



Research article

Investigating the effect of meditation on spiritual wellbeing of Type-2 diabetic amputees: A clinical trial study

Ali Heydari Movahed^a, Fakhri Sabouhi^b, Reza Mohammadpourhodki^c, Sepideh Mahdavi^d, Sima Goudarzian^e, Malihe Amerian^f, Mona Mohtashami^g, Mansoure Kheiri^h, Malihe Imeni^{h,*}^a Student Research Committee, School of Public Health, Shahrood University of Medical Sciences, Shahrood, Iran^b Nursing and Midwifery Care Research Center, Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran^c Kashmar Center of Higher Health Education, Mashhad University of Medical Sciences, Mashhad, Iran^d Department of Epidemiology, School of Public Health, Shahrood University of Medical Sciences, Shahrood, Iran^e Goldis Hospital, Shahinshahr, Isfahan, Iran^f Department of Midwifery, School of Nursing and Midwifery, Shahrood University of Medical Sciences, Shahrood, Iran^g Department of Anesthesiology, School of Allied Medicine, Shahrood University of Medical Sciences, Shahrood, Iran^h Department of Nursing, School of Nursing and Midwifery, Shahrood University of Medical Sciences, Shahrood, Iran

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ABSTRACT

Objectives: Diabetes is a chronic, progressive and life-threatening metabolic syndrome that causes physical complications such as amputation, psychological complications and crisis in one's life, which leads to increased expression of spirituality and increased use of spiritual support as a coping mechanism. The aim of the present study was to investigate the effect of spiritual care on the spiritual wellbeing of type-2 diabetic amputees.**Materials and methods:** In the present clinical trial study, 54 type-2 diabetic amputees were randomly divided into two groups; namely, experimental and control in 2014 and underwent meditation in three sessions. The 20-item spiritual well-being scale (SWBS) (Paloutzian and Ellison), which measures the spiritual well-being dimensions, was completed by patients before and after the intervention. Data analysis was performed using descriptive and inferential methods (paired T-test, independent t-test, Fisher's exact test, mann-whitney test, and chi-square) in SPSS ver. 16.**Results:** The results showed no statistically significant difference between the experimental and control groups in terms of mean spiritual wellbeing before the intervention, but, the post-intervention mean spiritual wellbeing score in the control and experimental groups was 97.82 ± 9.25 and 88.40 ± 9.47 , respectively. ($\alpha = 0.05$) ($P = 0.001$).**Conclusion:** According to the results of the present study, it seems that spiritual care is able to improve the spiritual wellbeing status of individuals.

1. Introduction

Diabetes is the most common endocrine disease worldwide, accounting for about 4 million deaths a year, affecting more than 230 million people worldwide. It is a chronic, progressive, and life-threatening metabolic syndrome characterized by impaired carbohydrate, protein, and fat metabolism, and is one of the most costly global problems, accounting for 2.5 to 15 percent of the total health budget. Type 1 diabetes and type 2 diabetes are the two main types of chronic disease, both of which have abnormal glucose homeostasis [1]. The global prevalence of this disease is 1–2% and is 3–5% in Iran. The World

Health Organization (WHO) has declared it as a latent epidemic, given the growing number of diabetes in the world. WHO predicted that the global prevalence of diabetes will reach 592 million in 2035. At the meantime, Iran ranks third in the Middle East in terms of prevalence of diabetes [2, 3]. Diabetes causes chronic complications and problems over time, which can lead to depression, frustration, low interest in activities, and low motivation, which in turn can also affect a patient's personality and self-esteem [4].

One of the complications of diabetes is amputation, and its annual incidence rate in the United States is about 50,000 cases [5]. Based on studies conducted in Iran Amputations are performed on 41.5% of the

* Corresponding author.

E-mail address: Malihe.imeni@yahoo.com (M. Imeni).<https://doi.org/10.1016/j.heliyon.2020.e05567>

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patients with diabetes [6]. People with diabetes are more likely to have lower-limb amputations (10–30%) than normal people [5]. Approximately, 15% of patients with diabetes may develop foot ulcer during their lifetime [7]. Lower-limb amputation is associated with long-term hospitalization, rehabilitation, and home care and social support [8].

Diabetes leads to an increase in the use of spiritual support used as a mechanism to cope with the subsequent crisis [9]. The results of various studies have shown that people with chronic diseases, such as diabetes, use spirituality as a method to cope with the disease, cultivate a purpose in life, reduce the feeling of suffering from the disease, despair, and proper management of the disease [10, 11]. Spirituality is a concept indicating meaning, hope, belonging, faith, and dependence, and is a driving force that compels a person to move [12] Researchers emphasize that increasing the level of spirituality will help one to overcome conflicts and increase life satisfaction [13]. According to Jafari's study, spiritual care improves spiritual wellbeing in Iranian adults with type 2 diabetes [14]. Spiritual care is recognized as the most important contributing factor to achieving balance in maintaining health and fighting diseases [15].

Medical meditation as a spiritual care is closely related to spirituality [16]. Meditation is often regarded as an auxiliary treatment. The goal of meditation techniques is to create and maintain a healthy balance between all physical and mental aspects [17]. A clinical trial study (2012) showed that the special advantage of meditation intervention is its preventive nature and the possibility of its use on a wide range of symptoms, as well as the fact that this intervention improves long-term psychological distress [18] Meraviglia showed an effective relationship between different methods of spiritual care with feeling of spiritual improvement in the course of the disease in Terminally ill older adults [19]. In their study, Akbari et al. reported that spiritual care was effective on the Hope of Diabetic Patients [9].

On the other hand, some studies showed no significant relationship between spiritual beliefs, religious practices, and improved mental status [20, 21]. In a study on cancer patients, stroke, and rehabilitation after a head trauma, researchers showed no relationship between individual religious activities and physical health [21].

In his study, Cho showed the effect of meditation on controlling the risk factors for chronic diseases such as type 2 diabetes [22].

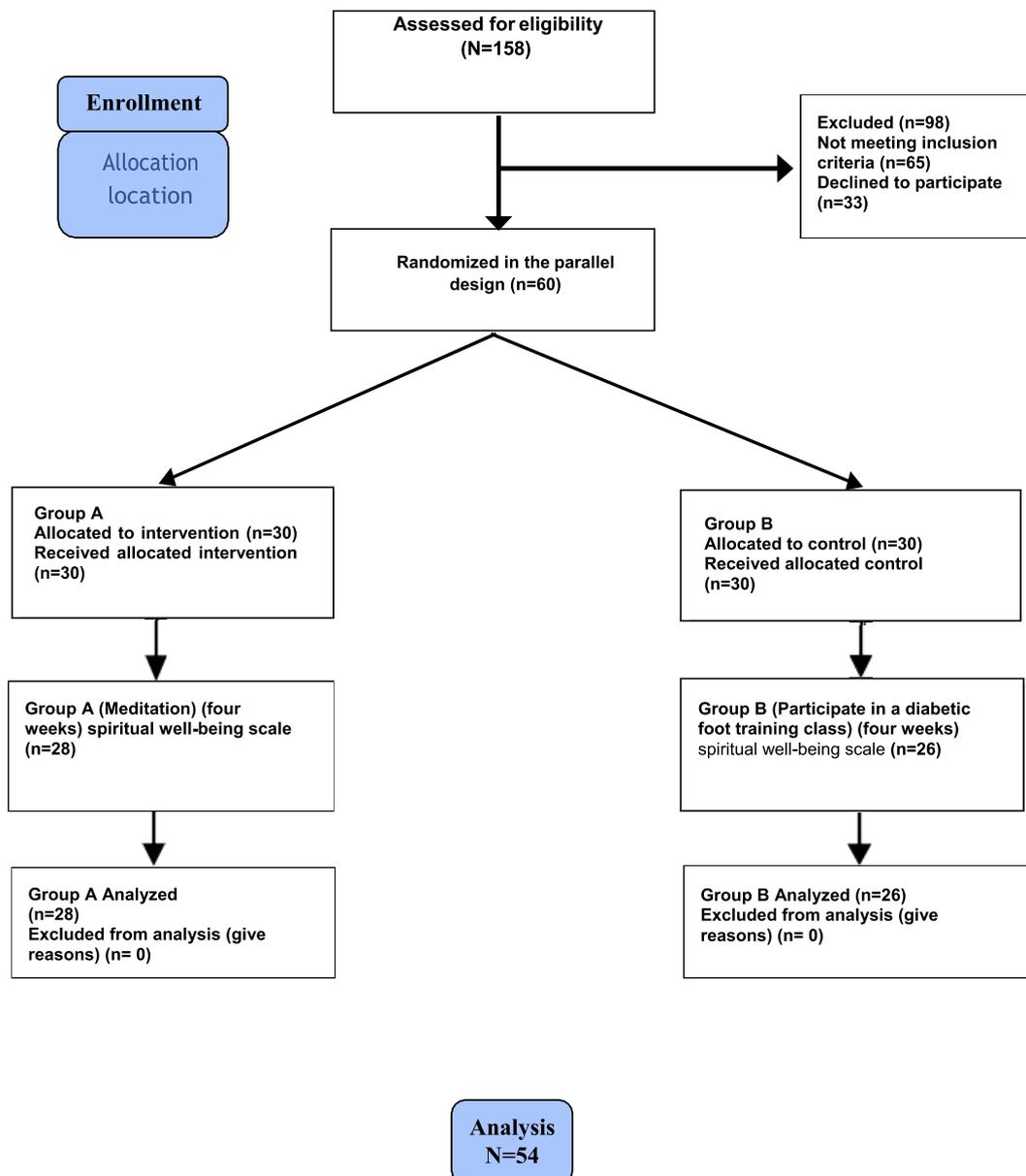


Figure 1. Consort diagram.

Spiritual wellbeing as a dimension of health includes the spiritual experience of human in two different perspectives: the perspective of religious health, which focuses on individuals' health perception, and the perspective of existential health, which focuses on the social and psychological concerns of individuals [23]. The spiritual wellbeing is very important to the extent that WHO has identified spirituality as one of the health dimensions [24]. Impaired spiritual wellbeing can cause confusion and mental disorders, depression, loneliness, and reduced ability to cope with problems and coordinate internal body structures [25].

Considering the multidimensional nature of human health and the critical position of spiritual wellbeing in these dimensions, as well as the progressive course of type 2 diabetes and growing increase in its complications, all aspects of human existence must be considered in order to provide care. Therefore, the aim of the present study was to determine the effect of spiritual care on the spiritual wellbeing of type 2 diabetic patients.

2. Materials and methods

The present study was a randomized clinical trial in 2014. This study had a clinical trial code (IRCT2014090219015N1) and was performed at Al-Zahra Hospital in Isfahan. Initially, information of 158 patients with amputation due to diabetes referred to Al-Zahra Hospital in Isfahan was evaluated, of which 65 were not eligible to participate in the study and 33 eligible patients were not willing to participate in the study. and only 60 patients were included in the study. The research groups included the experimental group (N = 30 people) and the control group (N = 30 people) (Figure 1). Sample size was calculated according to power analysis with $Z_1 = 1.96$, $Z_2 = 0.84$, $d = 0.80$. Among the study population, 60 patients who were eligible for the study and referred to Alzahra Hospital were selected via convenient sampling, and were divided into two groups of 30 using the experimental and control packages. The participants were asked to randomly choose a card from a box with control or experimental written on them, and then, the individuals with the control card were placed in the control group and those with the experimental card were placed in the experimental group.

Inclusion criteria included individuals aged over 18 years, amputation due to diabetes in the toes, wrists, below the knees, having amputation for at least 3 months, using no other complementary medicine methods in the last 3 months, being interested in participating in the study, lack of mental retardation, blindness, deafness, active mental illness based on the patient's medical record, lack of physical restrictions to perform the intervention, having audio and video facilities to perform the desired care at home, permitted spirituality intervention for participants based on the opinion of a specialist, familiarity or fluency in Persian language, reading and writing literacy. Exclusion criteria also included scheduled intervention times performed less than 75%, unwillingness to continue participating in the study, and any problem causing the research subjects unable to continue participating in the study.

Sampling was performed over a period of 3 months and Data collection was carried out using two demographic information form and the spiritual well-being questionnaire scale (SWBS) (1982), which were completed before and after the intervention. SWBS consists of two parts: Religious health and existential Health. Each section contains 10 questions, which are answered based on a 6-point Likert scale (ranging from Completely agree to Completely disagree) (1:completely disagree, 2: disagree, 3: Relatively disagree, 4: Relatively agree, 5: agree, 6: completely agree).

The possible score range is 10–60. Odd and even statements indicate Individual religious health and existential health, respectively. The total spiritual wellbeing score is obtained by summing up the scores of these

two subgroups, which is obtained between 20-120. In statements with a positive verb, Completely agree and Completely disagree options are assigned scores 6, and 1, respectively.

Moreover, in statements with a negative verb, Completely agree and Completely disagree options are assigned scores of 1 and 6, respectively. Ultimately, the spiritual wellbeing of individuals is divided into three categories: low (20–40), moderate (41–99), and high (100–120). The above scale was translated in Iran by Mojgan Abbasi in 2005 and was implemented on 283 nursing students of Iran, Tehran and Shahid Beheshti universities. The reliability of this scale was evaluated using Cronbach's alpha ($\alpha = 0.82$) [26].

To comply with ethical principles in the present study, an official license was obtained from the Research Ethics Committee of Isfahan University of Medical Sciences, Iran with the code 393479. Written consent forms were also obtained from all participants to conduct the research. The participants were assured of the confidentiality of information received and safety of interventions.

After obtaining the necessary meditation training from an experienced professor for a period of 15 days and obtaining the necessary permissions, the researcher started sampling based on inclusion criteria.

Then, the individuals were randomly assigned to the experimental and control groups and both groups were divided into 3 subgroups (N = 10 per subgroup). Prior to the intervention, the demographic information form along with SWBS was completed by all research subjects. Once the groups are identified, the researcher and the instructor explained to the groups on the proper implementation of the meditation technique.

The experimental group was taught meditation during three 60–90 min sessions using teaching aids, slides and direct role play by the researcher. For meditation training, first, the conference room of the Sedighe Tahereh Center was chosen, which had a quiet and serene environment. Then, the participants were asked to sit in a comfortable position, leaning against a chair with their feet placed on the ground, and choose a word to calm their mind. They were trained on relaxing and stiffening the muscles and regarding deep breathing and inhaling and exhaling. Then, they were asked to close their eyes during meditation, empty their mind, and bring their thoughts only on the selected word. The participants' meditation lasted for 15 min and was monitored by the researcher and trainer. Also, at the end of the session, the participants were asked to practically repeat the relevant techniques to ensure proper implementation of the techniques. Patients of the experimental group were also asked to practice the techniques learned for 4 weeks for 15–20 min each time day in a quiet environment at home [27]. In order to facilitate implementation of the relevant techniques and also to ensure the accuracy of the meditation, an educational CD approved by experienced professors and the checklist recording implementation of meditation was provided to the research subjects. Throughout the present 4-week study, the researcher followed up the research subjects via telephone on a weekly basis and answered their questions and ensured proper implementation of the meditation by the research subjects. The control group was given information about diabetes, its complications and methods of preventing diabetic foot ulcers its causes, symptoms, pathophysiology in a simple and understandable way. The researcher also taught the principles of foot care and personal hygiene during three 60–90 min sessions using teaching aids and slides. The educational CD and the diabetic foot ulcer prevention pamphlets were also approved by the professors and provided to the research subjects. After four weeks, individuals who performed 75% of the intervention cases remained in the study. The post-test evaluation of spiritual wellbeing was also evaluated immediately after the end of the 4-week period.

Data analysis was performed using descriptive and inferential methods (paired t-test, independent t-test, Fisher' exact test, man-*n*-whitney u test, and chi-square) in SPSS ver. 16. Chi-square and t-test

Table 1. Comparison of demographic characteristics in two groups of case and control.

Variable	Variable level	Case group (Percentage) frequency	Control group (Percentage) frequency	Significance level
gender	Woman	5 (17.85%)	8 (30.80%)	P = 0.267
	Man	23 (82.15%)	18 (69.20%)	
Marital status	Single	1 (3.60%)	1 (3.80%)	P = 1.000
	Married	27 (96.40%)	23 (88.50%)	
	Not reported	0 (0%)	2 (7.70%)	
Occupational status	Employee	3 (10.70%)	1 (3.80%)	P = 0.475
	unemployed	13 (46.40%)	14 (53.80%)	
	self-employed	5 (17.80%)	2 (7.70%)	
	retired	7 (25%)	9 (34.60%)	
Educational level	Illiterate	1 (3.60%)	2 (7.70%)	P = 0.928
	Elementary	14 (50%)	11 (42.30%)	
	Middle school	4 (14.30%)	5 (19.20%)	
	diploma	5 (17.90%)	5 (19.20%)	
	Bachelor's degree and higher	4 (14.30%)	3 (11.50%)	
Side of amputation	Left	17 (60.70%)	13 (50%)	P = 0.100
	Right	11 (39.30%)	9 (34.60%)	
	Both sides	0 (0%)	4 (15.40%)	
Using prosthesis	Yes	7 (25%)	9 (34.60%)	P = 0.491
	No	20 (71.40%)	17 (65.40%)	
	Not reported	1 (3.60%)	0 (0%)	
Surface of amputation	Fingers	11 (39.30%)	11 (42.30%)	P = 0.760
	Ankle	4 (14.30%)	1 (3.80%)	
	Below knee	12 (42.80%)	12 (46.20%)	
	Above knee	1 (3.60%)	2 (7.70%)	
Time passed from amputation	3–6 months	6 (21.40%)	1 (3.80%)	P = 0.390
	6–12 months	5 (17.80%)	9 (34.60%)	
	12–24 months	13 (46.40%)	10 (38.50%)	
	24–36 months	4 (14.30%)	6 (23.10%)	
Duration of diabetes	0–10 years	9 (32.10%)	3 (50%)	P = 0.304
	11–20 years	17 (60.70%)	10 (38.50%)	
	21–40 years	2 (7.10%)	3 (11.50%)	
method of diabetes treatment	Insulin oral tablet	1 (3.60%)	0 (0%)	P = 0.193
	Oral tablet and insulin	15 (53.60%)	9 (34.60%)	
		12 (42.80%)	17 (65.40%)	

were used to analyze demographic variables. The normality of data distribution was confirmed using Kolmogorov-Smirnov test and Significance level was considered at $\alpha = 5\%$ level.

3. Results

In this study, initially 60 eligible patients were present in the study, and finally 28 people participated in the experimental group and 26 in the control group. Two patients were excluded from the intervention group because they did not perform the intervention to the specified extent. Also, 4 people were excluded from the control group due to unwillingness to continue participating in the study. Finally, data analysis was carried out on 54 patients. The mean age of the experimental and control groups was 56.2 ± 7.7 and 56.6 ± 8.6 years, respectively, which indicated no significant difference ($P = 0.85$). Concerning other demographic characteristics, there was no significant difference between the two groups (Table 1). There was no significant difference between the

two groups in terms of the mean spiritual wellbeing score before the intervention ($P > 0.05$).

The mean \pm SD of post-intervention spiritual wellbeing score in the experimental and control groups were 97.82 ± 9.25 and 88.40 ± 9.47 , which showed a significant difference between the two 17 groups ($P = 0.001$, $t = 3.65$) (Table 2).

4. Discussion

The aim of the present study was to investigate the effect of spiritual care on spiritual wellbeing of type 2 diabetic amputees in 2014. The results of the present study revealed that spiritual care can improve spiritual wellbeing. Chhatre et al. showed that Transcendental Meditation intervention can improve specific health-related quality of life [28]. Consistent with the results of the present study, in a study on the effect of spiritual intervention on the spiritual wellbeing health of cancer patients, Mousavizadeh et al. showed that prayer improved patients' spiritual

Table 2. Comparison of the average score of spiritual well-being after intervention in two groups of case and control.

Group	Variable	MD \pm SD (Pre Test)	MD \pm SD (Post Test)	Significance Level	Confidence Interval	
					Lower Limit	Upper Limit
Case group	spiritual well-being score	86.86 \pm 13.914	97.82 \pm 9.25	T = 3.65 P = 0.001	4.25	14.59
Control group	spiritual well-being score	90.60 \pm 8.689	88.40 \pm 9.47			

wellbeing [29]. The results of Kemper et al.'s study, which confirmed the usefulness of the meditation technique in reducing stress and spiritual growth, were consistent with the results of the present study [30]. Derger et al., also showed the positive effect of meditation on the quality of life of adults with type 2 diabetes [31]. Hartmann et al. also found that meditation was able to improve depression symptoms and spiritual wellbeing in type 2 diabetic patients in the experimental group [18]. Fallah et al. showed that spiritual intervention has a positive and significant effect on promoting hope and spiritual wellbeing of breast cancer women [32]. Also, in their studies on the population with type 2 diabetes, Jafari et al. showed a significant positive relationship between spiritual wellbeing and quality of life, which showed the positive effect of spirituality and spiritual care on patients with chronic diseases such as diabetes [14].

Contrary to the results of the present study, in a study of the effect of meditation on emotional distress and quality of life in patients with diabetes, Van San et al. (2013) showed no significant difference in the experimental group in term of diabetes-specific distress [33]. It appeared that cultural differences and differences in the religious beliefs of the studied population, sample size, and the type of disease were the possible reasons for these contradictions.

In the study by Gustafson conducted as a systematic review, the results of the study did not show efficacy of mindful-based meditation in regard with improvement of laboratory indices of diabetes, which might be due to the nature of variable, since larger sample size and longer duration are needed to observe changes in regard with laboratory indices of diabetes [34].

The most important limitation of the present study was the physical limitation of the research units to participate in classes and Some of the other limitations of the present study include the following: Since the present study was performed only on the population of diabetic patients with amputation referring to Al-Zahra Hospital, caution should be exercised while generalizing the results to other areas. Caution should also be exercised in generalizing the results to others who do not meet certain study criteria. Also Socio-cultural differences were another limitation of the present study that can affect the results of the study, which of course can be controlled by using randomization.

It is recommended to conduct to conduct the present research in other cities as well, and evaluate its results. Therapists are recommended to use spiritual meditation to improve spiritual wellbeing and manage pain in diabetic amputees. The results of the present study can be used to provide a spiritual care program to promote the spiritual health of patients with amputation due to type 2 diabetes.

5. Conclusion

According to the results of the present study, it seems that spiritual care and emphasis on the spiritual dimension of health in people with chronic diseases can improve the overall health of individuals and in particular improve the spiritual wellbeing status of individuals.

Declarations

Author contribution statement

A. Movahed: Conceived and designed the experiments; Contributed reagents, materials, analysis tools or data; Wrote the paper.

F. Sabouhi: Performed the experiments; Contributed reagents, materials, analysis tools or data.

R. Mohammadpourhodki: Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data.

S. Mahdavi: Analyzed and interpreted the data; Wrote the paper.

S. Goudarzian: Conceived and designed the experiments; Wrote the paper.

M. Amerian: Conceived and designed the experiments; Performed the experiments.

M. Mohtashami: Conceived and designed the experiments; Contributed reagents, materials, analysis tools or data.

M. Kheiri: Performed the experiments; Analyzed and interpreted the data.

M. Imeni: Conceived and designed the experiments; Performed the experiments; Wrote the paper.

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Declaration of interests statement

The authors declare no conflict of interest.

Additional information

The clinical trial described in this paper was registered at the Iranian Registry of Clinical Trials under the registration number IRCT2014090219015N1.

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