

Predicting the Quality of Life in Patients With Painful Diabetic Neuropathy (PDN) Based on Pain Severity, Pain Catastrophizing, Pain Acceptance, Depression, Anxiety, and Sleep Disturbance: Assessing the Prevalence of Psychiatric Symptoms in Iranian Patients With PDN.

Parnian Rezaei

Shahid beheshti university

Fereshteh Rajaeiramsheh

University of Social Welfare and Rehabilitation Science

Mohammadreza Davoudi (✉ davoudi.phd.psy@gmail.com)

Ph.D. candidate of clinical psychology, department of clinical psychology, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran <https://orcid.org/0000-0003-0352-0290>

Amir Abbas Taheri

Kermanshah University of Medical Sciences

Research

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Abstract

Background: This study aimed to predict the quality of life in patients with Painful Diabetic Neuropathy (PDN) based on pain severity, pain catastrophizing, pain acceptance, depression, anxiety, and sleep disturbance. Also, assessing the prevalence of psychiatric symptoms in Iranian patients with PDN.

Method: In this descriptive correlational study, 1500 MTBI patients admitted to the diabetes centers in Tehran, Iran, from November 2019, to August 2020 were selected using the convenient sampling method. One thousand one hundred twenty patients (mean age, 53.6 ± 12.6 years) participated in the research. Data were collected using the Quality of life (NeuroQol) questionnaire (as a dependent variable); Beck Depression Inventory, Beck Anxiety Inventory, 10-cm visual analog scale (pain severity), Pain Catastrophizing Scale (PCS), Chronic Pain Acceptance Questionnaire (CPAQ) and Pittsburgh Sleep Quality Index (PSQI). Finally, the data were analyzed in SPSS-26 by multiple regression analysis.

Results: The study results showed that the regression model was significant ($P < 0.5$), in which variables predicted 42% of total changes in the quality of life in patients. Predicting factors from the most significant to the lowest include depression, pain catastrophizing, pain acceptance, pain severity, sleep disturbance, and finally, anxiety. Also, in patients with PDN, the prevalence rates of sleep disturbances, depression, and anxiety are 85.5%, 68.2%, and 62.1%, respectively. Also, comorbid depression and anxiety were found in 47% of patients.

Conclusion: The findings of this study show a considerable relationship between these factors and quality of life. Thus, it is suggested to design more specific psychological-based rehabilitation programs concerning these variables to improve these patients' quality of life, focusing on stronger variables (depression and pain catastrophizing) for reaching better treatment outcomes. Furthermore, according to the findings of this research, which shows a high level of anxiety, depression, and sleep disturbance in Iranian patients with PDN, all experts and clinicians must focus on these psychiatric symptoms to reduce disease problems.

Introduction

Diabetes has been known as the silent killer(1). This permanent disease happens when the pancreas gland is no longer capable of making insulin or when the body cells don't respond properly to the insulin that pancreas produces(2). The International Diabetes Federation (IDF) reported that more than 436 million people have diabetes globally (2, 3). Diabetes is associated with a wide range of health problems. Some of its symptoms, signs, and complications are fatigue, irritability, frequent infections, ketoacidosis, brain ischemia, nephropathy, and mental health problems (4, 5).

Among the various problems in diabetic patients, painful diabetic neuropathy (PDN) needs extensive attention. Peripheral neuropathic pain is a pain that rising as a straight consequence of the disease or lesion affecting the peripheral nervous system (PNS) (6). More than 30% of diabetic patients develop

PDN. Patients with PDN report a stinging, burning, and keen sensation that increases at night with a loss of sensation or numbness of the involved area (6, 7).

The chronic nature of diabetes reduces the patients' Quality of life (Qol). In addition to these problems, patients with PDN also experience severe pain. The main reason for experiencing disability and thus reducing Qol, is pain and pain-related symptoms in these patients. This pain occurs in varying degrees and intensifies at night. Due to its debilitating properties, neuropathic pain causes dissatisfaction, fatigue, and distress; ultimately reduces the Qol of these patients much more than diabetic patients without neuropathy (6, 8).

In addition to the severity of pain, the interpretation of pain and its consequences in everyday life are used to deal with pain. Pain Catastrophizing is associated with the mental sensation of losing physical activity due to pain severity. So, the estimated level of disability due to pain is much higher than the actual level (9). Pain catastrophizing is associated with increased disability and decreased Qol in patients with PDN (9). Pharmacological and psychological interventions, at best, relieve only 50% of pain severity (10). Therefore, pain acceptance and reducing pain catastrophizing decrease the severity of disability caused by this attitude; thus widely improve the Qol (11, 12). Extensive studies have examined the effectiveness of various treatment methods to improve the Qol of patients with PDN because the primary purpose of diabetes early diagnosis and treatment is to improve the Qol in these patients (12, 13). There are several definitions of Qol. However, all of them agree that Qol is multidimensional. Qol consists of four components: physical, psychological, cognitive, and social. In terms of physical components, pain relief medications and physical rehabilitation interventions have been successful. The psychological nature of Qol has complex components (9, 14). According to previous studies, patients with PDN have a high rate of psychological problems that reduce Qol. Depression and anxiety are the most common psychiatric problems in patients with PDN. These symptoms reduce the life expectancy of people with PDN and reduce treatment effectiveness (15). In these patients, the rates of depression and anxiety are reported to be between 15% and 50% and between 8% and 60%, respectively; also, more than 35% of patients with PDN experience comorbid depression and anxiety (16). According to various studies, the presence of these symptoms leads to a severe reduction in Qol (16, 17). Other prevalent problems in these patients are sleep-related problems. According to recent studies, more than 40% of patients with PDN have severe sleep-related problems. Sleep problems are highly correlated with decreased Qol in these patients. Also, the lack of improvement in sleep problems is an obstacle to improving other symptoms in these patients (16). Overall, problems related to pain, depression, anxiety, and sleep disturbance lead to a severe decline in Qol (as a primary goal of therapeutic interventions) in patients with PDN. However, various studies have targeted a number of these symptoms in various ways (6, 8, 11, 14). Therefore, the contribution of each one in reducing these patients' Qol has not been determined. It has been associated with limitations such as meager sample size (less than 60 people) (18, 19), failure to conduct individual interviews (9), and lack of examination in psychological variables (20). On the Qol, a better understanding of factors related to Qol is gained in this study. Specialists can also select more critical therapeutic targets. In Iran, the prevalence of diabetes is more than 15% in the general population (21). However, few studies have been performed on PDN. So far, no study has determined the prevalence of these psychiatric

problems (depression, anxiety, and sleep problems) in these patients in Iran. Therefore, in this study, the prevalence of these problems will be examined as a pilot study. So, the study aimed to predict the QoL in patients with PDN based on pain severity, pain catastrophizing, pain acceptance, Depression, Anxiety, and sleep disturbance. Then, assessing the prevalence of psychiatric symptoms in Iranian patients with PDN.

Methods

Study Design

This descriptive cross-sectional investigation was conducted on all patients with PDN admitted to the Diabetes centers in Tehran Province, Iran. Then, 1500 patients with PDN were selected using the convenience sampling method.

Research criteria

Inclusion criteria consist of (1) Willingness to participate in research, (2) age range 18 to 70 years, (3) Diagnosed with PDN by a neurologist, (4) No history of hospitalization in psychiatric wards, and (5) No history or current diagnosis of substance abuse. Exclusion criteria: (1) dissatisfied with entering the research for any reason, and (2) Failure to complete the questionnaires.

Procedure

Based on the convenience sampling method, 1500 patients with PDN were selected to participating in this research. All of these patients had medical records in one of the specialized diabetes treatment centers in Tehran Province. All of them had received PDN diagnosis and were under treatment. One thousand five hundred patients were contacted. Extensive explanations were given about the study. Then each individual was given an appointment at the clinic to complete the tools of the research. The researchers utilized an anonymous paper survey for gathering data from November 1, 2019, to August 1, 2020. After screening based on criteria, an appointment was made for each patient. These sessions were held by five psychologists separately (to speed up the implementation process).

Patients separately answered the questionnaire booklet under the five psychologists' administration and supervision (blinded about research aims). Besides, written informed consent was taken from all patients.

Assessments

Quality of life: The Neuropathy Specific Quality of life questionnaire (NeuroQoL) is an appropriate validated measure for neuropathic QoL that has 27 items. NeuroQoL assesses diabetic neuropathy-related emotional and physical problems affecting diurnal life and well-being. NeuroQoL consists of painful symptoms, dependence on others, emotional distress, unsteadiness while walking or standing, restriction in daily activities, paresthesia, interpersonal problems, and Etc. NeuroQoL reliably captures the critical aspects of the patients' experience of PDN and is a valid instrument for examining the impact of neuropathy on QoL (22). The reliability of the subscales ranged from 0.86 to 0.95. As four items repeated

in more than one subscale, the total score is 31 to 155. Persian Version of NeuroQol has demonstrated high psychometric properties with Cronbach Alpha 0.87 that assessed by authors of current paper

Pain Severity: The severity of pain of the subjects was assessed by a 10-cm visual analog scale (VAS) where the "0" means not feeling any pain, and "10" shows unbearable severe pain (23).

Pain catastrophizing: Pain Catastrophizing Scale (PCS) was used to assess pain catastrophizing in PDN patients. The PCS is a 13-item self-report scale developed to assess individuals' rate of catastrophic beliefs related to painful experiences. PCS ranged on a 5-point Likert scale (0 = not at all to 4 = always). Higher scores mean greater pain catastrophizing. The PCS has shown good psychometric properties for clinical /non-clinical Iranian samples (Cronbach's alpha=0.88) (24, 25).

Pain Acceptance: Chronic Pain Acceptance Questionnaire (CPAQ) was used to assess pain acceptance. The CPAQ is a 20 item assessment tool for chronic pain that each subject should answer to every item using a 7-point Likert scale. Each item scored on a 7-point Likert scale, ranging from 0 (never) to 6 (always), and the items for the pain satisfaction scale scored reversely, ranging from 0 to 120. Higher scores indicate higher levels of pain acceptance. The Persian version of the CPAQ also has shown adequate psychometric properties. The assessment of the psychometric properties of the Persian version has shown that the CPAQ had a Cronbach's alpha of 0.89 and test-retest reliability of 0.71(11).

Depression: Second edition of the Beck Depression Inventory (BDI-II) is a 21-item scale for assessing depression. *Each item scored on a 4-point Likert scale, ranging from 0 (never) to 3 (always).* The minimum score in this test can be 0, and the maximum can be 63. The cut-off scores of BDI include minimal or nothing depression (0-13), mild depression (14-19), moderate depression (20-28), and severe (above 29). In the BDI.II, the cut-off point for adulthood depression in the medical context is 14 (26).BDI is utilized for measuring depressed patients' signs and symptoms. The test-retest correlation coefficient of this scale was 0.93. BDI has been widely used in various countries and demonstrated a suitable application Its Persian version also has shown acceptable validity and reliability (27, 28).

Anxiety: Beck Anxiety Inventory (BAI) is also used for assessing anxiety. BAI is a 21-item scale which is scored on a Likert scale from zero to three. Each item represents one of the most prevalent symptoms of anxiety; the total score ranges from 0 to 63. The Cronbach's alpha of the English version of BAI has been reported to be 0.82. Researches have demonstrated that the Persian version of BAI has high-grade reliability ($r=0.72$), a suitable validity ($r=0.83$), and an excellent internal consistency ($\alpha=0.92$) (29).According to the manual, the suggested cutoff for clinically significant anxiety on the BAI is 16. The BAI category includes no anxiety (0–16), moderate anxiety (17–35), and severe anxiety (36–63) (30, 31).

Sleep disturbance: Pittsburgh Sleep Quality Index (PSQI) is used for assessing sleep quality. PSQI contains 18 items about variables related to sleep quality in the past month. The total score ranges from zero (without any sleep disturbance) to 21 (wholly impaired sleep). This scale has a reliability of 0.83. In the Iranian psychiatrically healthy community, this scale has a Cronbach's alpha of 0.78 and a sensitivity

coefficient of more than 0.95. The PSQI has an average sensitivity of 90% and specificity of more than 86% for identifying cases with a sleep disorder, using a cut-off score of five(8, 32).

Statically analysis

Pearson’s correlation and multiple linear regression models were employed to investigate the relationship between variables. SPSS version 26 statistical package for social sciences was utilized for analyzing data. The Kolmogorov–Smirnov test was applied for normalizing data. Homoscedasticity was examined using the scatter plot. Multiple outliers were evaluated by Mahalanobis distance.

Results

Of the 1,500 patients selected to participate in the study and were contacted, 284 neither went to the center nor responded to the researchers' calls; Forty-eight patients had a history of substance use or were taking it; Fifteen had a history of hospitalization in a psychiatric hospital, reported in psychiatric hospitals or had traumatic brain injury; Thirty-three people answered the questionnaires incompletely or without accuracy. Finally, 1120 people entered the results analysis process.

Essential characteristics of the study population

Five hundred sixty patients with PDN participated in this study. The mean age of the subjects was 53.6± 12.6 years, of which more than half were male (342 patients, 61.1% of them) and married (90.9%). Also, the mean duration of their diabetes was 13.3± 3.4 [Table 1].

Table 1: Demographic information of participants

Variables	Status	Free count (%)
Gender	Male	342(61.1)
	Female	218(38.9)
Marital status	Married	483(86.3)
	Single	9(1.6)
	Other Statuses	68(12.1)
Education Level	Under Diploma	389(69.5)
	Diploma	158(28.2)
	University	13(2.3)
Insulin Treatment	Yes	399(71.3)
	No	161(28.7)

All of the patients were residents of Isfahan, Iran, and were Persian-native speakers. The mean and standard deviation of the variables are reported in Table 2. Results from an independent t-test showed that no significant difference was observed between the mean scores of Qol, pain severity, pain acceptance, depression, pain catastrophizing, and sleep disturbance in two groups of males and females ($P>0.05$).

Table 2: Descriptive statics of research variables

Variable	Mean \pm SD			P value
	Total	Male	Female	
Depression	18.61 \pm 8.5	18.1 \pm 8.5	19.3 \pm 8.4	0.1
Anxiety	20.9 \pm 9.5	20.7 \pm 9.6	21.2 \pm 9.2	0.5
Quality of Life	69.6 \pm 21.4	69.5 \pm 21.9	69.5 \pm 20.7	0.9
Pain Severity	6.1 \pm 2	6.1 \pm 2.1	6.1 \pm 1.9	0.7
Pain Acceptance	39.1 \pm 19.07	38.8 \pm 18.5	39.6 \pm 19.8	0.6
pain Catastrophizing	27.3 \pm 12	27.4 \pm 11.8	27.1 \pm 12.2	0.7
Sleep Disturbance	11.1 \pm 4.6	11.3 \pm 4.05	11.2 \pm 4.5	0.5

Correlational matrix among variables

Pearson's correlation (univariate correlations) between QI, pain severity, anxiety, depression, pain acceptance, pain catastrophizing, and sleep disturbance are presented in Table 3.

According to the table.3, Qol increases with increasing pain acceptance. There is also an inverse relationship between anxiety, depression, pain catastrophizing, pain severity, sleep disturbance and Qol. Interactions between all of the variables with each other are significant, except for the correlation between pain severity and pain acceptance. Depression has the strongest negative correlation ($r = -0.484$) with Qol. Also, Pain severity has the weakest negative correlation ($r = -0.32$) with Qol.

Table 3: Correlation matrix among variables

Variables	Qol	Pain Severity	Anxiety	Depression	Pain Acceptance	Pain Catastrophizing
Qol	1					
Pain Severity	-0.321**	1				
Anxiety	-0.352**	0.135**	1			
Depression	-0.484**	0.154**	0.273**	1		
Pain Acceptance	0.409**	-0.104*	-0.3**	-0.289**	1	
Pain Catastrophizing	-0.426**	0.271**	0.252**	0.273**	-0.295**	1
Sleep Disturbance	-0.367**	0.154**	0.338**	0.275**	-0.356**	0.271**

****Significant at level $P < 0.01$, *Significant at level $P < 0.05$**

Normality and homoscedasticity of the error distribution were examined before operating the regression. The Kolmogorov–Smirnov analysis determined the normality of distribution of the variable scores. The results showed that the variables had a normal distribution. Homoscedasticity was examined using the scatter plot. In the current data, the residuals and the variance of the residuals were the same for all predicted variables. Multiple outliers were evaluated by Mahalanobis distance. None of the distances were bigger than or equal to Chi-square, so there were no multiple outliers among the data.

Regression analysis

A step-by-step multiple regression analysis was conducted to predict life quality (criterion variable) based on pain severity, pain catastrophizing, pain acceptance, depression, anxiety, and sleep disturbance (predictive variables). Six models were implemented in which the sixth one demonstrated the highest R square.

According to Table 4, a significant regression equation was found: ($F(10, 1110) = 74.1, P < 0.001$) with an $R^2 = 0.42$, which confirmed that the model adequately fits the data. Overall, the results showed that all independent variables significantly predicted quality of life ($P < 0.05$).

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	218691.775	11	19881.070	74.108	.000
	Residual	297245.936	1108	268.273		
	Total	515937.711	1119			

a. Dependent Variable: quality of life

b. Predictors: (Constant), Insulin treatment, pain catastrophizing, age, education, sex, diabetes duration, sleep, pain acceptance, anxiety, pain severity and depression

Table 5 assesses the regression analysis of variables regarding QOL. Based on the R square measure, the current model explained approximately 42% of the variance. This model takes the form of a statistical equation.

$$Y_{pred} = a + b_1 * 1 + b_2 * 2 + b_3 * 3 + b_4 * 4 + b_5 * 5 + b_6 * 6$$

$$Y_{pred} = 110.8 - 0.71 * \text{Depression} - 0.353 * \text{Pain catastrophizing} + 0.207 * \text{Pain acceptance} - 1.67 * \text{Pain Severity} - 0.549 * \text{sleep disturbance} - 0.219 * \text{Anxiety}.$$

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	110.878	4.769		23.250	.000
	Pain Severity	-1.671	.257	-.157	-6.509	.000
	Pain Catastrophizing	-.353	.045	-.197	-7.773	.000
	Pain Acceptance	.207	.029	.184	7.143	.000
	Depression	-.710	.064	-.283	-11.016	.000
	Anxiety	-.219	.058	-.097	-3.788	.000
	Sleep Disturbance	-.549	.120	-.118	-4.555	.000

a. Dependent Variable: quality of life

Psychological Symptoms Prevalence

With a cut-off point of 14, the prevalence of depressive symptoms in this population was 63.2%. Scores are distributed in the Spectrum of Depression, which are reported in Table 6.

Table.6 Spectrum of depression in the study population

Depression category	Range	No. of Patients	Percentage (%)
Non depression	0-13	412	36.8
Mild depression	14-19	186	16.6
Moderate depression	10-28	328	29.3
Severe depression	29-63	194	17.3

As stated in the method section, the cut-off point for clinically significant anxiety on the BAI is 16. The prevalence of anxiety in patients with PDN is 62.1%. Scores are distributed in the Spectrum of anxiety, which are reported in Table 7.

Table7. Spectrum of anxiety in the study population

Anxiety category	Range	No. of Patients	Percentage (%)
Nothing anxiety	0-16	204	18.2
Mild anxiety	17-35	327	32.8
Moderate and severe anxiety	36-63	392	35.4

Also, regarding the comorbidity between depression and anxiety, 47% of patients with PDN have the comorbidity symptoms of depression and anxiety. Regarding sleep problems, the cut-off point for sleep problems is 5. Therefore, according to data, the prevalence of sleep problems in the sample is 85.5%. That is, 85% of people have significant problems related to sleep needing to follow.

Discussion

The present study has predicted the quality of life in patients with PDN based on pain severity, pain catastrophizing, pain acceptance, Depression, Anxiety, and sleep disturbance. Also, in this research, we estimated the prevalence of anxiety, depression, and sleep disorders/symptoms in Iranian patients with PDN. Correlation analyses demonstrated that Qol has a significant connection with all predictive variables. The results collected from the regression analyses also showed that these variables could predict nearly half of the Qol PDN patients' variance. Depression has the most contribution to this equation. Then pain catastrophizing achieved the second position, and the latest position belongs to anxiety.

This is the first study for assessing the most prevalent psychological variables as predictors of QoL in PDN. However, results are in line with previous researches. For example, a study examined correlations between anxiety, disability, and QoL in patients with PDN. Results showed that anxiety can reduce QoL both directly and indirectly (with increasing pain-related disability) in PDN(9). In another study, pain-related factors reduced QoL in patients with diabetes (33).Furthermore, Cherif et al. (2020) found that depression symptoms extensively reduced QoL in patients with PDN. Moreover, they found that depression was positively correlated with pain severity (18).Also, Pain Catastrophizing Is Independently Associated with QoL in medical contexts (34).

Our research showed that pain catastrophizing has more portion than pain severity in QoL. Previous results are in line with this result too. For example, Lame et al. (2005) found that QoL is more correlated with beliefs about pain (especially pain catastrophizing) than pain severity in chronic pain (35). These researches have similar results with the current paper. Recently, the first and corresponding author of this paper conducted extensive research in PDN. In our published works for that project, we found that increasing sleep quality and pain acceptance and reducing pain catastrophizing and depression can reduce PDN symptoms and also increase response to treatment and consequently improve QoL in patients with PDN (8, 11).

Based on the present study, depression is the strongest variable in predicting QoL. Depression largely leads to physical disability. This disability reduces social participation, medical/psychological rehabilitation, and enjoyable activities. These factors, in turn, increase depression. Thus, the patient engages in a vicious cycle of depression and disability, which leads to severe depression and an extensive reduction in QoL. It has also been shown that the symptoms of depression lead to increased anxiety (anxiety symptoms) and sleep disturbance (36).Therefore, depression also reduces the quality of life by changing the quality of sleep and increasing anxiety and therefore has a major role in reducing the quality of life (37).After the depression, variables related to pain perception (pain acceptance and pain catastrophizing) play an important role (even more than pain intensity) in reducing the quality of life. Based on the results of previous studies, this level of estimated disability due to pain is much higher than the actual level (9).Catastrophizing pain increases anxiety through increasing estimation of the level of disability, leading to make no effort to improve the quality of life. Catastrophizing pain also reduces self-efficacy, and the person thinks he is very disabled, so even aspects that are still healthier despite severe pain cause a wide reduction in quality of life due to the catastrophic pain(13, 34, 35)..Also, in patients with PDN, the prevalence of sleep disturbances, depression, and anxiety are 85.5%, 68.2%, and 62.1%, respectively. Also, comorbid depression and anxiety were found to be 47% of patients. These results are in line with previous studies in other countries. For example, in Tunisian patients with PDN, depression, and anxiety rates are 65.6% and 73.7% (18).Also, in the USA, the anxiety rate in PDN is reported to be 57% which is close to our results (38).Also, various researches in chronic pain found that sleep disturbances rate range between 50% to 80% (39, 40). So, in Iranian patients with PDN, sleep disturbances are higher than in almost all countries. Therefore an especial focus in the course of treatment plans is needed.

Along with these promising results, this study has a significant limitation. Our research is cross-sectional, and the results cannot be generalized to the long-term patients' life. Future researches can assess the effectiveness of biopsychosocial treatment based on our equation. Also, researchers can assess the prevalence of other psychiatric problems in PDN and classify them by age. Another research topic can compare this equation before and after successful treatment and analyze the network shape of symptoms to determine core symptoms.

Conclusion

The current paper found that depression, pain catastrophizing, pain acceptance, pain severity, sleep disturbance, and anxiety determine 42% of QoL in patients with PDN. The order to determine a role in QoL from the strongest to the weakest is depression, pain catastrophizing, pain acceptance, pain severity, sleep disturbance, and anxiety. Also, in patients with PDN, the prevalence of sleep disturbances, depression, and anxiety are 85.5%, 68.2%, and 62.1%, respectively. Also, comorbid depression and anxiety were found to be 47%. So, it is essential to focus on these psychiatric symptoms in PDN that increase QoL and treatment outcomes.

Abbreviations

QOL: Quality of Life, PDN: Painful diabetic neuropathy

Declarations

Ethics approval and consent to participate: Written informed consent (about participation in the study) was received from all patients before the beginning of the study. The scales used in this research were all filled anonymously and a numeric code was used. This project was assessed and certified by the ethics committee of Kermanshah University of medical science (Ir.kums.rce.1399.295).

Consent for publication: during sampling individual session was held. We received consent for publication results from each participant.

Availability of data and material: Data of participants who consented to the public sharing of data are accessible from the corresponding author upon reasonable demands.

Competing interests: The authors certify that they have no competing interests.

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Authors' contributions: The PR and MD conceived of the presented idea. The FR with MD developed and performed the sampling. PR and AAT operating the analytical methods. The MD encouraged the PR and AAT to investigate this matter and supervised the results of the findings. All authors discussed, read and approved the manuscript.

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Authors' information: 1.M.Sc. in clinical psychology, Department of clinical psychology, Shahid Beheshti University, Tehran, Iran. 2.M.Sc. in clinical psychology, Department of Clinical Psychology, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran. Ph.D. candidate of clinical psychology, department of clinical psychology, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran. 4. M.Sc. in clinical psychology, Department of Clinical Psychology, Kermanshah University of Medical Sciences, Kermanshah, Iran

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