



Is the Staple Food Consumed Changes in Diabetics Can Affect the Quality of Life? A Parallel Randomized Controlled Trial.

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Abstract

Background: Diabetes is one of the chronic diseases that need continual medical care and self-care education, as well as nutritional therapy as an integral part of dietary management. This study was carried out to investigate the effect of bulk bread formulated with portulaca oleracea on quality of life (QOL) in patients with type 2 diabetes.

Methods: This parallel randomized controlled trial was conducted on 104 patients with type 2 diabetes. Participants received bulk bread containing 10% portulaca powder for 8 weeks (intervention group); the control group used their normal daily bread. The quality of life score was estimated in both groups by the use of the short-form 36-Item (SF-36) questionnaire before the intervention, and 8 weeks after dietary intervention, the quality of life score between both groups was compared. The significant level was set at 0.05.

Results: The difference in the mean score of quality of life of the studied units in different dimensions of physical function, role limitation due to physical problems, role limitation due to emotional problems, physical pain, social function, energy and vitality, mental health, general health, and overall quality of life showed that there was a significant difference in the mean in all dimensions and quality of life, except mental health, was observed in the case group after the intervention. The mean difference in quality of life in different dimensions before and after the intervention in the intervention group is significant.

Conclusions: According to the results, it was revealed that consumption bulk bread formulated with portulaca oleracea can promote the quality of life in patients with type 2 diabetes. So, it can be concluded that portulaca oleracea as a functional plant can be found in bread as a new treatment and prevention method in patients with diabetes.

Keywords: Bread, Portulaca oleracea, Quality of life, Type 2 diabetes.

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Introduction

Diabetes mellitus (DM) is a common and growing problem around the world. According to the report of the international diabetes federation in 2017, 425 million adults had diabetes,¹ and this trend is expected to continue.² The prevalence of this disease is also increasing in developing countries. For example,

the number of patients with DM in the countries of the MENA WHO region in 2019 was reported to be 54.8 million patients. The latest report from Iran in 2016 by the WHO stated that 10.3% had type 2 diabetes.³ The complications in patients with type 2 diabetes have increased dramatically over the past two decades.⁴ The rising trends are due to aging, obesity, physical inactivity, genetic predisposition, rural to urban migration, and family history.⁵⁻⁷ Every diabetic patient's life is unique and they feel psychologically overwhelmed by the numerous rules that the disease constrains them to follow. Therefore, assessing the quality of life (QoL) of patients is important since each individual has their individualized perception of their physical, emotional, and social well-being, which includes a cognitive element satisfaction as well as emotional component happiness. There are various factors associated with both short-term and long-term diabetes management that enumerate to the QoL negatively or positively. The microvascular and macrovascular complications and longer duration of illness associated with the disease are the foremost important factors that affect the patient's QoL. The sociodemographic factors such as age, gender, marital status, income status and educational status adherence to proper glycemic management, and strictly advised diet and exercise routine may have a significant positive or negative correlation.⁴ A declining QoL and depression can also strongly influence a patient's commitment toward controlling his disease.⁴ Also, alike the other chronic disease, mellitus diabetes in addition to high fatality leads to lots of personal, familial, social and financial problems, muscular- skeleton difficulties, physical weaknesses, generic disorders, and blood vessel problems are cases which influence patients' life.⁸ These patients due to failure in their challenge with disease encounter the impressed mental feelings and despair leading them to have a sense of anger, sin, and panic about their illness. They often lose their motivation to control and take care of disease.⁹ That is why these patients are depressed 3 times more than non-diabetics.¹⁰ Moreover, losing the job, recurrent bedridden, the need for medical and nursing care, indirect expenditures due to untimely death, a decrease of social and family interactions, and change of lifestyle, are kinds of main problems which influence the patient's familial, social and economic conditions.^{11,12} Most specialists are of common belief in taking physical as well as the mental symptoms of the patients into consideration identically. Since the physical, mental and social welfare of the patient will be under influence, their quality of

life should be of specific importance. Today diabetic science is based on clinical medicine investigation with the quality of life on its core. Preventive programs and effective management of diabetes in several countries show the positive effects of these programs on the patients' personal and familial life qualities. One of the main parts of diabetic management is recognizing the psychological, socio-economic, and emotional changes and thereby planning a proper diet.¹³ Unsuitable diet planning, meager in fiber, much consumption of saturated fatty acids and carbohydrates, inactive life style are some factors responsible for obesity and the other diabetic complications, and the other chronic diseases.¹⁴ Therapeutic dietary goals in type 2 diabetes are access to positive metabolic results including; levels of hemoglobin, Glucose, levels of triglyceride, hypertension, weight, prevention and therapy of chronic complications, and other diabetic associated diseases. Reforming the lifestyle and diets, improving health and physical activities, removing the nourishing needs of patients matched with their personality, culture, lifestyle and economic situations will finally lead to a healthy and satisfactory long life.¹³ Diets have been changed significantly during recent years and must be planned so as not to put at hazard the patients' health, quality of life, and security.¹⁴ Medical therapy is one of the priorities for diabetic patients, however, it is associated with side effects in some patients.¹⁵ On the one hand, the use of herbal medicines to treat diabetes depends on the cultural background of each country.¹⁶ Therefore, studies on plants with more effective and safer hypoglycemic properties and/or even auxiliary treatment of native plants of an area are among the important studies. The use of chemical medicines has also increased today due to the spread of diabetes, but due to factors such as patients' dissatisfaction with the use of these medicines, side effects of long-term and excessive use, drug intolerance and ineffectiveness over time, and the costs imposed to patients, there is a growing interest in alternative and traditional therapies. For this reason, the use of medicinal herbs, in addition to reducing the cost of treatment, has had satisfactory results in many communities.¹⁷

Currently, studies have been conducted on the role of this plant in lowering blood sugar and lipid profile of diabetic patients.^{18,19} The results of a systematic review and meta-analysis show that in some studies, portulaca oleracea may be effective in improving blood lipid and sugar levels.²⁰ But the challenge is to use nutrients that can be used as a substrate. Since bread can be a good carrier for adding nutrients to meet the needs of consumers, it is considered as a staple food, a good source of nutrition, and a cheap diet in half the world.²¹ Given that in Iran, white wheat flour is used for bread, vitamins and minerals are lost during the milling and refining process, and bread made from these ingredients will be much poorer than the original grain. Although several studies have been conducted to enrich flour with portulaca oleracea and researchers claim the effects of manufactured products on sugar and fat reduction, the effect of the product on diabetic patients has not been measured and the missed effect using staple food is still felt. On the other hand, the bread used in Iran is mostly flat, which does not have enough fermentation time and has a high glycemic index in terms of nutrition. Therefore, this study was conducted aimed to investigate the effect of bulk bread formulated with portulaca oleracea on the quality of life

patients with type 2 diabetes in referring to Shahroud Diabetes Clinic in Iran.

Materials and Methods

The present study is a parallel randomized clinical trial. In this intervention study, 104 patients with diabetes and dyspepsia referred to Shahroud Diabetes Clinic in 2018-2019 based on the study inclusion and exclusion criteria, and after explaining the objectives of the study and obtaining informed consent, were selected and randomly based on four blocks assigned to two intervention and control groups.

The patients who met our inclusion criteria were then enrolled after written consent was obtained. The inclusion criteria were the age of 30–60 years; definitive diagnosis of type 2 diabetes with no insulin therapy; no pregnancy or lactation; absence of self-reported specific diseases and malignancies, kidney failure, heart disease, thyroid, and other inflammatory diseases; not taking vitamin and anti-oxidant supplements during the last 6 months, and no smoking or drinking.

Moreover, participants were excluded if they were taking included diabetic patients treated with insulin or with cardiovascular, renal, and hepatic disorders, hypothyroidism and seizures; diabetic patients with a history of kidney and bladder stones; diabetic patients treated with estrogen, steroid, beta, and thiazide inhibitors; diabetic women who decided to become pregnant; diabetic pregnant women, women who breastfeed, users of E and C supplements, and omega-3 at least six months before sampling, smoking, and drug users. Methods and protocols of this study were reviewed by the ethics council in medical sciences research of Shahroud university of medical sciences and approved with the code (IR.SHMU.REC.1397.200). All identifiable information collected from participants was coded. Also, all participants provided signed, written informed consent, and was registered with the Iranian Clinical trials register IRCT registration number: IRCT20110309006010N1, Registration date: 2019-05-18.

The sample size in this study was determined according to the objectives of the study and using Sabzghabae et al.'s study which the sample size was 38 and 55 in each group, respectively.²² So, the number of samples in each group was 55 (figure 1).

The data were collected using demographic information form as well as experiments. The form of demographic information included age, gender, number of household members, level of education, occupation, marital status, type of medicines used, and the onset of diabetes completed by patients before the intervention in both groups. All study participants completed the questionnaire which comprised demographic information, as well as information in this clinical trial study, most of the existing QoL questionnaires for diabetics have been developed in the Western population which are socially, culturally, and economically different from Iranian participants. we utilized a validated Persian sort form of SF-36.²³

The SF-36 is a general quality of life instrument that measures eight health-related concepts: physical functioning (PF-10 items), role limitations due to physical problems (RP-4 items), bodily pain (BP-2 items), general health perceptions

(GH-5 items)), vitality (VT-4 items), social functioning (SF-2 items), role limitations due to emotional problems (RE-3 items), and perceived mental health (MH-5 items).

Besides, a single item that indicates perceived change in general health status over a one year (health transition) is also included in the SF-36. Based on these eight scales, two summary scales have been constructed: The Physical composite score (PCS) and the mental composite score (MCS). Item responses were transformed using scoring algorithms to yield standardized health scale scores ranging from 0 (worst possible health) to 100 (best possible health).

Portulaca oleracea powder was added to buckwheat flour in a proportion of 10%. The cooled bread was packed in polyethylene packages and provided to the intervention group

daily in several distribution centers from the beginning of the study to 8 weeks of intervention. The control group used their normal daily bread. Assessments were done at the beginning and repeated at 8 weeks of intervention periods.

To analyze the data, we used descriptive statistics (mean, and standard deviation) and the effectiveness of the intervention method was compared with the difference between the mean before and after the intervention (change score) in the two groups using t-test. Also, a new short-form 36 item health survey questionnaire for both groups was completed and was classified and then analyzed using descriptive and deductive statistics, i.e. independent T-test, Pearson correlation coefficient, and One-Way Variance Analysis. Using SPSS 16 and Stata software, data analysis was performed at a significant level of 0.05.

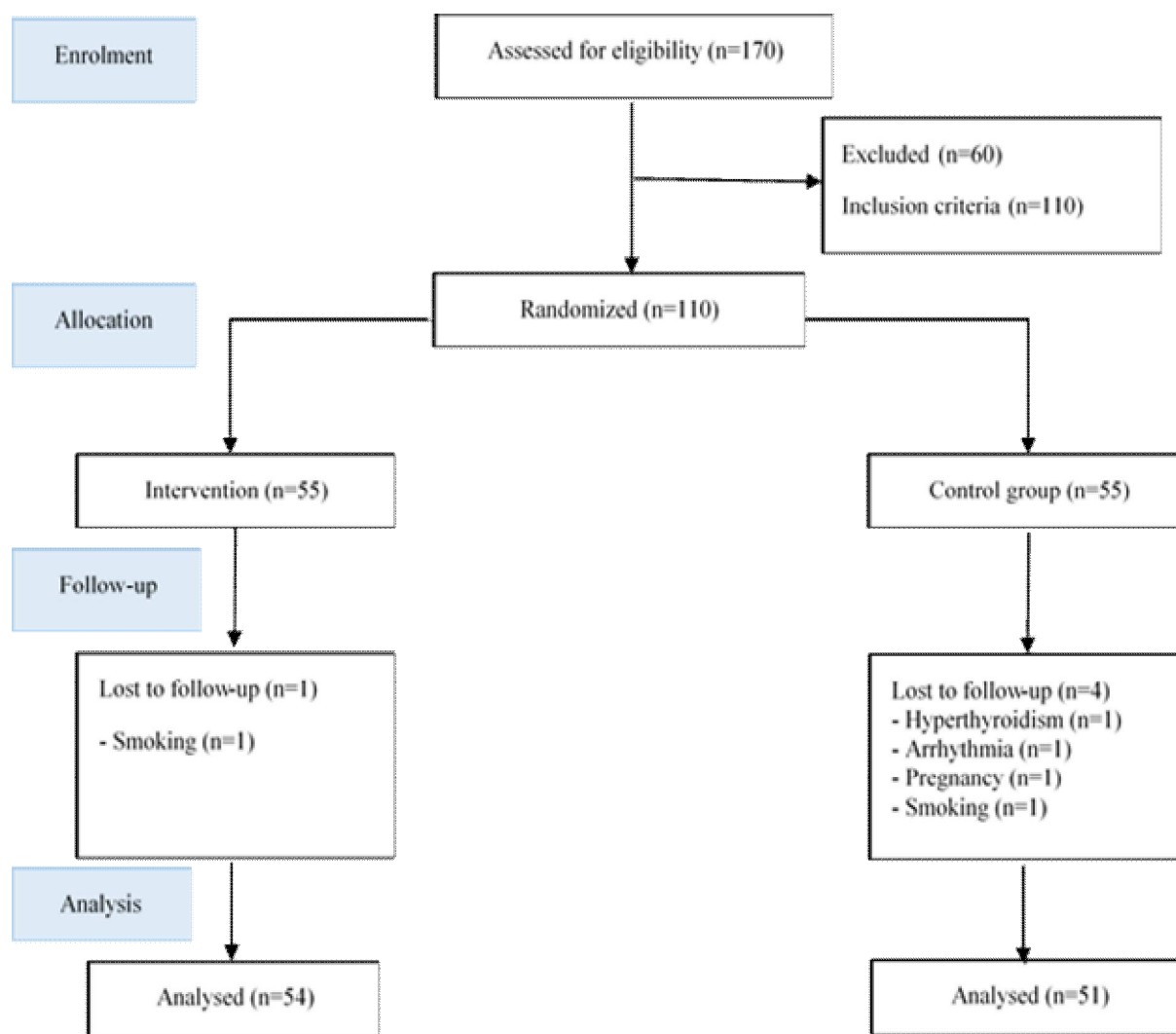


Figure 1. The study flow diagram

Results

Of the 110 participants in the study, who were randomly divided into two groups of 55 patients in the intervention and control during the study, 4 patients were excluded from the control group and one patient was excluded from the intervention group due to smoking. Data of 104 patients (54 in the intervention group and 51 in the control group) were analyzed.

According to findings, the average age of investigated subjects was 53.6 ± 6.5 of whom %51 were male and %49 were female. Among the participants, 11(20.4%) were unemployed, 20(37%) were housewives and the rest were employed. All participants were married and 4(7.4%) were illiterate. There was no significant difference between the intervention and control groups in terms of age and education ($P > 0.05$). In terms of demographic properties, no significant difference was observed between case and control groups before the intervention.

Table 1 shows the average score of quality of life of the studied units in different dimensions of physical function, role limitation due to physical problems, role limitation due to emotional problems, physical pain, social function, energy and vitality, mental health and general health, and quality of life as a whole before the intervention. Statistical tests didn't show a significant relationship among the subjects' average score of quality of life and other demographic variables before the intervention.

Table 1. The comparison of mean before the intervention of the SF-36 scales in between groups

Variable	Intervention(54) Mean±SD	Control(50) Mean±SD	Pvalue
Physical functioning	64.62±26.65	57.8±20.65	0.14
Physical role	2.31±8.77	1±4.9	0.35
Emotional role	0.00	2±7.9	0.08
Vitality	40.46±14.8	42.4±13.44	0.41
Mental health	47.40±9.87	49.2±10.35	0.36
Social functioning	39.12±12.51	43.0±15.6	0.16
Pain	60.78±18.75	57.25±16.69	0.31
General health	50.27±8.26	48.50±8.28	0.27
Total score QOL	38.12±4.63	37.64±5.09	0.16

SD. Standard deviation

Mean score of quality of life of the studied units in different dimensions of physical function, role limitation due to physical

problems, role limitation due to emotional problems, physical pain, social function, energy and vitality, mental health and general health, as well as total quality of life after intervention has shown in table 2.

Table 2. The comparison of mean after the intervention of the SF-36 scales in between groups

Variable	Intervention Mean±(SD)	Control Mean±(SD)	Pvalue
Physical functioning	83.14±8.761	62.0±20.35	<0.001
Physical role	16.20±34.04	0.5±3.53	<0.001
Emotional role	10.49±30.24	1.33±6.59	0.04
Vitality	56.20±12.73	42.1±12.08	<0.001
Mental health	54.22±8.35	50.40±9.83	0.035
Social functioning	56.94±13.22	53.0±13.49	0.013
Pain	42.31±21.79	48.60±22.11	0.014
General health	55.09±7.73	52.80±9.69	0.1
Total score QOL	46±83±10.97	38.84±4.08	<0.001

SD. Standard deviation

Table 3 shows the difference in the mean score of quality of life of the studied units in different dimensions of physical function, role limitation due to physical problems, role limitation due to emotional problems, physical pain, social function, energy and vitality, mental health and general health, and overall quality of life. Independent t-test showed a significant difference ($P < 0.05$) in terms of the difference in the mean score of quality of life, except mental health, in all dimensions of physical function, role limitation due to physical problems, role limitation due to emotional problems, physical pain, social function showed energy, vitality, and general health before and after the intervention in the experimental and control groups. The mean difference of quality of life in the different dimensions before and after the intervention in the interventional and control groups has shown in figure 2.

Based on the findings of the study, before the intervention, 16.7% of the subjects in the intervention group stated that in general, their quality of life is poor, while after the intervention, this rate reached zero percent. Also, before the intervention, none of the studied units had a good quality of life, while after the intervention, 9.3% of the studied units stated that in general, their quality of life is at the hob level (figure 3). 35.6% of them stated that their health condition has slightly worsened compared to the last year.

Table 3. Comparing of mean differences before and after of QOL scales in between groups

Variable	Intervention Mean difference±(SD)	Control Mean difference±(SD)	Pvalue
Physical functioning	18.51±17.5	4.20±19.67	<0.001*
Emotional role	10.49±30.24	-.66±4.71	0.01*
Physical role	13.88±30.96	-.50±6.16	0.001*
Vitality	15.74±16.72	-.30±9.96	<0.001*
Mental health	6.81±12.20	1.20±11.77	<0.019*
Social functioning	17.82±20.11	10.0±18.03	.04*
Pain	-18.47±23.54	-8.65±19.07	0.022*
General health	4.81±9.46	4.30±10.78	.796
Total score QOL	8.70±11.20	1.19±4.84	<0.001*

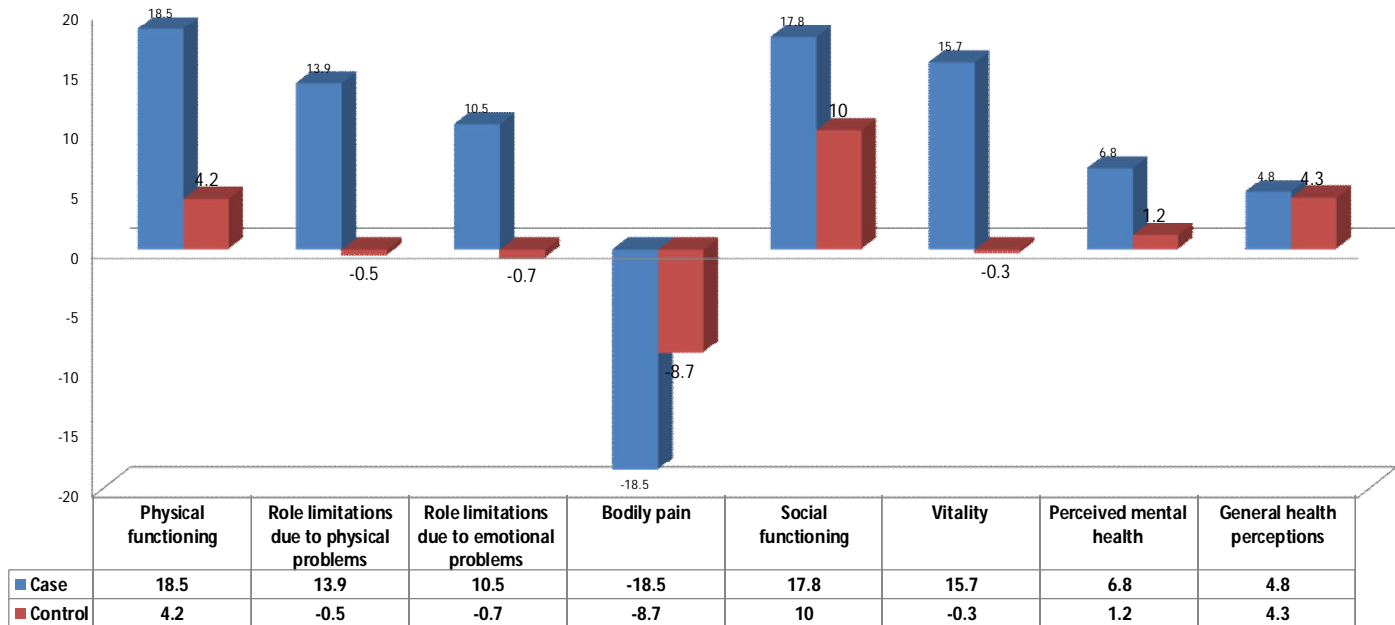


Figure 2. Comparing of mean difference of quality of life in the different dimensions before and after the intervention in between groups

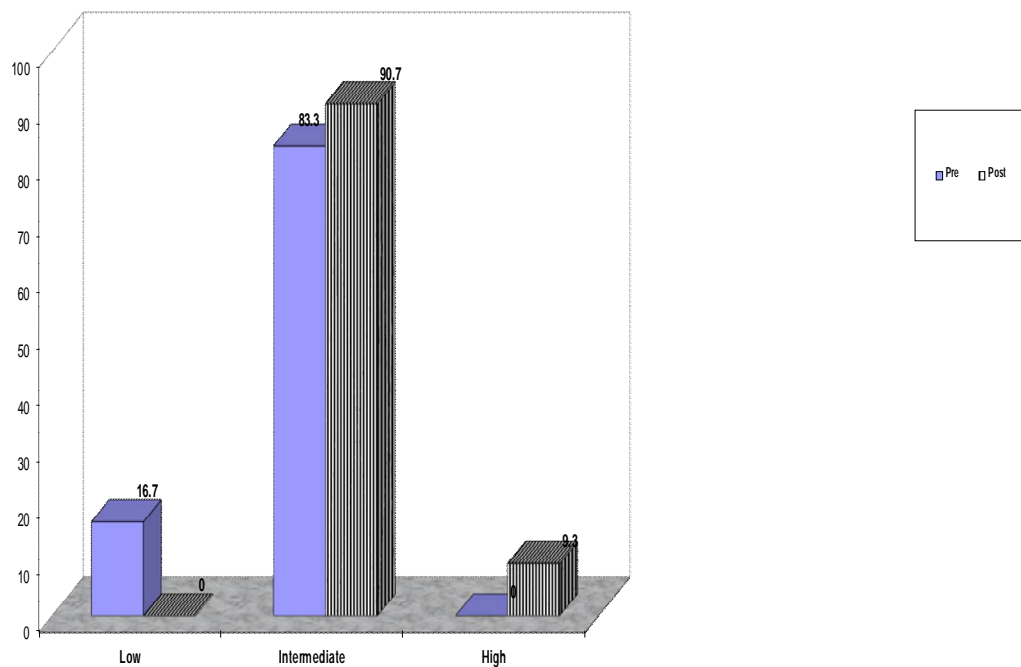


Figure 3. Comparison of different levels of quality of life before and after the intervention in case and control group

Discussion

Diabetes is a kind of chronic disease that needs to receive continuous medical attention and self-management to prevent acute complications and reduce the danger of complications' occurrence in a long time. Taking care of diabetes is an intricate action and its scheduling apart from blood sugar control requires different measures in various diabetic related issues. Standard supervisions for diabetes have been provided for researchers, therapeutic staff including, physicians and nurses to improve the feasibility of access to curative aims and care quality evaluations²⁴ and the cost is reduced.²⁵

The results of the present study showed that the intervention of consuming bread containing portulaca oleracea can significantly reduce the indicators of metabolic syndrome (results not shown). In particular, the fact that the government pays subsidies to the people for its preparation is among the strategies that improve and improve the adjustable risk factors in patients. These interventions have more beneficial effects on reducing the incidence of disease and improving the lifestyle of patients than anti-diabetic drugs and reduce the risk of cardiovascular disease in patient.²⁶

Tobert et. al also examined 279 menopause women who were suffering type 2 diabetes and found out that employing schedules for changing lifestyle (low-fat diets, training to control stress, physical exercise, group support and stop-smoking sessions) will improve body mass index (BMI), plasma fatty acids, and quality of life of diabetes compared with the patients who do not receive any training, except regular one.²⁷

Sone et. al also concluded in a prospective interventional clinical trial involving 2,205 patients with type 2 diabetes that at first, the lifestyle modification program included intensive lifestyle management at each outpatient clinic visit and frequent telephone counseling, which was small but significant three years after initiation of the intervention.²⁸

Delvarianzadeh et. all have done a randomized clinical trial study on 144 patients with type 2 diabetes who were chosen from patients referred to Imam Hossein hospital dietary clinic and were randomized in case and control groups. A dietary schedule consisting 50-6-% carbohydrate, 10-20% protein, and less than 30% fat was prescribed at first orally in a 30-minute counseling session, then in written form for the case group, while the control group was left without any intervention and then the score of the quality of life was estimated in both groups by the Short-form 36-Item (SF-36), before dietary counseling, and one month after the dietary counseling. Also, the quality of life score between both groups were compared. According to the results, it was revealed that dietary counseling can promote the quality of life in patients with type 2 diabetes in all dimensions.²⁹ Sami et al. reported in a review study that the patients could be prevented from developing the diabetes complications. Awareness about diabetes complications and consequent improvement in dietary knowledge, attitude, and practices lead to better control of the disease. The stakeholders (health-care providers, health facilities, agencies involved in diabetes care, etc.) should encourage patients to understand the importance of diet which may help in disease management, appropriate self-care, and better quality of life.¹⁴ The findings

of the present research denoted that the consumption of bread fortified with purslane improvement of quality of life of the participants improved significantly the patients' total quality of life and its various facts within one month of treatment onset. Controlling blood sugar through diets caused the patients' life satisfaction and decreased related curative expenditures.

Paisey et. al compared the effect of low caloric diets and weight loss programs on the quality of life, fasting blood sugar, and lipid in 45 type 2 diabetes and found out that dietary schedules compared with other weight controlling programs had lasting and more effect on high-density lipoprotein increase and fasting blood sugar and hypertension decrease, hence improved the patient's quality of life.³⁰

Metz et. al examining 119 patients found out that using dietary planned programs compared with a regular diabetic diet led to weight loss up to 3 ± 5.4 kg and the improvement in hypertension, fat, and hemoglobin glycogen levels as well as the patients' increasing satisfaction. It was evident that dietary interventions caused significant weight loss and amelioration of cardiovascular in high-risk patients.³¹

Nizami et.al examined the effect of high-fibrous bread diet on 40 type 2 diabetes and found out that consuming a high fibrous bread diet during 4 weeks will improve significantly fasting blood sugar, satisfactory hypertension, and cholesterol and triglyceride reduction in patients. This kind of diet also reduced the use and dose of anti-diabetic drugs.³²

Lemon et. al examined 244 type 2 patients and found out that after a 3- month Nutritional intervention program they grew better significantly in their blood sugar, weight, self-managing care. Controls and cardiovascular disease risks lessened remarkably. Applying for the consulting program also led the patients to gain an optimistic overview and reduce the number of their off days from their jobs.³³ Thus Successful diabetic management needs enough and expedient training on the disease itself and related cares. Moreover, they should be technically supported.³⁴ Health and care staff should be provided and supported with training, evaluation, and patient management. So there should be necessarily coordination between patients on one hand and health supervisors, health and care systems, and society on the other.³⁵ Nutritional therapy is a part and parcel of diabetic management and plays an essential role in diabetes.³⁶ Through the instruction on the importance of proper nutrition, physical exercises, and new drugs use to and type diabetes will not only keep away the epidemic expansion of the disease but also there will be an increasing quality of life betterment.³⁷

Overall, the findings of this clinical trial showed that receiving enriched bread with whole portulaca oleracea leads to improve quality of life. It can be concluded that portulaca oleracea as a functional plant can be found in bread as a new treatment and prevention method in patients with diabetes and hyperlipidemia.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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