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## **ORIGINAL PAPERS**

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# The effect of spiritual care on spiritual well-being and quality of life in diabetic patients: a clinical trial

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A – Study Design, B – Data Collection, C – Statistical Analysis, D – Data Interpretation, E – Manuscript Preparation, F – Literature Search, G - Funds Collection

Summary Background. Diabetes negatively affects patients' quality of life and increases the use of spirituality as a coping mechanism. Spiritual well-being is regarded as one of the basic concepts for coping with problems caused by this disease.

Objectives. This study was conducted to determine the effect of spiritual care on spiritual well-being and quality of life in patients with type-2 diabetes.

Material and methods. This randomized clinical trial was conducted on 90 eligible patients with type-2 diabetes visiting a diabetes clinic in Shiraz in southern Iran. Patients were selected by systematic random sampling and divided into the intervention and control groups by block randomization. The intervention group received six sessions of spiritual interventions, and the control group received routine care. Data was collected using the spiritual well-being (SWB) and diabetes quality of life (DQoL) questionnaires, which were completed before and one month after the intervention. The data was analyzed in SPSS-22, using descriptive and inferential statistics, and p < 0.05 was considered significant.

Results. In the intervention group, the mean score of the DQoL  $(54.04 \pm 2.3 \text{ vs } 39.38 \pm 4.8; p < 0.001)$  and SWB  $(107 \pm 10.3 \text{ vs } 91.7 \pm 9.2; p < 0.001)$ p < 0.001) was significantly higher than the control group after the intervention. In dimensions of DQoL and SWB, significant differences were also seen between the two groups (p < 0.001).

Conclusions. The development and implementation of holistic care programs in conjunction with spiritual care programs can be beneficial for diabetic patients and help improve their spiritual well-being and quality of life.

Key words: diabetes mellitus, quality of life, spirituality.

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## **Background**

Diabetes is a relatively common chronic disease around the world that affects all races, albeit at different rates. The prevalence and incidence of this disease is increasing in many countries, especially in developing countries [1].

The number of patients with diabetes has doubled in less than 40 years. The overall prevalence of this disease is increasing, especially in developing countries, with a considerable prevalence in Iran as well [2].

The increasing prevalence of diabetes, especially type-2 diabetes, and its complications have turned this disease into a global health problem also affecting Iran. Diabetes causes major changes in most body systems, leading to immediate or delayed complications, disability, debilitation, treatment costs and high mortality rates [3]. Diabetic patients are faced with several physical, mental and social problems that can adversely affect their physical function, mental status and personal, family and social relationships [3]. These problems together can decrease the quality of life in these patients [4]. Moreover, the long-term microvascular and macrovascular complications of diabetes, such as neuropathy, heart disease and stroke, can also negatively affect the patients' quality of life [5]. Various studies have revealed a decline in quality of life in these patients [5, 6].

Since quality of life can be considered an indicator of the quality of health care and part of the treatment program, its assessment in chronic diseases can provide further information

about the state of health and disease and act as a useful guide for improving the quality of care [7].

Spirituality and spiritual well-being are some of the components that have a major role in the quality of life. Spiritual well-being is regarded as the central philosophy of life and results from the satisfaction of the need for purpose, meaning, love and forgiveness [8]. Spiritual well-being has existential and religious dimensions, and existential well-being refers to the attempt to understand the meaning and purpose of life, while religious well-being is the satisfaction derived from a connection to a superior power or God [9]. With the crisis it creates in life, diabetes may lead to an increased expression of spirituality and spiritual support as a coping mechanism. Psychologists currently believe that using conventional techniques alone do not suffice for the treatment of different diseases and adaptation to them, and religious motivations and beliefs should also be utilized as other means [10]. The results of a study conducted on AIDS patients showed that those who had found meaning for life with an illness based on spirituality enjoyed a better quality of life compared to when they were initially diagnosed [6]. Other studies on Multiple sclerosis (MS) patients showed that spiritual beliefs and faith were beneficial for coping with an illness, and spiritual well-being exerts an appreciable influence on adaptation to MS. Rehabilitation psychologists may wish to consider its beneficial role as part of their clinical work [11, 12]. The results of another study showed that religion and religious beliefs play a major role in people's lives and are associated with health and satisfaction with life. A strong correlation between spirituality and quality of life in patients with type 2 diabetes and discussed the role and responsibility of healthcare providers, including physicians, nurses and families, in meeting the diverse spiritual and religious needs of patients alongside their therapeutic management. Focusing on improving spiritual health is also important in educational programs for these patients [13]. In recent years, the relationship between spirituality and quality of life has been more extensively investigated [14]. Another study demonstrated the positive effects of spirituality and spiritual care in improving quality of life in diabetic patients [15]. The results of another research showed that spirituality and spiritual care enhance the patients' sense of well-being and consequently improve their quality of life [16].

## **Objectives**

Despite the increasing attention to spirituality and religion in the treatment and care of diabetic patients, the treatment and care approach for these patients is still mostly based on physical and clinical interventions, and very few studies have been conducted on spirituality and spiritual interventions in this group. Given the research gap in this area, this study purports to determine the effect of a spiritual-religious intervention on quality of life and spiritual well-being in diabetic patients.

### Material and methods

This randomized clinical trial was conducted with a control group and a pretest-posttest design. The research setting was a diabetes clinic affiliated with the Shiraz University of Medical Sciences, and the study was carried out in Shiraz, south of Iran. In addition to patients from the Fars province, many patients from a vast part of southern Iran are also referred to this clinic. Based on a previous investigation and using the equation for taking into account a potential attrition of 10%, 50 patients were taken per group as the sample size (Fig. 1).

The patients were divided into the control and intervention groups by block randomization with a block sizes of four. The study inclusion criteria were having type-2 diabetes, consenting

to participate in the study, age 18–60 years and no history of amputation. Any physical or mental event during the study and non-cooperation at any stage were considered the exclusion criteria.

Of the 240 patients covered by this clinic, 172 who met the inclusion criteria were determined, and then 100 patients were selected by systematic random sampling and divided into the control and intervention groups. Throughout the study, 5 patients from the control group and 5 from the intervention group were excluded due to not participating in all sessions, returning incomplete questionnaires or unwillingness to continue their cooperation. Ultimately, the data of 90 patients was analyzed (Figure 1).

In addition to the demographic questionnaire, two other questionnaires were also used to assess spiritual well-being and quality of life.

The Spiritual Well-Being Scale (SWBS) was used to assess spiritual well-being [17]. This questionnaire was first designed in 1982 by Paloutzian and Ellison, and its reliability was confirmed with a Cronbach's alpha of 0.89. The construct validity of this instrument was assessed using exploratory factor analysis and the Varimax rotation supported two factors based on the study of 206 students at three religiously-oriented colleges. Further investigation through confirmatory factor analysis (eigenvalues greater than 1) confirmed a third factor construct associated with the SWBS. Two factors were retained and first three eigenvalues were 7.136, 2.716 and 0.859. The divergent validity of this instrument with a strong negative correlation using the Spiritual Well-Being Scale was confirmed. The correlation between the subscales ranged from 0.62 to 0.32 (p <0.001). Test-retest reliability coefficients for the total questions was 0.93, and for religious well-being and existential well-being, they were 0.96 and 0.86, respectively [17].

According to the results of Soleimani et al., Cronbach's alpha and construct reliability of the Persian Version of the Spiritual Well-Being Scale imply good reliability and convergent validity ( $\alpha=0.915-0.840$ , CR: 0.917-0.835). The correlation between the two factors was also less than the squared root of average variance extracted from the factors, which fulfills the requirements of discriminant validity (results showed 2-fators, 20-item, X2(114) = 330.22, p < 0.05, RMSEA = 0.08) [18].

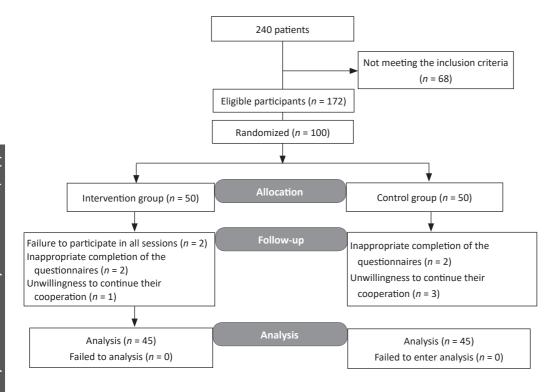


Figure 1. CONSORT diagram

The Farsi version of this questionnaire has been used in several studies in Iran with a confirmed validity and reliability. Allahbakhshian et al. confirmed the content validity of this questionnaire based on the views of ten experts and reported its reliability with a Cronbach's alpha of 0.82 [19]. This questionnaire contains 20 items: 10 odd-numbered items which assess religious well-being and 10 even-numbered items which assess existential well-being. Each item is scored based on a 6-point Likert scale from 20 to 120 and is categorized as follows: poor (scores of 20–40), moderate (41–99) and high (100–120) spiritual well-being [17].

In 1986, Jacobson et al. reduced the number of items in the 60-item Diabetes Quality of Life-Brief Clinical Inventory to 46; later, Burroughs reduced this number further to 15 and determined its validity and reliability [20]. This short 15-item questionnaire is used for type-1 and type-2 diabetic patients, and its items include the patients' diabetes care behaviors and satisfaction with diabetes control. The responses to this questionnaire are scored based on a 5-point Likert scale, from 'very satisfied' = 5, to 'very dissatisfied' = 1, and the total score ranges from 15 to 75 and is categorized as follows: poor (scores of 15–30), moderate (30-45) and high (greater than 45) quality of life [20, 21]. For validity and reliability of the short-form DQoL (15 items), the questionnaire was completed by 498 patients (32% type-1, 68% type-2). Principal component analysis showed that 5 principal components of the instrument accounted for 9.23-15.35% of the total item variance collectively. The internal consistency of the shortened DQoL was good by  $\alpha$  = 0.85, and this tool strongly correlated with each of the subscales with a correlation coefficient from 0.43 to 0.97 [22]. The content validity and internal consistency reliability of the Farsi version of this questionnaire were assessed and confirmed in a study by Nasihatkon et al. The reliability of the questionnaire was assessed using Spearman's correlation coefficient between each item and the total score. Moreover, the questionnaire reliability was confirmed with a Cronbach's alpha coefficient of 0.77 [23].

To provide the intervention group with spiritual care, the researcher first introduced herself and explained her professional competencies in an attempt to gain the patients' trust, since the participation and cooperation of the patients in the execution of the care measures and their acceptance of the means of care provision comprise one of the main pillars of spiritual care. The spiritual care program was implemented for the intervention group over 6 consecutive weeks (one session per week) in classrooms, with group discussions and individual Q&A (Table 1 presents details of the intervention program). The control group received routine medical care. To comply with ethical principles, the control group also received the educational program in the form of a booklet, their questions were answered, and a double blind method was used during the study.

After receiving the necessary explanations, the participants signed a consent form and completed the SWBS and DQoL as the pretest. The intervention group then received 6 weeks of intervention, and 1 month after this intervention, both groups completed the questionnaires again.

Data was analyzed using SPSS-22. Due to normal data distribution according to Kolmogorov–Smirnov test (p>0.05), descriptive statistics used for describing the characteristics of samples and the independent and paired t-Tests and the Chisquare test were used to verify the study hypotheses. The level of statistical significance was set at 0.05.

This study was approved by the Research Ethics Committee of the Shiraz University of Medical Sciences under the code IR.SUMS.REC.1396.1.7 and was registered at the Iranian Registry of Clinical Trials under the code IRCT20171113037441N2. The study objectives and methods were verbally explained to all the participants, and they were ensured of the confidentiality of the data and that their non-participation would have no effect on their process of treatment and care. They then signed the informed written consent forms.

### **Results**

The mean  $\pm$  SD age of the participants was 54.7  $\pm$  13.3 years. The majority were female (n = 66, 73.3%), married (n = 66, 73.3)

Session	Intervention
One	Establishing verbal and non-verbal communication with the patient Creating trust, empathy and honesty between the nurse and the patient to facilitate an appropriate relationship Carefully listening to the patient's words Responding to the patient's questions and explaining the treatment process, giving information and informing the patient about the disease to reduce physical and mental stresses Providing the patient with psychological support Boosting the patient's hope and inner strength Using positive energy statements and reinforcing healthy and constructive thoughts Encouraging the patients to use recreational spaces and visit sites and exercise at their doctor's discretion
Two	Helping the patients find meaning in their life and noting that no life event is outside God's will Providing the facilities needed for religious practices Encouraging the patients to pray, cite the names of holy figures, say prayers and recite the Quran Encouraging the patients to express their religious beliefs Encouraging the patients to visit the clergy and religious counselors
Three	Relaxation and visualization Explaining communication and visualization, spiritual visualization and taking advantage of religious beliefs
Four	Forgiving as a key element of spiritual care Discussing various forms of forgiveness (forgiving others, oneself and accepting others' plea for forgiveness), finding the connection between forgiving others and oneself, practicing in the session by role-play
Five	Encouraging the patients to visit those with whom they feel comfortable Emotional support of the patients by their relatives and medical personnel Advising the patients' relatives to help the patients in carrying out their routine daily responsibilities, such as household chores
Six	Summarizing the topics covered in the previous sessions Asking for feedback and questions about the spiritual care program implemented Resolving any ambiguities about the materials covered in the sessions

and had less than high school diploma (n=43, 50.5). The Chisquare test showed no significant differences between the control and intervention groups in the frequency distribution of the demographic variables (p>0.05; Table 2). Before the intervention, there were no significant differences between the two groups in the mean score of spiritual well-being and its dimensions (p>0.05), but one month after the intervention, a significant difference was observed in this respect (p<0.001; Table 3).

In the intervention group, the paired t-Test showed significant differences in the mean scores of religious health, existential health and spiritual well-being before and one month after

the intervention (p < 0.001), but this difference was not significant in the control group (p = 0.57).

The results of the independent t-Test showed no significant differences between the intervention and control groups of type-2 diabetic patients before the intervention in the mean score of quality of life (p = 0.06), but the difference between them was significant one month after the intervention (p = 0.001; Table 4). The mean changes in the score of quality of life before and after the intervention were also significantly different between the two groups (p < 0.001). The patients' spiritual well-being and quality of life had no significant relationships with any of the demographic variables (p > 0.05).

Table 2. Comparison of the personal and clinical characteristics between the control and intervention groups					
Group Characteristic	Total (n = 90)	Intervention (n = 45)	Control (n = 45)	p	
Gender, n (%) female male	66 (73.3) 24 (26.7)	34 (75.6) 11 (24.4)	32 (71.1) 13 (28.9)	0.63*	
Marital status, <i>n</i> (%) single married	11 (12.2) 66 (73.3)	6 (13.3) 31 (68.9)	5 (11.1) 35 (77.7)	0.72*	
Education, <i>n</i> (%) high school dropout high school diploma higher education	43 (50.5) 33 (38.5) 14 (11)	21 (46.7) 17 (37.8) 7 (5.5)	22 (48.9) 16 (35.6) 7 (5.5)	0.07*	
Employment, n (%) unemployed housewife employed	26 (28.9) 58 (64.4) 6 (6.7)	12 (26.7) 31 (68.7) 2 (4.4)	14 (31.2) 27 (60) 4 (8.8)	0.06*	
Age (year) Mean (SD)	54.7 (13.3)	55.7 (14)	53.7 (12.5)	0.06**	
Duration of disease (year) Mean (SD)	8.8 (5.8)	10.5 (7.9)	9.7 (6.9)	0.25**	

<sup>\*</sup> Chi-square test, \*\* independent t-Test.

Variable	Time	Before intervention	After intervention	Mean change	р
		M ± SD	M ± SD	M ± SD	
Religious health	control	48.3 ± 6	48.8 ± 4.6	0.19 ± 0.03	0.33*
	intervention	48.3 ± 6	53.4 ± 6.5	5.1 ± 1.3	< 0.001*
	р	0.65**	< 0.001**	< 0.001**	
Existential health	control	43.2 ± 8.8	43.1 ± 4.6	0.02 ± 0.01	0.9*
	intervention	43.3 ± 8.8	53.6 ± 4.6	10.7 ± 4.3	< 0.001*
	р	0.9**	< 0.001**	< 0.001**	
Total spiritual	control	91.1 ± 9.5	91.7 ± 9.2	0.17 ± 2	0.57*
nealth	intervention	91.6 ± 13.5	107 ± 10.3	15.4 ± 15.5	< 0.001*
	р	0.89**	< 0.001**	< 0.001**	

<sup>\*</sup> Paired t-Test, \*\* t-Test.

Table 4. Comparison of the mean score of quality of life before and after the intervention in the control and intervention groups						
Variable	Time	Before intervention M ± SD	After intervention  M ± SD	Mean change M ± SD	p	
Satisfaction with controlling	control	18.53 ± 2.7	18.68 ± 2.8	0.16 ± 0.85	0.22*	
the disease	intervention	17.7 ± 3.2	26.9 ± 1.2	9.1 ± 3.4	< 0.001*	
	p	0.8**	< 0.001**	< 0.001**		
Self-care behavior	control	20.82 ± 2.5	20.69 ± 2.5	-0.13 ± 0.46	0.07*	
	intervention	20.1 ± 2.8	27.1 ± 1.4	7 ± 3.4	< 0.001*	
	p	0.7**	< 0.001**	< 0.001**		

Table 4. Comparison of the mean score of quality of life before and after the intervention in the control and intervention groups							
Variable	Time	Before intervention	After intervention	Mean change	p		
		M ± SD	M ± SD	M ± SD			
Total	control	39.35 ± 4.7	39.38 ± 4.8	0.02 ± 0.8	0.8*		
	intervention	37.8 ± 5.3	54.04 ± 2.3	16 ± 6.5	< 0.001*		
	p	0.06**	< 0.001**	< 0.001**			

<sup>\*</sup> Paired t-Test, \*\* t-Test

## **Discussion**

The present findings showed moderate levels of spiritual well-being in both groups before the intervention. Similar finding have also reported moderate spiritual well-being in diabetic patients [24].

The spiritual well-being score increased after the intervention in the intervention group. The results of some other studies also confirm the effectiveness of religious-spiritual interventions in improving spiritual well-being in patients with diabetes or other chronic diseases [25, 26]. A similar study reported that praying can improve spiritual well-being in dialysis patients and thereby demonstrated the effect of prayer as a spiritualreligious intervention on spiritual well-being in patients [27]. The increase in the patients' score of spiritual well-being in this study can be attributed to Iranian society's religious-cultural background. The majority of Iranians (99.4%) are Muslim [27], and as such, spirituality and religion are intertwined in Iranian society and have a huge effect on behaviors and interactions [14]. Therefore, given the dominant religious culture of Iranians and people's beliefs, religious interventions are expected to be acceptable and effective as a source for coping. In the present research, no significant relationships were found between spiritual well-being and the patients' demographic characteristics, which agrees with the results obtained by other studies which showed no relationships between spiritual well-being and certain demographic variables, such as age and gender [19, 28]. Interventions leading to increased spiritual well-being in these patients are thus expected to apply to people with different characteristics and to be effective in different age, gender and social groups.

The scores of quality of life and its dimensions (satisfaction with diabetes control and diabetes care behaviors) were unfavorable in the diabetic patients before the intervention. Similar research conducted in this regard [19] also reported a poor quality of life in these patients. Since, just like other chronic diseases, diabetes is also associated with a high mortality rate and many personal, family, social and financial problems, and since it affects most body organs, it has significant negative effects on all dimensions of quality of life [29]. The constant battle with the disease and the restrictions imposed by its complications lead to negative feelings and dissatisfaction with life in these patients, resulting in a poorer quality of life. In addition, the chronic nature of the disease, the exhausting treatments and the debilitating and threatening complications of diabetes affect the physical, mental and social dimensions of patients' lives, i.e. their quality of life [30]. The poor quality of life in diabetic patients can be due to the physical and mental problems caused by diabetes complications. In the present study, the score of quality of life increased in both dimensions after the spiritual--religious interventions, which concurred in the results obtained in another study [31]. Given that religion and spirituality are important sources of strength and support in all stages of life and can help end conditions of crisis and stressful situations [32], the improvement observed in the patients' quality of life in this study had no relationship with any of the studied demographic variables. Some other investigations have also shown that no relationship exists between these variables [33]. Consequently, receiving support from spiritual or religious sources and connecting to a higher power are beneficial for the improvement of quality of life and interpersonal support, reducing the severity of symptoms and increasing the medical outcomes [32]. Nevertheless, a study conducted in this regard reported a significant relationship between demographic variables such as age and gender and quality of life in diabetic patients and revealed that a poorer quality of life was associated with older age and the female gender [34]. This disparity may be due to the cultural and sociological differences between the study populations.

Given the effect of spiritual-religious interventions on spiritual well-being and quality of life in diabetic patients, health service providers are recommended to combine spiritual care with routine nursing care with a holistic approach and consider the patients' cultural-religious background and priorities as well.

The study limitations included sampling patients from only one diabetes center, even though it was a central/referral center covering a large part of the Shiraz metropolis. Another limitation was the use of the same intervention for all the patients, i.e. not basing the intervention on the patients' assessment of needs.

#### **Conclusions**

The results showed that spiritual-religious interventions improve spiritual well-being and quality of life in diabetic patients. The need to reinforce spiritual well-being as a key factor for improving quality of life in these patients is thus evident. Considering this key point in a country like Iran, with such a deeprooted cultural and religious background, it can be helpful in the design of care-therapy programs for this group of patients. With a holistic approach, nurses can incorporate spiritual care into the care they give to diabetic patients in order to improve their quality of life. Nevertheless, there is still a need for further research on this subject with longer follow-up periods. Future studies are recommended to use multi-center sampling and to design their interventions based on patients' needs.

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