



Predictors of health-related quality of life among Iranian people with type 2 diabetes

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ABSTRACT

Introduction: Diabetes is a common disease with several macro-vascular and microvascular complications, which can result in long-term damage of various organs. Health-related quality of life (HRQOL) is commonly impaired in patients suffering from prolonged diseases. Inadequate attention to HRQOL leads to decreased compliance with treatment and health-care interventions. **Objectives:** This study was aimed to identify possible determinants of HRQOL in Iranian people with type 2 diabetes mellitus (T2DM).

Patients and Methods: A cross-sectional study of 160 patients with T2DM registered at endocrinology clinic of the Alzahra teaching hospital of Isfahan university of medical sciences, Iran, was conducted in 2019-2020. HRQOL was measured using the Short Form 36 Health Survey Questionnaire (SF-36). Multivariate linear regression models were used to analyze the variables associated with HRQOL.

Results: A total of 160 patients took part in this study. The mean age of the respondents was 59.3 (9.9) years. Around 107 patients (66.9%) were women. The mean (SD) for sub-scales of SF-36 in all patients were physical functioning 57.1(32.5), role limitation due to physical health 62.4 (42.1), role limitation due to emotional health 82.3 (35.8), energy/fatigue 58.8 (21.4), emotional well-being 72.5 (17.5), social functioning 80.4 (28.3), pain 70.5 (26.9) and general health 46.9 (26.3). The most common factors contributing to lower SF-36 subscales were being female, having a higher body mass index (BMI), and having macro-vascular complications.

Conclusion: HRQOL among Iranian people with T2DM is mostly influenced by gender, weight, and diabetes complications. By reducing complications of diabetes, especially macrovascular complications, and implementing obesity prevention policies, HRQOL could be improved. A patient-centered approach is needed to improve HRQOL for each patient.

Implication for health policy/practice/research/medical education:

Diabetes is a disease that can damage several organs over time. Long-term diseases like diabetes commonly impair patients' health-related quality of life (HRQOL). A poor HRQOL leads to decreased compliance with healthcare interventions and treatment. Our study showed that HRQOL among Iranian people with diabetes is mostly influenced by gender, weight, and diabetes complications. By reducing complications of diabetes, especially macro-vascular complications, and implementing obesity prevention policies, HRQOL could be improved. A patient-centered approach is needed to improve HRQOL for each patient.

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Introduction

Non-communicable disease like heart disease and diabetes are the primary causes of death (1). The global burden of these diseases is high, particularly in middle- and low-income countries (1,2). Over the past decade, diabetes has become more prevalent due to rapid urbanization, lifestyle changes and aging (3). In 2013, it was estimated that 8.3% (382 million people) of the world's population suffer from diabetes (4). Globally, diabetes is anticipated to reach 592 million by 2035 (4).

Diabetes is associated with several macro-vascular and microvascular complications caused different types of organ failure and damage (5,6). Most complications are preventable and a combination of life style modification and medication to achieve metabolic control is the cornerstone of treatment (5,6). The goals of treatment are to prevent or delay complications and maintain quality of life.

Quality of life is explained by the World Health Organization (WHO) as a person's realization of

their state in life regarding their context, values of the civilization they live in, their goals, expectations and standards in the context of the culture values they live in (7). Chronic diseases including diabetes, could decrease the overall health of patients by limiting their capacity to live well, reducing their functional status, productivity, and Health-related quality of life (HRQOL). HRQOL usually is measured in long-term disease. Chronicity, complications, dietary restrictions, and daily medication could negatively impact the quality of life of individuals with lengthy diseases.

Objectives

Inadequate attention to quality of life leads to life dissatisfaction, decreased social activity and decreased compliance with treatment and healthcare interventions. This study was designed to evaluate associated factors of quality of life among people with type 2 diabetes mellitus (T2DM) in Isfahan county in 2019-2020.

Patients and Methods

The present research is a cross-sectional study performed at the endocrinology clinic of Alzahra hospital, a large and referral hospital in Isfahan, central region of Iran, in 2019-2020. The patients with T2DM were included by continuous enrollment if they consent to join in this investigation.

The inclusion criteria were a diagnosis of T2DM by an experienced internist or endocrinologist for at least 1 year and a signed informed consent form in accordance with the Helsinki declaration by patient. The exclusion criteria were age under 18 years, diagnosis of maturity-onset diabetes of the young, gestational diabetes mellitus, type 1 diabetes mellitus, diabetes secondary to endocrinopathies or pancreatic exocrine disorders, as well as history of cognitive impairment or substance abuse.

Data collection

Patients were asked to fill out two self-checked questionnaires: 1) A questionnaire was developed by the research team which included questions about demographics and baseline characteristics of patients including age, gender, literacy and education level, living area (urban or village), home ownership status, smoking history, height and weight and 2) the SF-36, 36-item short form survey, which is a HRQOL questionnaire which contains eight scales including role limitations due to physical health problems (RP), bodily pain (BP), physical functioning (PF), role limitations due to emotional problems (RE), social functioning (SF), general mental health (MH), general health perceptions (GH) and vitality or energy/fatigue (VIT). If the person was illiterate, the forms were completed by the researchers based on their answers. The researchers extracted some clinical data from the patients' files, including duration of diabetes, existing macrovascular or microvascular complications

and treatment type.

According to self-reported height and measured weight, body mass index (BMI) was determined by dividing the weight in kilograms by the height squared; it was demarcated as normal weight, overweight and obese by values of 18.5–24.9 kg/m², 25–29.9 kg/m² and ≥ 30 kg/m², respectively (8); Macrovascular complications were divided into coronary artery disease (angina, congestive heart failure, myocardial infarction and revascularization surgery) and cerebrovascular disease (stroke and transient ischemic attack). Microvascular complications were categorized into retinopathy, nephropathy and neuropathy.

We used the Persian translated version of SF-36 questionnaire provided by Montazeri et al (9) which had a very desirable internal reliability (Cronbach's alpha = 0.77–0.90). The raw score of each scale was transformed into a 0–100 scale, in which a higher score corresponds to a greater state of health.

Statistical analysis

All data were quantified and documented into by the Statistical Package for Social Sciences (SPSS®) software for Windows®, version 25, (SPSS Inc., Chicago, IL, USA). Continuous and categorical variables were described with mean (standard deviation) and number (%), respectively. Continuous data were compared between different groups using analysis of variance (ANOVA). Chi-square test was conducted to analyze the difference of categorical data. Factors influencing subscales of quality of life of individuals with T2DM were analyzed using regression analysis. Statistically significant results were defined as those with *P* values below 0.05.

Results

A total of 160 patients took part in this study. 107 patients (66.9%) were women and 53 patients (33.1%) were men. The mean (SD) age of all people was 59.3 (9.9) years. Baseline clinical and demographic characteristics of patients with T2DM were shown in Table 1. The majority of the patients were married (85.6%) with education levels under high school (88.2%), living in urban areas (86.9%) with family (91.9%) in their own home (81.2%) and also, most of the patients had BMI more than 25 kg/m² (82.5%). The proportion of patients received oral medications, insulin and combination of insulin and oral medications were 44.2%, 19.5% and 36.4%, respectively. In addition, baseline characteristics according to gender were shown in Table 1. Males and females were different in educational level, marital status, smoking, BMI and types of microvascular complications. Men were more educated, married, smoker and suffered nephropathy than women. On the other hand, female was dominant in BMI greater than 25 kg/m². Distribution of SF-36 subscales among respondents according to patient and disease-related characteristics was shown in Table 2. The gender of the patient, macrovascular complications and

Table 1. Baseline demographic and clinical characteristics of patients with T2DM according to the gender

Variable	Category	Group			P [*]
		Overall (n=160)	Men (n=53)	Women (n=107)	
Age (y)	<40	7(4.4%)	2 (3.8%)	5 (4.7%)	0.96
	≥40 &<60	73(45.6%)	24 (45.3%)	49 (45.8%)	
	≥60	80(50.0%)	27 (50.9%)	53 (49.5%)	
Literacy	Illiterate	63 (39.4%)	9 (17%)	54 (50.5%)	<0.001
	Under high school	78 (48.8%)	30 (56.6%)	48 (44.8%)	
	Diploma or higher	19 (11.8%)	14 (26.4%)	5 (4.7%)	
Obesity status (BMI category)	Normal weight	28 (17.5%)	12 (22.6%)	16 (15%)	0.028
	Overweight	64 (40.0%)	27 (51%)	37 (35%)	
	Obese	67(42.5%)	14 (26.4%)	53 (50%)	
Marital status	Single	3(1.9%)	1 (1.9%)	2 (2%)	0.017
	Married	137(85.6%)	51 (96.2%)	86 (80.3%)	
	Widowed	20(12.5%)	1 (1.9%)	19 (17.7%)	
Living area	Urban	139(86.9%)	45 (84.9%)	94 (87.8%)	0.60
	Village	21(13.1%)	8 (15.1%)	13 (12.2%)	
Home ownership	Owned	130(81.2%)	45 (84.9%)	85 (79.4%)	0.21
	Rented	30(18.8%)	8 (15.1%)	22 (20.6%)	
Roommate status	With family	147(91.9%)	50 (94.3%)	97 (90.7%)	0.42
	Alone	13(8.1%)	3 (5.7%)	10 (9.3%)	
Smoking	Yes	11(6.9%)	7 (13.2%)	4 (3.7%)	0.026
	No	149(93.1%)	46 (86.8%)	103 (96.3%)	
Duration of DM (y)	<10	80 (50.0%)	23 (43.3%)	57(53.3%)	0.238
	10-20	65(40.6%)	26 (49.0%)	39(36.4%)	
	>20	15(9.4%)	4(7.7%)	11(10.3%)	
Macrovascular C	CAD	39(24.4%)	12(22.6%)	27(25.2%)	0.719
	CVA	6(3.8%)	1(1.9%)	5(4.7%)	0.383
Microvascular C	Nephropathy	94(60.3%)	37(71.2%)	57(54.8%)	0.049
	Neuropathy	108(67.5%)	34(64.2%)	74(69.2%)	0.524
	Retinopathy	63(39.9%)	22(41.55%)	41(39%)	0.765
Treatment	Insulin	33(20.6%)	10(18.9%)	23(21.5%)	0.279
	ODM	70(43.8%)	20(37.7%)	50(46.7%)	
	Insulin + ODM	57(35.6%)	23(43.4%)	34(31.8%)	

Data are presented as number (percentage). T2DM: type 2 diabetes, BMI: body mass index, C: complication, CAD: coronary artery disease, CVA: cerebrovascular disease, ODM: oral diabetes medication.

* The difference of the variables between the two genders was analyzed using chi-square test for categorical data.

BMI had an important influence on most of the subscales of quality of life. Individuals with higher BMI, female patients, and those with macrovascular complications had lower average scores on the whole SF-36 component. Age, married status and level of education had an influence on some of the sub-scales of quality of life. Some variations including duration of diabetes, smoking, type of treatment for T2DM, area where the patient lives, being owner of home, and microvascular complications had no impact on the quality of life. The mean (SD) for sub-scales of SF-36 in all patients were physical functioning 57.1 (32.5), role limitation due to physical health 62.4 (42.1), role

limitation due to emotional health 82.3 (35.8), energy/fatigue 58.8 (21.4), emotional well-being 72.5 (17.5), social functioning 80.4 (28.3), pain 70.5 (26.9) and general health 46.9 (26.3).

The influence of all variables listed in Table 1 on SF-36 sub-scales was presented in Table 3. A multiple regression was run to predict quality of life score from mentioned variables. The β coefficient in the present of $P<0.05$ simply states that with one unit increase in the independent variable, how much does the dependent variable (any component of the SF-36) change. The increase in one unit of the categorical data is equivalent to change from

Table 2. Distribution of SF-36 scales among patients with T2DM according to demographic and clinical characteristics

Variable	PF	RP	RE	EF	EW	SF	P	GH
Age (y)								
<40	76.4 (35.4)	82.1 (31.3)	80.9 (37.8)	53.6 (34.1)	71.4 (23.9)	73.2 (38.4)	77.8 (34.7)	37.8 (30.9)
40-60	67.4 (29.2)	65.8 (42.2)	83.6 (34.7)	60.8 (21.2)	71.5 (17.3)	81.7 (26.8)	73.9 (27.1)	48.5 (26.1)
>60	46.0 (31.7)	57.5 (42.4)	81.3 (37.1)	57.5 (20.5)	73.5 (17.1)	79.7 (28.9)	66.7 (25.7)	46.2 (26.2)
P value ^a	<0.001	0.214	0.920	0.506	0.771	0.723	0.193	0.563
Gender								
Men	69.7 (31.5)	75.5 (37.8)	93.1 (23.9)	68.9 (20.3)	76.7 (18.3)	84.8 (25.0)	80.3 (25.3)	56.5 (25.7)
Women	50.8 (31.3)	55.8 (42.7)	76.9 (39.5)	53.8 (20.2)	70.4 (16.6)	78.1 (29.6)	65.6 (26.4)	42.1 (25.3)
P value ^b	<0.001	0.005	0.007	<0.001	0.030	0.164	0.001	0.001
Literacy								
Illiterate	45.8 (31.8)	54.8 (43.3)	81.2 (37.0)	53.2 (18.7)	69.2 (16.0)	77.4 (29.7)	65.2 (26.2)	41.7 (25.3)
Under diploma	62.4 (30.3)	63.8 (41.6)	79.9 (37.3)	60.2 (22.8)	73.1 (18.7)	79.4 (29.5)	71.8 (26.9)	49.5 (25.3)
≥Diploma	76.1 (30.1)	82.4 (36.2)	94.1 (24.2)	72.3 (18.6)	80.5 (15.1)	94.1 (11.8)	81.6 (27.3)	51.8 (32.4)
P value ^a	<0.001	0.053	0.334	0.003	0.054	0.095	0.063	0.153
BMI (kg/m ²)								
Normal	66.6 (36.6)	75.0 (39.2)	86.4 (31.0)	60.9 (25)	77.8 (16.1)	83.8 (28.7)	74.5 (27.8)	55.7 (22.5)
Over weight	67.4 (30.2)	71.4 (40.3)	84.1 (35.8)	65.1 (19.1)	73.9 (18.6)	81.8 (28.1)	80.1 (25.2)	53.9 (26.8)
Obese	45.4 (29.2)	48.5 (41.0)	78.6 (38.4)	51.6 (20.0)	68.6 (16.1)	77.8 (28.0)	59.5 (23.9)	35.9 (23.2)
P value ^a	<0.001	0.001	0.549	0.001	0.044	0.571	0.000	<0.001
Marital status								
Single	68.3 (50.6)	83.3 (28.9)	100.0 (0.00)	48.3 (17.5)	73.3 (15.1)	58.3 (38.2)	81.7 (31.7)	48.3 (12.5)
Married	59.5 (32.0)	63.3 (42.1)	81.5 (36.6)	59.4 (21.9)	72.5 (17.7)	80.5 (27.8)	72.4 (26.3)	47.4 (26.2)
Widowed	39.0 (28.8)	52.5 (42.8)	85.0 (33.3)	56.7 (18.2)	72.4 (16.8)	82.5 (30.2)	55.7 (26.9)	43.2 (28.9)
P value ^a	0.025	0.386	0.637	0.611	0.996	0.382	0.026	0.805
Living area								
Urban	56.7 (32.6)	63.7 (41.7)	80.6 (37.2)	59.4 (21.4)	73.2 (17.0)	80.4 (28.0)	70.5 (27.2)	48.0 (26.1)
Village	58.0 (32.8)	53.6 (44.2)	93.6 (22.6)	55.2 (21.3)	68.0 (19.6)	79.8 (30.5)	70.2 (24.9)	39.5 (26.7)
P value ^b	0.888	0.310	0.120	0.411	0.206	0.919	0.967	0.170
Home ownership								
Owner	57.3 (33.3)	62.9 (42.5)	81.8 (36.4)	60.1 (21.3)	73.4 (16.8)	81.6 (27.8)	71.9 (26.6)	47.1 (26.3)
Rented	56.8 (30.5)	60.2 (40.6)	82.7 (35.0)	52.2 (21.8)	67.1 (20.3)	71.9 (30.6)	62.5 (28.0)	44.9 (26.7)
P value ^b	0.951	0.310	0.120	0.411	0.206	0.919	0.967	0.170
Roommate status								
With family	58.7 (32.0)	63.4 (42.2)	82.1 (35.8)	59.3 (21.7)	72.5 (17.5)	81.2 (27.6)	71.2 (27.0)	47.3 (26.2)
Alone	39.1 (34.0)	50.0 (39.6)	84.6 (37.5)	53.1 (17.0)	72.0 (17.6)	70.2 (34.4)	62.3 (24.0)	41.5 (28.2)
P value ^b	0.038	0.273	0.808	0.313	0.915	0.178	0.255	0.446
Smoking								
Yes	52.7 (35.9)	72.7 (46.7)	69.7 (45.8)	85.2 (28.6)	72.7 (18.8)	80.7 (25.8)	67.7 (32.9)	48.6 (22.2)
No	57.4 (32.3)	61.6 (41.7)	83.2 (35)	58.9 (20.9)	72.5 (17.4)	80.3 (28.5)	70.7 (26.5)	46.7 (26.6)
P value ^b	0.646	0.399	0.228	0.917	0.964	0.968	0.727	0.820
Duration of DM (y)								
<10	59.0 (32.5)	62.8 (42.0)	82.5 (37.7)	57.8 (22.6)	71.7 (17.8)	81.8 (26.5)	68.2 (29.0)	45.1 (26.1)
10-20	55.2 (32.2)	60.8 (42.1)	79.5 (39.4)	58.5 (20.7)	71.9 (18.1)	77.9 (28.9)	71.2 (24.8)	48.3 (27.5)
>20	60.0 (31.9)	73.2 (39.8)	92.9 (26.7)	68.2 (17.4)	81.1 (10.1)	91.9 (23.8)	80.0 (22.5)	53.6 (21.9)
P value ^a	0.747	0.603	0.454	0.242	0.164	0.212	0.313	0.498

Table 2. Continued

Variable	PF	RP	RE	EF	EW	SF	P	GH
Treatment								
Insulin	53.0 (32.3)	50.0 (43.3)	77.8 (41.2)	54.8 (21.7)	68.7 (18.3)	73.6 (31.4)	69.6 (30.9)	45.1 (27.0)
ODM	61.4 (31.4)	67.5 (40.0)	82.8 (34.3)	60.1 (20.9)	74.4 (16.1)	82.7 (28.4)	71.6 (26.1)	48.5 (25.8)
Insulin + ODM	54.1 (33.9)	63.2 (43.0)	84.8 (34.5)	59.7 (21.8)	72.3 (18.4)	81.3 (26)	69.6 (25.7)	45.9 (26.8)
P value ^a	0.332	0.142	0.586	0.475	0.307	0.295	0.896	0.782
Macrovascular complication								
Yes	36.3 (26.0)	39.6 (41.0)	66.7 (45.3)	52.4 (20.8)	69.7 (17.6)	67.7 (32.9)	56.8 (22.0)	36.6 (24.3)
No	64.3 (31.5)	70.2 (39.6)	87.7 (30.3)	61.0 (21.3)	73.6 (17.3)	84.7 (25.2)	75.7 (26.9)	50.4 (26.1)
P value ^b	<0.001	<0.001	0.008	0.025	0.183	0.004	<0.001	0.003
Microvascular complication								
Yes	54.5 (31.9)	59.7 (42.6)	81.5 (36.8)	58.3 (20.8)	72.8 (16.8)	79.8 (28.9)	69.7 (26.0)	45.0 (25.7)
No	66.6 (33.6)	72.1 (38.8)	85.3 (32.0)	60.6 (23.7)	71.4 (19.7)	82.4 (26.0)	73.2 (30.2)	53.7 (27.6)
P value ^b	0.055	0.129	0.584	0.592	0.683	0.629	0.501	0.088

BMI: body mass index, ODM: oral diabetes medication, PF: physical functioning, RP: role limitation due to physical health, RE: role limitation due to emotional health, EF: energy/fatigue, EW: emotional well-being, SF: social functioning, P: pain, GH: general health.

Data are presented as mean (standard deviation).

^a P value was calculated with variance analysis. ^b P value was calculated with independent *t* test.

one category onto the next (below) in order presented in Table 1. The findings of Table 3 showed that quality of life was influenced most by gender and macrovascular complications, as well as BMI. Being female, having a higher BMI, and having macrovascular complications all lowered the quality of life score.

Discussion

The present research aimed to assess the significant factors that influence the quality of life of Iranian patients with T2DM. Diabetes and patients' quality of life can affect each other's. The patients have more energy to take care of themselves when they have positive feelings about

Table 3. Patient's characteristics and SF-36 subscales (multivariate regression analysis)

QOL component	Variable	β coefficient	P value
Physical functioning	Age	-0.939	0.002
	Gender	-16.298	0.005
	BMI	-1.436	0.001
	Macrovascular complication	-19.855	<0.001
Role limitation due to physical health	BMI	-1.279	0.046
	Macrovascular complication	-28.502	<0.001
Role limitation due to emotional health	Gender	-18.827	0.015
	Macrovascular complication	-18.288	0.012
Energy/Fatigue	Gender	-10.968	0.010
	BMI	-0.968	0.002
	Literacy	6.634	0.024
Emotional well-being	BMI	-0.968	0.015
	Literacy	6.450	0.012
Social functioning	Macrovascular complication	-17.170	0.001
	Marital status	8.071	0.033
Pain	BMI	-1.313	0.001
	Macrovascular complication	-14.531	0.003
General health	Duration of T2DM	8.121	0.017
	BMI	-1.590	<0.001
	Macrovascular complication	-13.185	0.006

QOL: quality of life, BMI: body mass index.

The only variables with significant *P* value reported.

their life. In this manner, for a long time, when they take care of themselves more, the quality of their lives will improve, because they will be healthier. On the other hand, inadequate attention to quality of life can lead to depression and a lack of perseverance in maintaining the needed treatment and monitoring (10). Therefore, it is important to investigate how diabetes may affect different aspects of health, and which aspects of a person's quality of life are affected primarily by diabetes.

This study showed that male patients have higher quality of life than female patients. This finding is consistent with other studies of similar patients (11-14). In a study done in Greece, SF-36 scores for women in all domains indicated remarkably lower quality of life and multivariate analyses for the SF-36 displayed that female gender had the greatest negative effect on HRQOL (14).

To exclude the effects of other sociodemographic factors on quality of life in women like lower level of education or higher average BMI than men, the effect of being female was investigated after adjusting for other sociodemographic factors (Table 3). Results showed being female was negatively associated with several aspects of quality of life. It indicates that women with diabetes need more attention and a special program for bettering their quality of life, including investing in education, should be developed. By educating women, they can improve their health literacy, which will enable them to take better care of themselves.

Lower quality of life in individuals with higher BMI was another finding of this study. In our study obese patients had low ratings in the all aspects of HRQOL except social functioning.

Studies indicate that obesity negatively affects HRQOL not only for people with T2DM but for general population as well (15-17). Regular exercise and weight loss were shown to be effective to improve the functional or emotional status of patients with T2DM (12,18,19). In this study, lower education level, being divorced or widowed and older age were negatively related to several aspects of quality of life. Prior researchers in a number of countries have confirmed these results (11,20). A report in Korea stated being single and having less than a high school education could predict poor HRQOL (20). Among French people with T2DM, older age, macrovascular complications, female gender, a higher BMI were linked to lower HRQOL (21). In our study, existing macrovascular complications were combined with lower values in all scales of quality of life which all were significant except for emotional well-being (Table 2). A study done in Serbia reported chronic diabetes complications including microvascular and macrovascular complication were the most important factors affecting the HRQOL (22). Some studies concluded that macrovascular events can have both immediate and long-term effects on HRQOL (23,24). A study has found that macrovascular complications are correlated with a decline in HRQOL in patients with

T2DM, but only part of the total impaired quality adjusted life year is experienced during the first year following an event. Macrovascular complications changed quality of life in the years following disease onset as well (23).

Conclusion

HRQOL among Iranian people with T2DM is mostly influenced by gender, weight, and diabetes complications. Consequently, the appropriate strategies are necessary to promote the quality of life in Iranian individuals with T2DM. By reducing complications of diabetes, especially macrovascular complications, and implementing obesity prevention policies, HRQOL could be improved. A patient-based approach should be assessed to improve HRQOL for each patient and decrease the weight of diabetes.

Limitations of the study

This study has some strengths and limitations. To our best knowledge it is the first study to investigate HRQOL of patients with T2DM in the center of Iran, Isfahan county. We collect complementary data about sociodemographic characteristic of patients including education level, marital and roommate status. There were some limitations in this study. The present study was designed as a cross-sectional study, and without longitudinal data, it is difficult to establish a cause and effect relationship between HRQOL and sociodemographic factors. In addition, this study assessed HRQOL at a point in time, and measured HRQOL may fluctuate at different points in time.

Authors' contribution

RS was the principal investigators of the study. MA, RSS and RS were included in preparing the concept and design. MA and RS revisited the manuscript and critically evaluated the intellectual contents. All authors participated in preparing the final draft of the manuscript, revised the manuscript and critically evaluated the intellectual contents. All authors have read and approved the content of the manuscript and confirmed the accuracy or integrity of any part of the work.

Conflicts of interest

The authors declare that they have no competing interests.

Ethical issues

Informed consent was obtained from all study participants. The research followed the tenets of the Declaration of Helsinki. The Ethics Committee of Isfahan University of Medical Sciences approved this study (Ethical code#IR.MUI.REC.1398.049). Accordingly, written informed consent was taken from all participants before any intervention. This study was extracted from the postdoctoral thesis of Maryam Alamdari at this university (Thesis# 398050). Moreover, Ethical issues (including plagiarism, data fabrication and double publication) have

been completely observed by the authors.

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