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The efficacy of the diet therapy based on Traditional Persian Medicine on blood glucose and lipid profile in adults with type 2 diabetes mellitus patients: A randomized controlled clinical trial



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ABSTRACT

Background: Diabetes mellitus (DM) is one of the most common chronic diseases in the world. There are several therapeutic strategies that are obtainable in the viewpoint of Traditional Persian Medicine (TPM) knowledge ranging from changes in lifestyle to pharmacological remedies.

Objective: To evaluate the effect of the TPM based nutritional recommendations on blood glucose and lipid profile in patients with type 2 DM.

Materials and Methods: In this randomized controlled clinical trial, we divided 54 participants with type 2 DM into two groups. The intervention group received a three months TPM based nutritional style, and the control group had the routine care from their health care providers. The fasting blood glucose and glycosylated hemoglobin (HbA1c) as primary

outcome measures and triglyceride and total cholesterol as secondary outcome measures were determined for this study at the baseline and three months after the intervention in both groups.

Results: There was a statistically significant reduction in fasting blood glucose (165.48 ± 30.18 versus 203.92 ± 42.66 $p=0.001$), HbA1c (7.57 ± 0.51 versus 8.05 ± 0.82 $p=0.000$), triglyceride (154.91 ± 50.52 versus 197.40 ± 71.87 $p=0.000$), and total cholesterol (167.79 ± 28.87 versus 184.76 ± 38.36 $p=0.006$) respectively in the intervention group compared to control group after study.

Conclusion: TPM based nutritional recommendations as an affordable free and accessible approach could be introduced as a non-pharmacological strategy for the control of blood glucose and lipid profile in diabetic patients.

Keywords: diabetes mellitus, lifestyle, Traditional Persian Medicine, clinical trial

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INTRODUCTION

Diabetes mellitus (DM) is one of the most common chronic diseases in the world. It is estimated that diabetes affects 387 million people worldwide¹. Given the changes in human modern lifestyle, there is a concern that the increasing prevalence of diabetes will continue.²

Type 2 DM is characterized by high blood sugar, peripheral resistance to insulin function, and relative impairment in insulin secretion. The pathogenesis of DM is poorly understood, however, both genetic and environmental factors, such as nutrition, smoking, physical activity, alcohol consumption, body weight, and sleep pattern are important.²⁻⁴ Therefore, lifestyle modification is the key point in the management of DM. Previous studies have shown dietary patterns have an effect on the risk of type 2 DM.⁵ Diets comprised of red meat, processed meat, and sugared beverages present high risk of diabetes, whereas diets containing fruits, olive oil vegetables, nuts, whole grains, and cereal fiber are associated with low risk of DM.⁵⁻⁷

Over the past decades, there has arisen increasing interest in the use of complementary and alternative medicine for the treatment of chronic diseases such as diabetes.⁸ Traditional Persian Medicine (TPM) is a field of traditional and complementary medicine commonly practiced among Iranian people.⁹ In TPM approach, there are several therapeutic strategies ranging from lifestyle changes to herbal remedies for management of diseases. The optimization of food and beverage was considered as the main preventive approach in TPM for the management of DM.¹⁰

Regarding the proven effect of dietary patterns on controlling of DM in recent studies and lack of evidence on the clinical effects of preventive approaches of TPM, in the management of chronic disease like DM, we designed a randomized, controlled clinical trial to evaluate the effect of the TPM based nutritional recommendations on blood glucose and lipid profile in adults with type 2 DM.

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MATERIALS AND METHODS

We conducted a randomized, parallel group, open-label controlled clinical trial. No changes were made to methods after the commencement of the trial. Participants were randomly allocated to receive either a three months TPM based nutritional style, as the intervention group, or the routine care from their health care providers as the control group. Participants were assigned to control and intervention groups following simple randomization procedure by using computerized random numbers.

The trial was registered by Iranian Registry of Clinical Trials with the following code: IRCT2016080129150N1. The trial was in compliance with the Declaration of Helsinki (1989 revision), and was, as well, reviewed/ approved by the related local research ethics committees of Shahid Sadoughi University of Medical Sciences (SSU): reference number IR.SSU.REC.1394.120). We selected 54 type 2 diabetes patients between 84 patients who referred to Diabetes Center of Yazd Shahid Sadooghi University of Medical Sciences from May to September 2016. These 54 patients met inclusion criteria comprising having diabetes history for more than 5 years and taking no insulin or oral agent except metformin. Patients

were recognized according to American Diabetes Association (ADA) criteria 2009 with fasting blood sugar (FBS) more than 126 mg/dL or 2 hours post-prandial glucose (2hpp) more than 200mg/dL or HbA1c more than 6.5%.¹¹ The exclusion criteria were pregnancy; lactation, need for insulin therapy, serious cardiac or renal diseases, Alzheimer disease, and cancers. It is noted that patients who were hospitalized during the study or did not abide by the study protocol were excluded from the study. All patients were visited by an endocrinologist and enrolled in the trial based on the inclusion criteria.

The intervention group received dietary commands written forms including 10 items (TPM based nutritional recommendations) with each item being explained in detail to every patient by the researcher (Table 1). This 10-factors recommendation was extracted from Al Qanon Fi Al-tibb, Zakhireh Kharazmshahi, Tibb Akbari, Exir Azam, Aghili's Treatments, Kholaseh Al-Hekmat. After extraction, these items were validated by two nutritionists. They were instructed to follow their lifestyle in line with TPM recommendations. TPM recommendations were assessed via a feedback form filled daily by participants in this group and this was followed by a weekly estimation. The control group was only under routine care from health care providers without any recommendation based on TPM. Both groups were instructed not to change their dosage of metformin. The dietary intake of the both groups was controlled by using one 24 hr dietary recall before and after the study.

Blood samples were drawn after 12–14 hours overnight fasting and sent to Yazd Diabetes Research Center laboratory. No changes applied to trial outcomes commenced after the trial.

FBS, triglyceride, and total cholesterol were measured by means of the enzymatic colorimetric

Table 1 Traditional Persian Medicine (TPM) based nutritional recommendations

| No | Recommendation |
|----|---|
| 1 | Avoid drinking water and beverage between meals and at least two hours thereafter |
| 2 | Avoid drinking cold water |
| 3 | Avoid eating when you are not hungry and do not have appetite |
| 4 | Chew your food morsel well until it is almost a liquid |
| 5 | Stop eating before you fully satiated |
| 6 | When you get hungry, do not postpone eating |
| 7 | Keep dietary diversity during several days, not in each meal |
| 8 | Be relaxed and silent when you are eating |
| 9 | Eat a light meal for dinner and avoid fries, chili or salty foods |
| 10 | Fruits, yogurt, and salads should be only eaten during the day, and not within a meal |

Table 2 Basic characteristics of participants

| Basic characteristics | Control | Intervention | P-value |
|---|--------------|--------------|-------------------|
| Sex [women %] | 55.6% | 51.9% | 0.78 [‡] |
| Mean age (years) | 46.48± 8.28 | 45.88± 7.38 | 0.37 [†] |
| Mean duration of diabetes (months) | 97.33± 43.05 | 80.00± 49.11 | 0.73 [†] |
| Mean body mass index (kg/m ²) | 28.11±3.12 | 28.94±4.00 | 0.55 [†] |

[‡] Chi-square test

[†] Independent sample t-test

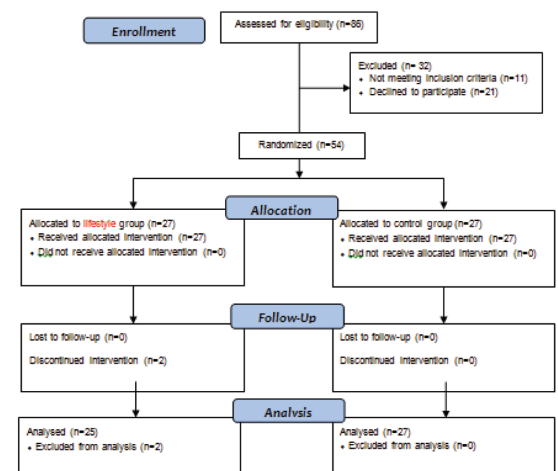


Figure 1 Flow diagram of the groups' allocation, enrolment, intervention, follow-up, and the analysis in both groups of the study

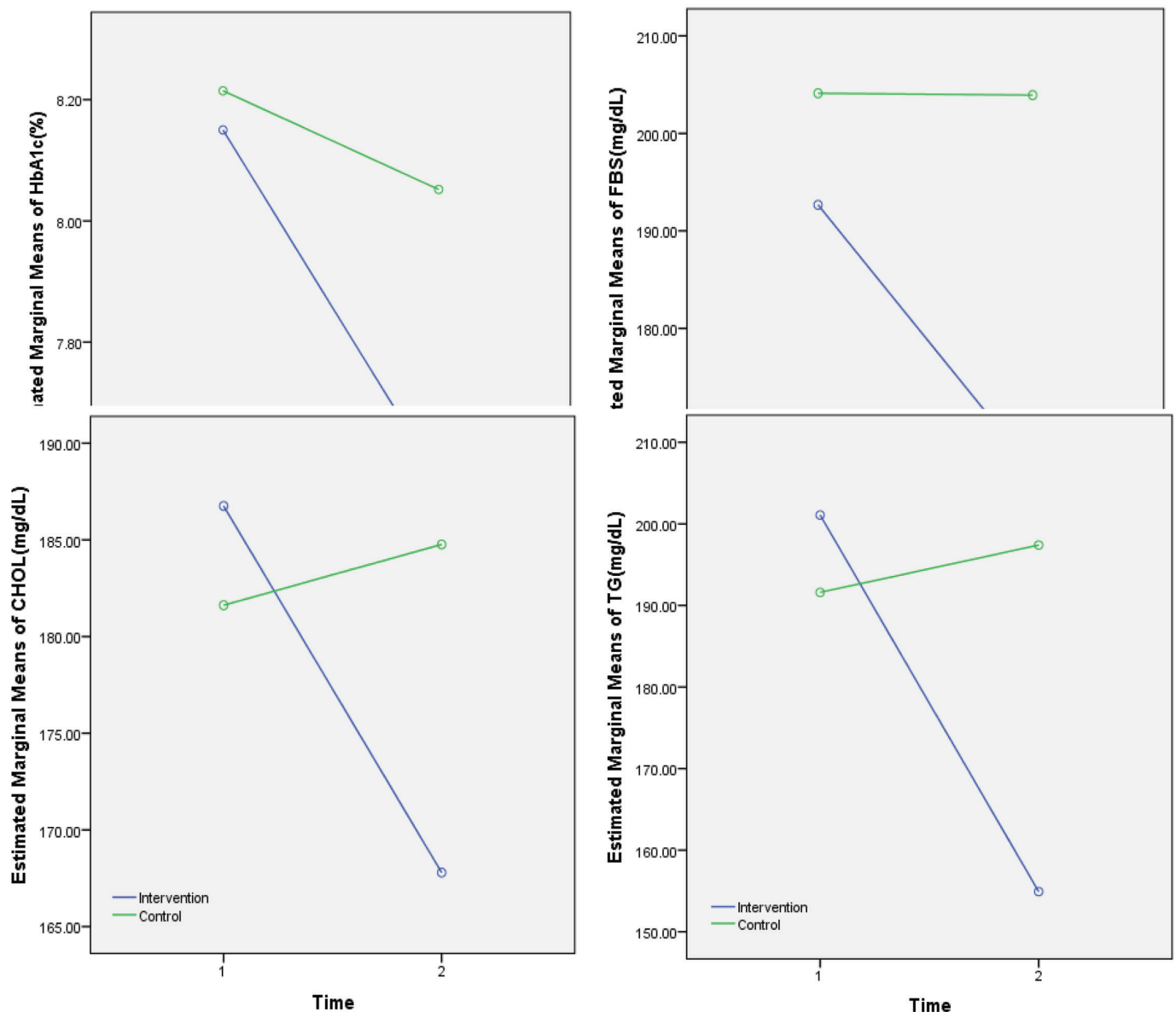


Figure 2 Comparative HbA1c, Fasting blood glucose, Triglyceride and Cholesterol before and after three months of Traditional Persian Medicine based nutritional style modification in type 2 diabetic patients

(glucose oxidase technique) method and by Prestige machine with the scale of milligrams per deciliter. High-Performance Liquid Chromatography (HPLC) was used as the laboratory test technique for assaying HbA1c. Regarding the objectives and the study type and with the previous studies in perspective, 26 patients from each group were chosen with the assumptions of 5% error, 80% power and 50% effect size.^{12,13}

Statistical Analysis

Descriptive records analysis was done by using descriptive statistical methods (frequencies, means and standard deviations). Chi-square test was used for statistical comparison of base line characteristics and repeated measurement ANOVA was used

to determine the changes in outcomes between the two groups of the study. A *p* value of less than 0.05 was considered significant. The intention to treat protocol applied in data analysis. To analyze the data, Statistical Package for the Social Sciences (SPSS) software version 15 was used.

RESULTS

From May 2016 to Sep 2016, from a total of 86 people who evaluated for eligibility, 75 adults were eligible. Of whom 21 people refused to participate in the trial and finally, 54 participants were included in this study. Twenty-seven of them were allocated to the intervention group and the other 27 to control group, randomly. **Figure 1** is a

flow diagram of the enrollment, groups' allocation, interventions, follow-up, and the analysis of the results.

All patients were visited and evaluated at baseline and three months after the study. Two participants did not adhere to the protocol of trial but were included in the result analysis due to the intention to treat the protocol. Baseline demographic data of the study groups (age, sex, body mass index, and duration of diabetes) are shown in [Table 1](#). No significant differences were observed in baseline demographic data between two groups of the study. ([Table 2](#))

In addition, there were no significant differences between the outcome measures of the study in the intervention and control group respectively before the study: FBS (192.66 ± 32.24 versus 204.11 ± 34.85 $p=0.21$), HbA1c (8.15 ± 0.53 versus 8.21 ± 0.59 ; $p=0.68$), triglyceride (201.08 ± 70.58 versus 191.60 ± 68.94 ; $p=0.65$) and total cholesterol (186.75 ± 39.58 versus 191.60 ± 68.94 ; $p=0.88$).

There was a statistically significant reduction in the states of FBS (165.48 ± 30.18 versus 203.92 ± 42.66 $p=0.001$), HbA1c (7.57 ± 0.51 versus 8.05 ± 0.82 $p=0.000$), triglyceride (154.91 ± 50.52 versus 197.40 ± 71.87 $p=0.000$), and total cholesterol (167.79 ± 28.87 versus 184.76 ± 38.36 $p=0.006$) respectively in the intervention group compared to control group after the end of the trial. The trend of the changes of outcome measures is shown in [figure 2](#). No adverse event was reported during the study period in the two groups of the study.

DISCUSSION

In the present trial, we have evaluated the effectiveness of the TPM based nutritional recommendations on blood glucose and lipid profile in patients with type 2 DM via an open-label randomized controlled clinical trial. TPM-based nutritional style turned out to have significant effects on reducing serum blood glucose (FBS and HbA1c) in diabetic patients as compared to the control group. Additionally, this study showed the total cholesterol and triglyceride of the intervention group significantly reduced after the study compared with the control group.

Several studies have been done on the effectiveness of lifestyle interventions to prevent or manage diabetes. Most of these studies considered the effectiveness of dietary and exercise intervention or the combination of both.¹⁴ However, other important factors of lifestyle like counseling, stress management, and smoking cessation have also been studied.¹⁵ Moreover, rigorous behavioral change

interventions focusing on increasing activity levels and weight reduction are flourishing in reducing weight and improving glycemic control.¹⁶

In general, a variety of nutritional advice to patients is currently recommended. A diet including the uncertain amount of carbohydrates from whole grains, fruits, vegetables, low-fat milk, and legumes is acceptable. In addition, a range of intake patterns (low-fat, low-carbohydrate Mediterranean diet, vegetarian) is suitable. It is better for diabetic patients to replace foods containing saturated fats (meats, cheese, and ice cream) with monounsaturated and polyunsaturated fatty acids (fish, olive oil, nuts). In addition, trans-fatty acid use should be kept as low as achievable. Diabetic patients should be encouraged to replace red meat with fish, eggs, lean meats, beans, peas, soy products, nuts, and seeds. Patients also should be encouraged to use high fiber diet because higher fiber intake may improve blood glucose control.^{17,18}

It is noteworthy that the majority of studies in the field of effect of lifestyle and nutrition on diabetes have focused on dietary content and dietary patterns. Our study, however, examined eating habits or advice on how to eat more deeply. These eating manners are derived from TPM. TPM is a field of complementary and alternative medicine commonly practiced among Iranian people.⁹ As previous studies have shown, there is an increasing interest in the use of complementary and alternative medicine especially in chronic diseases.¹⁹ Although most of the studies in the field of TPM have been focused on the use of medicinal plants in treatment of diseases, Emami and colleagues evaluated the efficacy, acceptability and cost-effectiveness of a medical protocol involving schemes and recommendations mentioned in traditional manuscripts of Persian medicine for modification of lifestyle versus lactulose as a conventional treatment for constipation.^{8,20-25} This study in line with similarly conducted studies demonstrated that TPM schemes as lifestyle modification, for at least 3 months can be introduced as cheap, available and also accessible approaches for the management of constipation. Given the positive results of our study and previous studies, it seems that suggestions from TPM or other traditional medical systems on lifestyle adjustment are more obtainable and cheaper methods in the management of some chronic diseases.

Despite the upsides such as randomized controlled trial design and intention-to-treat analysis in this study, we are faced with limitations which should be considered for achieving a reliable and thoughtful understanding of results of our

study. The small sample size ought to be declared as the main problem. The adherent level of patients to study protocol in the intervention group was assessed by a self-administered questionnaire as a subjective tool. Therefore, another important limitation was the lack of objective scale for the assessment of patients' adherence to the study protocol in the intervention group. In addition, this study is an open-label study that may possibly have some bias. Although designing placebo arm for such a study may not be possible, the absence of the placebo comparator arm is another methodological problem in this study. Because of lifestyle impact on the human body is slowly and long-term follow-up is a better representative for this impact, so the longer duration of follow-up might result in that we could opine better on the effectiveness of TPM based nutritional style. Hence, longer duration of follow-up is suggested to be evaluated in upcoming studies.

CONCLUSION

This randomized open-label controlled clinical trial demonstrated that TPM based nutritional recommendations as a free of charge and accessible approach could be introduced as a non-pharmacological strategy for the control of blood glucose and lipid profile in diabetic patients. However, longer trails of larger study participants are entailed for the production of more reliable evidence in our study.

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CONFLICT OF INTERESTS

No conflict of interest was declared.

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