Translation and validation of an Iranian version of the Diabetes Quality of Life measure

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ABSTRACT

Aims/Introduction: The objective of this study was to translate and validate an Iranian version of the Diabetes Quality of Life (DQOL) questionnaire in an Iranian population of males and females with a diagnosis of type 2 diabetes.
Materials and Methods: A total of 503 patients with type 2 diabetes were recruited from nine diabetes clinics across several Iranian cities. A standard backward and forward translation procedure was used to convert the English version of the DQOL into the Iranian language (Persian). Internal consistency, convergent validity, known group comparison, confirmatory factor analysis (CFA) and factorial invariance were applied for the assessment of psychometric properties of the translated version.
Results: The translated version of the DQOL showed adequate internal consistency reliabilities for all subscales (Cronbach's α >0.70). CFA confirmed the underlying domain structure to be the same as for the original English version, therefore supporting the factorial validity of the translated questionnaire. In addition, questionnaire responsiveness showed good sensitivity to interventions.
Conclusions: In conclusion, the translated Iranian version of DQOL has shown high internal reliability and good construct validity, and can potentially be applied as an assessment tool for health-related quality of life in patients with diabetes. (J Diabetes Invest, doi: 10.1111/j.2040-1124.2012.00217.x, 2012)

INTRODUCTION

Type 2 diabetes mellitus is a complex metabolic disorder characterized by hyperglycemia, and is associated with relative deficiency of insulin secretion, along with a reduced response of target tissues to insulin[1–2]. Type 2 diabetes mellitus is a major chronic disease, and an important cause of morbidity and mortality worldwide. The burden of diabetes is globally growing, as a dramatic worldwide increase in disease-prevalence can be observed, particularly in developing countries[3]. The magnitude of healthcare problems from type 2 diabetes results not just from the disease itself, but also from its association with obesity and cardiovascular impairments, particularly dyslipidemia and hypertension[4–5].

According to statistics published by the World Health Organization (WHO), today, more than 346 million people worldwide suffer from diabetes[6], and more than 80% of diabetes deaths occur in low- and middle-income countries[7]. This number will rise to 439 million adults (aged 20–79 years) by 2030 (7.7% of the estimated world population), as estimated by a recent prospective epidemiological study[8–9]. There are major ethnic differences in susceptibility to type 2 diabetes, which are probably largely genetically determined; for example, people of Micronesian, Polynesian, Indian or Chinese background are at a substantially higher risk[5–7]. In Iran, a recent epidemiological study carried out on a large sample of Tehran's population (n = 9489) found that 8.1% of the male and 10% of the female population aged over 19 years had type 2 diabetes, with prevalence increasing progressively with age[10]. Although precise figures for the prevalence of metabolic syndromes are not usually freely available, the study concluded that overall approximately one-third of adult citizens in Tehran had impaired glucose metabolism or type 1 or 2 diabetes.

Obesity, hypertension, insulin resistance and physical inactivity are known to be major risk factors for type 2 diabetes[4,5,11,12]. Furthermore, some medical conditions can cause the disease, including acromegaly, Cushing's syndrome, thyrotoxicosis, pheochromocytoma, chronic pancreatitis and cancer[11–14]. Studies also show that socioeconomic status is inversely correlated with the prevalence of type 2 diabetes; that is, people from deprived areas and low social class are more likely to suffer from diabetes[15].

Diabetes has many complications and long-term health-related consequences. By far the greatest cause of morbidity and mortality in type 2 diabetes is cardiovascular disease. Recent data suggest that approximately 50% of type 2 diabetes patients die of a cardiovascular disease[11]. Furthermore, approximately 10% develop severe visual impairment, and approximately 2% become blind after 15 years of disease onset[12,13]. Other long-term

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complications include neuropathies – a damage to the nerves as a result of the disease – affecting up to 50% of patients, as well as kidney failure, affecting 10–20% of patients[6,14].

It is well recognized that diabetes, with its complications and comorbidities, is a growing public health burden with significant economic impact on individuals, families, health systems and countries[16]. The WHO estimates that in the period between 2006 and 2015, China will lose up to $558 billion in foregone national income as a result of heart disease, stroke and diabetes alone[6]. Apart from the economic burden, this epidemic has profound effects on the quality of life of people in terms of social and psychological well-being, as well as physical ill health[16]. Health-related quality of life (HRQOL) is now recognized as an important outcome for people suffering from chronic disease, such as diabetes[17]. HRQOL reflects the value assigned to duration of life as modified by the impairments, functional states, perceptions and social opportunities that are influenced by disease, injury, treatment or policy[18,19].

Measuring HRQOL is an important issue for diseases, such as diabetes, especially because the disease requires intensive self-care behaviors to avoid complications[20]. Numerous instruments exist for the assessment of quality of life in people suffering from diabetes[21]. However, the majority of these measures was originally developed for use in English-speaking countries and is not available in other languages[22–32]. Quantifying the prevalence of diabetes and the extent of impaired HRQOL as a result of the condition, now and in the future, it is important to allow rational planning and allocation of resources. Epidemiological data needs to become available so that prevention and intervention programs can be designed, especially for high-risk countries, such as Africa, India and the Middle East.

The objective of the present study was to translate and validate an Iranian version of the Diabetes Quality of Life (DQOL) questionnaire in an Iranian population of males and females with the diagnosis of type 2 diabetes.

MATERIALS AND METHODS
Study Sample
From October 2010 to August 2011, 503 male and female patients with type 2 diabetes were recruited from nine diabetes clinics in the Iranian cities of Qazvin, Tehran and Rasht. For patient recruitment, a multistage sampling method was used. Three clinics per city were chosen randomly from a directory listing all clinics in the aforementioned cities. Subsequently, we selected the number of patients required. Inclusion criteria for participation in the study were: (i) being able to read and understand Persian/Farsi; (ii) lack of severe psychiatric illnesses (such as schizophrenia or bipolar affective disorder); (iii) older than 18 years-of-age; and (iv) a verified diagnosis of type 2 diabetes by means of medical records. Written consent was obtained from all 503 patients. Ethical approval was obtained from the Ethics Committee of Qazvin University of Medical Sciences (QUMS).

Measures
Demographic Measures and Endocrine Data
Demographic variables – including age, sex, educational status, marital status and monthly income – were assessed with a separate, self-constructed questionnaire. A trained nurse measured height and weight using a Seca 220. Blood pressure was evaluated by mercury sphygmomanometer in a seated position and after a 5-min rest[27]. Endocrine data were collected for all patients and included fasting plasma glucose (FPG) and glycated hemoglobin (HbA$_{1c}$). A colorimetric assay was used to estimate HbA$_{1c}$[28]. FPG was determined by taking a 10-mL blood sample after 12 h of fasting. Diabetes-related complications (i.e. retinopathy, neuropathy, foot complications and cardiovascular complications) were identified based on the patients' medical records.

Diabetes Quality of Life (DQOL) Questionnaire
The DQOL is a 46-item assessment instrument oriented towards both adolescents and adults with insulin-dependent diabetes mellitus that measures the burden associated with diabetes treatment and glycemic control. The original version of the DQOL was initially developed for the Diabetic Control and Complications Trial (DCCT) carried out from 1983 to 1993, and funded by the National Institute of Diabetes and Digestive and Kidney Diseases[29]. The DQOL consists of 46 items covering four subscales: (i) satisfaction with treatment (15 items); (ii) impact of treatment (20); (iii) worry about the future effects of diabetes (7 items); (iv) and worry about social/vocational issues (4 items). Apart from the subscale scores, the instrument also provides a total questionnaire score. Items are scored on a five-point Likert scale and are of two general formats. One format asks about the frequency of negative impact of diabetes itself or of the diabetes treatment (i.e. 'How often do you worry about whether you will pass out?') and provides response options from 1 (never) to 5 (all the time). The second format asks about satisfaction with treatment and quality of life (i.e. 'How satisfied are you with the time you spend exercising?') and is scored from 1 (very satisfied) to 5 (very dissatisfied). Higher scores on DQOL items and subscales are therefore negatively valenced, indicating more complications and greater dissatisfaction. The instrument has been shown to have excellent internal consistency ($r = 0.78$–0.92), test–retest reliability ($r = 0.78$–0.92), and convergent validity for all four subscales as assessed in people with type 1 and type 2 diabetes[30].

Short-Form Health Survey
The Short-Form Health Survey (SF-36) is a generic tool used to assess health-related quality of life (functional health and well-being). The SF-36 consists of 36 items measuring eight independent scales including: physical functioning (PF), role limitations as a result of physical problems (RP), bodily pain (BP), general health perceptions (GH), vitality (VT), social functioning (SF), role limitations as a result of emotional problems (RE) and perceived mental health (MH)[32]. The SF-36 can also be divided into two aggregate summary measures: the 'Physical Component

Summary' (PCS) and the 'Mental Component Summary' (MCS). The SF-36 has been translated into several languages, including Persian/Farsi, and is commonly used in numerous epidemiological studies assessing[34-36]. Answers to each question are scored on a five-point Likert Scale. These scores are then summed to produce raw scale scores for each health concept, which are then transformed to a 0–100 scale. Scoring algorithms can then be applied to produce the PCS and MCS scores. High scores indicate higher HRQOL. The excellent psychometric properties of the Iranian version of the SF-36 have been shown in a previous study[33], where the questionnaire showed acceptable internal consistency, satisfactory convergent validity and successful discrimination between subgroups of healthy individuals based on sex and age groups. Furthermore, a two-factor structure for the SF-36 was indentified[33].

Translation Procedure

A request to authorize the translation of the DQOL was submitted to the authors of the original questionnaire version. Translation procedures were initiated after permission was granted. According to the recommendations of Beaton et al.[37], a backward–forward translation procedure was carried out. First, the original DQOL questionnaire was translated into Persian/Farsi by two independent bilingual (Persian/English) translators. The translators compared their versions, and discrepancies in the translations were reconciled. The reconciled version was then back-translated into its original language by two independent bilingual translators who were not familiar with the original version and did not have a medical background. The purpose of this step was to ensure that the translated version reflected the same item content as the original version[37]. Next, the back-translated version was reviewed by an expert committee consisting of health psychologists, methodologists and translators. Finally, the amended instrument was piloted in a subsample of 30 patients with type 2 diabetes (17 men and 13 women, with a mean age of 47 ± 13.2 years). This sample was selected from Qazvin and Tehran diabetes clinics using a convenience sampling procedure, and was excluded from the main study sample. Once the patients completed the instruments, an interview was carried out to find out about patients' opinions on each questionnaire item and selected response. All items were kept and included in the final version. This final version was given to the full sample of 503 type 2 diabetic patients and to all individuals participating in the 6-month follow up ($n = 464$, drop-out rate of 7.8%).

Validation Procedure

After providing written consent, the participants were asked by physicians to complete the translated Persian version of the DQOL, the SF-36 and the self-constructed demographic questionnaire in the clinics. The physicians explained the importance of the study by clarifying its potential benefits in improving quality of life among diabetic patients. Participants able to complete the scales themselves were asked to do so. For illiterate

and/or disabled patients, a trained research assistant was available to help them with the questionnaire answers and responses. All instruments were completed onsite at the clinics. At all locations where data was collected, a researcher was present to address the patients' questions and concerns, and to guide them in the questionnaire completion procedure. Laboratory data were collected at the time of this baseline assessment. Two weeks later and then again 6 months later, the patients were asked to complete the Persian version of the DQOL; 3.3% and 7.7% of the patients dropped out from the 2 weeks' and 6-month follow up, respectively.

Statistical Analysis

Univariate and multivariate normality of the data were assessed with Kolmogorov–Smirnov and Mardia's tests, respectively. Reliability of the DQOL was assessed with internal consistency and test–retest reliability. A Cronbach's alpha coefficient (α) was used to assess the internal consistency. Cronbach's α values ≥ 0.70 were considered acceptable[38]. Intraclass correlation coefficients (ICC) were computed between scales scores twice (test–retest) with a 2-week interval. Values for ICC $r <0.40$, 0.41–0.60, 0.61–0.80 and 0.81–1.00 reflected poor, fair, moderate and good agreement, respectively[39]. Construct validity was examined by computing the intercorrelations between the DQOL domains and SF-36 scales. Pearson's correlations were calculated between the four domains of the DQOL and the eight domains of the SF-36. Discriminant validity of the DQOL was assessed using the known group method to assess the extent to which the DQOL could differentiate between subgroups of the patients with various clinical statuses. Based on previous study results, it was hypothesized that patients with high FPG (i.e. ≥ 110), high HbA$_{1c}$ (i.e. $\geq 7\%$), high body mass index (BMI; i.e. ≥ 24) and with complications would report lower HRQOL[23,40-43].

Questionnaire responsiveness to change was assessed over a 6-month follow up, during which four different diabetes treatment interventions were carried out. In the first intervention, 103 patients were treated with insulin therapy. Participants in this group were instructed on proper insulin use by trained physicians in two sessions, each lasting 40 min. The training included information on: (i) who can benefit from insulin treatments; (ii) when should insulin treatment be started; (iii) common insulin regimens; (iv) training of injection techniques; (v) choosing an injection site; and (vi) getting the dose right. Patients in the second intervention group ($n = 249$) received a stable dose of oral hypoglycemic agents (e.g. glyburide or metformin). The patients in this group were provided information on the importance of oral agents to reduce glucose levels to a desirable range. The intervention included two sessions, each lasting 50 min. In these sessions, the effects of this specific medication, as well as the unique advantages and disadvantages of oral agents, were discussed. Furthermore, routinely using oral agents, and blood glucose testing before breakfast and one other time during the day were recommended. The third intervention was based on lifestyle modification, and focused on changes in

eating behavior, quitting smoking and increasing the amount of physical exercise. The intervention was carried out in the afore-mentioned diabetes clinics and consisted of 10 weekly sessions. Each session lasted for 90 min and was guided by a health psy-chologist, nutritionist and a physician. In the last intervention group, 44 patients were assigned to combined therapy (i.e. life-style modification plus oral agent). Patients receiving combined therapy were provided with guidelines on the use of oral agents and lifestyle modification (for more details, please see above). Therefore, two groups of the patients received lifestyle modifica-tion intervention (i.e. lifestyle modification group and lifestyle modification plus oral agents group). The effects of interventions on DQOL score changes were analyzed by repeated measures analysis of covariance (ANCOVA). The data was adjusted for age, sex and educational status. In order to control of type 1 errors, the Benjamini–Hochberg procedure was used[44].

The factor structure of the Persian version of the DQOL was assessed by carrying out confirmatory factor analysis (CFA). A CFA with weighted least squares estimation was carried out on the data to test if the original four-factor model represents the best-fitting model[29]. The adequacy of model fit was evaluated by the following indices: Chi-squared goodness of fit statistic, good-ness of fit (GFI; ranges from 0 to 1: a value >0.90 being accept-able), comparative fit index (CFI ranges from 0 to 1: a value >0.90 being acceptable), non-normed fit index (NNFI; a value greater than 0.90 being acceptable) and root mean squared error of approximation (RMSEA; ranges from 0 to 1: a value <0.08 being acceptable)[45].

RESULTS

A total of 503 individuals with type 2 diabetes participated in the present study. The mean age of the participants was 59 years (SD = 10 years). Most of the patients were female (56.8%) and unemployed (76.1%). The demographic and clinical characteristics of the patients are shown in Table 1.

Table 2 lists the results of the reliability tests of the Persian ver-sion of the DQOL. Cronbach's α met the minimum acceptable criterion for all subscales (i.e. $\geq$0.70). The test–retest reliability showed no significant difference between baseline and 2 weeks retest for all DQOL subscales. In accordance with our prior assumption, all domains of the DQOL were significantly nega-tively correlated with all SF-36 dimensions (r ranging from $r = -0.43$ to $r = -0.84$; Table 3). Results of the discriminant analysis are summarized in Table 4. Overweight and obese patients reported higher DQOL subscale scores compared with patients who had normal weight. Furthermore, patients without a history of complications reported better quality of life in compari-son with those reporting one or more complications. As expected, higher scores on DQOL subscales were observed for patients with higher HbA_{1c} and FPG. According to the original conceptualiza-tion of the DQOL, a four-factor model was tested. The CFA results for the sample indicated that the four-factor model showed an acceptable fit; RMSEA = 0.071, χ^2 (776) = 2042.89, P-value <0.001, NNFI = 0.93, CFI = 0.94 and GFI = 0.91.

Table 1 | Demographic characteristic of patients

	n
Age (years)	59.25 (10.02)
Years of education	2.59 (3.82)
Sex	
Male	217 (43.14%)
Female	286 (56.85%)
Marital status	
Married	441 (87.67%)
Single	19 (3.77%)
Divorced/widowed	43 (8.54%)
Accommodation	
Urban	266 (52.88%)
Rural	237 (47.12%)
Employment status	
Employed	120 (23.85%)
Unemployed	383 (76.15%)
Monthly income	
Good (>$750)	205 (40.77%)
Moderate ($500–750)	236 (46.91%)
Poor (<$500)	62 (12.32%)
Diabetes complications	
Retinopathy	73 (14.51%)
Neuropathy	49 (9.74%)
Diabetic foot complications	51 (10.13%)
Cardiovascular complications	34 (6.75%)
Diabetes duration (months)	88.17 (57.83)
Glycated hemoglobin	8.11 (1.59)
Fasting plasma glucose (mg/dL)	156.87 (58.25)
Waist-to-hip ratio	0.893
Systolic blood pressure (mmHg)	146.31 (21.10)
Diastolic blood pressure (mmHg)	81.84 (13.54)
BMI (kg/m^2)	26.96 (4.72)
Treatment of diabetes	
Insulin	103 (20.47%)
Medication	249 (49.50%)
Lifestyle modification	107 (21.27%)
Lifestyle modification plus oral agents	44 (8.74%)

n = 503. BMI, body mass index.

Table 2 | Reliability of the Iranian version of the Diabetes Quality of Life questionnaire

Scale	ICC (*n* = 486) (95% CI)	Cronbach's alpha coefficient at baseline (*n* = 503)
Satisfaction	0.83 (0.81–0.86)	0.85
Impact	0.90 (89–95)	0.87
Diabetes-related worry	0.80 (0.82–0.85)	0.90
Social/vocational worry	0.93 (0.92–0.96)	0.86
Total DQOL	0.91 (0.90–0.96)	0.90

n = 503. DQOL, Diabetes Quality of Life questionnaire; ICC, intraclass correlation coefficient.

Table 3 | Pearson's correlation coefficients between the Diabetes Quality of Life questionnaire and the Short-Form Health Survey*

	Satisfaction	Impact	Diabetes-related worry	Social/vocational worry	Total DQOL
Physical functioning	−0.55	−0.84	−0.53	−0.49	−0.45
Role limitations due to physical health	−0.46	−0.77	−0.40	−0.43	−0.57
Role limitations due to emotional problems	−0.69	−0.46	−0.44	−0.55	−0.44
Bodily pain	−0.48	−0.63	−0.41	−0.52	−0.48
General health	−0.63	−0.62	−0.76	−0.52	−0.56
Social functioning	−0.40	−0.47	−0.63	−0.72	−0.58
Vitality	−0.54	−0.62	−0.41	−0.50	−0.46
Mental health	−0.64	−0.57	−0.43	−0.43	−0.49

$n = 503$. *All figures were significant at $P < 0.05$. DQOL, Diabetes Quality of Life questionnaire.

The interfactor correlation (IFr) ranged from $r = 0.25$ to $r = 0.77$. The highest IFr was observed between impact and satisfaction ($r = 0.77$), the lowest between impact and social/vocational worry ($r = 0.25$). All factor loadings were significant with standardized loadings ranging from 0.36 (for item 7 'satisfaction') to 0.98 (for item 1 'social/vocational worry'). Similarly, the largest and lowest residual variances were found for item 7 'satisfaction' (0.87) and item 1 'worry about the future effects of diabetes' (0.03).

The responsiveness of the DQOL to change was assessed in four interventional studies over a 6-month follow up. The results are listed in Table 5. All the DQOL subscales were sensi-

tive to interventions after adjusting for age, sex, education and diabetes duration with the exception of medication treatment.

DISCUSSION

Here, we present the results of a validation study of a translated Iranian version of the DQOL questionnaire in a clinical sample of Iranian patients with type 2 diabetes mellitus. Overall, the Iranian version of the DQOL proved to have acceptable psychometric properties and all patients found the translated items of the DQOL easy to understand.

Our findings showed that all domains of the DQOL had high internal consistency reliabilities. The internal consistencies were similar to those obtained for the original version of the DQOL, with Cronbach's α coefficients ranging from 0.66 to 0.92[29]. Similar findings were reported in other cross-cultural validation studies[40,46].

We also found the Iranian version of the DQOL to be stable across two assessment points over a 2-week interval. The agreement between the two assessments for all DQOL domains was excellent. Again, these results are comparable with the results obtained for the original DQOL, which proved to have good repeatability for all four subscales in patients with type 2 diabetes ($r = 0.78–0.92$)[29]. Similarly, another validation study carried out in Turkey reported a high reproducibility for the DQOL questionnaire over a 1-month interval[46].

As predicted, the correlations between all domains of the DQOL and all domains of the SF-36 were moderate to strong (r ranged from −0.401 to −0.842), showing the construct validity of the Iranian version of the DQOL. However, the correlations were negative as a result of the inconsistent scoring procedure of the DQOL and the SF-36. The strongest correlations were observed between the DQOL and the physical subscales of the SF-36 (i.e. physical function, role physical, bodily

Table 4 | Known-groups validity the Diabetes Quality of Life questionnaire

	Satisfaction†§	Impact*†‡§	Diabetes-related worry*†‡§	Social/vocational worry*†§	Total DQOL*†‡§
	Mean ± (SD)	Mean ± (SD)	Mean ± (SD)	Mean ± (SD)	Mean ± (SD)
BMI					
<24 ($n = 161$)	2.34 (0.65)	2.28 (0.65)	2.19 (0.75)	2.18 (0.94)	2.18 (0.94)
≥24 ($n = 342$)	2.44 (0.57)	2.51 (0.61)	2.32 (0.71)	2.34 (0.74)	2.34 (0.74)
Complications					
Absence ($n = 296$)	2.21 (0.57)	2.10 (0.57)	2.07 (0.72)	2.03 (0.84)	2.12 (0.57)
Presence ($n = 207$)	2.50 (0.56)	2.55 (0.57)	2.35 (0.72)	2.37 (0.93)	2.49 (0.58)
HbA$_{1c}$					
<7 ($n = 232$)	2.23 (0.60)	2.01 (0.66)	2.00 (1.04)	2.07 (1.14)	2.09 (0.81)
≥7 ($n = 271$)	2.42 (0.58)	2.35 (0.61)	2.31 (0.64)	2.29 (0.81)	2.30 (0.55)
Fasting plasma glucose (mg/dL)					
<110 ($n = 207$)	2.32 (0.52)	2.01 (0.66)	2.00 (1.04)	2.08 (1.14)	2.09 (0.81)
≥110 ($n = 296$)	2.42 (0.60)	2.35 (0.61)	2.39 (0.64)	2.43 (0.81)	2.37 (0.55)

$n = 503$. *Statistically significant according to Benjamini–Hochberg procedure for body mass index. †Statistically significant according to Benjamini–Hochberg procedure for complications. ‡Statistically significant according to Benjamini–Hochberg procedure for glycated hemoglobin (HbA$_{1c}$). §Statistically significant according to Benjamini–Hochberg procedure for fasting plasma glucose. DQOL, Diabetes Quality of Life questionnaire.

Table 5 | Diabetes Quality of Life questionnaire scores and type of treatment in baseline and follow up

Scale	Baseline (n = 503)	Follow up (n = 464)
Satisfaction		
Medication*	2.38 (0.59)	2.12 (0.84)
Insulin	2.39 (0.56)	2.21 (0.69)
Lifestyle modification*	2.38 (0.56)	2.17 (0.69)
Lifestyle modification plus oral agents*	2.35 (0.62)	1.21 (0.68)
Impact		
Medication*	2.36 (0.61)	2.26 (0.63)
Insulin	2.39 (0.59)	2.36 (0.59)
Lifestyle modification*	2.45 (0.59)	2.25 (0.69)
Lifestyle modification plus oral agents*	2.37 (0.63)	1.59 (0.68)
Diabetes-related worry		
Medication	2.21 (0.70)	2.14 (0.71)
Insulin	2.25 (0.70)	2.20 (0.72)
Lifestyle modification*	2.29 (0.66)	2.19 (0.62)
Lifestyle modification plus oral agents*	2.05 (0.72)	1.48 (0.77)
Social/vocational worry		
Medication	2.20 (0.86)	2.08 (0.86)
Insulin	2.29 (0.85)	2.23 (0.86)
Lifestyle modification*	2.38 (0.80)	2.23 (0.74)
Lifestyle modification plus oral agents*	2.38 (0.80)	1.45 (0.81)
Total DQOL		
Medication	2.31 (0.59)	2.15 (0.58)
Insulin	2.35 (0.58)	2.25 (0.60)
Lifestyle modification*	2.39 (0.56)	2.21 (0.54)
Lifestyle modification plus oral agents*	2.25 (0.61)	1.44 (0.53)

The data were adjusted for sex, educational status, age and diabetes duration. *Statistically significant according to Benjamini–Hochberg procedure. DQOL, Diabetes Quality of Life questionnaire.

pain and general health). It seems that the DQOL is more sensitive to the physical complications than the mental components. These results were also in accordance with findings from previous validation studies[30,40,46].

The Iranian version of the DQOL was also useful in distinguishing HRQOL between subgroups of patients based on BMI, complications, HbA_{1c} and FPG with notable differences[23,40,43]. HbA_{1c} is considered an indicator of diabetes control; that is, a lower level of HbA_{1c} is associated with a lower risk of diabetes complications[47]. Studies have shown that well-controlled diabetic patients experience fewer symptoms and complications, and therefore report better quality of life[48]. In the present study, patients with no or few complications reported better HRQOL for all DQOL domains. The original conceptualization of the DQOL as a four domain instrument has received some support from previous factor analytic studies[46]. Yet, these studies did not assume a prior structure for the DQOL (CFA), but carried out exploratory factor analysis (EFA)[46]. EFA is used to detect relationships between factors without previous assumption of a theoretical model. Therefore, EFA serves as a model-generating or structure-generating procedure, as it does not assume any

definite model and all variables are allowed to load on all factors[47,49]. In order to validate the translated questionnaire version, it is crucial that the DQOL is tested according to the original factor-supposition[29]. We therefore carried out a CFA to assess factorial validity of the DQOL based on the originally-hypothesized four-factor structure, which we were able to confirm as the best-fitting model. To the best of our knowledge, so far no study has tried to replicate the factor structure of the original DQOL using CFA. Therefore, comparison and validity of the present results with other cross-cultural validation studies is difficult. However, in a Turkish validation study of the DQOL, a four-factor model was identified using EFA[46]. In the present study, responsiveness to interventions was examined to detect HRQOL changes over a period of 6 months. DQOL in all domains decreased (i.e. improved) from baseline to the follow up for all four tested interventions, apart from insulin therapy intervention, which did not yield a significant effect on any of the domains. A potential reason is that insulin treatment requires a high compliance and daily planning; and, as a result of the invasive nature of the treatment, it might cause further anxiety and fear in patients, and therefore increase instead of decrease DQOL scores[50]. In contrast, insulin therapy is a costly remedy. Nevertheless, the present results support the sensitivity of the DQOL and its subdomains to change over time.

The present study had some limitations. The study sample was selected using a convenience sampling approach. Therefore, generalizability of the sample to the general population or other clinical samples is not recommended. Second, the study only assessed the midterm outcome of the applied interventions on DQOL domains. Thus, effectiveness of long-term interventions needs to be further evaluated. Furthermore, in regards to the interventions, no control group was considered, so these results should be interpreted with caution.

In conclusion, the translated Iranian version of DQOL has shown high internal reliability and good construct validity, and can potentially be applied as an assessment tool for health-related quality of life in patients with diabetes.

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