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# A preliminary validation of the impact on participation and autonomy questionnaire in an Iranian sample of patients with type 2 diabetes

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#### Abstract:

**BACKGROUND:** This study aimed to determine the face, convergent validity, internal consistency, and stability reliability of the impact on participation and autonomy-Persian version (IPA-p) scale for using among Iranian patients with type 2 diabetes.

**MATERIALS AND METHODS:** Trained experts interviewed 227 type 2 diabetes patients who were registered in out-patient Diabetes Clinic of Ali-Ibn Abi-Talib Hospital, (Rafsanjan, Southeast Iran from May 2018 to February 2019) and their relatives to assess the face and convergent validity, internal consistency, and stability reliability of the IPA-p scale. A checklist was used to collect demographic information and also to record expert's points of view about the scale to assess face validity. Internal consistency was measured using Cronbach's alpha, and stability was assessed using interclass correlation coefficients (ICCs). Test–retest method was used to detect the reliability of the questionnaire. Respondents completed the IPA-p scale on the two occasions with an interval of 30-45 days.

**RESULTS:** In relation to convergent validity, the confirmatory model showed an acceptable fit and the scale had a highly convergent validity. Exploratory factor analysis showed that the IPA-p scale has a ten-factor structure that explained 77.42% of the variance. Cronbach's alpha between the mean IPA-p scores achieved on the two occasions ranged from 0.65 to 0.92. Test–retest ICCs for the ten domains were between 0.64 and 0.81.

**CONCLUSIONS:** The IPA-p questionnaire can be a relatively valid and reliable instrument for assessing self-reported participation among Iranian type 2 diabetes patients. However, some improvement is needed to make it fully suitable for using among Persian-language diabetic patients. **Keywords:** 

Autonomy, diabetes, Internal validity, participation, reliability

#### Introduction

Diabetes mellitus (DM) describes a group of metabolic disorders characterized by high blood glucose levels. This disease is a major public health problem, and its prevalence has increased significantly in human societies in recent decades. DM is growing faster in the low- and middle-income countries than high-income

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countries.<sup>[1-4]</sup> Patients with diabetes are at high risk of life-threatening events increasing the costs of medical care and mortality while lowering quality of life.<sup>[2]</sup> The eighth edition of the International Diabetes Federation (IDF) 2017 Diabetes Atlas, a global reference report, estimates that 424.90 million (8.80%) adults were affected by DM in 2017 globally. This number is estimated to increase to 628.60 million

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(9.90%) by 2045.<sup>[5]</sup> The chronic nature of such diseases also leads to social isolation, lack of leisure time, family conflicts, and poor economic conditions which have been called the care syndrome by some authors. These conditions have a negative impact on caregivers' quality of life necessitating a comprehensive approach for watching patients and those caring for them.<sup>[6]</sup> The most distressing consequence of DM appears to be its late complications and<sup>[7]</sup> also significantly impacts disease management, patients' quality of life (QoL), and costs.<sup>[8,9]</sup> The concepts of quality of life (QOL), disability, impairment, and handicap are used increasingly in the medical and health sciences due to a perceived need in these fields. Health systems prioritize diseases according to the severity of the associated disability in both individuals and the community.<sup>[10]</sup> QOL is an important outcome of both clinical and social interventions and represents the conclusive goal of all health services. QOL is measured as "physical and social functioning, and perceived physical and mental well-being" patients with diabetes have a worse quality of life than patients with no chronic illness. Clinical complications of diabetes are the most important disease-specific determinant of quality of life. Methodologically, most often it is important to use multidimensional assessments of QOL and to include both generic and disease-specific measures. QOL measures should also be used to guide and evaluate treatment interventions.[11] The Cochrane collaboration highlighted the significance of investigating the outcomes of diseases while taking into account patient rehabilitation, including the restoration,<sup>[12]</sup> in the International Classification of Functioning, Disability and Health (ICF).<sup>[13]</sup> However, other factors may also influence level of participation, and a person that is involved in a life situation does not automatically experience higher participation.<sup>[14]</sup> Therefore, participation may be seen as the intersection of what a person can do, wants to do, has the opportunity to do, and is not prevented from doing by the context in which the person lives and seeks to participate.<sup>[15]</sup> Autonomy means self-rule and implies that people have the right to make their own choices and decide how, when, and where to participate in activities.<sup>[16]</sup> In a study commissioned by the Dutch Ministry of Health, the possibilities for outcome-driven social-support systems were explored.<sup>[17]</sup> Based on Brickley *et al.*<sup>[18]</sup>, three key elements for outcome-driven systems were identified: adequate organizational design, well-aligned incentives in payment models, and reliable assessment of outcomes. The impact on IPA questionnaire was identified as a promising instrument to assess relevant outcomes.<sup>[17]</sup> Originally, Berenschot and Grift (2017) evaluated the reliability and validity of the IPA for heterogeneous populations of social support clients (Cronbach alpha >0.80).<sup>[19]</sup> The IPA scale is a questionnaire that was originally designed to measure the level of participation and autonomy among people

with neurological disorders.<sup>[16]</sup> This questionnaire was at first developed in Dutch and has been translated for use among English-language speakers with neurological diseases. Its reliability and validity have been reported previously.<sup>[20]</sup> The IPA questionnaire has been validated and adopted in many countries both in and outside Europe.<sup>[21-25]</sup> Most studies focused on rehabilitation clients with well-defined, specific physical impairments.

The English IPA was a valid, reliable, and acceptable measure of participation and autonomy in people with a range of conditions (multiple sclerosis, rheumatoid arthritis, spinal cord injury, and general practice attendees, stratified by level of disability) and can make a unique and fundamental contribution to outcome assessment.<sup>[21]</sup> Karhula *et al.*, (2017) determined the validity of the Finnish version of IPA (IPAFin) questionnaire in persons with multiple sclerosis to be between 0.80 and 0.91<sup>[26]</sup> as well as a Cronbach's alpha ranging from 0.86 to 0.90 obtained in the Thai version in persons with spinal cord injury.<sup>[24]</sup> Berenschot and Grift (2019) obtained a Cronbach's alpha >.80 for rehabilitation clients in the Netherlands version.<sup>[27]</sup>

In Iran, IPA questionnaire has been evaluated in patients with stroke.<sup>[28]</sup> The results Vazirinejad et al., (2015) showed that IPA-p has been valid and reliable enough for using among Persian-language patients with multiple sclerosis (Cronbach's alpha between 0.858 and 0.913).<sup>[29]</sup> The results Mordouei et al. (2019) showed that IPA-p questionnaire was an acceptable tool for measuring the participation and autonomy level in patients with positive angiography in Persian language.<sup>[30]</sup> Vazirinejad et al. (2016) in Iran measured the level of participation and autonomy of patients with type 2 diabetes by IPA-p questionnaire and showed that type 2 diabetes reduces their participation in various aspects of life and therefore reduces the quality of life patients.<sup>[31]</sup> Due to the long course of the type 2 diabetes disease, it is necessary to take measures to increase the level of participation of patients with type 2 diabetes. Such a measure is supposed to help clinicians and service providers to target both cure and care interventions at the most affected domains of patients' life improving their participation and autonomy. Based on anticipated results, IPA-p could, at least, be used as a core for a valid and reliable questionnaire which is needed to measure the health level of Persian-language diabetic people and to evaluate the effectiveness of related clinical and social interventions. This is the first step for a long way ahead to introduce a comprehensive valid and reliable measure of participation and autonomy among diabetic patients worldwide. Therefore, further research is needed to identify a valid, reliable, and acceptable measure of participation and autonomy in patients with type 2 diabetes.

A review of the literature shows that currently there is no questionnaire to measure the level of participation among Persian-language patients with type 2 diabetes. Such a measure is supposed to help clinicians and service providers to target both cure and care interventions at the most affected domains of patients' life improving their participation and autonomy. The present study was designed to test the face, criterion, and construct validity, internal consistency, and stability reliability of the IPA-p scale among a group of Iranian patients with type 2 diabetes. This is the first step for a long way ahead to introduce a comprehensive valid and reliable measure of participation and autonomy among diabetic patients.

#### **Materials and Methods**

#### Study design and setting

All patients with type 2 diabetes registered in out-patient Diabetes Clinic of Ali-Ibn Abi-Talib Hospital, (Rafsanjan, Southeast Iran) were considered as the statistical population.

#### Study participants and sampling

About 10% (n = 300) of type 2 diabetes patients were randomly selected as our sample. to do systematic random sampling, first, according to the list of type 2 diabetic patients registered in the out-patient Diabetes Clinic of Ali-Ibn Abi-Talib Hospital diabetes (which included about 3000 patients) and using approximately 10%, a sample size of 300 people was obtained. Then, for systematic random sampling, a number from 1 to 10 was randomly selected and finally sampling was continued based on this number (as the sampling interval) until reaching the optimal sample size (n = 300). These groups of patients were, then, given information about the objectives of the study. Of these, 227 patients and their relatives agreed to help with assessing the reliability and construct validity of the IPA-p scale. Face validity had a sample size of ten individuals, and test-retest reliability had a sample size of 227 individuals. Three hundred questionnaires were distributed during the validity phase. A total of 249 questionnaires were returned, resulting in a response rate of 83%. Due to confounding information and a large number of missing values, 22 questionnaires were excluded after a review of the 249 questionnaires collected. Finally, 227 samples were subjected to the analysis. Inclusion criteria included being over the age of 18, being familiar with the Persian language, not having severe mental disorders or dementia. Diabetes patients with cognitive disorders and active psychological disorders were excluded from the study [Figure 1].

#### **Translation and adaptation**

IPA questionnaire has been validated and evaluated by Vazirinejad *et al.*<sup>[29]</sup> on multiple sclerosis patients in

Iran. In the present study, a validated questionnaire on multiple sclerosis patients in Persian was used, and this questionnaire was assessed on diabetic patients. The validity face and reliability (internal consistency and stability reliability) of the IPA-p scale were measured in Iranian patients with type 2 diabetes.

#### Measures

#### Demographic and clinical variables

Diabetes patients were asked for information about their age, gender, education status, marital status, economic status, and disease duration (years).

## *The impact on participation and autonomy questionnaire (IPA)*

The participation impact and autonomy questionnaire (32 items) is designed to assess two different aspects of participation, including perceived participation and perceived problem experience.<sup>[20]</sup> Perceived problem experience is scored independently, and the results are used to set goals in individual rehabilitation programs. The level of participation and autonomy in nine domains of patients' life is measured by the IPA scale. Psychometric properties of the IPA questionnaire such as internal reliability and test reliability at the domain level are good. The study by Wilki e et al.<sup>[32]</sup> showed that the IPA questionnaire has good face validity and its participation is comprehensive and relevant. However, Wilki e et al.<sup>[32]</sup> recommend further testing of construct validity and responsiveness because the populations studied were not very large and confirmatory factor analysis was difficult to use in validation studies.

In the study of Vaziri nejad *et al.*, the Persian version of the IPA questionnaire (45 items) has been used in multiple sclerosis patients. Also, in the Persian version, ten domains of IPA questionnaire have been reported.<sup>[29]</sup> In the study of Vaziri nejad *et al.*<sup>[29]</sup>, the description of the IPA questionnaire is as follows:

"The ten domains persian version of the IPA questionnaire are "mobility (5; 1a-1e)", "self-care (6; 2a-2f)", "household tasks (7, 3a-3g)", "looking after money (2; 4a-4b)", "leisure (2; 5a-5b)", "social relationships (8; 6a-6h)", "paid work (6; 7a-7f)", "education and learning (2; 8a-8b)", "getting help from others (2; 9a-9b)" and "religious affairs" (5; 10a-10e)." Items are expressed in a way that emphasizes control over tasks and activities (decision independence).

Vazirinejad *et al.* confirmed the validity of the Persian version of the IPA questionnaire with Cronbach's alpha between the mean IPA-p scale scores achieved on two separate occasions ranged from 0.858 to 0.913, and the test–retest interclass correlation coefficients (ICCs) for the



Figure 1: Study diagram

ten domains were between 0.789 and 0.919 in persons with multiple sclerosis.<sup>[29]</sup>

#### Validity

#### *Face validity*

Ten experts with different disciplines were requested to assess the face validity. Ten specialists agreed to help with assessing the face validity, comprising two epidemiologists, two nutritionist, four internists, one endocrinologist, and one gastroenterologist. The items in the checklist are designed to measure the extent to which expert's assessment of the extent to which IPA-p scale items, as a whole and in each area, can do what they are supposed to do. According to a study by Vazirinejad *et al.*<sup>[29]</sup>, the main goal was: "The items done on the scale were able to evaluate what was going to be done on the whole scale and in each subsection." Also, whether "respondents understand the concept of the questions," and whether "patients understand the questions in the same way as the investigators do."

#### *Convergent validity*

Science IPA scale was not originally designed for using among diabetic patients, to assess the convergent validity

of the questionnaire; a confirmatory factor analysis was performed using the maximum likelihood method at the matrix level of covariance using AMOS software. Inner consistency or convergent structural validity indicates that the questions of each domain are correlated. To verify the validity of the model as well as confirmation of the conceptual model, data from the general indexes of fitness including Comparative Fit Index (CFI), Normed Fit Index (NFI), Relative Fit Index (RFI), Standardized Root Mean Square Residual (SRMR), Root Mean Square Error of Approximation (RMSEA), and Goodness of Fit Index (GFI) were calculated [Table 3].

#### Internal consistency and stability reliability

At the Diabetes Clinic, patients with type 2 diabetes were asked to attend face-to-face interview sessions. Respondents were asked to leave any item that they did not understand. Participants completed the questionnaires for the second time (as a retest) 30 to 45 days later under similar conditions. The test–retest method was used to determine the reliability using Cronbach's alpha<sup>[18]</sup>, and stability reliability was assessed using ICCs.

#### Data collection and statistical analyses

The researcher identified the patients with type 2 diabetes and collected the required samples in morning shifts by obtaining the necessary permits and referring to the departments of the Diabetes Clinic of Ali-Ibn Abi-Talib Hospital. Samples were collected from May 2018 to February 2019. Questionnaire was completed as a self-report in the presence of the researcher. We used phone contacts to gather information from those who took part in the test reliability evaluation for the second time (in a time interval 30–45 days). SPSS 22 was used for all analyses (SPSS Inc., Chicago, Illinois, United States). The significance level of 0.05 was used in this study.

#### **Ethics considerations**

This study is the result of a research project approved by the Research Ethics Committee of Rafsanjan University of Medical Sciences (IR.RUMS.REC.1394.262). Initially, the researcher provided information to diabetes patients concerning the purposes of the study, the confidentiality of information collected, and voluntary participation and withdrawal. The diabetes patients completed and signed informed consent forms.

#### Results

#### **Study population**

Of the 300 type 2 diabetes patients who were invited to participate, 227 agreed to complete the IPA-p scale in both occasions. Demographic characteristics of patients are presented in Table 1. The mean age of respondents was  $54.06 \pm 12.2$  years. The majority of the participants were female (n = 115, 50.66%), with an age 30–60 years (n = 166, 73.13%), married (n = 222, 97.80%), and less than a diploma (n = 129, 57.10%).

#### Face validity

Expert's points of view regarding the ten domains of the IPA-p scale are presented in Table 2. The majority confirmed that the items in the ten domains of the IPA-p scale were indeed measuring what they were supposed to as "acceptable," "good," or even "excellent." Since there was no participation scale that could be used as a gold standard, convergent validity was evaluated by comparing the IPA-p data of patients with objective data collected from relatives living with the type 2 diabetes patients [Table 2]. As the table shows, ten domains were significant correlation between the two sets of scores representing suitable convergent validity.

#### Convergent validity

The path diagram of confirmatory factor analysis along with path coefficients and fitness indictors is presented in Figure 2. As Figure 2 shows, factor analysis

Socio-demographics	n	Freq	%
Age (years)			
<30	227	5	2.2
30–60	227	166	73.13
>60	227	56	24.67
Gender			
Female	227	115	50.66
Male	227	112	49.34
Education status			
<diploma< td=""><td>226</td><td>129</td><td>57.1</td></diploma<>	226	129	57.1
Diploma	226	55	24.3
>Diploma	226	43	18.6
Marital status			
Single	227	5	2.2
Married	227	222	97.8
Economic status			
Low	227	16	7.1
Moderate	227	166	73.4
High	227	45	19.5
Disease duration (years)			
<10	226	171	76
10–20	226	48	21.33
>20	226	8	2.67

Table 1: Demographic characteristics of respondents

method divided all IPA-p items into the ten domains of "mobility," "self-care," "household tasks," "looking after money," "leisure," "social relationships," "paid work," "education and learning," "getting help from others," and "religious affairs." Confirmation indexes of confirmatory factor analysis are presented in Table 3. The results of confirmatory analysis showed that the indexes of Comparative Fit Indexes (CFI), Normed Fit Index (NFI), Relative Fit Index (RFI), and Goodness of Fit Index (GFI) were close to one, which means the ideal fit of the pattern. However, to assess the Goodness of Fit, the Chi-square is usually used, but the squared increases with increasing sample size and degree of freedom. Therefore, in the literatures, the use of two indexes of Standard Residual Root Mean Square (SRMR) and Root Mean Square Error Approximation (RMSEA) is recommended. According to Schermeleh-Engel et al. (2003),<sup>[33]</sup> the Standardized Root Mean Square Residual (SRMS) values between 0.00 and 0.05 indicate good fit and between 0.05 and 0.10 indicate the acceptable fit of the model. Also Root Mean Square Error Approximation (RMSEA) values between "0.00 and 0.05" indicate good fit and from 0.05 to 0.08 indicate acceptable fitness. Therefore, according to the amounts in Table 3 and the standardized coefficients and the T index, it can be said that the confirmatory model has an acceptable fit. Table 3 also shows the results of confirmatory factor analysis.

#### **Exploratory factor analysis**

In the method of exploratory factor analysis, first of all, the appropriateness of the sample should be

Domain	Judgment* n (%)					$oldsymbol{lpha}^\dagger$	Stability (	test-retest reliability	ility)	
	1	2	3	4	5		Test score	Retest score	ICC	
Mobility	0 (0)	0 (0)	5 (50)	5 (50)	0 (0)	0.89	3.26±0.60	3.39±0.60	0.78	
Self-care	0 (0)	0 (0)	5 (50)	5 (50)	0 (0)	0.86	3.29±0.54	3.71±0.44	0.81	
Household tasks	0 (0)	0 (0)	4 (40)	0 (0)	6 (60)	0.91	3.08±0.51	3.44±0.58	0.71	
Looking after money	0 (0)	0 (0)	5 (50)	5 (50)	0 (0)	0.68	3.09±0.49	3.22±0.56	0.79	
Leisure	0 (0)	0 (0)	4 (40)	0 (0)	6 (60)	0.65	2.83±0.56	3.21±0.66	0.70	
Social relationships	0 (0)	1 (10)	3 (30)	5 (50)	1 (10)	0.90	3.86±0.39	4.03±0.38	0.73	
Paid work	0 (0)	1 (10)	6 (60)	3 (30)	0 (0)	0.85	2.22±0.84	2.92±0.86	0.64	
Education and	0 (0)	1 (10)	4 (40)	5 (50)	0 (0)	0.66	2.80±0.55	2.55±0.34	0.81	
Getting help from others	0 (0)	1 (10)	3 (30)	4 (40)	2 (20)	0.75	2.78±0.55	3.03±0.69	0.71	
Religious affairs	1 (10)	0 (0)	2 (20)	6 (60)	1 (10)	0.92	4.16±0.39	4.31±0.45	0.70	

Table 2: Judgment of experts, internal consistency, and stability (test-retest reliability) for the different domains of the IPA-p scale

\*Judgments of experts about the domains: 1=Unacceptable, 2=Poor, 3=Acceptable, 4=Good, and 5=Excellent. †a=Internal consistency of the different domains (Cronbach's Alpha)



Figure 2: Path coefficients map of confirmatory factor structure of the IPA-p scale for constructing different domains

ensured. The Kaiser-Mayer-Olkin (KMO) criterion is reported for the suitability of samples to perform factor analysis, and the closer this index is to 1 (values above 0.6), it indicates sampling adequacy. In this study, the value of this index was 0.885. Also, in this study, the Bartlett Test of Sphericity was also significant (P < 0.001). In performing principal component analysis for ten separate factors, the eigenvalue of each factor was higher than 1. Also, the percentage of common variance between the variables of the ten factors explains 77.42% of the total variance of the variables of the present study. In Table 4, the value of the eigenvalues of the ten factors of the IPA scale is reported.

In Table 5, the matrix of factor loadings after varimax rotation is reported. In this matrix, all items of the scale are reported to have a factor loading greater than 0.40. In this table, all the items of a factor that have the highest correlation with that factor are reported.

#### Internal consistency reliability

Cronbach's alpha coefficients between the mean scores of the ten domains for the two occasions of completion of the IPA-p scale ranged from 0.65 to 0.92, confirming suitable internal consistency for all domains of the IPA-p scale [Table 6]. The highest and lowest internal consistencies belonged to the "religious affairs" and "leisure" domains, respectively.

#### **Test–retest reliability**

The mean scores of the respondents for the ten domains in the first and second occasions of completing the IPA-p scale are presented in Table 2. The test–retest ICCs for the ten domains ranged between 0.64 and 0.81, among the ten domains of IPA-p, the lowest ICC was reported for "paid work" domain.

## Table 3: Confirmation indexes of confirmatory factor analysis of the IPA-p scale

RMSEA	PNFI	IFI	CFI	NFI	AGFI	GFI	CMIN/DF
0.082	0.74	0.89	0.92	0.84	0.93	0.91	2.75

Table 4: Eigenvalues and percentages of variance

 associated with ten factors of the IPA-p scale

Factors	Eigenvalues	% of Variance	Cumulative %
F1	5.28	11.74	11.74
F2	4.87	10.83	22.58
F3	4.87	10.83	33.41
F4	4.20	9.33	42.75
F5	4.14	9.20	51.95
F6	3.54	7.87	59.82
F7	2.89	6.44	66.26
F8	2.21	4.91	71.18
F9	1.73	3.84	75.02
F10	1.08	2.40	77.42

#### Discussion

#### Face and convergent validity

The present study investigated the reliability and validity of an appropriate IPA tool for patients with type 2 diabetes. We used data from acceptable population groups of patients with type 2 diabetes (n = 227). Based on the expert's points of view, the IPA-p scale demonstrated good face validity for ten. The results of some studies showed that in the IPA-P questionnaire, two domains include paid work and education-learning domains which were excluded to other versions of IPA-P. In Karhula et al. (2017) study, the work and educational opportunities domain was excluded from analysis, because it was only applicable to 51 persons with multiple sclerosis.<sup>[26]</sup> Also, in Berenschot and Grift (2019) study, due to high non-response on work and education domain, convergent validity was tested for a five-domain IPA for rehabilitation clients.<sup>[27]</sup>

For the ten domains, about 80% of experts rated items in different domains as "good" and "very good." In other words, giving expert's points of view, it seems that IPA-p scale could be a suitable core for developing a new participation scale for using among Persian-language patients with type 2 diabetes, based on its face validity. Based on our results, correlation between the scores obtained from patients via IPA-p scale and objective data collected from patients, for ten domains, was statistically significant showing acceptable convergent validity for these domains. Further, as mentioned above, indices calculated in our analysis showed good fit of items into the predicted model [Table 4], confirming good construct validity of the scale. We concluded from these results that IPA-p scale has acceptable validity in terms of face and construct validity when using among Persian-language patients with type 2 diabetes. However, some improvements could make it even more valid.

#### Internal consistency and repeatability

In terms of reliability, test–retest findings in our study showed that internal consistency of IPA-p is acceptable and Cronbach's alpha ranged from 0.65 to 0.92. The highest alpha and the lowest alpha were reported for "religious affairs" and "leisure" domains, respectively. The results of the present study showed that the IPA-p alpha score was similar to other versions of IPA, including the Cronbach's  $\alpha$  of Finnish version was between 0.80 and 0.91 in persons with multiple sclerosis.<sup>[26]</sup> Also the study of Vazirinejad *et al.* (2015) achieved Cronbach's alpha between 0.858 and 0.913 in multiple sclerosis's patients.<sup>[29]</sup> Internal reliability of the English IPA was confirmed (Cronbach's alphas > 0.8).<sup>[21]</sup> Suttiwong *et al.* study achieved Cronbach's alpha ranging from 0.86 to 0.90 in persons with spinal cord injury<sup>[24]</sup> type 2 diabetes

Subscale	Item	F1	F2	F3	F4	F5	F6	F7	<b>F8</b>	F9	F10
Social relationships	q6a	0.71									
	q6b	0.79									
	q6c	0.78									
	q6d	0.81									
	q6e	0.84									
	q6f	0.76									
	q6g	0.38									
	q6h	0.48									
Household tasks	q3a		0.67								
	q3b		0.70								
	q3c		0.76								
	q3d		0.75								
	q3e		0.67								
	q3f		0.77								
	q3g		0.42								
Getting help from others	q9a			0.49							
	q9b			0.75							
Paid work	q7a				0.90						
	q7b				0.89						
	q7c				0.76						
	q7d				0.95						
	q7e				0.93						
	q7f				0.44						
Religious affairs	q10a					0.78					
	q10b					0.80					
	q10c					0.84					
	q10d					0.78					
	q10e					0.79					
Mobility	q1a						0.73				
	q1b						0.77				
	q1c						0.76				
	q1d						0.75				
	q1e						0.40				
Self-care	q2a							0.67			
	q2b							0.64			
	q2c							0.73			
	q2d							0.79			
	q2e							0.41			
	q2f							0.49			
Education and Learning	q8a								0.86		
	d8b								0.82		
Looking after money	q4a									0.41	
	q4b									0.71	
Leisure	q5a										0.42
	a2p										0.75

patients who face numerous limitations in self-care due to increased physical and emotional problems as well as neuropathic symptoms and complications of diabetes. To control the disease and its complications, more time is needed for treatment and follow-up care. Various factors such as individual, social, and economic factors have an important role in the participation of patients with type 2 diabetes in life and treatment that should be given more attention. The results of the present study showed that test–retest reliability (stability reliability) was also shown to be acceptable based on the amounts of ICC which ranged from 0.64 to 0.81. The highest ICC and the lowest ICC were again reported for "self-care" and "paid work," respectively. The results of the present study showed that the IPA-p alpha score was lower than other versions of IPA, including the Cronbach's  $\alpha$  of Finnish version was between 0.789 and 0.919 in multiple sclerosis's

Subscale	Item	Standard coefficients	Significance level	Subscale	Mater	Standard coefficients	Significance level
Mobility	q1a	0.85	<0.001	Social	q6a	0.80	<0.001
	q1b	0.83	<0.001	relationships	q6b	0.80	<0.001
	q1c	0.86	<0.001		q6c	0.71	<0.001
	q1d	0.82	<0.001		q6d	0.80	<0.001
	q1e	0.56	<0.001		q6e	0.70	<0.001
Self-care	q2a	0.83	<0.001		q6f	0.78	<0.001
	q2b	0.78	<0.001		q6g	0.66	<0.001
	q2c	0.76	<0.001		q6h	0.68	<0.001
	q2d	0.72	<0.001	Paid work	q7a	-0.93	<0.001
	q2e	0.58	<0.001		q7b	-0.89	<0.001
	q2f	0.59	<0.001		q7c	-0.64	<0.001
Household tasks	q3a	0.76	<0.001		q7d	-0.94	<0.001
	q3b	0.71	<0.001		q7e	-0.93	<0.001
	q3c	0.83	<0.001		q7f	0.31	<0.001
	q3d	0.80	<0.001	Education and	q8a	0.55	<0.001
	q3e	0.79	<0.001	learning	d8b	1.01	<0.001
	q3f	0.81	<0.001	Getting help	q9a	0.78	<0.001
	q3g	0.67	<0.001	from others	q9b	0.79	<0.001
Looking after	q4a	0.82	<0.001	Religious affairs	q10a	0.72	<0.001
money	q4b	0.63	<0.001		q10b	0.73	<0.001
Leisure	q5a	0.68	<0.001		q10c	0.91	<0.001
	q5b	0.80	<0.001		q10d	0.88	<0.001
					q10e	0.84	<0.001

Table 6: Standard coefficients and T index of confirmatory factor analysis of the IPA-p scale

patients.<sup>[29]</sup> Also, Suttiwong *et al.* study achieved the ICC ranging from 0.76 to 0.93 in persons with spinal cord injury.<sup>[24]</sup> Memory is an unavoidable problem in retest situations, since subjects may remember how they answered the questions previously and attempt to reproduce those answers during the retest. However, a long duration between the two occasions might lead to a different situation of participation level of patients. To minimize over- or underestimation of reliability (due to the influence of memory or actual change on the two occasions), the research team considered a four- to six-week interval between the first (test) and second (retest) attempts.

Although the level of disease severity among the respondents was not considered in the present study, it could be an important factor. However, the severity of disease and the resulting disability are important in particular when we try to measure QOL, which is a subjectively measured concept. Measuring participation is different due to its objective nature and is less sensitive to the severity of disease compared with QOL. It is strongly recommended that the effect of disease severity (on the validity and reliability of this participation scale) among type 2 diabetes patients is to be considered in future investigations.

The findings of this study provide evidence for an acceptable level of face, convergent, and construct validity. Internal consistency and stability reliability

of the IPA-p scale among Iranian patients with type 2 diabetes were also good. However, it seems that some improvements are necessary to develop a more comprehensive scale, such as adding items about the respondents' ability to complete their special regular tasks based on respondent's social and cultural background (i.e. activities of daily living). For instance, in our study population (Persian-language people), religious affairs could be very important and a related domain might be needed to make IPA-p more comprehensive. Our research showed acceptable validity of IPA-p when it is applying among Persian-language patients with type 2 diabetes. IPA-p scale as the first step for assessing the impact of type 2 diabetes on the participation and autonomy of patients could be a good choice in terms of its validity.

One of the strengths of this study is that it provides a useful tool for measuring the participation of diabetic patients in Iran. However, this questionnaire should be reviewed in clinical settings and future research should examine different aspects of this questionnaire in different groups and conditions of type 2 diabetes patients. However, some precautions must be taken. Although our sample size was sufficient for the analysis and validation process, we believe that if we used different hospitals and geographical areas in Iran, our findings would be strengthened. Our study focused on type 2 diabetes patients who referred to a diabetic clinic. These conditions can affect patient participation levels, so generalizing the results to the diabetic community should be done with caution. Considering that the present study is one of the first studies conducted in type 2 diabetes patients, it is necessary to be careful in interpreting the results and conduct more studies in this regard.

#### Conclusion

The results of this study show that the IPA-p scale has a suitable conceptual structure and provides reliable information on the respondents' participation and autonomy. This questionnaire can be considered as a valid and reliable instrument for assessing self-reported participation among Iranian patients with type 2 diabetes. Also, this questionnaire can be used for policy makers and senior managers of the health system for health policy making. In fact, the ultimate goal is to create a transformation in the healthcare mechanism for type 2 diabetes patients in such a way that faster and more appropriate services are provided to improve their health and increase their quality of life and healthy life years.

#### **Relevance to clinical practice**

This study is the first to have considered participation and measured it as an outcome metric among a group of Iranian type 2 diabetes patients. More investigations are needed to help with developing a more comprehensive Persian participation scale. For this purpose, IPA-p is a suitable scale as a primary attempt, and some improvements could increase the utility of this scale. A valid and reliable IPA-p scale could be very helpful gadget in both clinicians and service providers hand to provide the most effective cure and care interventions among Persian-language type 2 diabetes patients regarding the most affected domains of patients' life which need to be improved.

#### **Ethical statement**

The code of ethics (IR.RUMS.REC.1394.262) was received from the Ethics Committee of Rafsanjan University of Medical Sciences.

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#### **Conflicts of interest**

There are no conflicts of interest.

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