patients when tested after a period of 2 weeks (α=0.917). Spearman coefficient was calculated for all 35 items of the instrument and results demonstrated Spearman coefficient more than 0.6 and none of items omit or transfer to another factors. Since, the application of the instrument is easy, its generalizability will depend on the size of the sample and population included in the study. The internal consistency of the F-DSMI-35 was sufficient (α =0.91) in this study. This finding is comparable to the original instrument that Cronbach's alpha coefficients were 0.94 and test-retest correlations for the DSMI total score was acceptable ($p<0.001$) (8).

Self-management behaviors help diabetic patients to cope better with the daily burdening tasks of diabetes care (18). In order to evaluate efficacy of self-management behaviors in type 2 diabetic patients, it is necessary to adopt a valid and reliable instrument that provides comparable information. The F-DSMI-35 which validated in this study can be helpful to determine total self-management score and related domains to provide more appropriate, relevant educational materials and to set suitable health promotion intervention programs in type 2 diabetic patients. Future researches need to validate the instrument among type 1 diabetic patients and to find out if the instrument is responsive to changes from a DSMI health promotion intervention programs. This study has some limitations as followed: this study was conducted in a single diabetes clinic in Isfahan, so generalizability of the study findings is unidentified. Participants were homogeneous, and the instrument is self-report and response bias is inevitable.

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