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Effect of the Islamic Self-care Nutrition Method on the Lipid Profile of Patients with Type 2 Diabetes: A Randomized Clinical Controlled Trial

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Abstract

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BACKGROUND: Dyslipidemia is one of the main risk factors of cardiovascular disease in people with diabetes. The principle of diabetes prevention and control is based on patient self-care and education. The Islamic self-care nutrition method is a common and successful way to modify behavior in Islamic ethics and mysticism.

AIM: The study aimed to determine the effect of the Islamic self-care nutrition method on the lipid profile of patients with type 2 diabetes.

MATERIALS AND METHODS: The present clinical trial was conducted in 2014 on 98 middle-aged patients with type 2 diabetes referred to the Diabetes Center of the Mazandaran University of Medical Sciences, Sari, Iran, who were randomly allocated into two groups of experimental and control. Lipid indices were measured before intervention, and the same education about diabetic healthy diet was provided in both groups. In addition, in the experimental group, Islamic teachings and the Islamic self-care method of nutrition were taught with the intention of pleasing God. Data were analyzed with SPSS 22 software using independent and paired t-test, Chi-square, Fisher's exact, and analysis of covariance (ANCOVA).

RESULTS: After adjusting for the effect of confounding variables with ANCOVA, significant improvement was observed in triglycerides and low-density lipoprotein indices in the experimental group after intervention compared to the control group. Two-proportion z-test results showed a significant increase in the use of lipid-lowering drugs in the control group compared with the experimental group after intervention.

CONCLUSION: The Islamic self-care nutrition method could be used to control chronic diseases such as type 2 diabetes affected by behavioral factors.

Introduction

The prevalence of diabetes is rising rapidly in low- and middle-income countries [1]. Type II diabetes (T2D) is commonly associated with obesity, hypertension, cardiovascular disease (CVD), and lipid disorders. Dyslipidemia may manifest itself by increasing levels of total cholesterol, low-density lipoprotein (LDL)-cholesterol, and triglycerides, and lowering high-density lipoprotein (HDL)-cholesterol [2]. The principle of diabetes care and control is based on self-care and patient education [3]. Theory-centered educational programs are more effective in modifying nutritional behaviors [4]. As a patient's need, spiritual care is a dynamic and subjective concept that implies recovery, exploring the spiritual viewpoint, and creating a spiritual environment [5]. Several reports have shown that there is a relationship between religious or spiritual attitudes and mortality, morbidity, or recovery of patients [6].

In Islam, "health" has a meaning beyond the health of the body and the absence of illness or disability. It includes physical, psychological, and social health, as well as spiritual competence [7]. One of the ways in which Islamic education is formed is through the self-care method. Islamic self-care in fact means piety and self-monitoring, and its components include commitment, self-care, probing, and blame [7], [8], [9], [10]. Commitment is to make a vow with someone; "a person pledges to himself that he will not act contrary to the divine covenant and, as far as possible, will do good" [11], [12]; in other words, the patient's commitment to adhere to the instructions such as observing educational and care tips and recommendations. Self-care: "To remain faithful to this covenant, human beings must know that God is present, observant, and aware of their actions and behaviors at all times" [12]; in other words, an attempt to fulfill the pledges and pay continuous attention to behavior control, while simultaneously considering the presence of God as a superior observer.

Probing is “to question the Ego or self whether it has fulfilled the covenant with God;” in other words, knowing and evaluating whether to perform committed behaviors. Blame means that “after probing and in the event of observing the fault and sin in the covenant, man should punish and educate his Ego or self and blame it” [11], and “if the self or Ego acted in accordance with the covenant, a man must thank and appreciate God” [7], [10], [11]; and in other words, positive and negative reinforcement of behaviors, rewards, and punishment.

Self-care behavior education should be provided in accordance with the culture, abilities, and resources available to patients [13], [14]. Several articles indicate the effective role of religion and spirituality in continuing the treatment process and improving patients' conditions [15], [16], [17], [18], [19]. On the other hand, several articles reported contradictory information about the ineffectiveness of religion, or the role of religion and spirituality in slowing down the healing process in patients with cancer or acute diseases [6], [20], [21], [22], [23]. One of the methods for developing theories is to infer and adapt them to other disciplines and specializations [24]. In this regard, evidence indicates that nutrition therapy is an effective part of the T2D treatment program [25] and that it is one of the key elements in Islamic and ethical texts on human's care of their diet in obedience to the commandments of God [26] [27]. In the Islamic self-care nutrition method, “a man must first sign a contract with himself regarding the rules of nourishment, sleep, speech, etc., in his mind or on paper, and must contract with himself regarding what to do according to the program” [11] [12]. The Islamic method of self-care nutrition not only utilizes the categories of spiritual and religious well-being but also has a significant consistency and alignment with the cultural and religious characteristics of the Iranian Muslim community. According to searches of scientific texts and valid literature on behavioral sciences and health education, there was no behavioral or self-care model based on religion, while numerous texts on Islamic ethics and mysticism repeatedly examined the self-care or probing method for modifying spiritual behavior and self-care [11], [12], [28]. Only one applied clinical trial based on the self-care nutrition method in T2D patients has been conducted by the authors [29]. The aim of this study was to investigate the effect of the Islamic self-care nutrition method on the lipid profiles of T2D patients.

Materials and Methods

The current randomized controlled clinical trial was conducted to investigate the effect of the Islamic self-care method on the lipid profile of patients with T2D in 2014. The project was approved by the Ethics

Committee of Tarbiat Modares University (registration No.1456/52, May, 2014). Furthermore, the study has been registered in Iranian Registry of Clinical Trials database (IRCT2016010325826N1). The research samples were patients referred to the Diabetes Center affiliated to the Mazandaran University of Medical Sciences in Sari. According to the results of a similar theory-centered study [30], also considering the 95% confidence interval ($\alpha = 5\%$), test power of 90% ($\beta = 10\%$) and 10% dropout, the minimum sample size was 30 patients in each experimental and control groups. Inclusion criteria were age range of 30–65 years, history of T2D for at least 1 year, last HbA_{1c} result of 6.5–9%, primary school or higher education, Iranian nationality, being Muslim, lack of pregnancy and lactation, no history of acute illnesses, hypoglycemia, ketoacidosis, and severe physical, motor, and cognitive impairment over the past 3 months. Exclusion criteria were non-attendance at classes for two or more sessions, and hospitalization. All 160 patients were referred to the laboratory of the university affiliated hospital in Sari to ensure an HbA_{1c} level of 6.5–9%. Fifty patients were excluded for not meeting the inclusion criteria due to an HbA_{1c} level of more than 9. HbA_{1c} assay was performed using the immunoturbidimetric method with a Hitachi 911 auto-analyzer. Other lipid tests were performed using the enzymatic method with an Erba600 machine. The laboratory kits were manufactured by Pars Azmoon Company in Tehran, Iran.

After receiving the results, 110 eligible patients were referred to the diabetes center in the following days. To randomize the samples, we prepared 55 sealed envelopes each containing two cards of the same shape and color with the letter A printed on the one of them (experimental group) and the letter B printed on the other one (control group). The eligible patients randomly selected one of the envelopes and randomly took one of the two cards assigned to either the experimental or the control group. In the end, 55 patients were randomly allocated to the experimental group and 55 subjects to the control group. Three experts trained by the researcher completed the questionnaires by face-to-face interview with patients and using medical records. Patients signed an informed consent form for voluntary participation in the study and provided a blood sample for testing. They were also assured of the confidentiality of their personal information.

The data collection tool comprised demographic information, medical records, and used drugs that were prepared after studying valid texts and papers, especially postgraduate and PhD dissertations. This study was a single-blinded research. All patients were merely informed that they were participating in an Islamic study on the nutrition of patients with T2D, and subjects were unaware of their own assignment to the intervention and control groups. In addition, laboratory staff, physicians, and other colleagues were unaware of the allocation of samples to the experimental and control groups. After the end of the intervention, the package of Islamic teachings and

self-care nutrition method was provided to the control group as well. Both groups participated separately in five 2-h sessions each for 10 h. Educational topics were presented to each group every 2 weeks, and twice in the morning and afternoon. All patients were reminded of class time 1 day before each session. Educational content included a nutritional guide for T2D patients, food groups and permissible values, cholesterol and hypertension control, exercise and physical activity, and stress control. Educational packages were prepared in the form of colorful pamphlets using scientific literature, texts, journals, papers, theses, and valid educational manuals under the supervision of professors and qualified experts. Educational topics were presented by the same four experts in nutrition, sports, psychology, and health education using PowerPoint presentations, lectures, question and answer sessions, practical training in exercise movements (low intensity stretching and aerobics), and practical training in imagination for relaxation.

In addition to nutrition issues, the researcher provided the experimental group with Islamic teachings on health topics, features of the nutrition method of Islamic self-care and probing, principles and rules of jurisprudence (Islamic law) and for preservation and promotion of health, and nutrition in view of Islam using the above educational techniques and tools. The scientific educational package was prepared based on a framework of Islamic self-care method with elaborating its constructs in the form of a checklist. After reading the self-care tips contained in the form and explaining them, patients were asked to declare their commitment and adherence to the tips in the commitment section by signing the form. In the self-care section, patients were asked to install self-care forms in places where they are most likely to be seen by them and review the tips several times throughout the day. In the probing section, patients were asked to record how to follow self-care tips in the forms every day and evaluate them at the end of each week. In the Blame section, patients were requested to score their self-care function out of 20 points. The quote, "Does he not know that Allah sees" (Āyah 14, Surah Al-Alaq, holy Qur'an) [31], was used to remind patients in the intervention group during all sessions that God is the observer of actions at all moments and that they should adhere to their covenant with God at all stages of nutritional care and please God. The experimental group samples returned the completed self-care nutrition forms without their name during each session. After the researcher studied the forms, verbal feedback was given to the patients and then weaknesses and strengths were discussed in the next session. Patients' education lasted for 2 months.

Statistical analysis

Data were analyzed with SPSS 22 software using parametric and nonparametric independent and paired t-test, Chi-square, Fisher's exact, and analysis

of covariance (ANCOVA) at a significance level of 0.05. The ANCOVA test was used to investigate the possible effects of several confounding variables such as age, sex, educational level, stress, sleep disorders, diabetes mellitus, lipid, glucose and blood pressure-lowering drugs, alcohol consumption, exercise, vegetarian diet, and sources of information on T2D in both stages before and after intervention. The confounding variables known to affect lipid parameters were the effect size of cholesterol, triglyceride, HDL, and LDL indices. The effect of these variables was adjusted by one-way and multivariate ANCOVA in the experimental and control groups.

Results

In total, 160 patients were screened during the study period. Of these, 98 completed the study (Figure 1).

There were no significant differences in demographic variables between the experimental and control groups ($p > 0.05$) (Table 1).

After adjusting for the effect of confounding variables with ANCOVA, significant improvement was observed in triglycerides ($p < 0.001$) and LDL ($p < 0.01$) indices in the experimental group after intervention compared to the control group (Table 2).

Two-proportion z-test results showed a significant increase in the use of lipid-lowering drugs in the control group compared with the experimental group after intervention ($p < 0.002$) (Table 3).

Table 1: Demographic characteristics in the experimental and control groups

Variable	Experimental group n=48 (%)	Control group n=50 (%)	p-value
Age			0.842*
35–39.9	8 (16.7)	6 (12.0)	
40–44.9	4 (8.3)	7 (14.0)	
45–49.9	9 (18.8)	9 (18.0)	
50–54.9	9 (18.8)	10 (20.0)	
55–59.9	11 (22.9)	8 (16.0)	
60<	7 (14.6)	10 (20.0)	
Education			0.710*
Less than elementary	2 (4.2)	0 (0.0)	
Elementary	11 (22.9)	15 (30.0)	
Guidance	14 (29.2)	15 (30.0)	
Diploma	16 (33.3)	17 (34.0)	
Associate	2 (4.2)	0 (0.0)	
Bachelor	2 (4.2)	2 (4.0)	
Master and higher	1 (2.1)	1 (2.0)	
Income status			0.826*
Low	6 (12.5)	7 (14.0)	
Average	33 (68.8)	30 (60.0)	
Good	8 (16.7)	12 (24.0)	
Very good	1 (2.1)	1 (2.0)	
Gender			0.161**
Female	41 (85.4)	37 (74.0)	
Male	7 (14.6)	13 (26.0)	
Marital status			0.313*
Married	42 (87.5)	47 (94.0)	
Single	6 (12.5)	3 (6.0)	
Job			0.086*
Housewife	34 (70.8)	31 (62.0)	
Worker and farmer	3 (6.3)	11 (22.0)	
Employee	2 (4.2)	3 (6.0)	
Retired	6 (12.5)	5 (10.0)	
Other	3 (6.3)	0 (0.0)	

*Fisher's exact, **Chi-square.

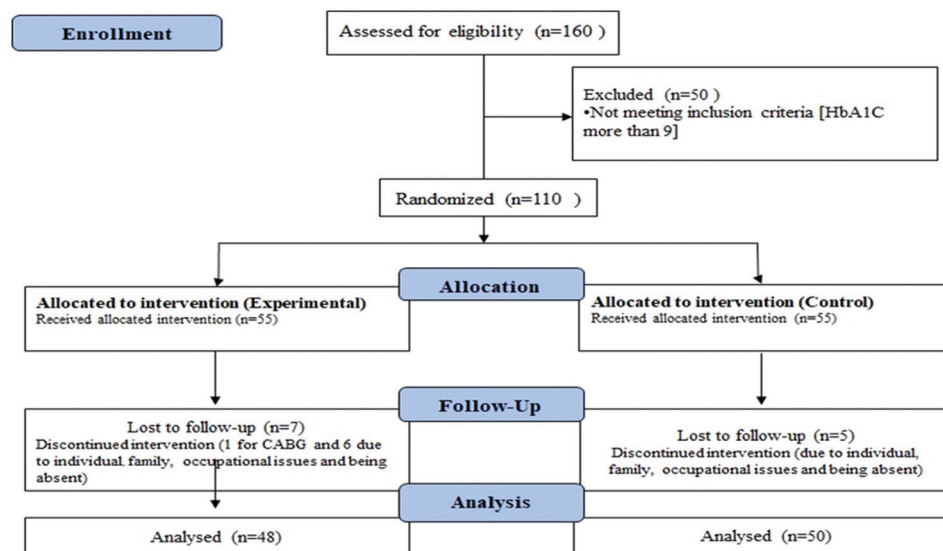


Figure 1: Flow chart of the study population

Table 2: Lipid profile levels before and after intervention in the experimental and control groups

Variable	Experimental group (n=48)			Control group (n=50)			p-value**	p-value***
	n	Mean	SD	n	Mean	SD		
Cholesterol								
Before	48	183.88	51.91	50	182.02	49.33	0.856	-
After	48	163.79	41.56	50	174.46	43.27	0.217	0.057
p-value*					0.147			
Mean difference		-20.08			-7.56			
Triglycerides								
Before	48	190.08	100.24	50	181.90	96.47	0.681	0.837
After	48	144.60	74.62	50	162.62	81.81	0.258	<0.001
p-value*					0.122			
Mean difference		-45.48			-19.28			
HDL								
Before	48	45.63	9.02	50	44.16	8.50	0.410	0.791
After	48	41.06	10.24	50	39.78	8.02	0.491	0.877
p-value*					<0.001			
Mean difference		-4.56			-4.38			
LDL								
Before	48	114.02	40.17	50	113.86	41.27	0.984	0.980
After	48	97.67	37.43	50	101.04	38.19	0.660	0.010
p-value*					0.001			
Mean difference		-16.35			-12.82			

*Paired-samples t-test, **independent-samples t-test, ***analysis of covariance, -no covariate.

Table 3: Changes in drugs usages in the experimental and control groups during intervention

Variable	Experimental group (n=48)		Control group (n=50)		p-value*
	Yes n (%)	No n (%)	Yes n (%)	No n (%)	
Antilipids	0 (0.0)	48 (100.0)	7 (14)	43 (86)	0.002
Antihypertensives	2 (4.2)	46 (95.8)	5 (10)	45 (90)	0.128
Insulin	0 (0.0)	48 (100.0)	1 (2)	49 (98)	0.156
Oral hypoglycemics	8 (16.7)	40 (83.3)	14 (28)	36 (72)	0.087
Tranquilizers or sedatives	1 (2.1)	47 (97.9)	1 (2)	49 (98)	0.512

Discussion

The present study was conducted to determine the effect of the Islamic self-care nutrition method on the lipid profile of patients with T2D. After adjusting the effect size of plasma lipid indices with ANCOVA, a significant decrease was observed in triglycerides and LDL-cholesterol levels in the experimental group compared to the control group after intervention. This can be explained by the role and effect of the Islamic self-care method, since both groups received the same education in terms of nutrition and healthy lifestyle, but the nutrition method of Islamic self-care and Islamic

teachings was also carried out in the intervention group.

According to the cohort study of Kobayashi *et al.*, religiousness was always associated with a lower likelihood of smoking and alcohol consumption, and higher rates of regular exercise and lower T2D incidence in the future [16]. This study did not consider the effect of several confounding factors such as education, types of religions, and treatment of CVD risk factors. In a meta-analysis, Shattuck *et al.* demonstrated that several outcomes, such as blood pressure, CRP, and cardiovascular health indicators, are significantly related to religiosity and spirituality (R/S). Evidence has shown that the R/S improves health by possibly reducing the adverse effects of stress and depression on inflammation [19].

The results of a study by Anyfantakis *et al.* indicated that people with religious beliefs and spirituality had significantly lower carotid intima media thickness, less T2D, and lower serum cortisol levels [17]. This study had no control group and the effect of probable

confounders such as praying time, fasting, and dietary habits was not investigated. The results of our study are consistent with two recent studies by Hosseini *et al.* In their randomized clinical trial, they found similar efficacy of religious cognitive behavioral therapy (RCBT) and CBT, citalopram, and sertraline to reduce symptoms of anxiety and depression in patients with breast cancer and elderly patients after coronary artery bypass graft surgery (CABG), and all three were more successful than routine treatment.

In these trials, those who obtained a score of more than 25 from the religious attitude questionnaire were included in the study [32], [33], but just stating to be Muslim was enough to participate in our research.

The results of a clinical trial by Sajadi *et al.* indicated that spiritual counseling had a significant effect on the improvement of spiritual health and the sense of frustration and suffering of women with cancer [34]. Shia Muslim patients participated in the study. During psychotherapy counseling sessions, relaxation and meditation were presented along with Islamic teachings. The control group received only routine care in this study. The trial by Nasiri and Dolatyan showed that the mention of the name Allah had a positive effect on the physiological responses of Shia patients after CABG surgery, especially on respiration and mean SPO₂, and was effective in reducing stress during pregnancy [15], [35]. However, Daher *et al.* showed that the effect of RCBT and conventional CBT (CCBT) interventions on the goal of life in patients with chronic illness and severe depression was not significant [36]. In their study, the intervention and control groups believed in the various religions of Christianity, Judaism, Islam, Hinduism, and Buddhism. In a study by Berk *et al.* CCBT in less religious people and RCBT in more religious individuals resulted in decreased pro-inflammatory cytokine interleukin-6 level. Contrary to expectation, the baseline of more religiosity was related to increasing stress biomarkers [22]. In a study by How *et al.*, Muslims had the weakest glycemic control and attributed their health to destiny and divine will [23]. The limitations of this study were the convenience sampling method and the existence of a bias in excluding alcohol consumers and smokers. A cross-sectional study by Bellinger *et al.*, in patients with chronic physical illnesses also showed little evidence on the presence of a continuing relationship between stress or religious symptoms and stress biomarkers [20].

In our study, there was no significant difference in cholesterol and HDL-cholesterol indices after intervention between experimental and control groups. This could be due to other confounding variables such as exercise and medications. Significant increase in the use of lipid-lowering drugs was observed in 14% of the control group during the intervention, while no increase in the use of lipid-lowering drugs was detected in the experimental group. In our study, significant improvement in lipid indices may be due to

greater awareness and concern of patients to reduce fat intake. The same is true in a study by Kontogianni *et al.* [37]. In our study, the serum level of HDL in both the experimental and control groups decreased significantly. This seems to be due to a decrease in fat intake, even the useful type, in subjects' diet. The same has been reported in other reviews. Body mass index, physical activity, smoking, alcohol, and hormones mostly affect HDL levels [4], [38], [39]. Paying attention to the spiritual and religious dimensions of patients and their commitment to nutrition self-care to perform divine orders and to satisfy God, the implementation of nutrition self-care by patients in a systematic and structured process, along with self-evaluation of care, is exquisite points of this study. In addition, the exact identification of the confounding variables and the adjustment of their effects are the other strengths of this trial. However, misunderstandings and misreporting by patients due to factors such as the level of learning, level of education, and psychological differences were the observed and uncontrollable limitations of this study.

Conclusion

The results of this study suggest the efficacy of the innovative Islamic self-care nutrition method for significant improvement of triglyceride and LDL indices, and there was no increase in taking lipid-lowering drugs in the experimental group compared to the control group within 2 months.

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