International Journal of Nutrology
(Official Journal of the ABRAN - Brazilian Association of Nutrology)

REVIEW ARTICLE

DOI: 10.54448/ijn2133

Effects of functional foods in diabetic Patients: A Systematic Review

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DOI: https://doi.org/10.54448/ijn2133
Received: 09-21-2021; Accepted: 10-02-2021; Published: 10-11-2021

Abstract

The control of Type II Diabetes Mellitus is directly related to the dietary profile, so an adequate diet for this group of patients must be implemented as soon as possible. But what foods can we use to facilitate glycemic and insulin control? Therefore, this study aims to systematically review the literature on the effects of functional foods in diabetic patients. Method: Systematic review of randomized clinical trials published between 2014 and 2021. Using as descriptors: Diabetes Mellitus Type 2 (Diabetes Mellitus Type 2), Functional Food. Results: Of the 566 articles found, 65 articles were selected, which passed the PEDro scale of methodological quality, and 11 articles were included. Of which they addressed different functional foods and their effects on different variables in diabetic patients. It can be concluded that several foods have beneficial effects on glycemic and insulin control in diabetic patients. Still, as a benefit, they had side effects in controlling dyslipidemia, blood pressure, and BMI.

Keywords: Diabetes Mellitus type 2. Functional. Nutrion

Introduction

Life expectancy increased as a result of technical-scientific advances in medicine, but despite living longer, there was an increase in the prevalence of chronic non-communicable diseases (NCDs) due to the demographic-epidemiological transition **[1-3]**. Thus, the indiscriminate use of drugs can affect eating behavior, especially in the absorption of nutrients essential to the functioning of bodily functions, impacting the health of this population and consequently reducing their quality of life **[4-6]**.

Contributing to this growth in the prevalence rates of these CNCDs in Brazil is the exchange of traditional foods such as beans, rice, and vegetables for processed foods, increasing the consumption of sodium, saturated fats, and sugars. Data from VIGITEL (Surveillance of Risk Factors and Protection for Chronic Diseases by Joint Telephone Survey of the 26 capitals and the Federal District) from 2016 show that 80.4% of the population aged 18 years old did not reach the recommended consumption of fruits and vegetables. This research also reports that the number of Brazilians with diabetes rose from 5.5% of the population to 8.9% in the period corresponding to 2006 to 2016 **[7]**.

The control of Type II Diabetes Mellitus is directly related to the dietary profile, regular practice of physical activity, as well as the use of medication prescribed by the physician regularly, if necessary, culminating in a healthy lifestyle. However, numerous barriers to this change in lifestyle are found in the path between professionals and patients **[8-12]**.

According to the Brazilian Ministry of Health, Diabetes Mellitus is a chronic disease where the pancreas does not produce insulin or when the body is unable to use it effectively, the latter being the definition of type II diabetes. Constituting 90% of the diabetic population, type 2 diabetes is also called insulin resistance, since it is difficult to connect insulin to its cellular receptor, due to the fat layer that makes this coupling difficult. Therefore, obesity is directly proportional to the occurrence of Diabetes Mellitus Type II **[12,13]**.

Patients who do not have access to the health system, professionals who cannot guide with accessible language for their clients, and as most diabetic patients are elderly, the ability to understand some guidelines is limited, which culminates in non-adherence to change in lifestyle and self-care management. Added to biopsychosocial factors, the chances of non-adherence to treatment and lifestyle changes increase **[12]**.

The authors' Lopes et Al (2005) [8], Kant (2010) **[9]**, Hiza et Al (2013) **[10]** and Giuli et Al (2012) **[11]** point out that healthy eating patterns are associated with better

control of blood glucose and hypertension, as well as other chronic diseases such as dyslipidemia. The authors Fernandes et al (2017) [6] and Bento et al (2018) [5] presented results that suggest that the greater use of medication for chronic diseases among elderly Brazilians is associated with a healthier diet, perhaps because this portion of the population is more careful with your health, not meaning that these drugs do not have an impact on the absorption of these nutrients.

Functional food can benefit the individual in the prevention or treatment of chronic degenerative diseases. So the routine use of functional foods is recommended for the benefits to be achieved. Remembering that every diet must be balanced, and that excess, including functional foods, leads to eating dysfunction. Since inappropriate habits lead to an endogenous release of free radicals, which in turn cause oxidative stress in tissues. Functional foods are antioxidants and therefore have a protective effect on the individual's body [13,14].

Therefore, an adequate diet for this group of patients must be implemented as soon as possible. But what foods can we use to facilitate glycemic and insulin control? For this reason, this study aimed to systematically review the literature on the effects of functional foods in diabetic patients.

Methods

Study Design

This study performed a systematic review of randomized clinical trials, which was conducted following the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions. The rules of the Systematic Review-PRISMA Platform (Transparent reporting of systematic reviews and meta-analysis-HTTP: //www.prisma-statement.org/) were followed [15].

Search Strategy and Study Eligibility Criteria

The databases searched were Cochrane, Pubmed, and lilacs. With the descriptors: Diabetes Mellitus Type 2 (Diabetes Mellitus Type 2), Functional Food and its Boolean operators *AND, OR*, and *NOT*, when necessary. The search was carried out in the period corresponding to 05/01/2019 to 07/01/2021 and studies published between 2014 and 2021 were included. The inclusion criteria are to address functional nutrition and diabetes in adults (over 18 years old), the study must be a randomized clinical trial, which scores at least 05 on the PEDro scale. All studies that did not meet the inclusion criteria, that addressed pregnant adults or any other special populations, studies in animals, that had a publication before the predetermined period, and that had a different methodological design from that already stipulated, were excluded.

The selection took place as follows, after pre-selection, the articles were read in full, passed through the PEDro scale that assesses eligibility criteria, randomization, allocation concealment, similar groups at the beginning, subject masking, therapist masking, therapist masking, evaluator, intention-to-treat analysis, comparison between groups with statistical tests, variability, and follow-up measures. Therefore, the maximum score a study can get is 10 points.

Results and Discussion

Studies were searched in the databases with the descriptors previously described, and selected according to the inclusion criteria. Sixty-five articles were selected, which went through the PEDro scale of methodological quality, in the end, 11 were included, which obtained a score according to **Figure 1** and **Table 01**, taking into account the inclusion and exclusion criteria as previously described.

Figure 1. Study Eligibility

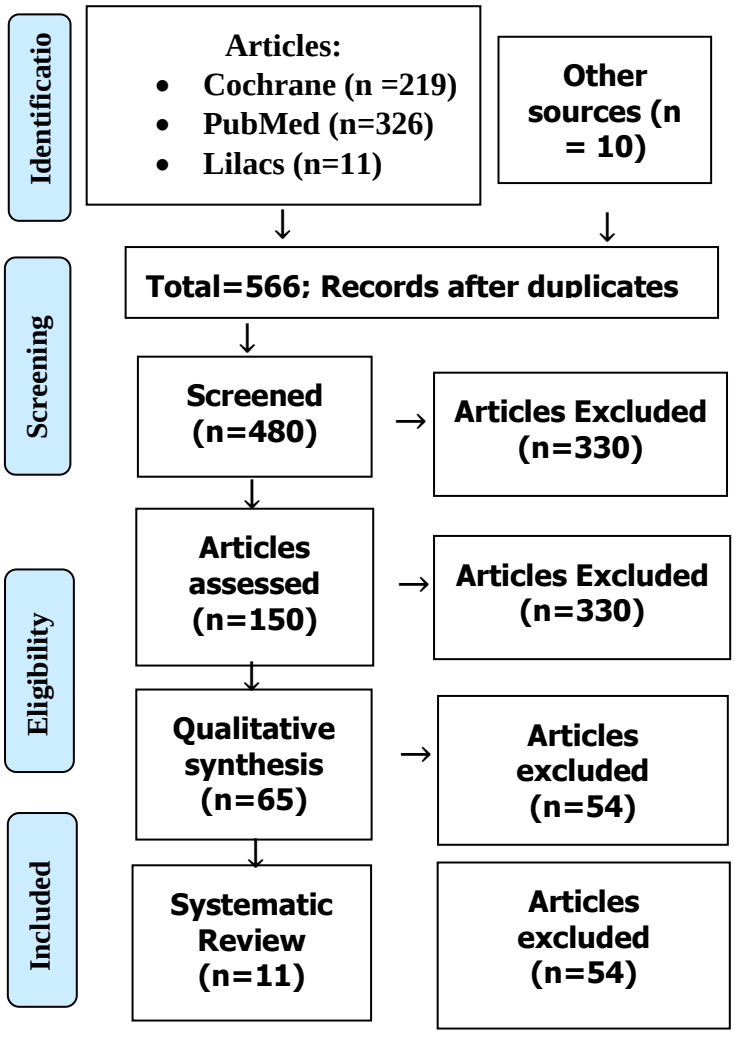

Table 1: Articles selected in the review

Author and Year	Participants	Objective	Primary outcome	Results	PEDro Scale (Score)
Jenkins et al. 2018 [16]	108 male and female	Evaluate the consumption of mixed nuts in replacement of carbohydrates in cardiovascular risk factors and HbA1c in type 2 diabetes.	Change in HbA1c	Intake of nuts as a carbohydrate substitute improves glycemic control and lipid risk in individuals with type 2 diabetes.	06
Dainty et al. 2016 [17]	24 male and female	This study aimed to examine the effects of consumption of Bagels with corn-resistant starch with high content of type 2 amylose on fasting and postprandial glycemic markers in adults at increased risk of type 2 diabetes.	Insulin Curve	Consumption of Bagel with corn-resistant starch with a high content of type 2 amylose improves glycemic efficiency, reducing the amount of insulin needed to control postprandial blood glucose, improving insulin sensitivity in adults prone to type 2 diabetes.	07
Azimi et al. 2016 [18]	204 male and female	To analyze and compare the effects of cinnamon, cardamom, turmeric, and ginger on markers of endothelial function and BP in diabetic patients.	Effects of spices on anthropometry, blood pressure, and serum concentrations of SICAM-1	No significant influences on endothelial function and blood pressure were found, so it has no benefits for cardiovascular disease in diabetic patients.	07
Oh et al. 2014 [19]	42 male and female	To investigate the effects of daily fermented Red Ginseng supplementation on glycemic status in individuals with impaired fasting blood glucose or with type 2 diabetes.	Changes in pre-and post-prandial glucose and pre- and post-prandial serum insulin levels.	Supplementation of fermented red ginseng led to a significant reduction in postprandial glucose levels and an increase in postprandial insulin levels.	08
Vera et al. 2018 [20]	81 men and women	To study the effects of a functional food-based dietary intervention on fecal microbiota and biochemical parameters in patients with type 2 diabetes.	Effect of dietary portfolio on fecal microbiota	Long-term adherence to a fiber-rich in polyphenols and based on vegetable proteins, the diet provides benefits for the composition of the fecal microbiota and improves glycemic control, dyslipidemia, and the inflammatory process.	08
Sathyapalam et al. 2016 [21]	200 male participants	Observe whether isoflavones can modify testosterone and blood glucose levels in diabetic men	Change in Testosterone Levels	Testosterone levels did not change, but there was a significant improvement in blood glucose and cardiovascular risk markers. Both strategies were able to promote the reduction of body weight, body fat, intrahepatic lipid, and visceral adipose tissue.	09
Barbosa-Yanes et al. 2018 [22]	36 were men and women, 60% of whom were women.	To compare low-calorie carbohydrate intake with a low-fat, low-calorie diet and the effects on flow-mediated dilation, intrahepatic lipid accumulation, and visceral adipose tissue as independent risk factors for CVD in patients with type 2 diabetes.	Changes in endothelial function, intrahepatic lipid deposition and visceral adipose tissue.	The use of soy in patients with type 2 diabetes improves endothelial function, improves glycemic control, increases brachial blood flow, increases total serum antioxidants and lipid profile. But it has no significant effects on blood pressure.	07
Sedaghat et al 2019 [23]	70	To investigate the effects of soy on glycemic conditions, blood pressure, lipid profile, antioxidant effects, and vascular endothelial function in these patients.	Changes in glycemic status, blood pressure, lipid profile, endothelial function and antioxidant effects.	The use of soy in patients with type 2 diabetes improves endothelial function, improves glycemic control, increases brachial blood flow, increases total serum antioxidants and lipid profile. But it has no significant effects on blood pressure.	06
Tajadadi-Ebrahimi et al 2014 [24]	81	To evaluate the effects of daily consumption of symbiotic bread on the metabolic status of patients with diabetes mellitus.	Change in serum insulin	Consumption of symbiotic bread had positive effects on insulin metabolism.	08
Li et al 2014 [25]	71	Determine if substituting breakfast for low glycemic index supplements can control type 2 diabetes.	Change in HbA1c	Replacing breakfast with a low-nutrient supplement with a low glycemic index can improve blood glucose weight control in T2DM.	06
Shidfar et al 2015 [26]	44	Effects of ginger supplementation on glycemic indices in type 2 diabetic patients.	Effects on the glycemic index.	Ginger supplementation improved glycemic indices and antioxidant capacity in type 2 diabetic patients	08

Knowing that diabetes is a disease that results from metabolic changes such as dyslipidemia and an increase in inflammatory markers. And that diet is the basis for successful treatment, it is urgently necessary to implement changes in the lifestyle of these patients. Several foods contribute to improving the quality of life of diabetic patients, but further studies on these foods and their metabolic actions in this population were needed. For this reason, many authors have based their studies on functional foods, which, according to the Ministry of Health, are foods that are capable of providing several health benefits, and preventing NCDs, as well as improving the quality of life of patients who already have them **[13]**.

Among these foods, there were studies with nuts, corn resistant starch, cinnamon, cardamom, saffron, ginger, red ginseng, vegetable proteins, isoflavones, symbiotic bread, low-calorie carbohydrates, among others. In this study, articles of the randomized controlled clinical trial type that addressed interventions in diabetic patients were selected. These studies corroborated to understand the effects of food to increase the therapeutic diet optimizing its effect.

Azimi et al (2016) divided its 204 participants into 4 experimental groups (3g of cinnamon, 3g of cardamom, 1g of turmeric, and 3g of ginger) and 1 control, in all of which anthropometric measurements were performed, sICAM-1, blood pressure, before and after interventions and no statistically significant differences were found to justify the use of these spices to control these mechanisms in diabetic patients **[18]**.

Although the study by Azimi et al (2016) **[18]** that compared spices (cinnamon, cardamom, turmeric, and ginger) did not find satisfactory results for blood pressure control and cardiovascular risk reduction in this profile of patients, and in diabetic patients, these must be controlled, since the disease predisposes to dyslipidemia that triggers a cascade of vascular diseases; there is a study against this result, Shidfar et al (2015) **[26]** conducted a study in which they used 3 grams of ginger in an experimental group and lactose in the placebo group. The authors claim that Ginger can improve the glycemic index and antioxidant capacity in this patient profile.

Oh, et al (2014) **[19]** adds that their 42 participants underwent supplementation of fermented red ginseng and placebo, as a result, they found that supplementation of red fermented ginseng improves postprandial plasma glucose levels and increases insulin levels. Two selected studies studied the effects of soy in diabetic patients Sedaghat et al (2019) **[23]** divided their sample into 02 distinct groups, a control, and an experimental group, with the experimental group ingesting 60g of soy per day for 8 weeks, as a result of the experimental group showed increased serum total antioxidant capacity and brachial blood flow, reduced total cholesterol, e-selectin, FPG, but had no significant effect on blood pressure, HDL and triglyceride levels.

The authors Sathyapalan et al (2016) **[21]** studied the use of isoflavones in diabetic male subjects, randomized 200 individuals into two groups, where one received soy protein with the presence of 66mg of isoflavones and the other group received 15 grams of soy protein without any isoflavone for 6 months. In the group that received isoflavones, there was a significant improvement in glycemic control, blood pressure, triglycerides, and calculated cardiovascular risk, while in the group without isoflavone there was no significant difference. In both groups, no changes in testosterone were observed. As a possible thyroid adverse reaction, the isoflavone group showed a substantial increase in TSH and a reduction in free T4.

Regarding diets due to restriction of some nutrients, two studies were selected. Jekins et al (2018) **[16]**, who evaluated the effect of nuts replacing carbohydrates, and found that in their 108 participants included in the project, wholemeal dumplings based on nuts were offered for 03 months, and in the group with the highest amount of ingested nuts (188 grams per day), there was a statistically significant reduction in LDL, HbA1c, ApoB, and total cholesterol. However, no statistical difference was observed in changes in body weight, blood glucose, CRP, and blood pressure. The study by Barbosa-Yañes et al (2018) **[22]** compared a low-fat diet with a low-carbohydrate diet, both of which had positive effects on reducing body weight, visceral fat, liver lipids, blood lipids, and fat. abdominal. However, the low-fat diet increased the brachial artery's ability to dilate, and the low-carbohydrate diet reduced HbA1c. Therefore, both had satisfactory results in carbohydrate restriction to this profile of patients, especially about HbA1c **[16]**.

Vera et al (2018) **[20]** in a controlled, randomized study, demonstrated the effects of a diet rich in functional foods on the fecal microbiota and glycemia of patients with type 2 diabetes. They subjected patients in both groups to a diet of less than 500 kcal /day than usual. The dietary plan consisted of 45-55% carbohydrates, 15-20% protein, 25-35% fat (less than 7% saturated fat), 200 mg per day cholesterol, 20-30g fiber, and 2000-3000 mg of sodium. The experimental group was offered a functional preparation (14g of nopal, 4g of chia seed, 30g of soy protein, and 4g of inulin) and the control group was offered a placebo supplement (28g of caseinate and 15g of maltodextrin). These supplements were consumed for breakfast and dinner. The group that received the functional preparation improved the composition of the fecal microbiota, glycemic control, dyslipidemia, and inflammatory process.

In their study, researchers Tajadadi-Ebrahimi et al (2014) **[24]** recruited 81 patients and randomly divided them into three distinct groups, one control, one using Lactobacillus symbiotic bread containing sporogenes (1 ×

10(8) CFU) and 0.07 g inulin for 1 g. And another group using probiotic bread containing porogenes (1 × 10(8) CFU per 1 g). The results did not show significant changes in BMI or weight of participants, but the symbiotic bread showed a significant reduction in serum insulin.

Li et al (2014) [25] studied the effects of replacing breakfast with low glycemic index supplementation and obtained satisfactory results in glycemic control and body weight. The participants who used the supplementation had a reduction in HbA1c by -0.2%, while the control group, which ingested a conventional breakfast, had an increase of 0.3%. And statistically significant data between BMI of the control group and the experimental group were observed, with the experimental group being favorable for a better BMI.

Conclusions

In this review, it can be concluded that even though the studies presented have evaluated different outcomes, and one has shown a positive result and the other negative, the use of ginger for diabetic patients should not be ruled out. Red ginseng appears to be beneficial for postprandial blood glucose and insulin control. The use of type 2 amylose to replace conventional wheat improves pre- and postprandial insulin.

Isoflavone improves glycemic control, blood pressure, triglycerides, and calculated cardiovascular risk, and soy improves total serum antioxidant capacity and brachial blood flow, lowers total cholesterol, e-selectin. Low-carbohydrate or low-fat diets promoted a reduction in body weight, body fat, intrahepatic lipid, and visceral adipose tissue. As well replacing high glycemic index foods with low glycemic index foods also resulted in improved BMI.

These functional foods are important alternatives for replacing foods that favor the increase in blood glucose, body fat, and metabolic disorders. Being opportunely offered to the patient as allies in the process of controlling blood glucose, insulin, and other elements, facilitating the patient's adherence to nutritional therapy. It is important to point out that the use of functional foods for diabetic patients must be inserted into a balanced diet and restricted to glucose, to obtain positive results. Therefore, in addition to the intake of functional foods, the use of nutraceuticals from a diet rich in fruits and vegetables is recommended, taking into account the limitations imposed by the patient's glycemic status. It is possible to observe that there are numerous studies on functional foods for diabetic patients, but many study isolated foods and with a small sample, and there is a scarcity of studies that study the same nutrient/food and its outcomes are common, which compromises the evidence-based practice.

Limitations

Studies with different functional foods, more studies are needed with the same food and primary outcomes. It is suggested that more studies of the clinical trial type be carried out, to corroborate, agree or disagree with the existing results.

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Acknowledgment
Nil

Funding
Nil

Data sharing statement
No additional data are available

Conflict of interest
The authors declare no conflict of interest